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THE USE OF AI IN CRIMINAL JUSTICE: UNPACKING THE EU'S HUMAN-CENTRIC AI STRATEGY

MUSTAFA T KARAYIGIT* & DENIZ ÇELIKKAYA†

In order to mitigate concerns over potential disruptive impacts of the integration of artificial intelligence in the criminal justice system on criminal justice, this article explores the European Union's human-centric approach towards that integration, emphasising the balance to be struck between technological advancement and fundamental values and rights on the basis of legal and ethical principles. While existing literature explores AI's role in the criminal justice systems, there is a gap in examining how the EU's human-centric strategy directly shapes legal, ethical and regulatory frameworks. Based on the EU AI strategy with the aim of moderately filling this gap, this article discusses how the framework addresses ethical concerns in order to keep human's place central with safeguarded fundamental rights and values in the application of AI systems within the criminal justice system. To attain that objective, the analysis highlights the mitigation of bias and enhancement of fairness, the protection of privacy and data, the significance of human oversight, encouraging multi-stakeholder engagement and the non-substitution of human judges by automated decision-making within the framework of the EU's commitment to developing AI technologies that all serve the public good while respecting fundamental rights and values. The article contributes to the ongoing discourse on responsible AI integration into criminal justice by synthesising insights from legal, ethical and AI governance frameworks.

1 INTRODUCTION

Artificial Intelligence (AI) has become a pivotal instrument in different sectors in recent years, including criminal justice. The reason behind the incorporation of AI in the criminal justice system lies in its capability to process and analyse large volumes of data, identify patterns that may escape human perception, generate predictions based upon those patterns and offer recommendations grounded in data.[1] From predictive policing algorithms that forecast crime hotspots and facial recognition technologies that assist in suspect identification to case-law analysis, enabling a more efficient legal research process and decision drafting, the scope of AI application is massive in criminal justice.[2]

In the criminal justice systems, AI is generally used for crime prevention, crime prediction, crime analysis and recidivism risk assessment, and technologies designed by

* Professor of EU Law; Marmara University, the Institute of European Studies.
† MA in EU Law; Solicitor of the Senior Courts of England & Wales; Partner at ARC Law Firm.
[1] European Commission, '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 on the EU Security Union Strategy' COM(2020) 605 final, 12.
[2] Fair Trials, 'Automating Injustice: The Use of Artificial Intelligence & Automated Decision-making Systems in Criminal Justice in Europe' (2021) <https://www.fairtrials.org/app/uploads/2021/11/Automating_Injustice.pdf> accessed 25 January 2025.

private companies are used especially for law enforcement.[3] Additionally, public authorities have begun to integrate surveillance data into their own systems by collaborating with private companies.[4] With the development of technology, the use of AI systems in the criminal justice field is expanding[5] and its use carries the potential to transform several aspects of the criminal justice domain, including analysing data, processing files, validating evidence, predicting criminal activity, identifying patterns and making legal decisions, and reshape the criminal judicial processes and the landscape of law enforcement. The AI-driven risk assessment tools that are now being used through complex digital evidence for unveiling insights mark a significant shift towards data-driven judicial processes.

The journey towards this AI-driven future in the criminal justice system nevertheless presents numerous ethical, legal and societal dilemmas. The adoption of AI technologies especially in the forms of machine and deep learning in criminal justice, as a sensitive field, necessitates a careful consideration of its ethical, social and legal implications and requires a precautionary approach towards their use in the criminal justice system. The European Union (EU) has been leading the effort to address these implications with its progressive policies on digital technology and fundamental rights. Its rights-driven regulatory model sets the European human-centric approach apart from market-driven United States and state-driven Chinese models.[6] Having defined its leadership in AI as 'the development and use of AI that is relevant and useful to all',[7] the EU in that respect puts human beings at the centre of AI development and regards AI primarily as a tool to maximise human well-being and prosperity. It is committed to using its resources, authority and political backing to collaborate and compete globally in the field of AI with the purpose of its development and utilisation that benefits all.[8] Its goal is to ensure that AI being created aligns with the EU founding values, in particular respect for human dignity and human rights, democracy and the rule of law, by prioritising the advantages of society and people as a whole.

Ultimately, according to the EU human-centric approach, the integration of AI into the criminal justice system must be guided by a commitment to enhance fundamental rights while protecting against potential harms. A human-centric approach provides a guidance to achieving this balance, ensuring that AI serves as a tool for justice that is equitable, just and reflective of the EU founding values. The utilisation of AI system in criminal justice could therefore be accompanied by legal safeguards and ethical values to reduce possible risks

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[3] Asma Idder, Stephane Coulaux, 'Artificial Intelligence in Criminal Justice: invasion or revolution?' (*International Bar Association*, 13 December 2021) <https://www.ibanet.org/dec-21-ai-criminal-justice> accessed 1 June 2024.

[4] Alfred Ng, 'Amazon's helping police build a surveillance network with Ring doorbells' (*CNET*, 5 June 2019) <https://www.cnet.com/features/amazons-helping-police-build-a-surveillance-network-with-ring-doorbells> accessed 13 July 2024.

[5] Aleš Završnik, 'Criminal justice, artificial intelligence systems, and human rights' (2020) 20 ERA Forum 567.

[6] Anu Bradford, *Digital Empires - The Global Battle to Regulate Technology* (Oxford University Press 2023) 131 and 145; Sümeyye Elif Biber, 'Between Humans and Machines: Judicial Interpretation of the Automated Decision-Making Practices in the EU' (2023) University of Luxembourg Law Research Paper Series 2023-19.

[7] European Parliament, 'EU guidelines on ethics in artificial intelligence: Context and implementation', (European Parliamentary Research Service, 2019), 3 <https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/640163/EPRS_BRI(2019)640163_EN.pdf> accessed 11 February 2024.

[8] European Commission, 'Artificial Intelligence for Europe, Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions' COM(2018) 237 final; European Commission, 'Building Trust in Human-centred Artificial Intelligence' COM(2019) 168 final.

associated with utilisation of AI system in criminal justice. The role of human rights, in this sense, nevertheless serves as a protective safeguard against the misuse of AI technologies in the criminal justice domain rather than a framework for conceptualising and developing AI in alignment with human values.[9] This approach placing humans at the heart of AI and prioritising human needs and wellbeing accordingly sets the EU AI strategy apart from those of other countries with the capacity to offer valuable global lessons in terms of the use of AI in the criminal justice system.

Within that comprehension, the European Commission's High-Level Expert Group on AI states in *Ethics Guidelines for Trustworthy AI* that a trustworthy AI system must be legally, ethically and technically sound and robust.[10] The guide reiterates the core principle that the EU needs to develop a human-centric AI in accordance with its own rules and values. The EU AI strategy is therefore founded on the human-centric principles and serves to balance the benefits of AI with societal values and individual rights.[11] Moreover the EU AI Act,[12] drafted with a risk-based approach, aims to reduce errors and biases, as part of a broad initiative to develop AI in a human-centred, safe and reliable way. In that regard, it sets important requirements regarding the quality of data sets used in the development of AI systems with a focus on minimising the risks of algorithmic discrimination. It also requires certain AI systems to operate under human control in order to reduce risks in critical fields such as health, security and fundamental rights.

The integration of AI in the criminal justice system concisely creates ethical, legal and societal concerns about the disruptive impacts of AI on criminal justice arising mostly from idiosyncrasies of AI. As a sensitive field, use of algorithm in criminal justice might lead in all its phases to unjust condemnation of persons on the basis of (potentially inaccurate) crime risk assessments or even the punishment of innocent persons. In order to mitigate potential disruptive impacts of deployment of AI on criminal justice and to be able to attain a fair criminal justice on the basis of legal and ethical principles, this article argues in the footsteps of the European human-centric approach that this integration must be guided by a commitment to enhance fundamental rights and values by putting the human at the centre of the AI development/deployment for the sake of human dignity and the common well-being of humans while protecting against potential harms. In order to extract key insights from the EU AI strategy, the article accordingly aims to unpack the EU's human-centric AI strategy with its specific legal and ethical implications and influence for/on the development and application of AI in the criminal justice system. For that purpose, it adopts a qualitative legal research approach relying upon a normative legal research in order to explore legal rules and ethical principles for addressing the legal issue at stake.

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[9] David Restrepo Amariles and Pablo Marcello Baquero, 'Promises and limits of law for a human-centric artificial intelligence' (2023) 48 Computer Law & Security Review, Article 105795.

[10] High-Level Expert Group on Artificial Intelligence (AI-HLEG), 'Ethics Guidelines for Trustworthy AI', (2019), 4 <https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines.1.html> accessed 21 July 2024.

[11] Access Now, 'Mapping Regulatory Proposals for AI in Europe' (2018) <https://www.accessnow.org/wp-content/uploads/2018/11/mapping_regulatory_proposals_for_AI_in_EU.pdf> accessed 4 August 2023.

[12] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L2024/1689.

The structure of the article is as follows. It initially analyses the notion of human-centric AI and then examines under five subtitles the issues and concerns arising from the incorporation of AI in criminal justice in the light of the EU's AI strategy in order to explore implications of that strategy for criminal justice. As the reflection of main concerns to be taken into consideration in the development and deployment of AI in the criminal justice systems, implications of the human-centric approach are therefore analysed from the points of: reducing bias and enhancing fairness; ensuring transparency and accountability; safeguarding privacy and data protection; encouraging multi-stakeholder engagement; and the choice of the degree of integration of AI as a tool of assisting or replacing the human judge. It ends with general remarks.

2 THE NOTION OF HUMAN-CENTRIC AI

The concept of human-centric/centred AI has emerged as a key goal in policy papers aimed at establishing public governance of AI.[13] According to *Ethics Guidelines for Trustworthy AI*, AI systems 'need to be human-centric, resting on a commitment to their use in the service of humanity and the common good, with the goal of improving human welfare and freedom'.[14] Human-centric AI is defined in the Ethics Guidelines as an approach that 'strives to ensure that human values are central to the way in which AI systems are developed, deployed, used and monitored, by ensuring respect for fundamental rights'.[15] The cornerstone of the EU human-centred approach is the belief that AI should be developed and deployed in a manner that respects fundamental rights and human values – ultimately the EU's fundamental values enshrined in Article 2 of the Treaty on European Union (TEU) – by putting the human at the centre of the AI development and so integrating them into the lifecycle of AI development.[16] This perspective is particularly important in the criminal justice field, where the potential for AI to impact human lives is significant and where maintaining public trust and accountability and ethical values such as respect for fundamental rights, equality, transparency and accountability are paramount.[17] Ethical concerns regarding privacy and the potential de-humanisation of justice are also at the forefront of this approach, emphasising the need to balance technological innovation with respect for fundamental rights.

As stated by the High-Level Expert Group, the strategy aims to ensure that human values are at the core of the way that AI systems are to be developed, deployed, used and monitored, by respecting fundamental rights and values as well as the natural environment and other living beings as part of the human ecosystem and so by serving the public good.[18] The common foundation that unites the EU fundamental rights can be comprehended as rooted in respect for human dignity and thereby reflecting a human-centric approach enabling the human being to enjoy a unique and inalienable moral status of primacy in the

[13] Anton Sigfrids et al, 'Human-centricity in AI governance: A systemic approach' (2023) 6 Frontiers in Artificial Intelligence 2 <https://www.frontiersin.org/articles/10.3389/frai.2023.976887/full> accessed 11 February 2024.
[14] AI-HLEG (n 10) 4.
[15] ibid 37.
[16] Anna Pirozzoli, 'The Human-centric Perspective in the Regulation of Artificial Intelligence' (2024) 9 European Papers 105.
[17] AI-HLEG (n 10) 37.
[18] ibid.

all civil, political, economic and social fields.[19] Briefly, the EU human-centric approach highlights the importance of human values, rights and dignity in the development and use of AI technologies and that humans should be repositioned at the centre of AI lifecycle.[20]

On the other hand, technology does not come without a cost. The EU human-centric approach acknowledges the potential of AI to preserve or even exacerbate existing biases and introduce new forms of discrimination if not carefully designed and regulated. Transparency and accountability are also central tenets of the EU human-centric approach, addressing the complex nature of many AI systems. By prioritising fairness, transparency and accountability, a human-centric approach seeks to mitigate the risks of algorithmic bias by maintaining human oversight and control over AI systems and ensuring that AI systems do not reinforce discrimination or target vulnerable groups. In that regard, the EU AI Act emphasises accuracy, reliability, transparency, accountability, fairness and equity in developing and utilising AI applications.[21] Moreover, the EU places a high value on privacy and personal data protection, especially in the sensitive context of the criminal justice system. Additionally, while AI can help streamline certain processes, how it is used must be carefully watched and analysed so that the justice system always works effectively and in line with human values. With concerns about the de-humanisation of justice and the allocation of liability, the EU's human-centric approach suggests within the comprehension of the human-in-the-loop approach that AI should only be a tool to complement and enhance human decision-making in ways that ensure fairness and impartiality and not to be used to replace human judgment in justice systems. Overall, the EU AI strategy guides how to create a more just and effective criminal justice system by prioritising human values in technological advancements. These guiding principles are rooted in the EU foundational values such as the protection of fundamental rights, ensuring human control and supervision, maintaining technical integrity and safety, ensuring equality and fairness and promoting societal and environmental welfare.

3 IMPLICATIONS OF THE EU HUMAN-CENTRIC AI STRATEGY

It should be expressed at the outset that implementing the human-centric AI framework involves a multi-faceted approach, including legislative measures, research and innovation funding, education and training and international collaboration. The EU AI Act primarily aims to ensure the use of AI systems in the EU in accordance with EU values and promote the uptake of human centric and trustworthy AI by creating a legal framework for trustworthy AI with strict standards of transparency, security and bias mitigation. Operationalising these principles however presents significant challenges. For instance, ensuring transparency and explainability in complex AI systems is a technical challenge that requires ongoing research and innovation. These complex systems are called 'black box', referring to the difficulty of providing clear explanations of their outputs. Whilst the

[19] AI-HLEG (n 10) 10.
[20] Ozlem Ozmen Garibay et al, 'Six human-centered artificial intelligence grand challenges' (2023) 39(3) International Journal of Human-Computer Interaction 391.
[21] 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)) OJ C 404/63; Recitals 27 and 59 of the EU AI Act.

technology progresses and we see more and more explainable AI models, the technical difficulty of making these systems fully explainable without sacrificing their effectiveness still remains. Additionally, there currently seems to be inverse proportion between performance and explainability in the AI systems, since the highest performing methods are the least explainable, whereas the most explainable methods are the least accurate.[22] Balancing innovation with regulation to maintain the EU's competitiveness on the global stage while safeguarding ethical standards also arises as an ongoing policy challenge. Similarly, preventing bias in AI systems necessitates continuous vigilance, diverse data sets, inclusive design processes and cross sector collaboration between ethicists, computer engineers and legal workers.

Supporters of the integration of AI systems into criminal justice argue that these systems offer a faster, fairer, more consistent and cost-effective solution to human errors, such as biased decisions, lack of up-to-date information and inconsistent reasoning, and reduction of courts' workloads.[23] However, these technologies also have possible negative effects, which require careful evaluation. For example, crime forecasting algorithms (predictive policing systems) are found to disproportionately target minority neighbourhoods, which leads to over-policing. In that respect, drawn from the EU human-centric AI strategy in the realm of criminal justice on the basis of substantial issues, the following key implications thus emerge.

3.1 REDUCING BIAS AND ENHANCING FAIRNESS

Algorithmic objectivity seems to be illusory. Discriminatory outcomes might arise from algorithms on the basis of endogenous and exogenous factors. The use of AI in criminal justice can be complicated by the fact that the data used in predictive profiling processes in particular has the potential to reflect historical biases and socio-economic inequalities. Data sets used by AI systems, which reflect the value judgments of their designers and operate essentially on the basis of generalisation, may therefore reflect societal biases and so may contain misleading information by perpetuating or even amplifying them. During the development of AI systems, the biases of human developers, regardless of malicious intent, can also produce biased results. In other words, despite the good intentions of their designers, algorithms may take an unpredictable path in reaching their goals through choices, connections, correlations, inferences and interpretations made.[24] Moreover, in terms of overall accuracy of algorithms, they naturally optimise better for the majority, at the expense of vulnerable minorities or marginalised communities.[25] Algorithms may even produce biased decisions and lead to direct or indirect discrimination not only because of replication,

[22] David Gunning et al, 'XAI - Explainable Artificial Intelligence' (2019) 37(4) Science Robotics aay7120.
[23] Wojciech Wiewiórowski and Michal Fila, 'AI and Data Protection in Judicial Cooperation in Criminal Matters' (*Eurojust*, 2022) <https://www.eurojust.europa.eu/20-years-of-eurojust/ai-and-data-protection-judicial-cooperation-criminal-matters> accessed 21 July 2024.
[24] Aleš Završnik, 'Algorithmic justice: Algorithms and big data in criminal justice settings' (2021) 18(5) European Journal of Criminology 623.
[25] Michael Kearns and Aaron Roth, *The Ethical Algorithm – The Science Of Socially Aware Algorithm Design* (Oxford University Press 2019) 78.

perpetuating or reinforcing of incorporated certain social values and existing societal biases, but also because of the reproduction of biases from input data.[26]

These biases in data can cause algorithms to produce biased results against certain demographic groups, increasing false positives or false negatives and so lead to direct or indirect discrimination due to biases (intentional or not) both in the training and operational phases. Within the context of criminal justice, AI tools such as predictive policing algorithms and decision-making aids for judges thus can inadvertently perpetuate or even increase existing biases if not carefully designed and monitored.[27] Algorithm biases thus may consolidate discrimination and impair the neutrality of judgments and the legitimacy of their use in the criminal justice system. This could lead to individuals and communities being unfairly targeted and discriminated with the consequence of hindering the equal and fair administration of justice. This situation would be exacerbated by proneness of judges to fall into judicial conformism by aligning themselves with the outcomes and recommendations generated by the algorithms.[28] Judges may also use AI technology selectively by relying more on extra-legal factors in criminal cases.[29]

Hacking and designing or reverse-engineering the decision-making processes in AI systems with the malicious intent by programmers, software engineers or information technology companies[30] with the purpose of manipulation of judgments present additional threats of the algorithmic systems to fair trial in criminal justice.

Furthermore, 'the risk assessment method yields probabilities, not certainties, and measures correlations, not causations'.[31] Machine learning provides statistical results deriving from the establishment of mere correlations and so not relying on causality as legal reasoning does.[32] Purely statistical-mathematical correlations would therefore remain unsatisfactory in meeting the standards of a reasoned decision, especially in criminal matters.[33] In that regard, AI generally operates to apply rules to the treatment of people through the use of statistical

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[26] Kathrin Hartmann and Georg Wenzelburger, 'Uncertainty, risk and the use of algorithms in policy decisions: a case study on criminal justice in the USA' (2021) 54 Policy Sciences 269; Raphaële Xenidis and Linda Senden, 'EU non-discrimination law in the era of artificial intelligence: Mapping the challenges of algorithmic discrimination' in Ulf Bernitz et al (eds), *General Principles of EU law and the EU Digital Order* (Kluwer Law International 2020) 151-182.

[27] Anastasia Siapka, 'The Ethical and Legal Challenges of Artificial Intelligence: The EU response to biased and discriminatory AI' (Thesis, Panteion University of Athens, 2018) 14.

[28] Florence G'sell, 'AI Judges' in Larry A DiMatteo, Cristina Poncibò, and Michal Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence, Global Perspectives on Law and Ethics* (Cambridge University Press 2022) 347-363.

[29] Dovilė Barysė and Roee Sarel, 'Algorithms in the court: does it matter which part of the judicial decision-making is automated?' (2024) 32 Artificial Intelligence and Law 117.

[30] Changqing Shi, Tania Sourdin, and Bin Li, 'The Smart Court – A New Pathway to Justice in China?' (2021) 12(1) International Journal for Court Administration 4; David Freeman Engstrom, Daniel E Ho, Catherine M Sharkey, and Mariano-Florentino Cuéllar, 'Government by Algorithm: Artificial Intelligence in Federal Administrative Agencies', Report Submitted to the Administrative Conference of the United States, February, 2020 <https://law.stanford.edu/wp-content/uploads/2020/02/ACUS-AI-Report.pdf> accessed 9 August 2024.

[31] Md Abdul Malek, 'Criminal courts' artificial intelligence: the way it reinforces bias and discrimination' (2022) 2 AI and Ethics 233.

[32] Juliette Lelieur et al, 'General Report' in Juliette Lelieur (ed), *Artificial Intelligence and Administration of Criminal Justice* (International Colloquium, Buenos Aires, Argentina, 28-31 March 2023) 94 Revue Internationale de Droit Pénal 11, 49.

[33] Jasper Ulenaers, 'The Impact of Artificial Intelligence on the Right to a Fair Trial: Towards a Robot Judge?' (2020) 11(2) Asian Journal of Law and Economics 1.

generalisations and so de-individualises decisions rather than assessing each individual on their own merits with the unavoidable outcome of the product of a generalisation and de-individualised assessment of the case at stake.[34] De-individualised assessment based on statistical generalisations may thus undermine the fair administration of justice by sacrificing individual justice for the sake of consistency. AI use in criminal justice may also infringe certain principles such as presumption of innocence enshrined in Article 6 of the European Convention on Human Rights (the ECHR) in the case of use of AI system for the purpose of risk assessment in the pre-trial phase.

Since the algorithm is based upon the inputs, inadequate, incomplete, inaccurate, misclassified, outdated, undiversified and biased data distort it and lead to poor performance.[35] Even though removing biased data from these systems can be thought of as a solution, it might nonetheless be challenging to determine whether the discriminatory output was caused by the data or the AI system itself.[36] For instance, if we propose that the training data should be inclusive,[37] we might be adding more variables that can lead to discrimination. On the other hand, removing too many variables that can be considered leading to discrimination can make the AI system non-functional.[38] Moreover, the call for diverse data sets in training AI models is not just about variety but also about depth and representativeness to ensure that the AI's 'learning' reflects the complexity and diversity of real-world scenarios. This is particularly crucial in criminal justice, where decisions can significantly affect not only individuals' lives, but also broader societal perceptions of fairness and justice. Continuous monitoring for biased outcomes represents an acknowledgement that AI systems are not static, but evolve and adapt over time. As such, their impacts can shift and so ongoing vigilance is necessitated to ensure that biases do not creep in or worsen as the system learns from new data. In that regard, a delicate balance as to data sets should be struck.

That is why the implementation of predictive profiling systems requires careful ethical and regulatory consideration throughout their development and use cycle with the EU's human-centred AI principle in mind. Training, validation and testing of data sets should therefore be subject to comprehensive data management and governance practices. Data sets should be evaluated for possible biases, omissions and improvements and should be representative, error-free and complete to avoid discriminatory outcomes. These data sets must lawfully represent the target audience of the AI system, including gender, ethnicity and other grounds of discrimination. Since not only would technology have legitimacy in

[34] Kate Jones, 'AI governance and human rights – Resetting the relationship' (January 2023) Chatham House Research Paper, International Law Programme, <https://www.chathamhouse.org/sites/default/files/2023-01/2023-01-10-AI-governance-human-rights-jones.pdf> accessed 10 April 2024; Laura Notaro, 'Predictive Algorithms and Criminal Justice: A Synthetic Overview from An Italian and European Perspective' (2020) 2 Roma Tre Law Review 49.

[35] Brandon L Garrett and Cynthia Rudin, 'The Right to A Glass Box: Rethinking the Use of Artificial Intelligence in Criminal Justice' (*SSRN*, 22 November 2022) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4275661#> accessed 25 August 2024.

[36] Fair Trials (n 2) 30.

[37] Lana Bubalo's lecture about Legal protection against discrimination by AI on GDHRNet Training school 'Human Rights and Artificial Intelligence', held in Kuressaare, Saaremaa, remotely on 7 July 2023.

[38] ibid.

correlation with the degree of scientific progress and objectiveness,[39] but also be truly human-centred in accordance with the principles of social justice, AI governance must look beyond the technical aspects of AI technology, respond to the pre-existing societal structures breeding algorithmic biases and remedy them.[40]

The EU AI Act in that regard includes a multifaceted approach aimed at reducing the risk of inaccurate or biased decisions made by AI in critical areas such as criminal justice. The Act imposes obligations to minimise algorithmic discrimination by focusing on the quality of the data sets used during the development of AI systems. This approach will be applied throughout the entire lifecycle of AI systems, namely testing, risk management, documentation and human oversight. Moreover, the Act introduces comprehensive regulation for the use of 'real-time' biometric recognition systems in public spaces. Rather than a blanket ban, these systems are allowed to be used under certain situations and conditions, for instance to identify certain victims of crime, prevent certain threats or find specific criminals. Such uses must comply with the legal framework, be approved in advance by a judicial or administrative authority and comply with detailed guidelines in the legislation of the Member States.[41] Lastly, according to Recital 42 of the EU AI Act crime risk assessments based solely on profiling natural persons or on assessing their personality traits and characteristics should be prohibited and so

> [n]atural persons should never be judged on AI-predicted behaviour based solely on their profiling, personality traits or characteristics, such as nationality, place of birth, place of residence, number of children, level of debt or type of car, without a reasonable suspicion of that person being involved in a criminal activity based on objective verifiable facts and without human assessment thereof.

Ultimately, mitigating bias is strongly correlated with other pillars of the human-centric AI model. Change in laws and regulations could force algorithms to be more transparent, accountable and effective tools subject to human oversight for identifying and preventing bias.[42] This strategy not only advocates for mechanisms that ensure transparent and accountable AI systems, but also emphasises the importance of human values and ethical considerations embedded at every stage of AI development and deployment. By integrating human oversight with efforts to minimise bias, the EU is charting a path toward AI application in criminal justice that are not only technologically advanced but also deeply aligned with societal values and fundamental rights. This holistic approach accordingly serves as a guiding principle for leveraging AI to enhance justice and equity, while vigilantly guarding against the perpetuation of existing disparities.

One of the critical implications arising from the EU AI strategy is thus the emphasis on reducing bias and enhancing fairness in AI systems. This emphasis is pivotal especially

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[39] Stanley Greenstein, 'Preserving the rule of law in the era of artificial intelligence (AI)' (2022) 30 Artificial Intelligence and Law 291.

[40] Karine Gentelet and Sarit K Mizrahi, 'A Human-Centered Approach to AI Governance: Operationalizing Human Rights through Citizen Participation' in Catherine Régis et al (eds), *Human-Centered AIA Multidisciplinary Perspective for Policy-Makers, Auditors, and Users* (CRC Press 2024).

[41] Article 5 of the EU AI Act.

[42] Bruno Lepri, Nuria Oliver, and Alex Pentland 'Ethical machines: The human-centric use of artificial intelligence' (2021) 24(3) iScience, Article 102249.

when considering the profound impact AI systems can have within the criminal justice sector. The potential for AI to either uphold or undermine justice is based on its design and application which necessitates a rigorous framework for its ethical use for positive results. The EU approach auspiciously goes beyond mere technical adjustments by advocating for a systemic integration of ethical principles throughout the AI development lifecycle. The EU advocates for the development of AI systems that are transparent and include mechanisms to identify and mitigate biases. This strategy involves diverse data sets for training AI models, continuous monitoring for biased outcomes and the inclusion of human oversight in AI-assisted decisions. A system of AI vigilance could accordingly be constructed to entail the systematic flaws in the system operations in terms of the protection of fundamental rights to be monitored and reported by stakeholders and so to trigger an obligation on the system designer to review, reassess and modify the design and operation of the system.[43]

The EU's stance on the use of AI in criminal justice, rooted in reducing bias and enhancing fairness, reflects a broader commitment to ensuring that technological advancements contribute positively to society. Incorporating human oversight into AI-assisted decisions in criminal justice serves multiple purposes. It not only acts as a safeguard against the uncritical acceptance of AI recommendations but also ensures that the nuanced and context-specific judgments that are often required in legal settings are preserved. Article 8a of Annex III of the EU AI Act appropriately qualifies in the administration of justice 'AI systems intended to be used by a judicial authority or on their behalf to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts, or to be used in a similar way in alternative dispute resolution' as high-risk AI systems. However, the EU has missed an important step here. Human rights impact assessments carried out on high-risk systems as an obligation for deployers under Articles 26 and 27 of the Act are restricted to certain areas such as AI use in public organisations and credit scoring, but do not cover all high-risk systems. The EU may nonetheless monitor the gradual implementation of the Act and expand its scope of application. However, some AI systems that we cannot fit into certain categories will be excluded from this human rights impact assessment, which may cause some AI solutions to slip under the radar. Although there are some missteps, such as not forcing all developers and deployers to implement human rights impact assessments, the EU approach generally highlights the necessity of a multidisciplinary approach to AI development, involving legal experts, ethicists, technologists and the wider community to create a criminal justice system that is not only technologically advanced but also socially responsible and just.

3.2 ENSURING TRANSPARENCY AND ACCOUNTABILITY

In the criminal justice system, where decisions can profoundly affect fundamental rights and freedoms, it is crucial that AI-assisted processes are transparent and those responsible for these systems are held accountable.[44] Non-transparent AI systems impede the detection of

[43] Karen Yeung, Andrew Howes, and Ganna Pogrebna, 'AI Governance by Human Rights-Centred Design, Deliberation and Oversight: An End to Ethics Washing' in Markus D Dubber, Frank Pasquale, and Sunit Das (eds), *The Oxford Handbook of AI Ethics* (Oxford University Press 2020) 76-106.
[44] AI-HLEG (n 10).

discrimination, the fact of which also prevents accountability.[45] Transparency and accountability arise as pillars of the EU human-centric AI approach. The EU AI strategy encourages the use of explainable AI, where the decision-making processes of AI systems can be understood and scrutinised by humans and the responsibility behind the decision made or supported by algorithms can be clarified.[46] The strategy also calls for transparency in data handling practices, ensuring that individuals are informed about how their data is used, stored and protected.[47] This transparency is crucial for maintaining public trust, especially in high-stakes domains like criminal justice, where the implications of data misuse can be profound. Transparency is therefore vital for building trust in AI systems and ensuring that they are used ethically and responsibly.

The emphasis on transparency and accountability in the EU AI framework is a recognition of the need for clarity in how AI systems make decisions, especially in the critical context of criminal justice. Opacity of AI system makes detection of shortcomings in the system and understanding the legal reasons underlying judicial decisions difficult. Explainable AI ensures that the rationale behind AI-driven decisions can be examined the fact of which accordingly may offer insights into the factors and data that influence outcomes. This level of transparency is essential for fostering an environment where AI's contributions to justice are not only recognised but also critically evaluated for fairness and integrity.[48] In essence, the EU's focus on transparency and accountability in AI applications within criminal justice is about ensuring that these powerful tools are developed and used in a manner that respects human dignity, human rights and democratic values. It is about creating a foundation of trust and ethical assurance, where AI's benefits are maximised and whose challenges are addressed with vigilance and a commitment to justice and equity.

The obligation to lay down the foundations behind the decision-making, especially when it comes to judicial decisions, is a principle that is established by the courts in many countries. The constitutional duty to provide reasons for judicial decisions taken place in the constitutional traditions of the Member States is also enshrined in Article 36 of Protocol (No 3) on the Statute of the Court of Justice of the EU (the CJEU), according to which '[j]udgments shall state the reasons on which they are based'. This Article has been upheld by the CJEU on various occasions as obliging that judgments shall give reasons upon which they are based. For instance the obligation laid down in Article 296 of the Treaty on the Functioning of the EU (the TFEU) and Article 36 of the Protocol and incumbent upon the General Court to state reasons for its judgments, as an essential procedural requirement, enables the persons concerned to understand the grounds of its judgment and provides the CJEU with sufficient information to exercise its powers of review on appeal.[49] Moreover according to the European Court of Human Rights (ECtHR), the general principles

[45] Lepri, Oliver, and Pentland (n 42).
[46] Ibid.
[47] CEPEJ, 'European Ethical Charter on the Use of Artificial Intelligence in Judicial Systems and Their Environment' (Ethical Charter, Council of Europe, 2018), 25 <https://rm.coe.int/ethical-charter-en-for-publication-4-december-2018/16808f699c> accessed 01 March 2025.
[48] David Leslie, 'Understanding artificial intelligence ethics and safety: A guide for the responsible design and implementation of AI systems in the public sector' (The Alan Turing Institute, 2019), 39-40 <https://www.turing.ac.uk/sites/default/files/2019-06/understanding_artificial_intelligence_ethics_and_safety.pdf> accessed 10 July 2024.
[49] Case C-486/15 P *European Commission* v *French Republic* EU:C:2016:912 paras 79-80; Case C-54/20 P *European Commission* v *Stefano Missir Mamachi di Lusignano* EU:C:2022:349 paras. 69-70.

concerning the right to a reasoned judgment and the corollary duty to give reasons oblige the courts and tribunals to provide for their judgments adequately stating the reasons on which they are based and presuppose that parties to judicial proceedings can expect to receive a specific and explicit reply and explanation to their arguments which are decisive for the outcome of those proceedings.[50]

Accountability extends beyond the technical aspects of AI systems to encompass the ethical responsibilities of those who design, deploy and manage these technologies. Transparency enables not only explainability, but also auditing. Third-party auditing thus may help to enhance trust in algorithms.[51] In that regard, the EU AI Act requires human oversight, especially in high-risk AI systems. It is therefore aimed to minimise risks in certain areas and ensure that the operations of the systems are sufficiently transparent so that users understand the system outputs and use them correctly. These requirements aim to contribute to respect for fundamental rights by ensuring transparency and traceability of the entire path to outcomes throughout the lifecycle of AI systems. It involves establishing clear lines of responsibility for AI's actions and decisions with the aim of ensuring that there are mechanisms in place for redress when AI systems cause harm to fundamental rights or operate contrary to ethical or legal standards. This aspect of the EU's AI strategy therefore aims to cultivate a culture of responsibility among AI practitioners that reinforces the principle that innovation should not come at the expense of ethical conduct or societal values. However, not facilitating the protection it expected to set, the Act places an additional burden on the citizens stating that if an individual wants to challenge the deployment of an AI system, he/she needs to prove individual harm.[52] This burden on individuals has the potential to restrict the public oversight of the societal impact of AI systems and so accountability.

Furthermore, the call for transparency and accountability aligns with broader efforts to demystify AI technologies by making them more accessible and understandable to the public and stakeholders within the criminal justice system. This democratisation of AI knowledge is pivotal for inclusive dialogue on AI's role in society, encourages diverse perspectives and fosters collaborative efforts to harness AI's potential while mitigating its risks. That is especially significant, since black box systems constantly underperform and conceal errors.[53] It is a fact that machine learning algorithms may rely upon assumptions about relationships of various categories of data which might remain hidden even to the designers of those AI systems.[54] In other words, AI, using especially machine learning, is too complex and inscrutable to fully understand even for the engineers who create it.[55] The black box nature of algorithms due to its complexity, lack of expertise by the system users/stakeholders or legal constructions associated with intellectual property rights[56] (business secret protection), which does not allow revelation of the algorithm even to

[50] *Zayidov v Azerbaijan* (No. 2) App no 5386/10 (ECtHR, 24 March 2022) para 91; *Çetinkaya v Türkiye* App no 76619/11 (ECtHR, 16 January 2024) para 18.
[51] Završnik, 'Algorithmic justice' (n 24).
[52] Leslie (n 48) 39-40.
[53] Garrett and Rudin (n 35).
[54] Kia Rahnama, 'Science and Ethics of Algorithms in the Courtroom' (2019) 1 Journal of Law, Technology & Policy 169.
[55] Jumpei Komoda, 'Designing AI for Courts' (2023) 29(3) Richmond Journal of Law & Technology 145.
[56] Greenstein (n 39).

prosecutors and judges,[57] and the lack of transparency make extremely difficult to discern whether the judicial decision is fair and unbiased and even to appeal decisions made by AI systems or with their assistance.[58] This poses also the risk of privatisation of justice because of the fact that AI systems designed by private companies endanger the role of lawmakers in criminal law.[59] The possibility of disclosure of the algorithm contrarily carries a risk that the algorithmic system could be manipulated and reverse-engineered by adversaries for the purpose of opposite outcomes.[60] For the human-centric AI system, prevalence of the rights of defendants should nevertheless be provided over the protection of interests of private companies in the preclusion of disclosure of their trade secrets.[61] As a consequence, not only would users and operators generally not be exactly aware of how the algorithm works and reaches its decision, but also the legal reasoning and justification behind a judicial decision may not always be transparent, which accordingly would lead to the deprivation of the capability of defendants to question a decision's accuracy and legality with the consequence of upsetting the very logic of adversarial proceedings and the undue influence on justice.[62] In order to establish this superiority and so strike a balance in favour of data subjects against intellectual property rights of programmers, the General Data Protection Regulation (GDPR) obliges that, though the right to explanation should not adversely affect trade secrets or intellectual property, the result nonetheless should not be a refusal to provide all information to data subjects.[63]

Lastly, regarding uncertainties around the EU AI Act and its application, there are no standards yet concerning compliance with the Act. The European Commission asked CEN/CENELEC to create European standards for compliance with the Act, which the providers of the high-risk systems will have to insert a CE marking showing their compliance according to Articles 43 and 48 of the EU AI Act. Although there is still time before the Act is implemented, some organisations are eager to start their compliance, as there are uncertainties with how the Act will be implemented. In that respect, there are some international standards which could be a starting point for some organisations trying to determine their risks when it comes to AI. For example, ISO/IEC 42001:2013

> is an international standard that specifies requirements for establishing, implementing, maintaining, and continually improving an Artificial Intelligence Management System (AIMS) within organizations. It is designed for entities

[57] Komoda (n 55).
[58] Taylor Brodsky, 'Artificial Intelligence in the Criminal Justice System: The Ethical Implications of Lawyers Using AI' (2023) Hofstra Law Student Works 25.
[59] Lelieur et al (n 32) 49-50.
[60] Komoda (n 55).
[61] Mirko Bagaric et al, 'The Solution to the Pervasive Bias and Discrimination in the Criminal Justice System: Transparent and Fair Artificial Intelligence' (2022) 59(1) American Criminal Law Review 95.
[62] Sergio Carrera, Valsamis Mitsilegas, and Marco Stefan, 'Criminal Justice, Fundamental Rights and the Rule of law in the Digital Age – Report of CEPS and QMUL Task Force' (Centre for European Policy Studies (CEPS) Brussels, May 2021).
[63] Recital 63 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1.

providing or utilizing AI-based products or services, ensuring responsible development and use of AI systems.[64]

For the current compliance practices, as it was stressed by the EU AI Office, current ISO standards lack very important aspects of the Act.[65] Current ISO standards, especially ISO 42001, ISO 31000 and ISO 23894, are not sufficient for regulatory compliance with the risk management approach under the Act. Given that they focus more on company policies and documentation, the requirements of the Act and the human-centred approach to transparency, human oversight, accountability, bias mitigation and continuous and comprehensive post-market monitoring frameworks are missing in those standards. This means that, until standards are published by CEN/CENELEC, organisations which are implementing ISO standards need to supplement them with additional controls and practices that address the EU AI Act's specific requirements, especially when it comes to transparency and accountability, in order to align themselves with the Act.

3.3 SAFEGUARDING PRIVACY AND DATA PROTECTION

The collection, processing, analysing and retention of biometric data from a variety of sources through AI systems such as predictive policing, facial recognition or probabilistic genotyping DNA, the security of stored data and duration of data storage all might create deep concerns about the right to privacy and data protection. In particular, while aiming to ensure public security, use of surveillance technologies such as public surveillance cameras, license plate recognition systems or social media platforms for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including data-driven predictive policing/justice in law enforcement, might pose risks to fundamental rights, in particular the right to privacy.

The integration of AI into the criminal justice system, with its inherent reliance on vast amounts of data, therefore makes the safeguarding of privacy and data protection a critical concern as well. In criminal justice, where sensitive personal data is often involved, safeguarding privacy is paramount. 'AI […] has an impact on the entire fabric of society'.[66] Given that modern justice universally tends to be a data-oriented justice,[67] the significance of respect for privacy and data protection escalates especially with the development of the technology-driven and network society and digitalisation.

The right to privacy is enshrined in Article 8 of the ECHR and Article 7 of the Charter of the Fundamental Rights of the EU (Charter), while the right to the protection of personal data is enshrined in Article 16(1) of the TFEU and Article 8 of the Charter. Privacy is interrelated to physical, psychological or moral integrity, personal identity, development,

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[64] ISO/IEC 42001:2023 - Information technology — Artificial intelligence — Management system <https://www.iso.org/standard/81230.html> accessed 17 July 2024.

[65] The European AI Office, 'Webinar on the risk management logic of the Act and related standards' (30 May 2024) <https://digital-strategy.ec.europa.eu/en/events/1st-european-ai-office-webinar-risk-management-logic-ai-act-and-related-standards> accessed 17 July 2024.

[66] Catelijne Muller, 'The Impact of Artificial Intelligence on Human Rights, Democracy and the Rule of Law' (Ad Hoc Committee on Artificial Intelligence, Council of Europe, Strasbourg, 24 June 2020) CAHAI(2020)06-fin.

[67] Pilar Martín Ríos, 'Predictive algorithms and criminal justice: expectations, challenges and a particular view of the Spanish VioGén system' (2024) 2/2024 Rivista italiana di informatica e diritto 547.

autonomy, the right to be forgotten, the right not to be the subject of solely automated decision-making and, as being its origin, to human dignity.[68]

The EU's strong stance on data protection and privacy, as also evidenced by the GDPR, extends to its AI strategy. The protection of personal data for the purposes of criminal matters is the subject of a specific Union legal act, namely Law Enforcement Directive (LED).[69] Article 6 and Recital 31 of the LED make a clear distinction between personal data of different categories of data subjects such as suspects, persons convicted of a criminal offence, victims, witnesses, persons possessing relevant information or contacts, associates of suspects and convicted criminals.

The EU's framework emphasises the importance of secure and ethical data handling practices, ensuring that the use of AI respects individuals' privacy rights and complies with data protection laws.[70] Under Article 10 of the GDPR, processing of personal data relating to criminal convictions and offences or related security measures shall be carried out only under the control of official authority or when the processing is authorised by Union or national law providing for appropriate safeguards for the rights/freedoms of data subjects. According to Recital 27 of the EU AI Act, AI systems shall be 'developed and used in accordance with privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity'. According to Recital 59 of the EU AI Act high-risk AI systems should include AI systems intended to be used by or on behalf of law enforcement authorities or in support of law enforcement authorities for assessing the risk of natural persons to become a victim of criminal offences, for the evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences and for crime risk assessing not solely on the basis of the profiling of natural persons or the assessment of personality traits and characteristics or their past criminal behaviour for profiling in the course of detection, investigation or prosecution of criminal offences.

According to Recital 69 of the EU AI Act, those rights shall be guaranteed throughout the entire lifecycle of the AI system and so the principles of data minimisation and data protection by design and by default are applicable when personal data are processed and not only are measures of anonymisation and encryption taken, but also the use of technology is carried out without the transmission between parties or copying of data. The EU AI strategy underlines the need for robust encryption and anonymisation techniques to protect data integrity and confidentiality. Recital 53 of the LED emphasises the use of pseudonymisation as a tool that could facilitate also the free flow of personal data within the area of freedom, security and justice. This is particularly vital in criminal justice applications, where data breaches could have severe repercussions for individuals' privacy and the broader integrity

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[68] Özgür Heval Çınar, 'The current case law of the European Court of Human Rights on privacy: challenges in the digital age' (2021) 25(1) The International Journal of Human Rights 26; Andrej Krištofík, 'The Role of Privacy in the Establishment of the Right Not to Be Subject to Automated Decision-Making' (2024) 2/2024 TLQ 236.

[69] Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA [2016] OJ L119/89.

[70] MSI-NET, 'Algorithms and Human Rights: Study on the human rights dimension of automated data processing techniques and possible regulatory implications' (2017), 12 <https://rm.coe.int/%20algorithms-and-human-rights-en-rev/16807956b5> accessed 06 July 2023.

of the justice system.[71] As declared by the Commission, a significant part of investigations against crime and terrorism involve encrypted information. Encryption, which is essential to the digital world, on the one hand secures digital systems and transactions and protects certain fundamental rights, in particular privacy and data protection, and on the other hand, if used for criminal purposes, may mask the identity of criminals and hide the content of their communications. In that regard, while combating crime and terrorism, balanced technical, operational and legal solutions to those challenges to maintain the effectiveness of encryption in protecting privacy and security of communications should be provided.[72]

According to Recital 94 of the EU AI Act, any processing of personal (biometric) data needs to respect the principles of data minimisation, purpose limitation, accuracy and storage limitation. Under Article 4(1) of the LED, personal data shall be processed lawfully and fairly, collected for specified, explicit and legitimate purposes not to be processed in an incompatible manner with those purposes, adequate, relevant and not excessive in relation to those purposes, accurate and kept up to date, ensured that inaccurate personal data are erased or rectified without delay, kept in a form which permits identification of data subjects for no longer than is necessary for those purposes and processed in a manner that ensures appropriate security of the personal data with protection against unauthorised or unlawful processing and against accidental loss, destruction or damage. According to Recital 47 of the LED, natural persons should have the right to have their inaccurate personal data rectified and the right to erasure where the processing of such data infringes the LED. Under Article 5 of the LED appropriate time limits are to be established for the erasure of personal data or for a periodic review of the need for the storage of personal data whose observation is to be ensured through procedural measures.

Furthermore, cases of AI systems wrongfully flagging individuals based on biased training data demonstrate the need for enhanced oversight and transparency. The EU emphasises the need for accountability mechanisms in data processing within AI systems to ensure that entities handling data can demonstrate compliance with privacy and data protection standards. Implementing legal accountability mechanisms is crucial for addressing any misuse of personal data. Deployment of AI technologies must be subject to regular audits, data protection impact assessments and transparent reporting to ensure compliance with the principles of privacy and data protection to ensure that the human-centric AI strategy aims to actively implement mechanisms to counteract AI-driven privacy and data protection infringements.

In essence, the EU's emphasis on privacy and data protection within its AI strategy reflects a comprehensive approach to ensuring that the deployment of AI in criminal justice not only enhances efficiency and effectiveness, but also rigorously protects individuals' rights and maintains the ethical integrity of the justice system.

3.4 ENCOURAGING MULTI-STAKEHOLDER ENGAGEMENT

The development and deployment of AI in criminal justice, according to the EU approach, should not be left solely to technologists or law enforcement agencies. It requires

[71] CEPEJ (n 47) 25.
[72] Commission, 'Communication on the EU Security Union Strategy' (n 1).

a multi-stakeholder engagement, including lawyers, legal academics, bar associations, legal ethicists, civil society organisations and the general public.[73] A lack of inclusive dialogue could lead to biased AI frameworks, democratic deficits and reduced public trust in AI-driven criminal justice systems. This inclusive approach thus helps to ensure that AI tools are developed with a broad perspective, considering various ethical, social, democratic and legal implications. By involving a wide array of stakeholders, the strategy aims to capture the complexity of ethical, legal, democratic and social dimensions that AI technologies intersect with, especially in sensitive areas such as criminal justice. Devising and ensuring that the principles of transparency, explainability and accountability are respected along the entire algorithmic design chain also requires a holistic multidisciplinary approach in the criminal justice system in which all stakeholders such as computer scientists, lawyers and social scientists, psychologists, sociologists, philosophers, etc. will have to join forces.[74] Engagement should include active stakeholder participation in AI system evaluations, policy development and ongoing monitoring to ensure that the AI systems operate within ethical and legal constraints. The EU's emphasis on multi-stakeholder engagement within the context of use of AI in criminal justice is therefore grounded in the understanding that diverse perspectives enrich the development process and lead to more equitable and effective solutions.[75]

This collaborative approach also facilitates a more transparent AI development process, where decisions are made openly and with the consideration of public interest. It encourages the co-creation of AI solutions, where stakeholders can contribute their expertise and insights, which would lead to more robust, fair and socially beneficial AI systems. Furthermore, multi-stakeholder engagement in AI development helps in identifying and addressing potential risks and unintended consequences early in the process. It ensures that safeguards and corrective measures are integrated into AI systems from the outset rather than as afterthoughts. Multi-stakeholder engagement alone is not however sufficient. AI decision-making in criminal justice must also address power imbalances between stakeholders. Law enforcement and private tech companies often hold disproportionate influence over AI policy development, which may lead to bias in or influence on regulatory decisions. To counteract this, civil society organisations must be granted greater access to AI evaluation processes, impact assessments and regulatory discussions. Diverse stakeholder representation, balanced stakeholder engagement and multi-stakeholder collaboration not only feed regulatory frameworks and public trust and foster greater transparency and ethical/legal oversight, but also enhance accountability in AI development and responsibility.[76] Consultation and collaboration with stakeholders may accordingly enhance in the end the legitimacy of use of AI in the criminal justice system.

Wide range stakeholder involvement, as being an essential aspect of the EU human-centric approach, in designing, deploying and developing (trustworthy and robust) AI systems in criminal justice, accordingly provides for meaningful input and deliberation from various components of the criminal law society and so ensures reflection of human

[73] Leslie (n 48) 3.
[74] Xenidis and Senden (n 26).
[75] ibid.
[76] Dimitrios Sargiotis, 'Fostering Ethical and Inclusive AI: A Human-Centric Paradigm for Social Impact' (2025) 6(1) International Journal of Research Publication and Reviews 3754.

element in its social context, balancing of interests and concerns of divergent components of the society, keeping the notion of criminal justice along with the evolving society and its values, mitigating concerns, promoting public awareness, building public trust, positive contribution of the integration of AI system in criminal justice to the society and in the end consolidating the legitimacy of the criminal justice system.

Briefly, the EU's call for multi-stakeholder engagement in the development and deployment of AI in criminal justice reflects a commitment to democratic, inclusive and responsible innovation. This approach not only enhances the legitimacy and effectiveness of AI applications in criminal justice but also aligns with broader societal values and the principle of good governance.

3.5 IS AI ASSISTING OR DECENTRING/REPLACING THE HUMAN JUDGE?

It is crucial to determine which tasks and to what extent they could be delegated to AI in the administration of justice, in particular to automated decision-making. In that respect it is significant under the primary question of whether certain judicial decisions should be made subject to automated decision-making or whether algorithms should merely support the decision-making process in criminal justice. While AI applications can streamline legal research, automate case law analysis and provide risk assessments and automated recommendations/decisions in helpful way to human judges, let alone fully automated judicial decision-making, even in the form of AI integration in assistance to human judge decision-making there arise significant concerns. In that respect accuracy/reliability of AI-generated evidence, overreliance on automation, inappropriate trust in AI outputs/recommendations affecting discretion of human judges, automation bias (discrimination) especially in recidivism risk assessments, de-individualisation/standardisation[77] and dehumanisation[78] of (criminal) justice, opacity preventing defence and then appeal, openness of the system to malicious reverse engineering and manipulation,[79] the certain loss of human control/oversight and the erosion of judicial independence and impartiality come to forefront.

The following three factors contributing to automation bias should be taken into consideration when determining the appropriate degree of delegation of decision-making to any AI system in the form of AI integration in assistance to human judges:

1) Under the cognitive miser hypothesis, there is a tendency of humans to choose the path of the least cognitive effort and so adhere to what the algorithm decides by relying on automated decisions, even when they suspect malfunction, and by following directives or suggestions of automated decision-making systems as a strong decision-making heuristic;

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[77] Giulia Gentile, 'Artificial Intelligence and the Crises of Judicial Power: (Not) Cutting the Gordian Knot?' (*SSRN*, 22 February 2024) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4731231> accessed 10 July 2024.

[78] Jiahui Shi, 'Artificial Intelligence, Algorithms and Sentencing in Chinese Criminal Justice: Problems and Solutions' (2022) 33 Criminal Law Forum 121.

[79] Engstrom, Ho, Sharkey, and Cuéllar (n 30).

2) There may arise humans' perceived trust of automated decision-making systems as with superior and outperforming analytical capabilities by overestimating their performance and ascribing them greater capability and authority than humans;
3) When sharing decision-making tasks with machines, humans may feel less responsible for the outcome as a result of diffusion of responsibility and may reduce their own effort in analysing and monitoring the data available.[80]

As regards fundamental rights, there are certain risks regarding the integration of AI in criminal justice. As mentioned above, there is a risk of alterations of the system or intrusions/interventions on the algorithm/data aimed at manipulating the system and influencing the judicial decision-making process.[81] Moreover, automated judicial decision-making would also amount to turning criminal law and criminal justice over to technocrats and experts by making it less sensitive to popular emotion and more sensitive to expertise and would thus transform 'criminal law from the public re-enactment of a society's moral habitus into the coldly calculating work of minimising net social harm'.[82] Given that data is in fact contextual and spatio-temporal and that the meaning of data is dependent upon the context in which it is used and variable according to the situation with the course of time, bias can creep into data through context to lead to unfair outcomes where contextual data or algorithmic systems being developed for one context are used in another.[83]

When it comes to risks arising from solely automated judicial decision-making in the criminal justice system, empathetic human judges equipped with emotional rationality to understand human beings having motivations, intentions and goals by relying upon their intuitive experiences[84] should thus be preferred to executory cold-blooded algorithmic machines.[85] Without human involvement, AI would be unable to replicate contextual notions of fairness.[86] The removal of humans may also remove human virtues, such as human discretion and judgment, empathy, conscience and intuition, from the criminal justice system.[87] This is because current algorithms either screen out value issues or interpret them as factual issues and are unable to accommodate value judgments. Thus, they may produce justice only on a formal level without dealing with the substantive legal questions.[88]

Secondly, automated decision-making may also risk de-humanising the court experience with the consequence of standardised justice under the auspices of computational law.[89] Given that the human judge constitutes an integral part of judicial decision-making, de-humanised justice might arise in cases where a human might delegate responsibility to an

[80] Willem H Gravett, 'Judicial Decision-Making in the Age of Artificial Intelligence' in Henrique Sousa Antunes et al (eds), *Multidisciplinary Perspectives on Artificial Intelligence and the Law* (Springer 2024) 291.
[81] Notaro (n 34).
[82] Vincent Chiao, 'Fairness, accountability and transparency: notes on algorithmic decision-making in criminal justice' (2019) 15(2) International Journal of Law in Context 126.
[83] Greenstein (n 39).
[84] Nina Peršak, 'Automated Justice and its Limits: Irreplaceable Human(E) Dimensions of Criminal Justice' in Gert Vermeulen, Nina Peršak, and Nicola Recchia (eds), *Artificial Intelligence, Big Data and Automated Decision-Making in Criminal Justice* (2021) 92/1 Revue Internationale de Droit Pénal 13.
[85] Završnik, 'Algorithmic justice' (n 24).
[86] Jones (n 34).
[87] Karen Yeung, 'Why worry about decision-making by machine?' in Karen Yeung and Martin Lodge (eds), *Algorithmic Regulation* (Oxford University Press 2019) 29.
[88] Shi (n 78).
[89] Gentile (n 77).

AI decision-support system or where AI system is designed not to have any human involvement in decision-making.[90] Automated decision-making offers an aura of objectivity or de-subjectivation, replaces subjectivity and the case-specific narrative and curtails the discretion of the practitioners.[91] Algorithms, which are not completely free of biases/prejudices, might draw inappropriate or offensive inferences[92] and thus lead not only to indirect discrimination, as generally regarded, but also to direct discrimination.[93] Due to liability and responsibility concerns, decision-making processes should not be automated, and decisions should be taken by persons capable of carrying responsibility and liability which are strongly related to the exercise of discretion in reaching those decisions.

Thirdly, as regards processes of case law analysis, legal research and decision drafting, quantitative legal analysis operates by identifying the most probable outcome out of past decisions and so makes tentative moves in operation toward the common law tradition, albeit on the strict basis of *stare decisis*, by linking future case law to past case law rather than the civil law tradition.[94] What happens in situations where no identical or similar precedent exists? AI systems, which are not currently able to go beyond the reproduction of precedence, remain unable to adapt to social changes. There is accordingly another risk of standardisation of decisions based on the prevalent case law and so the ossification of that case law.[95] Mechanical jurisprudence may thus stagnate the evolution of the law and lead to petrification of the legal system, which will be unable to adapt to contemporary legal and social challenges with different perspectives.[96] Probable risks arising from unprecedented situations should be taken into consideration for the sake of the development and adaptation of law to maintain its vivid characteristics.

Fourthly, lack of legal reasoning in decisions undermines the effectiveness of the justice system. On inscrutable integral aspects of AI, regarding utilisation of AI algorithms in judicial decisions Volokh expresses that consider the output, not the method[97] by advising to focus on the outcomes of such utilisation rather than to comprehend the decision-making process. Legal reasoning has, however, various functions, such as teaching/training legal minds, convincing fairness of the judgment and to provide legitimacy of justice, enables the right to contest/appeal. Full replacement would however make meaningless not only the defences made by human lawyers, but also the very existence of the appellate system. This is because of the deterministic nature of automated judicial decisions, since they, with the ultimate decision-making quality, would not be subject to any further interpretation, thus entailing that machines would influence or even create laws, which may lead to the invasion

[90] The Law Society Commission on the Use of Algorithms in the Justice System, 'Algorithms in the Criminal Justice System' (04 June 2019) Report, The Law Society of England and Wales <https://www.lawsociety.org.uk/topics/research/algorithm-use-in-the-criminal-justice-system-report> accessed 20 October 2024.
[91] Završnik, 'Algorithmic justice' (n 24).
[92] Joshua P Davis, 'Of Robolawyers and Robojudges' (2022) 73(5) Hastings Law Journal 1173.
[93] Jeremias Adams-Prassl, Reuben Binns, and Aislinn Kelly-Lyth, 'Directly Discriminatory Algorithms' (2023) 86(1) MLR 144.
[94] Lelieur et al (n 32) 49.
[95] Notaro (n 34).
[96] Federico Galli and Giovanni Sartor, 'AI Approaches to Predictive Justice: A Critical Assessment' (2023) 5 Humanities and Rights, Global Network Journal 165.
[97] Eugene Volokh, 'Chief Justice Robots' (2019) 68(6) Duke Law Journal 1135.

of automation of decisions beyond the courtroom and into the legislative process.[98] The paralysis of the appeal system thus arises if the software used at first instance and on appeal become identical, the fact of which would render the right to appeal illusory.[99] In this regard, how to devise the criteria for appellate court machines' decision-making is challenging.[100] Such an automated decision-making encoded with an ultimate paradigmatic conception would also hamper the right to lawful judge. Automated decision-making has the potential to affect also the preliminary ruling procedure.

The application of automated decision-making in the criminal justice system should therefore be examined from the perspective of certain criminal law principles, such as the right to lawful judge, the right to a fair trial, the right to defence and equality of arms in adversarial proceedings.[101] For instance, on the one hand, while law enforcement authorities have access to data possessed by private companies constructing AI systems, defence lawyers may not, on the other hand, while private parties can afford AI tools, due to budgetary restrictions, prosecutors and judges might not.[102] The right to access to court, the right to fair trial under Article 6(1) of the ECHR and the principle of effective judicial protection enshrined in Article 47 of the Charter would also be infringed. The right of access to court under Article 6(1) of the ECHR requires judicial review by a domestic court of full jurisdiction to examine all questions of fact and law relevant to the dispute before it, the factual background of the case, the relevant evidence and the application of the relevant law to the facts of the case.[103] Article 6(1) of the ECHR requires effective access to court to obtain such a review, being deprived of access to an appellate jurisdiction satisfying the requirements of Article 6(1) would in that regard constitute infringement of the right to access to justice.[104] In terms of the right to a fair trial, the asymmetries in information between the parties, especially within the context of the black-box problem and inequality of arms further carry the potential to infringe both the ECHR and EU fundamental rights law. De-humanised, de-subjectivated, non-individualised and legal reasoning absent justice based upon automated decision-making would therefore undermine those rights.

On those grounds, certain instances of decision-making in criminal justice should remain a domain reserved to human judges.[105] Judicial decision-making that is especially subject to the exercise of discretion should be kept as a unique human faculty. Law has been a human activity and must remain as such, as merely supported by the technology of AI but

[98] Galli and Sartor (n 96).
[99] Lelieur et al (n 32) 46.
[100] Žarko Dimitrijević, 'Smart Algorithms as a Prerequisite for the Use of Artificial Intelligence in Judicial Decision-Making' (2023) Year XII Issue 2023, Harmonious Journal of Legal and Social Studies in South East Europe 78.
[101] *Sigurður Einarsson and Others v Iceland* App no 39757/15 (ECtHR, 4 June 2019) paras 66, 85-89.
[102] Lelieur et al (n 32) 46.
[103] *Capital Bank Ad v Bulgaria* App no 49429/99 (ECtHR, 24 February 2006) para 98; *Project-Trade D.O.O. v Croatia* App no 1920/14 (ECtHR, 20 December 2013) paras 50 and 67.
[104] *Credit and Industrial Bank v The Czech Republic* App no 29010/95 (ECtHR, 21 October 2003) paras 72-73; *Capital Bank Ad v Bulgaria* (n 103) para 117.
[105] Johanna Sprenger and Dominik Brodowski, "Predictive policing', 'Predictive Justice', and the use of 'Artificial Intelligence' in the Administration of Criminal Justice in Germany' (2023) A-02 Association internationale de droit penal 5.

never replaced by or subordinated to it.[106] Otherwise, judges and legal professionals may delegate their tasks to machines with the result of relegating humans to a subordinate position to algorithms.[107] Although there is lack of proper ethical criteria for a comparative assessment between the performance of algorithms and humans in criminal justice and of the theoretical resources to determine which is ethically preferable,[108] there should be categorical objection to the substitution or full replacement of human judges. Substitution of AI for human judgment would otherwise undermine judicial independence. There should not therefore arise concerns whether algorithms will bring the future with a rule of law or a rule of algorithm.[109] Categorical objection to such substitution is not only a matter of whether algorithms are at present capable of outperforming human judge decisions and judgments. It is also an ontological and a moral matter about: the determination of what kind of society we want to construct on the basis of whose value; where to place human element in it; who should be the ultimate arbiter to resolve disputes between humans; whether justice for humans could be delegated to AI, which lacks of factors peculiar to human beings such as emotion, empathy, intuition, discretion, common sense, conscience, value judgments and sense of justice/fairness. The latter matter arises as such despite the fact that no one could contrarily argue that the existing criminal justice system operates perfectly without any bias, discrimination, arbitrariness and injustice.

In that regard, the human-in-the-loop approach reinforces the idea that AI should support, but never supplant human expertise and ethical judgment. In that regard as declared by the Council, AI must not interfere with the decision-making power of human judges or judicial independence and a court decision cannot be delegated to an AI tool and must always be made by a human being.[110] In that respect, especially Recital 61 of EU AI Act expresses that '[t]he use of AI tools can support the decision-making power of judges or judicial independence, but should not replace it: the final decision-making must remain a human-driven activity'. To enforce this principle, legal frameworks should implement mandatory AI impact assessments before deployment in judicial settings and human-in-the-loop mechanisms, ensuring that human judges remain, with effective discretion, in the centre of judicial decision-making and AI outputs are reviewed and contextualised by legal professionals. This should be fostered by transparent auditing procedures for AI-generated recommendations, allowing external oversight and accountability. Additionally, there should be training programs for judges and legal professionals to enhance AI literacy, preventing uncritical acceptance of or overreliance on algorithmic outputs.

Furthermore, Article 22 of the GDPR, similarly to Article 15 of Data Protection Directive[111] and Article 11 of Law Enforcement Directive, gives the data subject 'the right

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[106] M Patrão Neves and A Betâmio de Almeida, 'Before and Beyond Artificial Intelligence: Opportunities and Challenges' in Henrique Sousa Antunes et al (eds), *Multidisciplinary Perspectives on Artificial Intelligence and the Law*, (Springer 2024) 123.
[107] Galli and Sartor (n 96).
[108] Jesper Ryberg, 'Artifcial intelligence at sentencing: when do algorithms perform well enough to replace humans?' (2024) AI and Ethics.
[109] Greenstein (n 39).
[110] Council of the European Union, 'Council Conclusions – Access to Justice – Seizing the Opportunities of Digitalisation' 2020/C 342 I/01.
[111] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31.

not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her'. This right, accompanied with the right to obtain human intervention and to contest the decision in order to maintain human oversight over AI systems, however, is subject to three exceptions: if it is necessary for contractual purposes; if it is authorised by Union or Member State law laying down safeguards for the data subject; and if it is based on the data subject's explicit consent. Recital 71 of the GDPR entails that automated processing should be subject to suitable safeguards for the data subject to obtain an explanation of the decision reached after such assessment and to challenge the decision. Article 13(2) of the GDPR also provides for the data subjects with the information of the existence of automated decision-making and meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject. The right not to be subject to automated decision-making, the right to obtain human intervention and the right to challenge such decisions are also recognised by the CJEU.[112]

Digital justice on the one hand may offer an algorithmic decision that replaces a human decision within the context of supporting judges with certain advantages in terms of effectiveness, efficiency, speed and margin of error[113] with capabilities of investigation, massive amount of data-processing, analysing information, bias-detecting, enhancing legal cognition, ensuring human judges access to widespread relevant precedents, identifying patterns, generating predictive risk assessments and identification of certain crimes such as cybercrimes or deepfakes. On the other hand, it may pose risks to fundamental rights, such as biases and discrimination, and to judicial impartiality and independence and human-centric judicial decision-making. Given the compensating performance of AI systems in the administration of justice it would not be plausible to raise a categorical objection to deploying AI system for assisting, but merely to any form of automated judicial decision-making replacing human judges. To be precise, human-centric conception of justice requires both categorical rejection to automated decision-making and precautionary utilisation of the assistive dimension of AI.

For the foregoing reasons, a human(-centric) component should be a must in the criminal justice system and so human-centric, human-made, human-supportive/complementary and human-controlled AI as declared by the European Parliament should be preserved in the system.[114] Given the certain advantages stemming from the use of AI in the criminal justice system, a hybrid model seems to be the best to ensure with the firm reservation of non-elimination of the human factor from decision-making in the criminal justice system. In such assistive form, AI should merely enable human judges to concentrate in their case analysis more on substantive legal issues and help judges with drafting legal documents and decisions. AI may collect and interpret data, process the information derived from them, find patterns in them and make predictions on the basis of those patterns. As declared by the Council, AI may 'improve the functioning of justice systems for the benefit of citizens and businesses by assisting judges and judicial staff in their

[112] Case C-634/21 *SCHUFA Holding* EU:C:2023:957 paras. 54-56, 66.
[113] Angela Busacca and Melchiorre Monaca, 'Using AI for Justice: Principles and Criteria of the "European Ethical Charter on the Use of AI in Judicial Systems"' in Domenico Marino and Melchiorre Monaca (eds), *Artificial Intelligence and Economics: the Key to the Future* (Springer 2023) 157-172.
[114] European Parliament Resolution (n 21).

activities, accelerating court/tribunal proceedings and helping enhance the comparability, consistency and, ultimately, the quality of judicial decisions'.[115] Argument-mining capability of AI may propose to human judges nuanced perspectives from precedents and so may provide a foundational basis for robust and well-informed decision-making.[116] Summarisation and analysis tools distil extensive legal documents and case law into concise and digestible insights and facilitate quicker comprehension of complicated cases.[117] Identifying similar cases may provide judges with a broader and holistic comprehension of legal issues.[118] For instance, evidence-based judicial decision-making would indeed be improved by the use of AI.[119] While leaving the human judge as the ultimate judicial decision-maker, it would thus be reasonable to use AI in the criminal justice system insofar as it replaces labour-intensive and paper-based systems.[120] Information technology could accordingly be used to facilitate the judicial task.[121] In using IT this way, judges certainly require technical expertise to efficiently use and evaluate outcomes of AI systems on the basis of AI specialised educational and training programs.

On the other hand, human judges should be able to distance themselves from AI outputs. Human judges should refrain from the blind pursuit of automated outputs. In that regard, accuracy, precision, recall, effectiveness, fairness, security, robustness, traceability, explicability and so trustworthiness and reliability are parameters to be taken into account when assessing algorithms to keep track of false positives and false negatives engendered by predictive models.[122] Ensuring the trustworthiness of AI is a significant step to achieve both individual and collective human wellbeing, the ultimate aims for using AI.[123] The principle of control by the user articulated in the Ethics Guidelines[124] thus enables the centrality of the human in the judicial decision. Human oversight therefore keeps the human at the centre and provides for the supportive operation of AI in compliance with fundamental rights and ethical values to draw public confidence and support. Human oversight is significant for the protection of fundamental rights and human autonomy against AI/machine autonomy.[125] Accountability for abuses and errors committed in automated decision-making processes and the possibility to review and overturn mistaken judicial

[115] Council of the European Union, 'Seizing the Opportunities of Digitalisation' (n 110).
[116] Galli and Sartor (n 96).
[117] ibid.
[118] ibid.
[119] Hartmann and Wenzelburger (n 26).
[120] Teodor Manea and Dragos Lucian Ivan, 'AI Use in Criminal Matters as Permitted under EU Law and as Needed to Safeguard the Essence of Fundamental Rights' (2022) 1(1) International Journal of Law in Changing World 1.
[121] Mikael Rask Madsen and Robert Spano, 'Authority and Legitimacy of the European Court of Human Rights: Interview with Robert Spano, President of the European Court of Human Rights' (2021) iCourts Working Paper Series, no. 236.
[122] Federico Boggia, 'Artificial intelligence in the Criminal Justice System The Role of decision-makers and how big data tools support them' (2 June 2022) <https://drive.binatomy.com/AIJustice.pdf> accessed 10 July 2024; Francisco J Castro-Toledo, Fernando Miró-Llinares, and Jesús Carreras Aguerri, 'Data-Driven Criminal Justice In The Age Of Algorithms: Epistemic Challenges And Practical Implications' (2023) 34 Criminal Law Forum 295.
[123] AI-HLEG (n 10) 9-11.
[124] ibid., 26-27.
[125] Riikka Koulu, 'Proceduralizing control and discretion: Human oversight in artificial intelligence policy' (2020) 27(6) Maastricht Journal of European and Comparative Law 720.

decisions made by or with the support of AI with the chance to challenge them accordingly may reduce negative consequences of algorithmisation.[126]

4 CONCLUSION

The EU's Human-Centric AI Framework represents a pioneering vision for the responsible deployment and development of AI technologies. By prioritising ethical principles and fundamental values and rights at the core of its AI strategy, the EU aims to foster an ecosystem where AI can be a force for good, enhancing societal well-being while mitigating risks. As this framework is put into practice, particularly in critical areas like criminal justice, it will likely evolve in response to emerging challenges and technological advancements, maintaining its core commitment to placing humans at the centre of the AI (r)evolution.

The EU's human-centric AI strategy in that regard offers a blueprint for the future of integrating AI into the criminal justice system in a way that upholds human rights, promotes fairness and maintains public trust. As countries around the world grapple with the challenges and opportunities presented by AI in criminal justice, the implications arising from the EU's approach therefore appear both timely and instructive. The EU's AI strategy can be a model for balancing innovation with fundamental rights and values. With international collaboration, the EU can lead global efforts towards trustworthy AI practices. By prioritising ethical considerations, transparency and inclusivity, the criminal justice system therefore can harness the power of AI to improve outcomes without compromising fundamental values and rights. Moreover, to prevent and rectify biases in AI algorithms, the EU rigorously scrutinises the implementation of AI, which may perpetuate historical biases and injustices leading to discriminatory outcomes. Additionally, the EU advocates for explainable AI, as it enables stakeholders to understand and evaluate the logic behind AI-driven decisions.[127] This approach builds public trust and ensures that AI is used ultimately in compliance with the rule of law and EU fundamental values.

By prioritising human oversight, the EU stands as a guardian against the de-humanisation, de-subjectivation, de-individualisation of justice or legal reasoning absent justice and underscores the importance of keeping human judgment at the core of AI systems, especially those designated as high-risk. The strategy's focus on reducing bias and enhancing fairness addresses critical ethical concerns, aiming to ensure AI tools supporting equitable justice rather than perpetuating existing disparities. Transparency and accountability form another cornerstone of the EU's framework, advocating for explainable AI systems in fostering trust and enabling ethical and responsible use. The strong emphasis on privacy and data protection aligns with the EU's broader commitment to fundamental rights, ensuring that AI applications in criminal justice safeguard sensitive personal information. The call for multi-stakeholder engagement reflects the EU's recognition that the development and deployment of AI in criminal justice require a collaborative effort, drawing on the expertise and perspectives of a diverse range of actors. This inclusive approach not only enriches the AI development process but also ensures that these powerful technologies are aligned with societal values, ethical and legal norms. Categorical objection

[126] Carrera, Mitsilegas, and Stefan (n 62).
[127] CEPEJ (n 47) 25.

to substitution of human judges by AI also keeps the human component always at the centre of the judicial decision-making, especially in criminal justice.

As AI continues to evolve and its application in criminal justice becomes more pervasive, the implications arising from the EU AI strategy offers timely and essential guidance for the development of AI systems that are not only to be technologically advanced, but also to be ethical, equitable, human-centred and aligned with fundamental rights. The EU's framework accordingly sets a benchmark for trustworthy AI practice. Ultimately, the EU's AI human-centred AI strategy emphasises that the path to a safe, technology-integrated criminal justice system must be navigated with a commitment to human dignity and the common well-being of humans.

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RETHINKING THE LIST-BASED APPROACH TO HIGH-RISK SYSTEMS UNDER THE AI ACT

TIAGO SÉRGIO CABRAL*

In this article, I critically analyse the expedited procedure for amending the list of high-risk systems under the AI Act. I conclude that the expedited procedure, along with the list-based approach in general, are suboptimal solutions as they fail to safeguard two key objectives: (i) protection of individuals' fundamental rights; and (ii) legal certainty for businesses. The option of carrying out a revision of the legal instrument through the ordinary legislative procedure, while always a possibility, may be too slow for its purpose and its success is far from certain. As such, I argue: that a test-based approach would have been a better option to future-proof the AI Act; that its building blocks are already include in the AI Act; and that it would have been advantageous both for individuals and businesses.

1 INTRODUCTION

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence ('the AI Act')[1] is the first comprehensive sectorial regime focusing on artificial intelligence ('AI') in a major world economic bloc. In regulating AI, the AI Act opts for a risk-based approach, adapting its obligations in accordance with the risk that different AI systems/models represent to fundamental rights.[2]

Within the categories of AI systems/models established by the AI Act, high-risk systems were given particular focus by the EU's legislator, with Articles 6 to 49 of the AI Act (Chapter III) being focused on such systems.[3] When defining which systems should fit in this category, the legislator opted for a (double) list-based classification through Annexes I and III of the AI Act.[4]

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* PhD Candidate at the University of Minho (Portugal) | Researcher at JusGov (Portugal) | Project Expert for the Portuguese team in the 'European Network on Digitalization and E-governance' (ENDE).

[1] For an overview of the process resulting in the approval of the AI Act and the evolution of this legal instrument through the legislative procedure, see Francesca Palmiotto, 'The AI Act Roller Coaster: The Evolution of Fundamental Rights Protection in the Legislative Process and the Future of the Regulation' (2025) First View European Journal of Risk Regulation 1.

[2] See, European Commission, 'Artificial Intelligence – Q&As' <https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_1683> accessed 18 January 2025.

[3] Bird&Bird, 'European Union Artificial Intelligence Act: A Guide' 22–34 <https://www.twobirds.com/-/media/new-website-content/pdfs/capabilities/artificial-intelligence/european-union-artificial-intelligence-act-guide.pdf> accessed 1 January 2025.

[4] 'EU AI Act: First Regulation on Artificial Intelligence' (Topics | European Parliament, 6 August 2023) <https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence> accessed 16 January 2025; 'AI Act | Shaping Europe's Digital Future' (12 December 2024) <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai> accessed 16 January 2025; 'Entry into Force of the European AI Regulation: The First Questions and Answers from the CNIL' <https://www.cnil.fr/en/entry-force-european-ai-regulation-first-questions-and-answers-cnil> accessed 16 January 2025; 'Understanding the EU AI Act' <https://www.hunton.com/insights/legal/eu-ai-act> accessed 16 January 2025.

This type of approach, while in theory better from a perspective of legal certainty for businesses, may not be flexible enough to ensure that the legislation is future-proof. In this article, I argue that the AI Act does not offer adequate solutions to review the list of high-risk systems currently established, which may represent an added risk to fundamental rights of individuals (particularly in an innovative field, such as AI) and that even the supposed benefits for legal certainty for businesses may become less clear if we consider the implementation of the AI Act's lists of high-risk systems.

2 HIGH-RISK AI SYSTEMS THROUGH THEIR INCLUSION IN EU PRODUCT SAFETY LEGISLATION

While not outright forbidden, like the AI uses included in Article 5 of the AI Act, the legislator still considered that high-risk systems require significant guardrails to mitigate the negative impacts for fundamental rights of individuals that the incorrect, negligent or improper use of these systems could have.[5] High-risk systems can be divided into two sub-categories, based on the source of their classification: (i) high-risk AI Systems through their inclusion in European Union ('EU') product safety legislation which we will analyse in this section; and (ii) high-risk AI Systems based on their direct identification in the AI Act which we will further delve into in the next section.[6]

Under Article 6(1) of the AI Act, an AI system will be considered as high-risk[7] when it is both (i) either intended to be used as a safety component[8] of a product or the AI system in itself is a product, covered by one of the legislative acts listed in the list of product safety legislation in Annex I of the AI Act; and (ii) the product for which the AI system is a safety component, or the AI system itself as a product, has to undergo a third-party conformity assessment procedure[9] with a view to its placing on the market or putting into service under one of the legislative acts referred to in Annex I. For the assessment of the level of risk of the product, it is not relevant whether the placing on the market or putting into service of the AI system takes place at the same time or independently from the product to which it is linked, if it is linked to any product.[10]

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[5] In addition to prohibited AI uses (Article 5 of the AI Act) and high-risk AI systems (Article 6 of the AI Act), the AI Act also regulates AI systems subject to specific transparency requirements (Article 50 of the AI Act), general-purpose AI models. and general-purpose AI models with systemic risk (Article 51 and following of the AI Act).

[6] Regarding the regulation of high-risk AI systems and the obligations that are applicable. See, Nuno Sousa e Silva, 'The Artificial Intelligence Act: Critical Overview' (*SSRN*, 24 September 2024) <https://papers.ssrn.com/abstract=4937150> accessed 20 October 2024; Asress Adimi Gikay et al, 'High-Risk Artificial Intelligence Systems under the European Union's Artificial Intelligence Act: Systemic Flaws and Practical Challenges' (SSRN, 18 December 2023) <https://papers.ssrn.com/abstract=4621605> accessed 20 October 2024.

[7] For an overview of the rules applicable to the qualification and regulation of these systems, see Sousa e Silva (n 6); Guillaume Couneson, 'Commentary to Article 6' in Ceyhun Necati Pehlivan, Nikolaus Forgó and Peggy Valcke (eds), *The EU Artificial Intelligence (AI) act: a commentary* (Wolters Kluwer 2025).

[8] Under Article 3(14) of the AI Act a safety component is 'a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property'.

[9] Eva Thelisson and Himanshu Verma, 'Conformity Assessment under the EU AI Act General Approach' (2024) 4 AI and Ethics 113.

[10] See, Arnoud Engelfriet, *The Annotated AI Act: Article-by-Article Analysis of European AI Legislation* (Ius Mentis 2024) 94–97; Guillaume Couneson, 'Commentary to Article 7' in Ceyhun Necati Pehlivan,

3 HIGH-RISK AI SYSTEMS BASED ON THEIR DIRECT IDENTIFICATION IN THE AI ACT

As explained above, Annex III of the AI Act sets down a number of systems, divided into 8 categories that are directly established as high-risk. These are:

Table 1

Type of System	Source
Biometrics, in so far as their use is permitted under relevant EU or national law	
Remote biometric identification systems. *This shall not include AI systems intended to be used for biometric verification the sole purpose of which is to confirm that a specific natural person is the person he or she claims to be.*	Annex III(1)(a)
AI systems intended to be used for biometric categorisation, according to sensitive or protected attributes or characteristics based on the inference of those attributes or characteristics.	Annex III(1)(b)
AI systems intended to be used for emotion recognition.	Annex III(1)(c)
Critical infrastructure	
AI systems intended to be used as safety components in the management and operation of critical digital infrastructure and road traffic or in the supply of water, gas, heating or electricity.	Annex III(2)(a)
Education and vocational training	
AI systems intended to be used to determine access or admission or to assign natural persons to educational and vocational training institutions at all levels.	Annex III(3)(a)
AI systems intended to be used to evaluate learning outcomes, including when those outcomes are used to steer the learning process of natural persons in educational and vocational training institutions at all levels.	Annex III(3)(b)
AI systems intended to be used for the purpose of assessing the appropriate level of education that an individual will receive or will be able to access, in the context of or within educational and vocational training institutions at all levels.	Annex III(3)(c)
AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of or within educational and vocational training institutions at all levels.	Annex III(3)(d)
Employment, workers' management and access to self-employment	
AI systems intended to be used for the recruitment or selection of natural persons, in particular to place targeted job advertisements, to analyse and filter job applications and to evaluate candidates.	Annex III(4)(a)

Nikolaus Forgó and Peggy Valcke (eds), The EU Artificial Intelligence (AI) act: a commentary (Wolters Kluwer 2025) 7.

Type of System	Source
AI systems intended to be used to make decisions affecting terms of work-related relationships, the promotion or termination of work-related contractual relationships, to allocate tasks based on individual behaviour or personal traits or characteristics or to monitor and evaluate the performance and behaviour of persons in such relationships	Annex III(4)(b)
Access to and enjoyment of essential private services and essential public services and benefits	
AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services, as well as to grant, reduce, revoke or reclaim such benefits and services.	Annex III(5)(a)
AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems used for the purpose of detecting financial fraud.[11]	Annex III(5)(b)
AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance	Annex III(5)(c)
AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by police, firefighters and medical aid, as well as of emergency healthcare patient triage systems.	Annex III(5)(d)
Law enforcement, in so far as their use is permitted under relevant EU or national law	
AI systems intended to be used by or on behalf of law enforcement authorities, or by EU institutions, bodies, offices or agencies in support of law enforcement authorities or on their behalf to assess the risk of a natural person becoming the victim of criminal offences.	Annex III(6)(a)
AI systems intended to be used by or on behalf of law enforcement authorities or by EU institutions, bodies, offices or agencies in support of law enforcement authorities as polygraphs or similar tools.	Annex III(6)(b)
AI systems intended to be used by or on behalf of law enforcement authorities, or by EU institutions, bodies, offices or	Annex III(6)(c)

[11] Adding to the extensive existing regulation of this practice – see Joana Rita Sousa Covelo de Abreu, Diogo Morgado Rebelo and César Analide, 'O Mercado Único Digital e a "(Leigo)Ritmia" Da Pontuação de Crédito Na Era Da Inteligência Artificial' (2020) 2 Revista de Direito e Tecnologia 1; Francisco Andrade and Diogo Morgado Rebelo, 'Schufa's Case C-634/21 on ADM: The "Lenders" Quest' for GDPR-Friendly Scoring Has Not Been Settled Yet!' (*SSRN*, 2 July 2024) <https://papers.ssrn.com/abstract=4882806> accessed 19 January 2025; Alessandra Silveira, 'Automated Individual Decision-Making and Profiling [on Case C-634/21 - SCHUFA (Scoring)]' (2023) 8(2) UNIO – EU Law Journal 74.

Type of System	Source
agencies, in support of law enforcement authorities to evaluate the reliability of evidence in the course of the investigation or prosecution of criminal offences.	
AI systems intended to be used by law enforcement authorities or on their behalf or by EU institutions, bodies, offices or agencies in support of law enforcement authorities for assessing the risk of a natural person offending or re-offending not solely on the basis of the profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680, or to assess personality traits and characteristics or past criminal behaviour of natural persons or groups.	Annex III(6)(d)
AI systems intended to be used by or on behalf of law enforcement authorities or by EU institutions, bodies, offices or agencies in support of law enforcement authorities for the profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of the detection, investigation or prosecution of criminal offences.	Annex III(6)(e)
Migration, asylum and border control management, in so far as their use is permitted under relevant EU or national law	
AI systems intended to be used by or on behalf of competent public authorities or by EU institutions, bodies, offices or agencies as polygraphs or similar tools.	Annex III(7)(a)
AI systems intended to be used by or on behalf of competent public authorities or by EU institutions, bodies, offices or agencies to assess a risk, including a security risk, a risk of irregular migration or a health risk, posed by a natural person who intends to enter or who has entered into the territory of a Member State.	Annex III(7)(b)
AI systems intended to be used by or on behalf of competent public authorities or by EU institutions, bodies, offices or agencies to assist competent public authorities for the examination of applications for asylum, visa or residence permits and for associated complaints with regard to the eligibility of the natural persons applying for a status, including related assessments of the reliability of evidence.	Annex III(7)(c)
AI systems intended to be used by or on behalf of competent public authorities, or by EU institutions, bodies, offices or agencies, in the context of migration, asylum or border control management, for the purpose of detecting, recognising or identifying natural persons, with the exception of the verification of travel documents.	Annex III(7)(d)
Administration of justice and democratic processes	
AI systems intended to be used by a judicial authority or on their behalf to assist a judicial authority in researching and interpreting	Annex III(8)(a)

Type of System	Source
facts and the law and in applying the law to a concrete set of facts or to be used in a similar way in alternative dispute resolution.[12]	
AI systems intended to be used for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda. *This does not include AI systems to the output of which natural persons are not directly exposed, such as tools used to organise, optimise or structure political campaigns from an administrative or logistical point of view*	Annex III(8)(b)

4.1 THE PROCEDURE FOR INTRODUCING AMENDMENTS TO ANNEX III OF THE AI ACT

4.1[a] Description of the procedure to add or modify the list of high-risk AI systems

The AI Act allows for the introduction of amendments to Annex III by means of a delegated act[13] adopted by the European Commission (Article 7 of the AI Act)[14] and requires the European Commission to annually assess whether a revision of this annex is necessary (Article 112(1) of the AI Act).[15]

As per the rules of the AI Act, the European Commission can add or modify the list of high-risk systems under Annex III of the AI Act when two cumulative criteria are fulfilled:

a) the AI systems are intended to be used in any of the areas listed in Annex III; and

[12] Regarding the use of AI systems by judicial authorities and particularly courts, see, Joana Covelo De Abreu, 'The "Artificial Intelligence Act" Proposal on European e-Justice Domains Through the Lens of User-Focused, User-Friendly and Effective Judicial Protection Principles' in Henrique Sousa Antunes et al (eds), *Multidisciplinary Perspectives on Artificial Intelligence and the Law* (Springer International Publishing 2024); Tiago Sérgio Cabral, 'Inteligência Artificial e Atividade Judicial: Análise Das Principais Questões a Nível de Proteção de Dados Pessoais e o Futuro Regulamento Da União Europeia Sobre IA' in Ricardo Pedro and Paulo Caliendo (eds), *Inteligência artificial no contexto público: Portugal e Brasil* (Almedina 2023).

[13] About the rules and limitations governing delegated acts see Alina Kaczorowska-Ireland, *European Union Law* (4th edn, Routledge 2016) 160; Tiago Sérgio Cabral, 'A Short Guide to the Legislative Procedure in the European Union' (2020) 6 UNIO – EU Law Journal 161; Tiago Sérgio Cabral and Marília Frias, 'National Laws and Implementing Regulation 2019/947/EU' (VdA - Vieira de Almeida, Cabinet d'avocats) <https://www.vda.pt/fr/publications/insights/by-marilia-frias-tiago-sergio-cabral/21300/> accessed 20 October 2024.

[14] See also the text of Recital 52 stating that 'As regards stand-alone AI systems, namely high-risk AI systems other than those that are safety components of products, or that are themselves products, it is appropriate to classify them as high-risk if, in light of their intended purpose, they pose a high-risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in this Regulation. *The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems that the European Commission should be empowered to adopt, via delegated acts, to take into account the rapid pace of technological development, as well as the potential changes in the use of AI systems*' (emphasis added).

[15] Until the end of the period of the delegation of power laid down in Article 97 of the AI Act. Additionally, by 2 August 2028 and every four years thereafter, the European Commission is required to evaluate and report to the European Parliament and to the Council, among others, the need for amendments extending existing area headings or adding new area headings in Annex III of the AI Act.

b) 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.

Furthermore, the evaluation of the risk of harm to health and safety, or an adverse impact on fundamental rights and its seriousness should follow the detailed criteria established in Article 7(2) of the AI Act. These criteria seem, based on the wording and logic behind this provision, to be exhaustive.

4.1[b] Description of the procedure to suppress systems from the list of high-risk AI systems

Likewise, through a delegated Act, the European Commission may suppress AI systems from the list of high-risk AI systems in Annex III of the AI Act (Article 7(3) of the AI Act). To do so, the following cumulative criteria must be fulfilled:

a) the high-risk AI system concerned no longer poses any significant risks to fundamental rights, health or safety (in light of the same criteria used to evaluate the addition or modification of systems in the list); and
b) the deletion does not decrease the overall level of protection of health, safety and fundamental rights under EU law.

4.1. [c] Interplay between the procedure to amend Annex III under Article 7 of the AI Act and the procedure to amend the derogations to the high-risk classification under Articles 6(6-8 of the AI Act).

Article 6(6)-(8) of the AI Act also provides tools which allow the European Commission to, through delegated acts, exercise a degree of control over AI systems considered high-risk. While Article 7 achieves this through the addition, modification or suppression of AI systems considered high-risk under Annex III (as long as they are part of the areas listed in Annex III), Article 6(6)-(8) allow the European Commission to add, modify or suppress conditions for triggering the derogation to the general rule that AI systems included in Annex III of the AI Act will be considered high-risk[16] Aware of the interplay between both regimes, the European legislator goes as far as to establish that any amendments to the derogation regime should remain consistent with amendments to Annex III adopted under Article 7 [17]

Paragraphs 6 to 8 of Article 6 allow the European Commission to broaden or narrow the application of the high-risk regime to AI systems already included in Annex III by adding, amending or suppressing derogations. This may be useful if the European Commission concludes: (i) that certain specific applications of the AI systems in Annex III are facing

[16] According to Article 6(3) of the AI Act, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. This derogation should apply when: (i) the AI system is intended to perform a narrow procedural task; (ii) the AI system is intended to improve the result of a previously completed human activity; (iii) the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or
(iv) the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III of the AI Act.
[17] See Article 6(8) of the AI Act.

regulatory overburden even though they do not pose a significant risk of harm to the health, safety or fundamental rights of natural persons and, thus, that it is necessary to add new derogations or amend existing derogations to exempt them; or (ii) that certain specific applications of the AI systems in Annex III currently benefiting from the derogations do, in fact, pose a significant risk of harm to the health, safety or fundamental rights of natural persons and, thus, that it is necessary to ensure they will be subject to the general rule by suppressing or amending existing derogations exempting the abovementioned AI systems.

There are, however, significant differences between Article 7 and paragraphs 6 to 8 of Article 6. . First, it is not possible to add new systems to Annex III based on paragraphs 6 to 8 of Article 6 even within the areas already in this Annex. Secondly, it is not possible to fully suppress AI systems from Annex III based on this regime.[18] Moreover, while Article 7 is limited by the eight areas in Annex III, the regime under paragraphs 6 to 8 of Article 6 is even more limited, as it can only affect the specific systems already included in Annex III. Article 7 is, hence, significantly broader, being a tool designed for more throughout changes to Annex III.

4.1[c] Why the procedure for introducing amendments in Annex III of the AI Act may not be fit for purpose

In essence, as explained above, Article 7 of the AI Act establishes an expedited procedure for introducing amendments to Annex III. The aim of this expedited procedure is to avoid the challenges of legislative interventions under the regular rules of the ordinary legislative procedure.[19]

The expedited procedure, which at its core has not changed much since the Commission's initial proposal,[20] does, however, have one very strong shortcoming: if a new system cannot be included in one of the eight areas currently in Annex III, the European Commission cannot intervene.[21] Therefore, a system that supports the use of AI in a new domain could remain unregulated[22] for an extended period of time, even if the seriousness of the risks and negative consequences it could bring to individuals is clear.

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[18] Although, in theory, the European Commission could add new derogations or broaden the current derogations to a degree that it would result in a, de facto, suppression. Nonetheless, doing this would likely breach the consistency requirements under Article 6(8) and, if that were the aim, it would be wiser and more adequate to suppress the AI system from Annex III through Article 7(3).

[19] The EU AI Act where approved both under the Article 16 TFUE and Article 114 TFEU legal basis both subject to the ordinary legislative procedure. For more development on the legislative procedures in the EU, see Cabral, 'A Short Guide to the Legislative Procedure in the European Union' (n 13); Christilla Roederer-Rynning, 'Passage to Bicameralism: Lisbon's Ordinary Legislative Procedure at Ten' (2019) 17 Comparative European Politics 957; Justin Greenwood and Christilla Roederer-Rynning, 'Taming Trilogues: The EU's Law-Making Process in a Comparative Perspective' in Olivier Costa (ed), *The European Parliament in Times of EU Crisis* (Springer International Publishing 2019); Christilla Roederer-Rynning and Justin Greenwood, 'The Culture of Trilogues' (2015) 22(8) Journal of European Public Policy 1148.

[20] See Article 7 of the 2021 Commission proposal.

[21] Articles 6(6-8) also do not offer a solution as new systems cannot be added to Annex III under the rules for amending the derogations.

[22] At least in what concerns the AI Act, as it might still be subject to other EU legislation. See, inter alia, Giovanni Sartor, 'The Impact of the General Data Protection Regulation (GDPR) on Artificial Intelligence' (EPRS, 2020) <https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641530/EPRS_STU(2020)641530_EN.pdf> accessed 30 October 2024; Magda Cocco et al, 'European Parliament Think Tank Study on the Impact of the General Data Protection Regulation (GDPR) on Artificial Intelligence' (*VdA*, 30 June 2020)

In fact, in my opinion, the criticism of the lack of flexibility in the expedited procedure for revising Annex III could be extended to the list-based classification itself.

Under the current system established in the AI Act, if the legislator deems in the future that it must expand the scope of this legal instrument to further types of AI systems, it may rely on two options. The first option is the revision of the AI Act through a new legislative procedure and introduction of the system in Annex III. As well as being time-consuming and complex, this has the disadvantage of potentially reopening the entire law to new discussion.[23] A sub-option of this approach would be to conduct a targeted revision of Annex III when adopting another legal instrument. For example, if the EU was regulating a specific type of AI system through a separate legal instrument, it could also amend Annex III of the AI Act through this instrument to include the type of system being regulated in Annex III. There are some advantages to this approach, mainly that the likelihood of extensive amendments to the AI Act is lower.[24] However, it still depends on separate legislation and is a fairly complex process. Additionally, the legal instrument used to amend the AI Act should have a scope that is adequate for this purpose (i.e. unrelated legislation such as, for example, legislation about the financial sector would be inadequate).

The second hypothesis would be to either introduce changes in product safety legislation by: (i) expanding current product safety legislation already considered in Annex I

<https://www.lexology.com/library/detail.aspx?g=6f8813cf-0c7a-4a50-aa8e-20ccb48367bf> accessed 30 October 2024; Tiago Sérgio Cabral and Alessandra Silveira, 'Da Utilização de Inteligência Artificial Em Conformidade Com o RGPD: Breve Guia Para Responsáveis Pelo Tratamento' in Henrique Alves Pinto, Jefferson Carús Guedes, and Joaquim Portes De Cerqueira César, *Inteligência Artificial aplicada ao processo de tomada de decisões* (Editora D'Plácido 2020); Tiago Sérgio Cabral, 'Regulamento Sobre a Inteligência Artificial Na União Europeia : Potenciais Impactos Nas Entidades Públicas' (2021) 12 Revista de Direito Administrativo 89; Inês Neves, 'The EU Directive on Violence against Women and Domestic Violence – Fixing the Loopholes in the Artificial Intelligence Act' (*UNIO – EU Law Journal: The Official Blog*, 29 March 2024) <https://officialblogofunio.com/2024/03/29/the-eu-directive-on-violence-against-women-and-domestic-violence-fixing-the-loopholes-in-the-artificial-intelligence-act/> accessed 30 October 2024; CIPL, 'Artificial Intelligence and Data Protection How the GDPR Regulates AI' (*CIPL*, 12 March 2020) <https://www.informationpolicycentre.com/uploads/5/7/1/0/57104281/cipl-hunton_andrews_kurth_legal_note_-_how_gdpr_regulates_ai__12_march_2020_.pdf> accessed 4 January 2024; Diogo Morgado Rebelo and César Analide, 'Inteligência Artificial Na Era Data-Driven: A Lógica Fuzzy Das Aproximações Soft Computing e a Proibição de Sujeição a Decisões Tomadas Exclusivamente Com Base Na Exploração e Prospeção de Dados Pessoais' (2019) 6 Forum de Proteção de Dados 60.

[23] That is not to say that it is not possible to conduct very targeted amendments of EU legislation. See, for example, the recent amendment to the EU Cybersecurity Act which is intended introduce European certification schemes for managed security services. However, even in this case from the proposal to its approval more than one year and half passed. In addition, while it is certain that the European Commission could define the scope very narrowly to limit the amendments that can be introduced by the remaining institutions. After all, as clarified by Advocate General Tesauro in *Eurotunnel SA and Others v SeaFrance,* 'the amendments adopted [cannot[fall outside the scope of the measure in question, as defined by the proposal'. However, this in itself could raise issues, for example, by resulting in the other institutions voting the proposal down for not agreeing with its scope or, worst case scenario, introducing significant amendments and testing the limits of current case-law, bringing further uncertainty. Cabral, 'A Short Guide to the Legislative Procedure in the European Union' (n 13); Opinion of Advocate General Tesauro in Case
C-408/95 *Eurotunnel SA and Others v SeaFrance* EU:C:1997:250; Case C-408/95 *Eurotunnel SA and Others v SeaFrance* EU:C:1997:532; Case C-409/13 *Council v Commission* EU:C:2015:217.

[24] It would likely exceed the scope of the legal instrument as defined by the European Commission when presenting the proposal.

of the AI Act[25] to include the new type of system; or (ii) creating new product safety legislation and revising Annex I of the AI Act. In either case, this approach has strong limitations as it implies that the AI system is already subject or will become subject to product safety legislation, which could be difficult to implement and potentially costly/unnecessary for some systems.[26] In both cases, if a revision of the AI Act itself were necessary, it could degenerate into a full new discussion around the AI Act which would hinder legal certainty.[27]

4.1[d] A better system for defining high-risk systems under the AI Act

Considering the limitations of the procedure for introducing amendments in Annex III of the AI Act and of the list-based approach in general, the most appropriate approach to ensuring the protection of fundamental rights of individuals would be to establish a test to be carried out by providers, in which they would have to assess the level of risk of their system and, depending on the result, classify it as high-risk or not. Strictly speaking, the European legislator even established the fundamental rights impact assessment, which could probably have been adapted to this objective. That is, AI systems would be considered high-risk and subject to additional rules pursuant to the result of the fundamental rights impact assessment.[28] If the legislator wanted to guarantee that the AI systems currently

[25] To guarantee an efficient regulatory intervention Annex I.A. would be recommended.
[26] Option (ii) also shares the risk of reopening Annex III as explained above.
[27] The AI Act is required to carefully balance the protection of fundamental rights with the necessity to not hinder and, if possible, even foster, innovation. As argued by Manuel David Masseno, 'there is no real alternative to implementing public policies which centre on the data economy' (our translation) of which the current AI boom is one of the results. See, Manuel David Masseno, 'Entre dados e algoritmos: como a união europeia procura proteger os cidadãos-consumidores em tempos de inteligência artificial assente em big data' [2023] Revista do Direito 47. For more context around the AI Act some of its other issues, see also Tiago Sérgio Cabral, 'A proposta de Regulamento sobre a Inteligência Artificial na União Europeia: breve análise' in Joana Covelo de Abreu, Larissa Coelho, and Tiago Sérgio Cabral (eds), *O Contencioso da União Europeia e a cobrança transfronteiriça de créditos: compreendendo as soluções digitais à luz do paradigma da Justiça eletrónica europeia* (e-Justice, vol II (University of Minho 2021); Cabral, 'Regulamento Sobre a Inteligência Artificial Na União Europeia : Potenciais Impactos Nas Entidades Públicas' (n 22); Cabral, 'Regulamento Sobre a Inteligência Artificial Na União Europeia : Potenciais Impactos Nas Entidades Públicas' (n 22); Magda Cocco et al, 'Assessment List for Trustworthy AI & Inception Impact Assessment on the Requirements for AI' (*VdA*) <https://www.lexology.com/library/detail.aspx?g=be1686c3-8302-4263-b8f6-49ab7397e215> accessed 30 October 2024; Federica Paolucci, 'Shortcomings of the AI Act: Evaluating the New Standards to Ensure the Effective Protection of Fundamental Rights' (*Verfassungsblog*, 14 March 2024) <https://verfassungsblog.de/shortcomings-of-the-ai-act/> accessed 17 March 2024; Sousa e Silva (n 6); Marco Almada and Nicolas Petit, 'The EU AI Act: A Medley of Product Safety and Fundamental Rights?' (*SSRN*, 30 December 2022) <https://papers.ssrn.com/abstract=4308072> accessed 16 January 2025; Marco Almada and Anca Radu, 'The Brussels Side-Effect: How the AI Act Can Reduce the Global Reach of EU Policy' (2024) 25(4) German Law Journal 646; Emre Kazim et al, 'Proposed EU AI Act – Presidency Compromise Text - Select Overview and Comment on the Changes to the Proposed Regulation' (*SSRN*, 6 April 2022) <https://papers.ssrn.com/abstract=4060220> accessed 16 January 2025.
[28] Under the General Data Protection Regulation's data protection impact assessment, whose logic seems to, at least partially inspire the fundamental rights impact assessment, controllers who are required to carry out a data protection impact assessment should use this exercise to implement measures designed to lower the risk of the data processing activity. If they are unable to do so at a satisfactory level, they will be required to consult the supervisory authority. See, WP29, 'Guidelines on Data Protection Impact Assessment (DPIA) and Determining Whether Processing Is "Likely to Result in a High Risk" for the Purposes of Regulation 2016/679' <https://ec.europa.eu/newsroom/just/document.cfm?doc_id=47711> accessed 30 May 2024; Jens Ambrock and Moritz Karg, 'Commentary to Article 35' in Gerrit Hornung, Euangelos Papakōnstantinu, and Indra Spiecker Döhmann (eds), *General data protection regulation:*

included in Annex III would generally be considered high-risk, it would be enough to include a presumption, rebuttable only when the criteria of Article 6(3) of the AI Act are met.[29]

This would be, as I see it, a better approach from the perspective of protecting fundamental rights of individuals as it would avoid potentially allowing dangerous systems to remain outside of the scope of the AI Act for long periods of time. Additionally, and perhaps surprisingly, it is my conviction that this approach would also have advantages from a legal certainty for businesses perspective. For organizations with long development cycles, it is better to be able to conduct a test today and know if the system that they'll release to the public in a few years' time is likely to be considered as high-risk instead of releasing the system under the assumption that it is not going to be considered as high-risk, create some regulatory panic (as happened with general-purpose AI models)[30] and then have the legislator eventually impose additional requirements.[31] In short, the flexibility of the tests brings predictability and predictability tendentially is better for business.[32] All things considered, a closed list is much more likely to require amendments when faced with technological developments than a test designed to be flexible.[33] It is also important to note that businesses are likely to be in a better position to understand the likely risks of an AI systems at a relatively early stage of the development cycles in comparison to with the EU legislator which has to predict future risks based on extremely limited information.

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article-by-article commentary (1st edn Nomos 2023) 35; Jens Ambrock and Moritz Karg, 'Commentary to Article 36' in Gerrit Hornung, Euangelos Papakōnstantinu, and Indra Spiecker Döhmann (eds), *General data protection regulation: article-by-article commentary* (1st edn, Nomos 2023) 35; Eleni Kosta, 'Commentary to Article 35' in Christopher Kuner, Lee A Bygrave, and Christopher Docksey (eds), *The EU General Data Protection Regulation (GDPR): a Commentary* (Oxford University Press 2020) 35; Cecilia Alvarez Rigaudias and Alessandro Spina, 'Commentary to Article 36' in Christopher Kuner, Lee A Bygrave, and Christopher Docksey (eds), *The EU General Data Protection Regulation (GDPR): a Commentary* (Oxford University Press 2020) 36; Lukas Feiler, Nikolaus Forgó and Michaela Nebel, *The EU General Data Protection Regulation (GDPR): A Commentary* (2nd edn, Globe Law and Business Ltd 2021) 177–187; Tiago Sérgio Cabral and Alessandra Silveira, 'Commentary to Article 8' in Tiago Sérgio Cabral et al, *The Charter of Fundamental Rights of the European Union: A Commentary* (UMINHO Law School / JusGov 2024) 8.

[29] I.e., when it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making as explained above.

[30] See, Isabel Kusche, 'Possible Harms of Artificial Intelligence and the EU AI Act: Fundamental Rights and Risk' [2024] Journal of Risk Research 1.

[31] Even if provisions are put in place to avoid retroactive application (see Article 111(2) of the AI Act), significant changes will probably be common for many systems, making the exemption to the application only temporary in many cases.

[32] Among the extensive scholarship conducted in this area see, inter alia, Jiwon Lee, David Schoenherr, and Jan Starmans, 'The Economics of Legal Uncertainty' (*SSRN*, 22 November 2022) <https://papers.ssrn.com/abstract=4276837> accessed 18 January 2025; Michał Krzykowski, Michał Mariański, and Jakub Zięty, 'Principle of Reasonable and Legitimate Expectations in International Law as a Premise for Investments in the Energy Sector' (2021) 21 International Environmental Agreements: Politics, Law and Economics 75; Aurelien Portuese, Orla Gough, and Joseph Tanega, 'The Principle of Legal Certainty as a Principle of Economic Efficiency' (2017) 44 European Journal of Law and Economics 131; Benny Hutahayan et al, 'Investment Decision, Legal Certainty and Its Determinant Factors: Evidence from the Indonesia Stock Exchange' (2024) 11 Cogent Business & Management 2332950.

[33] The data protection impact assessment is proving as a flexible tool to address concerns related to AI. See CNIL, 'AI Development Guidelines: Sheet 5 - Carrying out an Data Protection Impact Assessment If Necessary' (*CNIL*, 7 June 2024) <https://www.cnil.fr/en/carrying-out-protection-impact-assessment-if-necessary> accessed 10 June 2024.

While it might take time until the legislator finishes the legislative amendment, organizations cannot really predict what will be the result or content of the legislative intervention. In the case of general-purpose AI systems, the legislator created an entirely new category with specific rules and obligations. Not knowing what to expect is never a development or implementation friendly scenario.

Furthermore, in certain frontier cases, the test-based approach could also provide an incentive for providers – and deployers, within the limitations of their capabilities – to implement additional safeguards directed at lowering the risk to fundamental rights of their systems, with the aim of lowering it enough to guarantee that the system would not be considered as high-risk.

4 POSSIBLE OBJECTIONS AND IMPLEMENTATION

A possible objection to this position is that it would further empower providers of AI systems, granting them decision power regarding which systems should be considered as high-risk. This objection is, however, vulnerable to three counterarguments: (i) the introduction of a presumption of high-risk covering AI systems currently included in Annex III would be sufficient to guarantee that the level of protection would not be lower than what is currently achieved (as referred in subsection 4.1.5.); (ii) adequate cooperation with providers and enforcement would significantly reduce any such risk; and (iii) the current framework may contribute to provider inertia. Providers who apply closed rules and conclude that their AI system is not high-risk will be less likely to implement additional mitigation measures. By reinforcing provider accountability our position enables providers, who have more comprehensive knowledge of their AI systems, to take a more active participation in risk mitigation.

A further possible objection is that the proposed approach would limit the flexibility of the European Commission in adapting the AI Act to new challenges and technologies through the delegated acts referred to in Article 7, paragraphs 1 and 3 of the AI Act. This objection faces three key issues: (i) this flexibility does not exist in a satisfactory manner due to restriction to the eight areas currently in Annex III; (ii) if necessary, introducing an expedited procedure to amend the abovementioned presumptions would provide the European Commission with some degree of control over the assessment; (iii) soft-law could contribute to guide providers in the assessment possibly even avoiding the necessity of amending the presumptions. In any case, the assessment should be, as much as possible, designed to be future-proof to protect legal certainty.

A third objection to my position is that it would require an amendment to the AI Act and create exactly what it tries to avoid: legal uncertainty. There is some merit to this objection since, ideally, my position would have been adopted as part of the negotiations that resulted in the AI Act and be part of the law as entered into force on 1 August 2024.[34] Since that was not the case, there are two suboptimal scenarios: (i) amend the very recent AI Act; or (ii) maintain the list-based approach, at least for the time being, regardless of its shortcomings.

[34] With progressive application of its requirements starting with Chapter I and Chapter II from 2 February 2025.

Introducing amendments to the AI Act at this point in time would be highly damaging to the expectations of all entities involved in the AI value chain and possibly hinder AI development in the EU. As such, even though the current framework could be vastly improved I cannot defend its immediate amendment. However, it is important to note that Article 112 of the AI Act includes various moments for the evaluation and review of the current text. By 2 August 2028 and every four years thereafter, the European Commission must evaluate and report to the European Parliament and to the Council on, inter alia, the need for amendments extending the existing eight areas or adding new areas in Annex III [35]. These reviews can result in proposals to review the AI Act.[36] As such, I consider that, if in any of the abovementioned revisions the European Commission concludes that the current Annex III is no longer fit for purpose,[37] namely because the eight areas need to be extended or new areas added, it should opt to implement the approach proposed in this article instead of simply reviewing the eight areas under Annex III.

If our proposed approach were adopted , high-risk systems would be defined based on whether: (i) they are considered high-risk by the proposed assessment; or (ii) are considered high-risk based on Article 6(1) of the AI Act (see Section 3). The current list of high-risk systems under Annex III of the AI Act might not disappear but instead, if deemed necessary, serve as a presumption (i.e. systems included in this list would be presumed to be high-risk). Article 6(3) should then regulate the derogations to the application of the presumption, and Article 6(6)-(8) should regulate the rules applicable to the introduction of amendments to the conditions that must fulfilled to trigger the derogations to the presumption.

It is important to note that, while these reviews seem to be the ideal time to implement such a change, the same logic applies to any change to Annex III that requires reopening the AI Act. That is to say, and although this would be undesirable, if outside of the abovementioned review period the legislator considers it absolutely necessary to revise the AI Act to introduce new high-risk areas (e.g. due to the emergence of new types of AI systems), replacing the simple introduction of the new high-risk areas by the introduction of our proposed approach would be best.

[35] See Article 112(2)(a) of the AI Act.
[36] See Article 112(10) of the AI Act.
[37] These may happen in 2028 or in any of the revisions occurring frequently thereafter.

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CAN DISSEMINATION OF TRUE INFORMATION CONSTITUTE MARKET MANIPULATION?

ANDRI FANNAR BERGÞÓRSSON*

This article discusses whether dissemination of true information can amount to market manipulation under the 2014 Market Abuse Regulation (MAR). Market manipulation typically involves misinformation, which can be seen as a form of lying, but it can also occur when material facts are omitted, making truthful statements misleading. A reasonable investor test helps determine when true information becomes misleading and thus potentially violates the ban on market manipulation under MAR. Nordic case law, which is discussed in this article, highlights how misleading statements, even if factually correct, can violate the ban on market manipulation.

1 INTRODUCTION

Bans on giving false or misleading information have existed for ages.[1] 'You shall not lie' is, for example, part of the Ten Commandments in the Bible. In contract law, the beneficiary of a promise is often excused from breaking the promise if the promise is extracted by lies on the grounds that it is fraud.[2] In capital market law, this ban is referred to as the ban on market manipulation, in which the manipulator misinforms the other party either with verbal communication, spoken or written, or with non-verbal communication, usually conveyed through behaviour, for example securities transactions.[3]

If misinformation, which is another form of lying, is the essence of market manipulation, it raises the question of whether it is possible to commit market manipulation by disseminating true information. The aim of this article is to clarify whether dissemination of true information can constitute market manipulation according to the 2014 Market Abuse Regulation (MAR)[4] and, if so, in what instances can such dissemination amount to market manipulation. Without giving away the whole ending (this article's conclusions), it can be revealed that market manipulation can indeed encompass dissemination of true information. The more difficult part is determining when dissemination of true information can constitute market manipulation.

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* Associate Professor, Reykjavik University.

1 Jesper Lau Hansen, *Introduktion Til Selskabsretten Og Kapitalmarkedsretten* (Jurist-og Økonomforbundets Forlag 2014) 123.

2 Robert Cooter and Thomas Ulen, *Law & Economics* (6th edn, Pearson Education International 2011) 297. See, e.g., Art 30 of the Icelandic act on contracts, agency and void legal instruments No 7/1936 (*i. Lög um samningsgerð, umboð og ógilda löggerninga*).

3 See Jesper Lau Hansen, 'The Trinity of Market Regulation: Disclosure, Insider Trading and Market Manipulation' (2003) 1 International Journal of Disclosure and Governance 82, 92. See also Hansen, *Introduktion Til Selskabsretten Og Kapitalmarkedsretten* (n 1) 123.

4 Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) [2014] OJ L173/1.

Section 2 provides an overview of the ban on market manipulation in MAR and then presents the essential elements of the offense. Section 3 focuses on verbal manipulation and various forms of dissemination in relation to verbal manipulation. The section examines the circumstances in which the dissemination of false information constitutes market manipulation. It also explores why the complete omission of material facts - where no information is disseminated - does not fall under the ban on market manipulation as defined in MAR.. Nordic case law is examined to address these issues. Section 4 concerns whether disseminating true information but withholding material facts can constitute market manipulation.

2 MISINFORMATION – AN ESSENTIAL ELEMENT OF MARKET MANIPULATION

2.1 THE BAN ON MARKET MANIPULATION IN MAR

The ban on market manipulation in the form of misinformation is an old phenomenon in Europe and existed in many countries long before the harmonization of the concept in the EU with the adoption of the 2003 Market Abuse Directive (MAD).[5] One of the first and most famous criminal cases of market manipulation in Europe dates all the way back to 1814 in the United Kingdom (U.K.) – the case of *Rex v de Berenger*,[6] which is a classic example of verbal manipulation (dissemination of false or misleading information).

The case concerned the fake death of Napoleon Bonaparte, the emperor of France. The U.K. had been at war with France,[7] and de Berenger, along with seven other members of the English aristocracy, conspired to deliver false news of Napoleon's death and the likely peace with the French.[8] De Berenger, dressed as a French military officer, appeared in the English town of Dover and pretended to have just arrived from France. He delivered the news of Napoleon's defeat, which would consequently bring peace between the two countries.[9] Soon after the 'good' news spread, stockbrokers and other people started buying government debt notes, pushing their price significantly higher. De Berenger and his seven conspirators were then able to sell their holdings with the same debt notes which they had bought a week earlier and made a considerable profit.[10]

They were all charged with conspiracy by 'spreading false rumours and reports in different places, to occasion a rise in the price of the public funds of the country, […] and thereby to injure all those subjects who might purchase stock on that particular day'.[11] The defendants argued that this was not a crime because this particular behaviour was not

[5] Directive 2003/6/EC of the European Parliament and of the Council of 28 January 2003 on insider dealing and market manipulation (market abuse) [2003] OJ L96/16.
[6] *Rex v de Berenger* (1814) 105 ER 536, 3 Maule & S 67.
[7] ibid 536-537.
[8] See, e.g., Stuart Bazley, *Market Abuse Enforcement: Practice and Procedure* (Bloomsbury Publishing 2013) 6.
[9] William Brodie Gurney, *The Trial of Charles Random de Berenger, Sir Thomas Cochrane Etc.* (Tower-Hill 1814) 589.
[10] *Rex v de Berenger* (n 6) 536-537. See also Hubert De Vauplane and Odile Simart, 'The Concept of Securities Manipulation and Its Foundations in France and the USA' (1997) 23 Brooklyn Journal of International Law 203, 206–207. See further discussion in Bazley (n 8) 6–7.
[11] Gurney (n 9) 588.

prohibited by law.[12] The courts dismissed it, saying that affecting the price of the government debt notes was not per se a crime but that 'if a number of persons conspire by false rumours to raise the funds on a particular day, that is an offence; and the offence is, not in raising the funds simply, but in conspiring by false rumours to raise them on that particular day'.

The crime was not raising the price of the debt notes per se but raising it using false information. De Berenger and the other defendants were found guilty of conspiracy to commit fraud and sentenced to prison (six of them) and to pay a hefty fine.[13]

Even though the ban on market manipulation has a relatively short history in capital market regulation of the Nordic countries[14] compared to the U.K. and the U.S., a ban on misinformation in securities transactions has been part of the countries' criminal codes, except for Iceland's, since the early 1930s.[15] Denmark has, for example, had a provision in its criminal code since 1930 criminalizing the spreading of false information that could affect the prices of securities.[16] Sweden, Norway and Finland have had similar provisions in their criminal codes.[17] Instead of having this kind of provision in the criminal code, Iceland chose to incorporate it into the Companies Act of 1978,[18] which criminalized spreading wrong or misleading reports that can affect the sales or the price of shares in the company.[19] It was not until the midst of the 1990s that a specific ban on market manipulation was introduced in the countries' capital market regulation.[20] The Finnish securities trading act did, however, have a provision since 1985 on improper business practices in securities trading, which had been applied to market manipulation.[21]

In the European Union (EU), a step was taken towards a harmonized regime on market manipulation in 1999, when the European Commission expressed its intention in a

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[12] The judgment stated 'that not any crime, known to the law, is alleged in the count'. See *Rex v de Berenger* (n 6) 537.

[13] Gurney (n 9) 599-600. See also Emilios E Avgouleas, *The Mechanics and Regulation of Market Abuse: A Legal and Economic Analysis* (Oxford University Press 2005) 122. It says that the defendants were also stripped of their titles and removed from public office. See further discussions of the judgment in Jan Eichelberger, *Das Verbot Der Marktmanipulation (§ 20a WpHG).,* vol 199 (1st edn, Duncker & Humblot 2006) 1.

[14] Iceland, Norway, Denmark, Sweden and Finland.

[15] Jesper Lau Hansen, 'MAD in a Hurry: The Swift and Promising Adoption of the EU Market Abuse Directive' (2004) 15(2) European Business Law Review 183, 205 (fn 90).

[16] Art 296 of Criminal Code No. 126/1930 (*D. Straffeloven*). See Jesper Lau Hansen, *Informationsmisbrug. En Analyse Af de Centrale Bestemmelser i Børsrettens Informationsregime* (Jurist-og Økonomforbundets Forlag 2001) 112. See also Jens Madsen, 'Kursmanipulation' [2000] Ugeskrift for retsvæsen 569, 573. The original Art 296(1) of the Danish Criminal Code states the following: 'Med Bøde, Hæfte eller med Fængsel indtil 2 Aar straffes den, som, uden at Betingelserne for at anvende § 279 foreligger […] udspreder løgnagtige Meddelelser, hvorved Prisen paa Varer, Værdipapirer eller lignende Genstande kan paavirkes'.

[17] In Sweden, the provision can be found in the Criminal Code No. 1962:700 (*brottsbalken*) under chapter 9 on fraud. See Hansen, *Informationsmisbrug* (n 16) 151.See also Catarina af Sandeberg, *Marknadsmissbruk: Insiderbrott Och Kursmanipulation* (Iustus 2002) 101. The Norwegian provision is situated in art. 273 of Criminal Code No. 10/1902 (*straffeloven*). See Odd-Harald B Wasenden, *Energimarkedsrett: Om Informasjonsplikt Og Markedsatferd i Det Finansielle Kraftmarkedet* (Cappelen Akademisk forlag 2007) 408. See also Hansen, *Informationsmisbrug* (n 16). Finally, the Finnish provision is situated in Art 3 in chapter 51 of Criminal Code No. 39/1889 (Straffelagen). See Mårten Knuts, *Kursmanipulation På Värdepappersmarknaden* (Finska juristföreningen 2010) 6 (fn. 11). See also Madsen (n 16) 570.

[18] Art 150 of Act No. 32/1978 on Public Limited Liabilities Companies (*Lög um hlutafélög*). Currently, the provision can be found in Art 154 of Act No. 2/1995 on Public Limited Liabilities Companies (*Lög um hlutafélög*).

[19] See, e.g., Jesper Lau Hansen, *Nordic Financial Market Law: The Regulation of the Financial Markets in Denmark, Finland, Iceland, Norway and Swede*n (Jurist-og Økonomforbundets forlag 2003) 199

[20] Hansen, 'MAD in a Hurry' (n 15) 205 (fn. 90). See also Hansen, *Informationsmisbrug* (n 16) 150–159.

[21] See, e.g., Hansen, *Informationsmisbrug* (n 16) 156-159.

report from 1999 to introduce a directive on market manipulation. Inspired by a recent major reform in the U.K., it was later decided to combine in one directive rules on market manipulation, insider dealing and disclosure obligation. The directive, referred to as MAD, was adopted in December 2002 and then implemented in national legislation of most Member States in 2005. The same applied to the EEA EFTA States,[22] which included and still include Iceland and Norway.[23] One of the main objectives of the directive was to 'heighten investor protection and make European financial markets more secure and more attractive for investors'.[24] More than six years after the adoption of MAD, the Commission announced its intention to review the directive – one of the many regulatory responses of the EU to the global financial crisis that started in 2007.[25]

Initially, the Commission did not intend to make any changes to the definition of market manipulation in the upcoming review, even though it pointed out that the existing definition with its broad concepts[26] could possibly explain why regulators had difficulties in detecting and sanctioning market manipulation more frequently.[27] Despite the Commission's initial intention, several changes were made to the rules on market manipulation when MAR was adopted in 2014, along with a directive on criminal sanctions for market abuse (MAD II).[28] These changes included extending the scope of the ban to further trading venues and financial instruments and to cover attempted manipulation.[29] The so-called core definition of market manipulation did not, however, change materially from the time MAD was adopted and is worded in the following way in article 12(1) of the regulation:

> (a) entering into a transaction, placing an order to trade or any other behaviour which:
>
> (i) gives, or is likely to give, *false or misleading signals* as to the supply of, demand for, or price of […]; or
>
> (ii) *secures*, or is likely to secure, the price of […] at an *abnormal or artificial level* […]
>
> (b) entering into a transaction, placing an order to trade or any other activity or behaviour which affects or is likely to affect the price of […], which employs a fictitious device or any other form of *deception or contrivance*;
>
> (c) disseminating information […], which gives, or is likely to give, *false or misleading signals* as to the supply of, demand for, or price of, […] or is likely to secure, the price […] at an *abnormal or artificial level*;

[22] Decision of the EEA Joint Committee No 38/2004 amending Annex IX (Financial services) to the EEA Agreement [2004] OJ L277/5.
[23] EFTA stands for European Free Trade Association. EEA stands for European Economic Area.
[24] Commission, "Commission welcomes Council agreements on Market Abuse and Financial Conglomerates Directives. Press release" (7 May 2002) IP/02/669 2.
[25] See, e.g., the discussion in Niamh Moloney, 'EU Financial Market Regulation after the Global Financial Crisis: "More Europe" or More Risks?' (2010) 47(5) Common Market Law Review 1317.
[26] Such as 'abnormal or artificial level', 'fictitious devices or any other form of deception or contrivance' and 'dominant position'. See European Commission, 'Call for Evidence. Review of Directive 2003/6' (2009) 15.
[27] ibid.
[28] Directive 2014/57/EU of the European Parliament and of the Council of 16 April 2014 on criminal sanctions for market abuse (market abuse directive) [2014] OJ L 73/179.
[29] See Art 5 of MAD.

> (d) transmitting *false or misleading information* or providing false or misleading inputs in relation to a benchmark […], or any other behaviour which *manipulates* the calculation of a benchmark (*emphasis added*).

MAR entered into force in the EU Member States on 3 July 2016[30] but not until 2021 in the EEA EFTA states. The reason for this time gap is the legislative processes required to incorporate EU regulations, such as MAR, into EEA EFTA States' national law. The relevant EU act must be incorporated into the EEA Agreement with a Joint Committee Decision, which is aimed at getting approval from both sides. Following that, the EEA EFTA states have some time to implement the act into their national legislation. This applies to regulations and directives.[31] Although MAR had to be implemented into their national legislation, its wording remains consistent across all EU Member States and EEA EFTA States, albeit in different languages.

2.2 WHAT KIND OF BEHAVIOUR DOES THE BAN COVER?

Market manipulation can be committed in various ways, either through verbal or non-verbal manipulation. Verbal manipulation can be committed by disseminating information, orally or in writing, through the media, including the internet, or by any other means to manipulate a financial instrument, a related spot commodity contract, an auctioned product based on emission allowances[32] or a benchmark.[33]

In the case of non-verbal manipulation, the misinformation is communicated through some kind of behaviour, such as trades. The MAD definition only mentioned 'transactions or orders to trade'.[34] Because the scope of the ban was limited to financial instruments traded on a regulated market, it can be assumed that the ban only applied to transactions and orders to trade these financial instruments, irrespective of whether the transaction (or the order) actually took place on that market.[35] Consequently, the ban did not cover other behaviour, such as preventing shares from being sold on the market to make sure the share price would not go down – only transactions and orders to trade.

The MAR definition is considerably broader, with its catch-all wording: 'transactions, placing orders to trade, or any other behaviour'.[36] This broad wording covers any kind of behaviour which manipulates financial instruments, related spot commodity contracts, auctioned based products based on emission allowances or benchmarks,[37] regardless of whether such behaviour takes place on a trading venue.[38]

Actions and omissions are included in the scope.[39] In the original MAR proposal, only 'actions' were mentioned, but after the European Parliament's first reading, 'omissions' was

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[30] Particular provisions applied from 2 July 2014. See Art 39(2) of MAR.
[31] See discussion in Standing Committee of the EFTA states – Subcommittee V on legal and institutional questions, "The two-pillar structure of the EEA – Incorporation of new EU acts" 16-532, 1-3.
[32] Cf. Art 12(1)(c) of MAR.
[33] Cf. Art 12(1)(d) of MAR.
[34] See Art 1(2)(a)-(b) of MAD.
[35] Cf. Art 9(1) of MAD.
[36] Cf. Art 12(1) of MAR.
[37] See a short discussion of this wording in Niamh Moloney, *EU Securities and Financial Markets Regulation* (Oxford University Press 2014) 717.
[38] Cf. Art 2(3) of MAR.
[39] Cf. Art 2(4) of MAR.

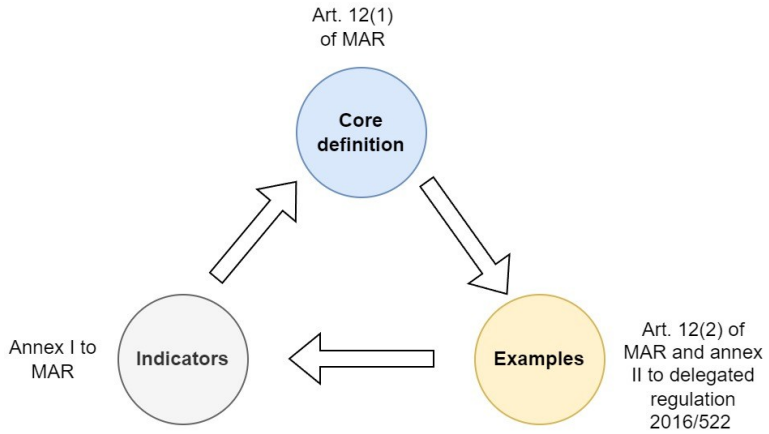
added to the scope.[40] It is easier to imagine examples of market manipulation committed through some kind of action – the most obvious ones would be transactions and orders to trade.

The scope also covers attempted market manipulation, which was not the case in MAD. This extension to the scope means that a person can be guilty of market manipulation in situations in which steps have been taken and there is clear evidence of an intention to manipulate the market but either an order was not placed or a transaction was not executed.[41]

2.3 TWO OBJECTIVE ELEMENTS: MISINFORMATION AND LIKELY EFFECT

The terms used in MAR to describe market manipulation,[42] such as 'manipulation', 'abnormal', 'artificial', 'fictitious' and 'contrivance', are open and, to some extent, vague words. Neither MAR nor any other EU legislation defines these terms. Instead, examples of market manipulation are given in Article 12(2) of the regulation and in an annex to a delegated regulation,[43] along with a non-exhaustive list of indicators of manipulative behaviour, as described in the following figure:

Figure 1: Market Manipulation Regime in MAR.[44]



Therefore, it is not obvious from the wording of the definition of MAR what the ban's objective elements are. However, an overall assessment of the text of MAD and MAR and related documents, along with extensive case law from the Nordic countries, shows that the core of the ban on market manipulation requires two objective elements: (i) material

[40] See European Parliament, 'Proposal for [MAR] – Outcome of the European Parliament's first reading' (18 September 2013) 12906/13 74.
[41] See European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on insider dealing and market manipulation (market abuse) COM(2011) 0651 final - 2011/0295 (COD), 8.
[42] Also applies to MAD.
[43] See Annex II to Commission Delegated Regulation (EU) 2016/522 of 17 December 2015 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council for an exemption for certain third countries' public bodies and central banks, the indicators of market manipulation, the disclosure thresholds, the competent authority for notifications of delays, the permission for trading during closed periods and types of notifiable managers' transactions [2015] OJ L88/1 (2015 Delegated regulation on indicators of market manipulation).
[44] Based partially on a figure in David Moalem, 'Om Forbuddet Imod Markedsmanipulation' (2021) 4 Nordisk Tidsskrift for Selskabsret 48, 52.

misinformation;[45] and (ii) its likely effect[46] on a financial instrument's value.[47] The focus here is mostly on how the objective elements of market manipulation are described – *the actus reus* – and less on the mental elements of the conduct – *the mens rea* – which are a necessary element in placing criminal responsibility on the manipulator.

Misinforming, essentially, is giving false or misleading information to another person. This occurs when there is a discrepancy between what is communicated and what the person who disseminated the information believes to be true. If a person believes a fact to be A but says it is B, then this is misinformation, even if it turns out the fact really was B.[48] It matters what the person believed to be true when the information was disseminated. It can also be misinformation when the whole truth is not revealed. If someone knows a fact includes A, B, and C but only mentions A and B, it may be misleading or even false, depending on the circumstances.[49] The point of departure is what the disseminator knew or ought to have known was false or misleading.[50]

Not all misinformation is covered by the ban on market manipulation – only material misinformation. Even though the definition in MAR does not specify such a limit to the ban, this conclusion can be drawn from one of the recitals in MAR. Recital 47 of the regulation specifically states that spreading false or misleading information may 'consist of manifestly false information, but also wilful omission of material facts'. Even though this only refers to verbal manipulation, it also can apply to non-verbal manipulation because the principal thought is the same in both forms of manipulation: misinformation.[51]

Requiring misinformation to be material essentially means the misinformation would likely influence an investment decision made by a reasonable investor if he or she had known of the misinformation.[52] For example, in a *wash trade*,[53] the trade becomes misinforming because the market is unaware that the same person was acting as the buyer and seller in the trade. It is safe to assume that such misinformation would be considered material, but this must be assessed on a case-by-case basis. The materiality requirement can concern false

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45 See arguments presented in Andri Fannar Bergþórsson, 'What Is Market Manipulation?: An Analysis of the Concept in a European and Nordic Context' (2018) 2(2-4) Brill Research Perspectives in International Banking and Securities Law 1, 82–140, 171–176.

46 See arguments presented in ibid 245–258.

47 Or other instruments covered by the ban.

48 Hansen, 'The Trinity of Market Regulation' (n 3) 84.

49 See Hansen, *Informationsmisbrug* (n 16) 15–17.

50 See, e.g., the wording of Art 12(1)(c) of MAR, which requires that 'the person who made the dissemination knew, or ought to have known, that the information was false or misleading'. See also recital 47 of the regulation, which states, 'It is therefore appropriate not to allow those active in the financial markets to freely express information contrary to their own opinion or better judgement, which they know or should know to be false or misleading, to the detriment of investors and issuers'.

51 See also one of the examples of market manipulation in section B of the Annex to the European Commission, 'Proposal for a Directive of the European Parliament and of the Council on insider dealing and market manipulation (market abuse)' COM(2001) 281 final (2001 MAD Proposal): 'Making untrue statements of material facts' and 'Non-disclosure of material facts or material interests'.

52 Similar to the definition of 'significant effect' in the definition of inside information in Art 7(4) of MAR. According to the article, 'significant effect' 'shall mean information a reasonable investor would be likely to use as part of the basis of his or her investment decisions'.

53 The practice is defined as an arrangement to sell or purchase a financial instrument 'where there is no change in beneficial interest or market risk or where beneficial interest or market risk is transferred between parties who are acting in concert or collusion'. See Art 3(a) of section A of Annex II to Commission Delegated Regulation (EU) 2016/522 of 2015 Delegated regulation on indicators of market manipulation). See also indicator A(c) of Annex I to MAR.

information but also true information. As discussed in this section and section 4, verbal misinformation can be in the form of dissemination of false information but also misleading information, in which material true information is omitted. In both instances, the false information in the former and the true information in the latter, it is required that the misinformation is material.

The ban on market manipulation only covers behaviour that has an actual or a likely effect on the value of a financial instrument or other instruments covered by the ban. The most obvious case in which this requirement is fulfilled is when it has been established that the misinformation has had an actual effect (de facto) on a financial instrument's price.[54] It is, however, not necessary to establish that the misinformation had an actual effect on the value. As the definition is worded, a likely effect is sufficient to fulfil the requirement. That means that it is irrelevant whether there was an actual effect in the market; it is enough that there was a risk of such an effect.[55]

3 VERBAL MANIPULATION

3.1 INTRODUCTORY REMARKS

Verbal misinformation is essentially covered by Article 12(1)(c) of MAR, which entails disseminating information through the media, including the internet, or by any other means which gives or is likely to give false or misleading signals as to the supply of, demand for or price of instruments covered by the ban or is likely to secure the price of one or several instruments at an abnormal or artificial level, including the dissemination of rumours, where the person who made the dissemination knew or ought to have known that the information was false or misleading.[56] Based on the provision's wording, the offense (verbal market manipulation) has been committed when the communication has reached one or more market participants.

It is easier to comprehend when misinformation is communicated verbally, either in written or spoken language, than through non-verbal communication, such as through trading or placing orders in the markets. This difference is reflected in the list of indicators of manipulative behaviour in Annex I to MAR and the examples of manipulative behaviour provided in another annex in a delegated regulation. There are plenty of indicators and examples of non-verbal misinformation in the annexes but very little on verbal misinformation, except when verbal misinformation is combined with orders or transactions before or after the dissemination.[57] One example is to cause a price movement in the shares to profit from a previous held position or a planned transaction.[58] This manipulative practice has sometimes been referred to as *scalping*[59] and is very similar to practices called *pump and dump* and *trash and cash*.

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[54] Or other instruments covered by the ban.
[55] See Knuts (n 17) 229.
[56] This form of manipulation is also covered by Article 12(1)(d) on benchmark manipulation and Article 21 on disclosure or dissemination of information in the media.
[57] See indicator B(a) of Annex I of MAR and Art 12(2)(d) of MAR.
[58] See Art 1(a) of Section 2 of Annex II of 2015 Delegated regulation on indicators of market manipulation.
[59] See CESR, 'Market Abuse Directive – Level 3 – first set of CESR guidance and information on the common operation of the Directive' CESR/04-505b 12. See also, e.g., Knuts (n 17) 268.

Using verbal misinformation in a *pump and dump* scheme involves taking a long position in a financial instrument, such as shares,[60] and then disseminating false or misleading positive information about the shares to increase the share price and then sell the shares at the inflated price. The same applies to *trash and cash* schemes, but instead of taking a long position and spreading positive information, a short position is taken in the financial instrument and false or misleading negative information is spread about the instrument to decrease the price. When the price has fallen, the short position is then closed.[61]

To be able to determine whether dissemination of true information can constitute market manipulation and in what instances such dissemination can amount to market manipulation, it is necessary to examine all aspects of verbal manipulation.

3.2 DISSEMINATION OF FALSE INFORMATION

It might seem peculiar to differentiate between false and misleading information because both constitute misinformation, but there is a difference between the two. Giving false information essentially means that there is a discrepancy between what is communicated and what the person who disseminated the information believes to be true.[62] An example of such dissemination is a Swedish case from 2009 concerning Morphic Technologies.[63]

The defendant in the case had used his family's savings to buy shares in Morphic Technologies, which was traded on First North, a multilateral trading facility (MTF) in Stockholm. For over a year, the defendant spread information he pretended to have about the company in an online internet chatroom and then sold shares in the company. In the period between 2006 and 2007, he made a profit of about one million SEK.[64] He was charged with market manipulation for spreading several pieces of misleading information about the company. According to the court, the case's circumstances were undisputed: the defendant spread fabricated information about the company in the way it was stated in the indictment, and he had nothing to do with the company in question.

The court approached the misinformation part by assessing whether the information the defendant spread was likely to mislead other investors. It was not enough that the information was false; it had to be misleading. The court found that only the information that Morphic Technologies planned to build a production plant in the U.S. and that a cargo plane was almost full of Morphic's equipment was concrete enough to be possibly misleading. It was doubtful that the information the defendant shared in the internet chatroom about a possible establishment in the U.S. was likely to mislead others to buy or sell shares in Morphic. The information was, however, sufficiently specific, according to the court, that this could have been the result. The court concluded that it was impossible to rule out that some individuals who visited the chatroom had been careless enough to base their investment decision on the defendant's information and that the defendant should have

[60] Or other instruments covered by the ban on market manipulation.
[61] See Arts 4(c) and (d) of Section 1 of Annex II of 2015 Delegated regulation on indicators of market manipulation.
[62] See, e.g., the discussion in Susanne Kalss, 'Article 12. Market Manipulation' in Susanne Kalss et al (eds), *EU Market Abuse Regulation. A Commentary Regulation (EU) No 596/2014* (Edward Elgar Publishing 2021) 176.
[63] Judgment from Court of Appeal for Northern Norrland No. HovR B 459-08 from 5 February 2009 (*Morphic Technologies AB*).
[64] See p 2 of the judgment.

realized that his lie could have had such an effect. However, the court considered the effect of the information in the market so small that the defendant's behaviour did not constitute market manipulation and acquitted him.[65]

This judgment illustrates situations in which it has been established that the information was false and disseminated with the aim of inducing others to buy shares to pump up the price, but the lie was unlikely to fool anybody. It is therefore not sufficient that the misinformation is material, which was certainly the case with the production plant in the U.S.; it also must be believable. Such assessment falls under the second objective requirement of whether the information is likely to affect the value of the shares and is of course subjective and depends on the circumstances in each case.[66]

In addition, if attempted market manipulation had been punishable in Sweden at the time, the court may have convicted the defendant of an attempt because it had been established he fabricated the information he disseminated on the internet chatroom to induce others to buy shares in the company. With the adoption of the MAR, the scope of the ban in all Member States, including Sweden, has been extended to attempted manipulation.[67]

In a Danish case from 2016 known as the Neurosearch case, it was clear that the false information was likely to mislead other investors and thereby to affect the price of shares issued by a Danish biotech company called Neurosearch, which was listed on the Copenhagen Stock Exchange.[68] Unlike in the Morphic Technology case, the source of the misinformation was the company and not an internet chatroom.

On 3 February 2010, Neurosearch issued a company announcement to notify that the company had reached its primary endpoint in its research on a medicine for Huntington's disease. It was shown before the court that the market had big expectations for this research. The announcement caused the price of Neurosearch shares to rise from 85 to 168 DKK in a day and to 224 DKK in three days. According to the Danish financial supervisory authority (Finanstilsynet), the company's market value increased by more than 2 billion DKK.[69]

It was considered proven that the endpoint had not actually been reached as it was described in the announcement from Neurosearch. The appeal court,[70] therefore, concluded that the announcement had been likely to give wrong or misleading signals. It was also shown that the company's director had known that the information in the announcement was wrong and misleading and that the information published in the announcement could have a significant effect on the price. On those grounds, the court found the company guilty of market manipulation.

In the indictment and before the district court in this case, it was assumed that the company's director had used a warrant, which is a derivative that gave the director the right to buy shares in the company at a predetermined price, right after the announcement was published. The share price on the warrant was considerably lower than the shares' market price after the announcement. Based on that assumption, the district court found the director

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[65] See *Morphic Technologies AB* (n 63) p 5-7 of the judgment.
[66] See discussion on the second objective element of the ban on market manipulation in Section 2.3.
[67] See Art 15 of MAR.
[68] Judgment from the Supreme Court of Denmark No U 2016.16 H from 14 November 2016 (*Neurosearch – Supreme Court*). The page numbers are based on the judgment from the High Court of Eastern Denmark No U 2016.653 Ø (*Neurosearch – High Court*).
[69] See p 659 of the judgment.
[70] Referred to as the high court in Denmark.

guilty of market manipulation.[71] This situation is similar to the one in the Morphic Technologies case in that the false or misleading information was used to move the price of the shares to sell the warrants at an inflated price – a classic *pump and dump* scheme.

The appeal court in this case, however, concluded that the director did not use his warrant right after the announcement was published but almost a month later. Therefore, it was not proven, according to the appeal court, that the director had published the false and misleading announcement to profit from his warrant but only to protect the company's interests. He was acquitted even though the company was found guilty of market manipulation.[72] The Supreme Court confirmed the appeal court's reasoning and verdict.[73]

The director's acquittal is understandable to a certain extent because it could have been problematic for the prosecution to prove that the director was responsible for the false and misleading company announcement. However, bearing in mind his responsibility as the director of Neurosearch and that it had been established that he knew that the endpoint had not actually been reached as it was described in the announcement, it is possible to argue that such involvement should have led to the director's criminal responsibility[74] because the company was convicted.[75]

3.3 NO DISSEMINATION – FULL OMISSION OF MATERIAL FACTS

The question here is whether the ban on market manipulation also extends to instances in which there is no dissemination of information – full omission of material facts.[76] The short answer is no – the ban on verbal manipulation does not seem to extend to full omission of material facts. This applies even to circumstances in which an issuer is obliged to disclose inside information to the market[77] but neglects to do so, which can be misleading to other market participants. It might seem peculiar to apply a more serious offense (market manipulation) with generally harsher punishments to situations in which the issuer disseminated some information but omitted material facts (inside information) and to apply a milder offense (violation of the disclosure obligation) to situations in which the issuer disseminated no information but the omission still misled the market.[78]

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[71] See *Neurosearch – High Court* (n 68) p 658 of the judgment.
[72] See ibid p 659.
[73] See *Neurosearch – Supreme Court* (n 68) p 29-30 of the Supreme Court judgment.
[74] If other objective and subjective requirements of the offense had also been fulfilled.
[75] See also the judgment from the High Court of Western Denmark No S-2313-14 V from 8 June 2016 (*Aarhus Lokalbank*), in which the approach is similar. In the case, one of the bank's managers was acquitted because the court did not consider it proven that he gave instructions or should have known of the excessive buying of own shares. See p 33 of the judgment.
[76] This does not cover full omission of inside information combined with trading in own shares, which constitutes insider dealing and not market manipulation. See Caroline Bang Stordrange, 'Kan brudd på utsteders løpende informasjonsplikt innebære markedsmanipulasjon?' (2014) 53 Lov og Rett 290, 292. This also does not cover violations of other obligations, such as the notification requirement, combined with trading in securities and other instruments covered by the ban.
[77] See Art 17 of MAR on public disclosure of inside information.
[78] See Stordrange (n 76) 307. In the article, the author actually argues that there is no need to stretch the ban on market manipulation to these situations because of the provision on the issuer's disclosure obligation. The author, however, does not mention that these offenses usually do not entail the same sanctions. See, e.g., Jesper Lau Hansen, 'Når Tanken Tæller: Om Forholdet Mellem Oplysningspligt Og Kursmanipulation', *Festskrift til Jørn Vestergaard* (Djøf Forlag 2008) 196.

The reason for this distinction is, however, the wording of the verbal manipulation provision in the MAR, which specifically refers to 'dissemination of information'. In some instances, it is possible to commit an offense by doing nothing even though the provision describes a positive act and not omission. An example of such an offense is homicide, in which there is a requirement of one person causing another person's death without referring to specific methods.[79] Another example of this kind of description is the non-verbal part of the market manipulation definition, which refers to transactions, orders to trade and 'any other activity or behaviour' that has certain a consequence.[80]

The same does not apply to the verbal manipulation provision, which specifies precisely the behaviour element of the offense – the spreading of information. It is very difficult to imagine that this kind of behaviour can be done through anything other than a positive act and not through pure inaction.[81] The failure to disclose inside information would therefore be covered by the provision on the issuer's disclosure obligation[82] and not by the ban on market manipulation.

This conclusion that the ban on market manipulation does not cover full omission is further supported by the fact that nothing in the EU legislation regarding market manipulation, including proposals, reports or guidelines, indicates that the ban on market manipulation was supposed to cover full omission. Stordrange has pointed out, however, that CESR, the predecessor to ESMA, had in one of its guidelines interpreted the verbal manipulation provision in MAD as covering also full omission of price sensitive information. Stordrange then argued that such interpretation was not binding when applying the Norwegian ban on market manipulation.[83] The comment by CESR is as follows:

> This type of market manipulation involves dissemination of false and misleading information without necessarily undertaking any accompanying transaction. This could include creating a misleading impression by failure properly to disclose a price sensitive piece of information which should be disclosed. For example, an issuer with information which would meet the Directive definition of 'inside information' fails properly to disclose that information and the result that the public is likely to be misled.[84]

If CESR's comment is examined more closely, it seems that this was actually not the case and the authority was only emphasising that verbal manipulation does not cover only dissemination of false information but also dissemination of misleading information in which material facts, such as inside information, are omitted, as discussed in the next section. There is nothing in CESR's comment or in other places in the guidelines which suggests that CESR was proposing that the ban also covered full omission of material facts. On the contrary,

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[79] See AP Simester et al, *Simester and Sullivan's Criminal Law: Theory and Doctrine* (4th edn, Hart Publishing 2010) 76.
[80] See Art 12(1)(a)-(b) of MAR.
[81] See, e.g., discussion of this kind of provisions in Simester et al (n 79) 76. See discussion of the same conclusion regarding verbal manipulation in Norwegian legislation in Stordrange (n 76) 311–312, and Kjetil Wibe and André Michaelsen, 'Forbudet mot kursmanipulering' (2002) 8(1) Tidsskrift for forretningsjus 64, 97.
[82] See Art 17 of MAR.
[83] See Stordrange (n 76) 308–310.
[84] CESR/04-505b 13.

based on the headline of the section where this comment is made, which reads 'Dissemination of false and misleading information', it seems that this comment was only supposed to refer to partial omission.

A related point to consider with full omission is the relationship between verbal manipulation and the issuer's disclosure obligation. The question is whether breach of the disclosure obligation could in any instances also constitute market manipulation. Section 4.2 also concerns this issue.

4 DISSEMINATION OF TRUE INFORMATION BUT WITHHOLDING MATERIAL FACTS

4.1 PARTIAL OMISSION OF MATERIAL FACTS

Before discussing whether dissemination of true information can constitute market manipulation, it is necessary to outline the main facts of a 2019 criminal case from a Norwegian appeal court known as the *Funcom* case, in which this issue is dealt with.[85] The case involved a former CEO of Funcom N.V., a publicly listed company that developed multiplayer online role-playing games. The CEO, A, was charged with market manipulation for publishing false and misleading information during the development of the game *Secret World*, which impacted the game's expected success and the value of the company's shares. A was also, along with two other members of the company's management and one board member, charged with insider dealing for selling shares in the company while possessing inside information about the market manipulation as well as information about other matters relating to the company. The focus here is only the charge regarding market manipulation. The case took place before the adoption of MAR in Norway. The ban on market manipulation was located in Articles 3-8 of Act on Securities Transactions No 75/2007,[86] which was based on the MAD definition. As previously mentioned,[87] the core definition of market manipulation did not change materially from MAD to MAR.

A was charged with two counts of market manipulation. The *former* count concerned a stock exchange notice from Funcom on 2 July 2012 regarding restrictions on A's ability to sell shares in the company. The *second* count concerned information the company provided in its first quarterly report for 2012 on the level of pre-orders of the game, which aligned with Funcom's expectations. A was acquitted of the second count on the grounds that the information was neither incorrect nor misleading.[88] The first one concerns whether dissemination of true information can constitute market manipulation and is discussed further here.

The stock exchange notice from 2 July 2012 primarily addressed A's transition to a new role as chief strategy officer (CSO) at Funcom and the appointment of B as the new CEO, along with statements from both individuals. The notice ended with a concluding paragraph that read,

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[85] Judgment from Borgarting Court of Appeal No. Court of Appeal for Northern Norrland No. LB-2017-153037-3 from 9 May 2018.
[86] In Norwegian: 'Lov om verdipapirhandel'.
[87] See discussion in Section 2.2.
[88] See p 27-30 of the judgment.

> The shares and options in Funcom NV held by A and his wholly owned company [Company 1] AS will remain regulated as shares held by management in Funcom with respect to red and green periods of trading. As part of the transition to the new role, Mr. A will also leave the Management Board of Funcom.[89]

Following the stock exchange notice, A sold shares in Funcom that he owned himself and through his company in 18 transactions on 9 and 12 July. The total amount of the transactions was close to 4.5 million Norwegian krone (NOK). Despite the sales, A remained one of the largest shareholders in Funcom. After the sales, there were negative reactions from shareholders, who indicated that they had interpreted the 2 July stock exchange notice to mean that A was not permitted to sell shares at that time. The reason for this is the reference in the notice to 'red and green periods of trading' regarding management of Funcom.

As described in the judgment, Funcom had implemented a system of 'red periods', when individuals in the company had sensitive information that could potentially develop into inside information.[90] The system was stricter than the legal prohibition against insider trading, for it encompassed information that did not meet the requirements for being inside information. The purpose of this system was to exercise caution with information that could develop into inside information. Individuals with such knowledge were placed on 'red lists' as long as the information remained sensitive, and they were advised not to trade Funcom shares.

As a precautionary measure, Funcom introduced a red period on 29 June 2012 for those employees who could gain access to either sales data or player activity related to *Secret World*. A was placed on the list because as CEO, he received such sensitive information. He was removed from the list on 2 July because he no longer had access to sales data or other market-sensitive information about the computer game. There was no evidence suggesting that A had access to or received information about sales data or player activity after this point or that he received any other information indicating that he should remain on the 'red list'.

The parties in the case agreed that the information in the stock exchange notice on the restrictions on A's ability to sell shares was not incorrect. It was correct that A left the Management Board, and it was true that he remained subject to the company's internal system for red and green periods for shares owned by management provided that in his new role he had access to sensitive information that was or could have developed into insider information. The notice did not state that A was subject to internal restrictions regarding the sale of shares at the time of the notice, nor did it specify how likely he was to become subject to such restrictions. Furthermore, it was clear that A, after stepping down as CEO on 2 July 2012, was no longer a primary insider at Funcom and therefore was no longer subject to the restrictions and obligations that apply to such persons under the law. Information that he was no longer a primary insider had been publicly available since 2 July.

The Norwegian Appeal Court had to determine whether the stock exchange notice, which was not incorrect and in fact accurate on the points mentioned in the notice, could constitute market manipulation. As the court noted, it is not a requirement that the

[89] See p 25 of the judgment.
[90] See definition of inside information in Art 7 of MAR.

information be false or incorrect. It is sufficient that it is likely to give misleading signals regarding matters with potential effect on the share price.[91]

But how can correct information amount to market manipulation? The Appeal Court was correct that it is sufficient that the information is viewed as misleading to constitute market manipulation. The determining factor is whether material information was omitted.[92] As stated in recital 47 of MAR, spreading of false or misleading information may 'consist of manifestly false information, but also wilful omission of material facts'.[93] To determine whether material facts were omitted, thus making the statement misleading, a reasonable investor test can be applied[94] by asking whether a reasonable investor would take the omitted information into account when making an investment decision and whether the information that was provided was likely to mislead a reasonable investor about the actual circumstances involved.[95]

Even though the Norwegian court did not apply this test exactly, it appears it took a similar approach in determining whether the stock notice amounted to market manipulation. The court stated that the information in itself has limited informational value because the recipients would need to conduct further investigations to understand what the company's internal rules regarding red and green periods entail and what this specifically means for A in his new role. Given that the stock exchange notice nonetheless mentioned this, the court found it difficult to see that the purpose could have been anything other than to signal to the market that A would be subject to the same restrictions in this regard as the rest of the management after his departure.[96]

The court concluded that investors would interpret this to mean that A – and the rest of management – would not be able to sell shares during the crucial phase the company was in. It must have been obvious to reasonable investors,[97] according to the court, that the management would possess price-sensitive information about this until Funcom publicly disclosed the information. The court considered that the stock exchange notice was intended to reassure the market that he would apparently not be able to sell shares immediately, which was incorrect. The reality therefore was that A was free to sell shares from the moment he stepped down, which he did relatively shortly after. Therefore, the court concluded that it was clear that the information about restrictions on A's ability to sell shares was likely to give misleading signals about Funcom's share price.[98] Because A was the one who initially suggested to the board they include this content in the notice and he should have known that this information was likely to mislead the market, the court convicted him of market manipulation.[99]

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[91] See p 26 of the judgment.
[92] See, e.g., discussion in Hansen, *Informationsmisbrug* (n 16) 494–499.
[93] See also one of the examples of market manipulation in Section B of the Annex to the 2001 MAD Proposal, 'Making untrue statements of material facts' and 'Non-disclosure of material facts or material interests'. See Commission, 'Proposal for a Directive of the European Parliament and of the Council on insider dealing and market manipulation (market abuse)' COM (2001) 281 final.
[94] See, e.g., Rüdiger Veil, 'Market Manipulation' in Rüdiger Veil (ed), *European Capital Markets Law* (3rd edn, Hart Publishing 2022) 235.
[95] See discussion in Kalss (n 62) 176.
[96] See p 26 of the Judgment.
[97] In Norwegian: 'fornuftige investorer'.
[98] See p 26 of the judgment.
[99] See p 27 of the judgment.

This approach by the Norwegian court aligns with two other cases, one from the Icelandic Supreme Court and the other from the Danish Supreme Court. In the so-called *Al Thani* case from 2015, the Supreme Court of Iceland convicted three bank executives and the largest shareholder of the bank of verbal manipulation for withholding material facts when discussing with the media a large sale of the bank's own shares to a foreign investor.[100]

On 22 September 2008, Kaupthing Bank (Kaupthing) announced to the market it had sold 5.01% of its issued shares to a wealthy businessman from the Middle East related to the Qatar ruler al Thani. This was only 17 days before the Financial Supervisory Authority of Iceland intervened in the bank's operations and appointed a resolution committee for the bank in accordance with the so-called Emergency Act.[101]

A police investigation later revealed that the share purchase was fully financed with a loan from the bank through a relatively complicated corporate structure. The defendants[102] were convicted of two separate violations of the ban on market manipulation. The *first* was related to the share purchase and falls under non-verbal manipulation, under which the court deemed the transaction misleading because it was constructed in a way to give the false appearance that a well-known foreign investor was the sole investor and thereby concealing the involvement of the existing major shareholder (who was Icelandic) to enhance confidence in the bank in the weeks prior to Kaupthing's collapse.

The *second* violation, which is relevant here, regarded dissemination of misleading information through the media following the bulk sale. As the Supreme Court pointed out, it was no coincidence that the amount bought was just above the threshold (0.01% above), so the bank would be legally obliged to notify the market of the transaction. As part of the notification, a press release was sent out with more details of the transactions and then followed with some interviews with the defendants, during which they spoke about the business deal. The court was not able to pinpoint any false information, but it concluded that the information disseminated through the press release was misleading because there was no mention of the fact that the bank had fully financed the share purchase and the Qatar investor was not the only buyer – the largest existing shareholder in Kaupthing, who owned before the purchase almost 10% of the issued shares, was in reality buying half of the 5.01% of the shares.[103] The omission of such material facts in the notification, the press release and the interviews is what made the dissemination misinforming.

A Danish case from 2012 known as the *journalist* case, much like the *Al Thani* case and the *Funcom* case, demonstrates how verbal communication can amount to market manipulation, even when it does not contain any false information.[104] In the case, the journalist, who was also the magazine's financial editor, regularly published recommendations to invest in specific illiquid shares traded on the Copenhagen Stock Exchange. On thirteen occasions, the journalist bought a considerable number of shares in companies he then recommended to his readers to invest in in the long term. After these companies' share prices had risen, the journalist sold his shares for a considerable profit. In

[100] Judgment from the Supreme Court No 145/2014 from 12 February 2015 (*Al Thani*).
[101] See 'Report of the Special Investigation Commission. Chapter 21: Causes of the Collapse of the Icelandic Banks – Responsibility, Mistakes and Negligence' (English version) 87. The Emergency Act is No 125/2008.
[102] One of the defendants, the large shareholder, was only convicted of verbal manipulation.
[103] See Al Thani (n 100) p 83-85 of the judgment.
[104] Judgment from the Supreme Court of Denmark No U 2013.196 H from 18 October 2012 (*the journalist*).

most of his articles, the journalist disclosed that he owned shares in the recommended companies. Even though the reservation was missing in some of his articles, it was not his fault, according to the district court in the case.[105]

Despite his reservation in the end of most his articles, the Supreme Court considered his recommendation market manipulation. The court considered it a material fact that the journalist had a considerable stake in the price movement of the shares he recommended. The court concluded that he did not sufficiently disclose this conflict of interest in light of Article 12(2)(d) of MAR,[106] which requires conflicts of interest to be disclosed to the public in a proper and effective way, and Article 20(1) of MAR,[107] which requires everybody who makes investment recommendations to ensure that such information is objectively presented and to disclose their interests or indicate conflicts of interest concerning the financial instruments to which that information relates.[108]

By not disclosing this material fact and essentially doing the exact opposite in his recommendation of investing long-term in the shares (by selling his shares shortly after making the recommendation), he was misleading his readers, according to the court. The behaviour of buying illiquid shares, recommending his readers invest long-term in the same shares and then selling the shares for a profit demonstrated, according to the court, that his recommendations were influenced, at least partly, by his desire to influence the share price. Because the journalist profited from his recommendation, the special rule regarding journalists did not apply to him, so the traditional ban applied to his behaviour. The journalist was convicted of market manipulation.[109]

The court's argumentation in this case for applying the ban on market manipulation is interesting, but some might say the court was stretching the ban too far because the journalist's actual recommendations did not seem to have contained any false or misleading information and the journalist informed the readers of his conflict of interest. Therefore, it can be argued that the journalist did not disseminate any misleading information or at least did not omit any material information in his recommendation.

However, the most important point in the case is that the journalist did not sufficiently disclose how much interest he had in the shares, and he only seemed to have made the recommendation to affect the price of the shares. When combining these two factors (conflict of interest and the trading pattern), it does not seem that the Danish Supreme Court went too far in applying the ban on market manipulation to the journalist's behaviour.

4.2 RELATIONSHIP BETWEEN VERBAL MANIPULATION AND ISSUER'S DISCLOSURE OBLIGATION

Another point that is necessary to touch upon is the connection between verbal manipulation and the issuer's disclosure obligation. In section 3.2, the Danish case from 2016, *Neurosearch*, was discussed in relation to dissemination of false information. As an issuer of shares that were traded on the Copenhagen Stock Exchange, Neurosearch was obliged to disclose as

[105] See *the journalist* (n 104) p 201 of the judgment.
[106] Art 34(2)(1) of the Danish Securities Transactions Act.
[107] Art 28 b of the Danish Securities Transactions Act.
[108] See *the journalist* (n 104) p 205 of the judgment.
[109] See *the journalist* (n 104) p 205-206 of the judgment.

soon as possible to the public inside information which directly concerned the company.[110] When Neurosearch issued the company announcement about its research, it was complying with its disclosure obligation; therefore, it is natural to contemplate whether the dissemination could have been seen as a violation of the Neurosearch's disclosure obligation instead of applying the ban on market manipulation.

In this case, it would have been difficult to apply the disclosure obligation because it had been established that the primary endpoint in the research had not been reached, and consequently there was no inside information to disclose.[111] However, a public disclosure of inside information can be formulated in such a way that in theory such dissemination can constitute a breach of issuer's disclosure obligation and the ban on market manipulation (verbal misinformation).[112] It is therefore important to determine which rule applies, particularly because a violation of the ban on market manipulation typically entails stricter punishments.[113]

The distinction is most likely that the ban on market manipulation would apply to cases in which the issuer disseminates (action) information to the public and it has been established that the misinformation[114] was material, as was the case with Neurosearch.[115] However, the disclosure obligation would apply to cases in which there was no dissemination by the issuer (full omission). For example, if it had been established that Neurosearch had actually reached the primary endpoint in its research, which constituted inside information, and the company had not disclosed the information to the public, it would be seen as a violation of the disclosure obligation.

This assumption is mainly based on the fundamental difference in the wording of verbal manipulation and the issuer's disclosure obligation in MAR. The former forbids certain actions (the spreading of false or misleading information), which is violated if the action takes place, whereas the latter prescribes a certain duty to act (disclose inside information) and is violated if the duty is neglected.[116] The Supreme Court in the *Neurosearch* case seems to agree with that distinction when it stated that the disclosure obligation was not supposed to cover behaviour which spreads false or misleading information in violation of the ban on market manipulation.[117]

Furthermore, this distinction is in accordance with previous conclusions made that material misinformation is an essential element of the concept of market manipulation.[118] This element separates market manipulation in a clear and predictable manner from disclosure obligation, which aims at ensuring true and accurate information from the issuer

[110] See Art 17(1) of MAR. In the case of a Danish company, such as Neurosearch, the obligation was based on Art 27(1) of the Danish Securities Transactions Act. See reference in *Neurosearch – High court* (n 68) on p 658 in the judgment.
[111] If it is assumed that there was no other inside information directly concerning Neurosearch at the time.
[112] See, e.g., discussion in Hansen, 'Når Tanken Tæller: Om Forholdet Mellem Oplysningspligt Og Kursmanipulation' (n 78).
[113] A breach of disclosure obligation usually entails some administrative sanctions. See ibid 196.
[114] In the form of false and misleading information.
[115] Given that other objective and subjective elements of the offense are fulfilled.
[116] See, e.g., discussion of this difference between the two rules in Hansen, 'Når Tanken Tæller: Om Forholdet Mellem Oplysningspligt Og Kursmanipulation' (n 78) 200–201.
[117] See *Neurosearch – Supreme Court* (n 68) p 29 of the Supreme Court judgment.
[118] See discussion in Section 2.3.

is available to the market[119] whereas the ban on market manipulation aims at preventing false and misleading information being disseminated to the market.

5 CONCLUDING REMARKS

Even though market manipulation can be seen as another form of lying, it is possible to commit market manipulation by disseminating true information. As the behaviour is described in MAR, it is sufficient that the information is viewed as misleading to constitute market manipulation. The key factor is whether material information was omitted. To assess whether omissions render the information misleading, a reasonable investor test can be applied. This involves asking whether a reasonable investor would consider the omitted information relevant to an investment decision and whether the information provided was likely to mislead a reasonable investor about the actual circumstances. Using this approach, it is possible to determine when truthful information becomes misleading and could therefore violate the ban on market manipulation under MAR.

[119] See, e.g., Hansen, 'Når Tanken Tæller: Om Forholdet Mellem Oplysningspligt Og Kursmanipulation' (n 78) 195. See also Stordrange (n 76) 301.

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MEMBER STATES' DISCRETION IN EMERGENCY PESTICIDE AUTHORISATIONS: THE ROLE OF THE EU PRINCIPLES OF GOOD ADMINISTRATION AND THE PRECAUTIONARY PRINCIPLE IN SHAPING BETTER NATIONAL ADMINISTRATIVE PRACTICES

PIETRO MATTIOLI*

The misuse of emergency pesticide authorisations under Article 53 of Regulation 1107/2009 by EU Member States systematically undermines the Regulation's core objective of prioritising health and environmental protection over improving plant production. The Member State authorities competent to decide on these authorisations lack independence and transparency safeguards and thereby frequently succumb to industry pressure, authorising pesticides without rigorous scientific scrutiny. With the intent to analyse how Article 53 can be realigned with the objective of Regulation 1107/2009, this article proposes leveraging the principles of good administration and the precautionary principle. To that end, it examines how the Court of Justice has interpreted and applied good administration principles to impose obligations of impartiality and transparency on Member States' authorities when acting within the scope of EU law. Additionally, it examines how the Court has resorted to the precautionary principle to guide the discretion of national competent authorities towards higher health and environmental standards in the context of pesticide authorisation procedures. However, recognising the uneven application of these principles across national administrative systems, this article ultimately argues that the EU should translate these principles into specific measures.

1 INTRODUCTION

In the *Pesticide Action Network Europe and Others* (*PAN Europe*) case, the Court of Justice of the European Union (CJEU) was asked whether Article 53 of Regulation 1107/2009 (the Plant Protection Products Regulation or PPPR) allows the controversial practice of granting emergency authorisations for plant protection products, commonly referred to as pesticides, containing active substances that are expressly prohibited under EU law.[1] The Court concluded that this practice is incompatible with the objectives of the Regulation, emphasising that even emergency authorisations under Article 53 should be consistent with the precautionary principle and the Regulation's objective of giving priority to the protection of health and the environment over the improvement of plant production.[2]

One of the merits of this judgment is that it draws attention to Article 53 of Regulation 1107/2009. Originally conceived as a mechanism to allow Member States to place

* PhD researcher at the Department of European law of the University of Liège, Belgium. The article relies on research being conducted in the framework of the ERC Starting Grant EUDAIMONIA. This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement n° 948473).

[1] Case C-162/21 *Pesticide Action Network Europe and Others* EU:C:2023:30.

[2] ibid paras 47-48.

plant protection products on the market for limited and controlled use in emergency situations, by way of derogation from the ordinary approval procedure, Article 53 has gradually become a routine unlawful procedure.[3] This provision has been used to repeatedly authorise the same products year after year, or to introduce products containing active substances that are still not approved or banned at the EU level.[4] In other words, emergency authorisations have evolved into a mechanism for bypassing standard EU regulatory procedures and placing pesticides on the market without the crucial safeguards that ordinary procedures provide. Nevertheless, the European Commission and the Member States have maintained an ambiguous stance toward reforming Article 53's implementation.[5] This paralysis stems from various factors, especially political and economic constraints. Notably, under the current system, agricultural lobbies can easily influence emergency authorisation procedures. Therefore, they have exerted pressure to maintain the current flexibility of the derogation regime.[6]

Against this backdrop, this article argues that the EU legal framework provides the necessary tools to reconcile Article 53 with the overarching objectives of Regulation 1107/2009. To this end, it illustrates that, according to the EU principles of good administration and the precautionary principle, as interpreted by the CJEU, national competent authorities are required to implement essential procedural safeguards and ensure that pesticide authorisations are consistent with the public interest in protecting health and the environment. At the same time, considering the limits of a consistent and effective application of these principles across the administrative systems of the Member States, this article suggests proceduralising these principles within EU law.

To develop this argument, section 2 begins with an overview of the procedures for placing pesticides on the market under Regulation 1107/2009. Subsequently, section 3 examines the factors that have allowed for the use of Article 53 emergency authorisations in ways that conflict with both the provision's intended scope and the objective of Regulation 1107/2009. Specifically, this section illustrates that the Member States' authorities responsible for deciding on these authorisations lack the safeguards of independence and

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1, recital 2 and Art 53. The list of emergency authorisations can be accessed at the following link: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/screen/home> accessed 30 October 2024.

[4] European Parliamentary Research Service (EPRS), 'Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market: European Implementation Assessment' (European Parliament 2018) <https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2018)615668> accessed 30 October 2024, Annex I-9.

[5] In response to a question from a Member of the European Parliament, the Commission has stated that it is following up with Member States regarding authorisations granted after the Court's ruling. Additionally, the Commission has reminded Member States that authorisations granted before the ruling should be withdrawn in accordance with their national legal procedures. European Parliament, 'Derogations for the use of pesticides that were banned for health and environmental reasons' (Question for written answer E-003023/2023, 12 October 2023) <https://www.europarl.europa.eu/doceo/document/E-9-2023-003023_EN.html#def2> accessed 30 October 2024. However, following the Court's ruling, the Commission has not yet adopted a formal position. European Commission, 'Summary report of the Informal Technical Meeting on emergency authorisations after the Judgment of 19 January 2023 in case C -162/21 (Pesticide Action Network Europe and Others vs. Belgium)' (13 February 2023).

[6] Banned pesticides still in use in the EU, 'Report: Banned pesticides still in use in the EU' (*Pesticide Action Network*, 2023) <https://www.pan-europe.info/resources/reports/2023/01/banned-pesticides-still-use-eu> accessed 12 February 2025.

transparency necessary to check and balance the pesticide industry's control over emergency procedures. To address these deficiencies, section 4 examines how the EU principles of good administration can create positive obligations for Member States' authorities when enforcing EU law, especially in terms of impartiality and transparency. This section also analyses how the precautionary principle has been successfully applied by the Court of Justice to increase health and environmental standards in the context of pesticide authorisation procedures. Against this background, section 5 concludes by highlighting that while these EU legal principles can recalibrate national administrative practices in pesticide authorisations, possible deficiencies in their implementation across Member States' administrative systems risk undermining the effectiveness of this approach. Therefore, the last section suggests operationalising the measures required by these principles within EU law.

2 PLACING PESTICIDES ON THE MARKET: FROM NORMAL TO EMERGENCY SITUATIONS

Pesticides are important for agriculture to protect plants and their products from harmful organisms and are therefore an essential component of food and agricultural production systems.[7] At the same time, their use creates some externalities. While the use of pesticides increases agricultural productivity, pesticides also pose significant risks to human and animal health, the environment and ecosystems.[8] For these reasons, it is crucial to establish a regulatory framework that balances these competing interests in the use of pesticides.

Considering these elements, the EU has established a legislative framework to regulate the use of pesticides.[9] At a time when EU lawmaking was influenced by the 'Better Regulation' initiative, which aimed to simplify legislation and administration,[10] the EU developed its pesticide regulatory framework guided by the precautionary principle.[11] Based on the Sixth Community Environment Action Programme, this framework aims to increase

[7] European Commission, 'Report from the Commission to the European Parliament and the Council. Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides' [2020] COM/2020/208 final; and European Commission, 'Commission staff working document: Drivers of food security' SWD (2023) 4 final, 67.

[8] European Environmental Agency (EEA), 'How pesticides impact human health and ecosystems in Europe' (2023) <https://www.eea.europa.eu/publications/how-pesticides-impact-human-health> accessed 30 October 2024; Luca Carisio, Noa Simon Delso, and Simone Tosi, 'Beyond the urgency: pesticide Emergency Authorisations' exposure, toxicity, and risk for humans, bees, and the environment' (2024) 947 Science of the Total Environment 174217; and Commission, 'Drivers of food security' (n 7) 67.

[9] The current EU legislative framework on pesticides consists of four key legislations: Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [2005] OJ L70/1; Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71; Regulation 1107/2009 (n 3) governing the placing of plant protection products on the market (PPPR); and Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides [2009] OJ L324/1. In literature, Emanuela Bozzini, *Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement* (Palgrave Macmillan 2017) 5-8.

[10] Interinstitutional agreement on better law-making [2003] OJ C321/1; and European Commission, 'Communication from the Commission to the Council and the European Parliament: Better Regulation for Growth and Jobs in the European Union' COM (2005) 0097 final.

[11] David Vogel, *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* (Princeton University Press, 2012) 274-275.

the level of protection of human and animal health and the environment, while enhancing the competitiveness of the EU internal market and ensuring food safety.[12] In this context, Regulation 1107/2009 lays down the main rules for the placing of plant protection products on the market, including rules for the approval of active substances (components that control harmful organisms), safeners (substances that reduce the effects of active substances) and synergists (substances that enhance the activity of the active substance) which plant protection products contain or consist of.[13]

Under normal circumstances, for plant protection products' market placement, Regulation 1107/2009 establishes a dual authorisation procedure: to be finally authorised at the Member State level, a product must contain active substances that have previously been approved at the EU level.

This ordinary procedure starts with the submission of a dossier by an applicant seeking approval for an active substance to the national competent authority of the designated Rapporteur Member State (RMS).[14] This dossier must contain extensive documentation demonstrating the safety of the substance for humans, animals and the environment. In particular, Regulation 1107/2009 imposes on the producer of these substances the responsibility to prove that these substances do not cause any hazard.[15] As an interim note, it is relevant to highlight that Regulation 1107/2009 applies a hazard-based approach to the authorisation of active substances.[16] This means that, when a substance meets one of the cut-off criteria set out in Article 4 of that Regulation, the evaluation stops at the hazard identification stage and the assessment does not proceed to the further steps of the risk assessment, which typically include exposure assessment and risk characterisation.[17]

Once the dossier has been submitted, the approval process for the active substance continues with the authority of the RMS assessing the admissibility of the application. This evaluation starts with a completeness check of the dossier, followed by a preliminary assessment.[18] The authority then prepares a draft assessment report (DAR), which is submitted to both the Commission and the European Food Safety Authority (EFSA).[19] At this stage, EFSA carries out the risk assessment of the active substance, in collaboration with the RMS. At the end of this evaluation phase, EFSA forwards its conclusions to the Commission, which acts as a risk manager.[20] The Commission prepares a review report, including a draft Regulation for either approval or non-approval of the substance. This draft is discussed in the Standing Committee on Plants, Animals, Food and Feed (PAFF

[12] Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme [2002] OJ L242/1, Art 7.
[13] Regulation 1107/2009 (n 3) Arts 1(1) and 1(2).
[14] ibid Art 7.
[15] ibid Art 8(1).
[16] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex II-22. The authors emphasise that strong public sentiments against pesticides, especially the fact that they are man-made hazards with severe health implications, have led to the adoption of strict standards based on a strong interpretation of the precautionary principle. This approach is different from the one typically employed in other food-related policy areas.
[17] Hazard identification represents the first phase of the scientific risk analysis process. Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* EU:T:2002:209 para 156; and Ragnar E Lofstedt, 'Risk versus Hazard – How to Regulate in the 21st Century' (2011) 2 European Journal of Risk Regulation 149, 153-154.
[18] Regulation 1107/2009 (n 3) Art 9.
[19] ibid Art 11.
[20] ibid Art 12.

Committee). If the Committee gives a favourable opinion, the Commission can then proceed to formally adopt the Regulation listing the approved substance.[21]

The list of approved substances contained in the Commission's Regulation allows pesticide manufacturers or other applicants to register plant protection products containing the approved essential substances for their placement on the market. This second phase takes place mainly at Member State level and is carried out by national competent authorities.[22] Generally, an applicant seeking to place a pesticide on the market must apply for authorisation in each Member State where the pesticide is intended to be placed.[23] The dossier must contain all the data required by the Implementing Regulation 284/2013.[24] The respective national competent authorities then evaluate the dossier. At the same time, companies wishing to place their product on the markets of multiple EU countries can apply for national authorisation in one Member State and then apply for mutual recognition in other Member States. Applications for mutual recognition can be made either in parallel or in sequence.[25] To facilitate mutual recognition and to avoid duplication of work and reduce administrative burden, Regulation 1107/2009 establishes three geographical zones (North, Centre and South) based on comparable agricultural, plant health and environmental conditions.[26] In this context, each Member State can still establish its own procedures for product authorisation while respecting the essential conditions and criteria set in the Regulation.[27]

By way of derogation from this two-stage ordinary procedure, Article 53 of Regulation 1107/2009 also allows plant protection products to be placed on the market under significantly less stringent conditions and safeguards than those prescribed above. Designed as a rapid, temporary, and last resort procedure for emergency situations, Article 53 essentially allows national competent authorities to authorise products for up to 120 days when there is a risk that cannot be contained by other reasonable means. If approved, the use of the product must remain limited and controlled.[28] The national authority must also immediately inform the other Member States and the Commission, providing detailed information on the measures taken and the considerations relating to consumer safety.[29] At this stage, the Commission may request an opinion, or scientific or technical assistance from EFSA, which must respond within one month. On the basis of this opinion, the Commission may decide whether the Member State may extend, withdraw or amend the measure.[30]

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[21] Regulation 1107/2009 (n 3) Art 13.
[22] A list of the Member States' competent authorities is available at the following link: <https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists_en> accessed 30 October 2024.
[23] Regulation 1107/2009 (n 3) Art 33(1).
[24] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market [2013] OJ L93/85.
[25] Regulation 1107/2009 (n 3) Arts 40(1) and 40(2).
[26] ibid Annex I.
[27] ibid Arts 29, 36 and 37.
[28] ibid Art 53(1).
[29] ibid Art 53(2).
[30] ibid Art 53(3)

While Regulation 1107/2009 establishes separate procedures for normal and emergency circumstances for pesticide authorisation, the practical implementation of this Regulation suggests that this distinction has become increasingly blurred. The next Section illustrates how Article 53 has become almost a routine procedure, often used in breach of the conditions set out in the provision.

3 HOW THE EXCEPTION HAS BECOME ROUTINE

Regulation 1107/2009 fully harmonises the approval of active substances while leaving the Member States the responsibility to authorise plant protection products according to national conditions, in light of harmonised criteria.[31] In this context, Member States can also exercise their autonomy by resorting to emergency authorisations under Article 53 in response to specific national circumstances such as environmental threats to plant production and ecosystems that cannot be mitigated by other reasonable means. However, contrary to both the explicit wording of the provision and the underlying objectives of Regulation 1107/2009, evidence suggests that Article 53 has become a routine practice, extending beyond its intended application to emergency circumstances.[32]

A major concern is the prevalence of repeated authorisations of the same product through emergency authorisation requests rather than through ordinary procedures.[33] Many derogations are renewed year after year, transforming *de facto* what should be a short-term emergency measure into a long-term solution.[34] Yet, many approvals concern products containing EU-approved active substances.[35] However, contrary to the spirit of Article 53, emergency authorisation requests do not relate to special circumstances, do not mention alternative products that may be used to contain the danger[36] and do not contain specific risk mitigation measures that would limit and control the use.[37] Furthermore, in clear contrast with the Commission's guidance document on Article 53, these authorisations are not replaced by either minor use extensions under Article 51 or standard authorisations.[38] Lastly, resorting to Article 53, pesticide manufacturers have unlawfully placed pesticides containing substances prohibited at EU level on the market.[39]

These misapplications of Article 53 are due to a complex interplay of economic, political and regulatory factors. In the current pesticide-dependent agricultural production system, national emergency authorisation procedures have become a reliable alternative to

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[31] Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market [2006] COM/2006/0388 final, points 331-332.
[32] A detailed analysis of Article 53 can be found in study conducted by Milieu Ltd and IEEP in Annex I to EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4).
[33] ibid Annex I-36 and 37.
[34] ibid 56, 57 and Annex I-9.
[35] ibid Annex I-28 and 29.
[36] ibid Annex I-33. One can read that 'less than one-third of derogations granted in 2017 (27%) referred explicitly to special circumstances in the text of the notification form. Around 18% of the derogations referred specifically to the control of a new or growing pest'.
[37] ibid Annex I-34.
[38] European Commission, 'Guidance on Emergency Authorisations According to Article 53 of Regulation (EC) No 1107/2009' (SANCO/10087/2013 rev 1, 2021) 6.
[39] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) 59; and European Parliament, 'European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides' (2018/2153(INI)).

time-consuming and cumbersome ordinary pesticide authorisation procedures.[40] Moreover, the inadequate or ineffective EU oversight of national practices likely contributes to the misuse of emergency procedures beyond the scope of Article 53. While the Commission has the possibility under Article 53(2) and (3) of Regulation 1107/2009 to request an opinion from EFSA and to decide on the extension, amendment, or withdrawal of emergency authorisations, this supervisory capacity has so far been little used.

Parallel to these considerations, this section specifically illustrates that the misapplications of Article 53 are the result of two key factors: firstly, the absence of independence requirements for national competent authorities within Regulation 1107/2009; and secondly, the lack of transparent procedures.

These two factors are largely linked to the complex trade-off between the Member States' autonomy and the necessity to achieve the EU policy objectives in the system of decentralised administrative enforcement of EU law. On the one hand, the principle of institutional autonomy gives the Member States the flexibility to fulfil their EU membership obligations in accordance with their individual constitutional and administrative frameworks.[41] As a result, when implementing EU law, each Member State determines which national bodies are competent to enforce EU law and which procedures apply to the enforcement of that law at the national level.[42] This approach is deliberately designed to accommodate the domestic organisational and administrative structures of each individual Member State.[43] On the other hand, this autonomy might represent an obstacle for the EU to reach its policy objectives, as Member States might establish enforcement structures that do not necessarily allow for an effective implementation of EU policies.[44] In response, the EU legislator may lay down structural and procedural arrangements related to the decentralised enforcement of EU legislation by Member States' administrations.[45] As an intermediate note, it should be recalled that although these interventions are currently

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[40] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex I-36 and 37. The authors highlight that 'the large number of derogations for PPPs undergoing an authorisation procedure, together with a large number of repeated derogations, suggests that Article 53 derogations are also used to fix structural problems occurring in authorisation procedures'.

[40] ibid 56 and 57.

[41] The precise content and scope of institutional autonomy under EU law remain unclear. However, references to institutional autonomy can be found in the Court of Justice's case law. For instance, most recently, Case C-796/19 *European Commission v Republic of Austria* EU:C:2020:920 paras 60-61; and Case C-378/19 *Prezident Slovenskej republiky* EU:C:2020:462 para 38. Furthermore, literature also refers to institutional autonomy, often together with the more well-developed concept of procedural autonomy. Annetje Ottow, 'The different levels of protection of national supervisors' independence in the European landscape' in Suzanne Comtois and Kars de Graaf (eds), *On judicial and quasi-judicial Independence* (Eleven International Publishing, 2013) 139; and Andrea Biondi and Giulia Gentile, 'National Procedural Autonomy' in Hélène Ruiz Fabri (ed), *Max Planck Encyclopedia of International Procedural Law* (Oxford University Press 2019).

[42] On the difference between implementation and enforcement of EU law, see Jan Jans, Roel de Lange, Sacha Prechal, and Rob Widdershoven, *Europeanisation of Public Law* (1st edn, Europa Law Publishing 2007) 13.

[43] Dionyssis G Dimitrakopoulos, 'The Transposition of EU Law: 'PostDecisional Politics' and Institutional Autonomy' (2001) 7 European Law Journal 442, 444.

[44] Robert Schütze, *European Constitutional Law* (2nd edn, Cambridge University Press 2016) 334.

[45] Stefan Kadelbach, 'European Administrative Law and the Law of a Europeanized Administration' in Christian Joerges and Renaud Dehousse (eds), *Good Governance in Europe's Integrated Market, Collected Courses of the Academy of European Law* (Oxford University Press 2002) 169-170; and Stéphanie De Somer, 'The Europeanisation of the Law on National Independent Regulatory Authorities from a Vertical and Horizontal Perspective' (2012) 5 Review of European Administrative Law 93.

widespread in many policy areas, they remain an interference with the autonomy of the Member States and therefore, are allowed under certain conditions. More specifically, once it has been established that the EU has the competence to act under the principle of conferral,[46] the exercise of that competence is governed by the principles of subsidiarity and proportionality.[47] Despite their questionable effectiveness in limiting EU regulatory intervention,[48] both principles are meant to act as safeguards to protect the autonomy of the Member States against overly expansive and intrusive EU regulatory initiatives.[49]

Considering this framework, it can be noticed that the enforcement of Regulation 1107/2009 is also delegated to national competent authorities; yet this Regulation imposes only minimal structural requirements on these authorities compared to other sectors.[50] Article 75 of that Regulation concerning competent authorities prescribes the appointment of a sufficient number of suitably qualified and experienced staff,[51] but it does not impose any formal condition to ensure the independence of these authorities.[52] In terms of independence, Article 36(1) regarding the examination of applications in the context of the ordinary authorisation procedure simply declares that Member States must carry out 'an independent, objective and transparent assessment in the light of current scientific and technical knowledge'.[53]

The omission of detailed independence requirements for national competent authorities when acting within the scope of Regulation 1107/2009 not only deviates from other EU sectoral regulatory interventions but also highlights inconsistencies across different levels of governance within the same policy domain. National administrative bodies entrusted with the enforcement of EU law have historically been granted varying degrees of independence across different sectors as an essential condition for fostering their specialised expertise, protecting their decision-making processes from short-term political and market

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[46] Article 5(2) TEU.

[47] Article 5(3) and (4) TEU. In literature, Koen Lenaerts, 'Proportionality as a Matrix Principle Promoting the Effectiveness of EU Law and the Legitimacy of EU Action' (Keynote speech, ECB Legal Conference 2021: Continuity and Change – How the Challenges of Today Prepare the Ground for Tomorrow, 25 November 2021) <https://www.ecb.europa.eu/press/conferences/shared/pdf/20211125_legal/ECB-Symposium_on_proportionality_25_November_2021.en.pdf> accessed 7 November 2024, 3-5.

[48] Rob Widdershoven, 'National Procedural Autonomy and General EU Law Limits' (2019) 12(2) Review of European Administrative Law 5, 13-14. Specifically, on the limited judicial application of subsidiarity compared to proportionality, Robert Schütze, 'Subsidiarity after Lisbon: Reinforcing the Safeguards of Federalism?' (2009) 68(3) The Cambridge Law Journal 525, 532-534; Paul Craig, 'Subsidiarity, a Political and Legal Analysis' (2012) 50(1) Journal of Common Market Studies 72, 75-77; Xavier Groussot and Sanja Bogojević, 'Subsidiarity as a Procedural Safeguard of Federalism' in Loïc Azoulai (ed), *The Question of Competence in the European Union* (Oxford University Press 2014) 234

[49] In more detail, Koen Lenaerts and José A Gutiérrez-Fons, 'A Constitutional Perspective' in Robert Schütze and Takis Tridimas (eds), *Oxford Principles Of European Union Law: The European Union Legal Order: Volume I* (Oxford University Press 2018) 115-117.

[50] For an overview on the evolution of EU law's interference on Member State authorities competent to enforce EU law, Stéphanie De Somer, 'EU impulse' in Stéphanie De Somer (ed), *Autonomous Public Bodies and the Law* (Edward Elgar, 2017) 23; and Pietro Mattioli, 'The Quasi-Judicial Role of National Competent Authorities: an Ambiguity that the Principle of Effective Judicial Protection could help address?' (2024) 17(2) Review of European Administrative Law 99.

[51] Regulation 1107/2009 (n 3) Art. 75(3).

[52] ibid Art 75. In more detail on the independence of national competent authorities, EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex III-81-85.

[53] Regulation 1107/2009 (n 3) Art 36(1).

pressures and enhancing the overall quality and impartiality of their decisions.[54] In this regard, the growing scope of EU integration has usually led to the gradual embedding of stricter degrees of independence for national administrative entities within the EU legislative framework.[55]

At the same time, the omission of independence safeguards in the context of Regulation 1107/2009 highlights an inconsistency between the limited independence of national authorities competent to authorise pesticides and the heightened independence scrutiny applied in the context of EFSA. In particular, this claim is illustrated by the recent debate regarding the independence and conflicts of interest of the members of 'Article 36 organisations',[56] which are specific organisations designated by Member States to assist EFSA in carrying out scientific tasks.[57] Considering that these organisations perform activities that typically fall within EFSA's competence but are executed at the national level, concerns were raised about whether these organisations operate with the same level of independence as EFSA's members when performing the same tasks. For instance, criticism has been directed at EFSA for the insufficient screening of potential conflicts of interest within these organisations, as well as the lack of clarity and consistency in the criteria used by Member States to designate them.[58] In response to these concerns, the EFSA 2024 Independence Policy recently extended the same transparency and independence requirements to individuals from Article 36 organisations as those applicable to EFSA's own scientific Working Groups when performing equivalent tasks.[59]

Another factor significantly contributing to the misuse of emergency authorisations is the limited transparency of the Member States' emergency authorisation procedures. Far from being an issue restricted to Article 53's procedures, concerns over the transparency of decision-making processes can be considered a common problem underpinning EU risk regulation.[60]

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[54] Mark Thatcher, 'Regulation after delegation: independent regulatory agencies in Europe' (2002) 9(6) Journal of European Public Policy 954; Matthew Flinders and Jim Buller, 'Depoliticization, Democracy and Arena Shifting' in Tom Christensen and Per Laegreid (eds), *Autonomy and Regulation: Coping with Agencies in the Modern State* (Elgar Publishing 2006) 58-59; and Christel Koop and Chris Hanretty, 'Political Independence, Accountability, and the Quality of Regulatory Decision-Making' (2018) 51(1) Comparative Political Studies 38.

[55] In relation to national competent authorities' independence, literature distinguishes different forms of independence. On the difference between formal and de facto independence: Martino Maggetti, 'De facto independence after delegation: A fuzzy-set analysis' (2007) 1(4) Regulation & Governance 271, 271-272; and Fabrizio Gilardi and Martino Maggetti, 'The independence of regulatory authorities' in David Levi-Faur (ed), *Handbook of Regulation* (Edward Elgar 2010) 202-204. On the difference between independence from market parties, political independence and complete independence: Ottow (n 41) 140-142.

[56] The term 'Article 36 organisations' originates from Article 36 of Regulation 178/2002, which is entitled 'Networking of organisations operating in the fields within the Authority's mission'. More information is available at <https://www.efsa.europa.eu/en/partnersnetworks/scorg> accessed 10 February 2025.,

[57] Economisti Associati, 'Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management – Executive Summary Report' (22 April 2021) 9. The authors of the report highlight how EFSA aims to increasingly rely on Article 36 organisations to act as working groups.

[58] Ellen Vos, Annalisa Volpato, and Guido Bellenghi, 'Independence and transparency policies of the European Food Safety Authority (EFSA)' (2023) PE 740.080, 22-23.

[59] EFSA, 'EFSA's policy on independence' (2024) <https://www.efsa.europa.eu/en/corporate-pubs/efsas-independence-policy#documents> accessed 10 February 2025.

[60] Alie de Boer, Marta Morvillo, and Sabrina Röttger-Wirtz, 'Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation' (2023) 14(2) European Journal of Risk Regulation 313, 314.

The recent glyphosate saga has illustrated the public's struggle to access scientific data and information related to EU level active substance authorisations.[61] In that context, in response to mounting public pressure, the EU has taken specific measures to enhance transparency in food chain risk assessment through the adoption of Regulation 2019/1381.[62] However, while this Regulation introduces more rigorous disclosure requirements and public engagement mechanisms at the EU level, these heightened transparency standards do not affect Member States when they implement EU law.[63] Again, this gap involuntarily creates a two-tiered system of accountability, where EU level procedures face increased scrutiny, whereas national authorities retain considerable discretion in their decision-making processes.

Nevertheless, Article 53's procedural design choices might appear in line with the inherently urgent and nationally specific nature of emergency authorisations, which resist the establishment of detailed harmonised procedures. At the same time, Member States' emergency pesticide authorisation procedures exhibit transparency deficiencies that cannot be ignored. Decisions often lack clear and comprehensive justification and public access to relevant technical information remains limited. More precisely, national emergency authorisations are normally published, but applications, their evaluations, and the scientific risk assessments contained therein are not always publicly available.[64] When interested parties gain access to these decisions, they nevertheless find that the information provided is not sufficiently detailed. The documentation submitted and the reasons provided by the authorities, such as evidence of exceptional circumstances and lack of alternatives to mitigate risk, as well as the scientific data underlying the risk assessment, are poorly justified or non-existent.[65] Furthermore, there is insufficient openness in the decision-making process, coupled with inadequate stakeholder participation. This is particularly evident in the absence of robust third-party consultation procedures.[66]

The limited transparency of national emergency procedures, coupled with the lack of independence of national authorities, contributes to the creation of an institutional environment that is vulnerable to two important issues. Firstly, these elements foster conditions that allow undue industry influence over the decision-making processes of national authorities.[67] The affected ability of national competent authorities to correctly

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[61] Marta Morvillo, 'The General Court Orders Disclosure of Glyphosate-related Scientific Studies: Tweedale, Hautala, and the Concept of Environmental Information in the Context of Plant Protection Products' (2019) 10(2) European Journal of Risk Regulation 419, 425-426.

[62] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain [2019] OJ L231/1.

[63] Regarding the potential implications of Regulation (EU) 2019/1381, see Claire Robinson et al, 'Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions' (2020) 11(3) European Journal of Risk Regulation 450; and de Boer, Morvillo, and Röttger-Wirtz (n 60) 323.

[64] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex I-53. The research conducted shows that 'none of the selected Member States publish the applications and related evaluations (e.g. assessment of alternatives and justifications) or any other documents. The representative of one CA stated that they provided such information on request (e.g. the application, evaluation), except where it relates to confidential information on the composition of the product'.

[65] ibid Annex I-59.

[66] ibid Annex I-54 and Annex III-23 and 25; and Robinson et al (n 63) 470-472.

[67] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex I-62: 'A large share of the Article 53 authorisations granted in 2017 (38%) were requested by agricultural or forestry companies and associations, 31% were requested by PPP manufacturers or the seed industry, 23% were

balance industry interests with public ones is generally referred to as 'regulatory capture'.[68] This phenomenon is a common concern for national competent authorities operating in the framework of Regulation 1107/2009.[69] For example, when applying for an authorisation to place plant protection products on the market under the ordinary procedure, the applicant submits a dossier containing a range of data and studies on the product. Pesticide manufacturers often possess significant detailed knowledge about the products that they intend to place on the market. Conversely, national authorities often face constraints, such as limited budgets and resources and insufficient technical expertise, making them rely on industry-provided data. Other interested parties, including farmers, typically have the least access to technical information about pesticides. The result of this process is that the industry can easily gain control over pesticide authorisation procedures.[70] In the context of Article 53's procedures, the even more limited access to information intensifies information asymmetries between the industry and national authorities, on the one side, and the public, on the other side. Coupled with a lack of independence, the 'black box' in which these procedures take place allows the industry to submit insufficient scientific data and to influence the authorities' outcomes without adequate public scrutiny.[71]

Secondly, the lack of transparency in decision-making of Member State authorities is also problematic because it undermines the very democratic foundations of public authorities' decisions. Access to information and stakeholders' participation, which are at the foundations of transparency, are meant to ensure public participation in the decision-making, legitimacy of public actions, and accountability of those decisions.[72]

To conclude, this section seeks to reveal that the misapplication of Article 53 stems from a critical gap in the institutional design of national competent authorities when acting within the scope of Regulation 1107/2009. The absence of independence and transparency safeguards exemplifies the ongoing tension between Member State autonomy and the need for EU harmonised administrative arrangements for the domestic enforcement of EU law, which is a key condition for the EU to see its policy objectives fully achieved. As a result, this article asks: what legal tools can the EU leverage to address systemic shortcomings in the implementation of Article 53 of Regulation 1107/2009? The following section addresses this inquiry by looking at the EU principles of good administration and the precautionary principle.

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requested by authorities, and a small number by other types of applicants, such as agricultural and agronomy research institutes and consultants (6%) or producers of animal health products or feed (1%)'.

[68] This article defines regulatory capture as a phenomenon in which national competent authorities responsible for authorising plant protection products are influenced by the pesticide industry's interests. This undue influence compromises the authorities' ability to maintain an appropriate balance between industry interests and the imperative to protect public health and the environment. More generally, Richard A Posner, 'The Concept of Regulatory Capture: A Short, Inglorious History' in Daniel Carpenter and David A Moss (eds), *Preventing Regulatory Capture Special Interest Influence and How to Limit It* (Cambridge University Press 2013) 49-50; and EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex III-18.

[69] EPRS, 'Regulation (EC) 1107/2009: European Implementation Assessment' (n 4) Annex III-23.

[70] ibid Annex III-18-20.

[71] Bruno Latour, *Science in Action. How to Follow Scientists and Engineers through Society* (Harvard University Press 1988); and Julien Bois, 'Taking the law seriously while acknowledging its social embeddedness: an Actor-Network Theory approach of EU law' (2024) ORBi-University of Liège <https://hdl.handle.net/2268/317536> accessed 30 October 2024.

[72] Case T-716/14 *Antony C. Tweedale v European Food Safety Authority* EU:T:2019:14 paras 54 and 91; Martino Maggetti, 'Legitimacy and accountability of independent regulatory agencies: A critical review' (2010) Living Reviews in Democracy 1, 4; and de Boer, Morvillo, and Röttger-Wirtz (n 60) 317.

4 THE PRINCIPLES OF GOOD ADMINISTRATION AND THE PRECAUTIONARY PRINCIPLE AS TOOLS OF EU ADMINISTRATIVE DESIGN: INSIGHTS FROM THE COURT OF JUSTICE CASE LAW

This section first examines the role of the EU principles of good administration in setting procedural standards, in particular impartiality and transparency, for Member States' administrations when enforcing EU law. Subsequently, it explores how the Court of Justice has leveraged the precautionary principle to impose higher standards of health and environmental protection within pesticide authorisation procedures. Ultimately, this section concludes by showing how the good administration and precautionary principles might together account for a possible solution to address the misapplications of Article 53 of Regulation 1107/2009.

4.1 GOOD ADMINISTRATION

Good administration is primarily recognised as a fundamental right within the EU legal framework.[73] Article 41 of the EU Charter of Fundamental Rights (CFR) establishes the right to good administration, encompassing several subjective individual rights.[74] These include, inter alia, the obligation to give reasons and the right for individuals to have their matters handled impartially, fairly and within a reasonable time. At the same time, this provision highlights certain principles of good administration, which are instead primarily reflected in the case law of the Court of Justice.[75]

Prior to the formal codification of this right, the Court had already invoked various principles of good administration to assess the legality of EU administrative actions. Some procedural rights, such as the right to be heard, to have access to files and the obligation of the administration to give reasons, were already well established before their codification in Article 41 CFR.[76] In this context, it is important to note that the rights under Article 41 CFR are not formally binding on Member State administrations. This provision is explicitly framed

[73] On the notion of good administration, Päivi Leino, 'Efficiency, Citizens and Administrative Culture. The Politics of Good Administration in the EU' (2014) 20(4) European Public Law 681; Hanns Peter Nehl, 'Good Administration as Procedural Right and/or General Principle?' in Herwig C H Hofmann and Alexander H Türk (eds), *Legal Challenges in EU Administrative Law* (Edward Elgar Publishing 2009) 322-323; and Takis Tridimas, 'The general principles of EU law and the Europeanisation of national laws' (2020) 13(2) Review of European Administrative Law 5.

[74] Jürgen Schwarze, 'European administrative law in the light of the Treaty of Lisbon: introductory remarks' (European Parliament, Directorate General for Internal Policies 2011) <https://www.europarl.europa.eu/thinktank/en/document/IPOL-JURI_NT(2011)432777> accessed 20 October 2024, 15-18.

[75] Herwig CH Hofmann and Bucura C Mihaescu, 'The Relation between the Charter's Fundamental Rights and the Unwritten General Principles of EU Law: Good Administration as the Test Case' (2013) 9(1) European Constitutional Law Review 73; Herwig C H Hofmann, Gerard C Rowe, and Alexander H Türk, 'General Principles Framing European Union Administrative Law' in Herwig C H Hofmann, Gerard C Rowe, and Alexander H Türk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011) 190 et seq.

[76] For an overview of the CJEU's case law on good administration, see HP Nehl, 'Good Administration as Procedural Right and/or General Principle?' (n 73) 323

in terms of EU institutions, bodies, offices and agencies.[77] However, national administrations must apply the principles of good administration when they act within the scope of EU law, including those principles now codified in Article 41 CFR.[78] Moreover, the Court has also declared that the right to good administration itself, as enshrined in Article 41 of the Charter, reflects a general principle of EU law.[79] Therefore, when enforcing EU law, national authorities must now generally respect the rights of individuals under Article 41 CFR.[80]

Against this background, to fully understand how good administration may impact national competent authorities when enforcing EU law, it is essential to delve into the CJEU's case law. The Court has extensively relied on the principles of good administration to establish and reinforce procedural safeguards that would limit the discretionary powers of public authorities, ensuring that these powers conferred on them by EU law are exercised in a manner consistent with public interests and EU law's objectives.[81] In this regard, the case law of the Court has referred to the impartiality, transparency and accountability of national administrative actions.[82] For instance, one can first notice that good administration requires Member State administrations 'to conduct a diligent and impartial examination of all the relevant matters' using the most complete and reliable information possible for that purpose, including scientific knowledge.[83] Furthermore, the principles of good administration also include the obligation to provide adequate reasons.[84] In this regard, the Court often refers to the duty to state reasons to highlight the transparency and accountability of decision-making, and the Court therefore facilitates judicial review of administrative decisions.[85] The duty to

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[77] Tobias Lock, 'Article 41 CFR Right to good administration' in Manuel Kellerbauer, Marcus Klamert, and Jonathan Tomkin (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (Oxford Academic, 2019) 2205. In this regard, also the Court: 'it is clear from the wording of Article 41 of the Charter that it is addressed not to the Member States but solely to the institutions, bodies, offices and agencies of the European Union'. See, Case C-249/13 *Khaled Boudjlida contro Préfet des Pyrénées-Atlantiques* EU:C:2014:2431 para 32 and case law cited.

[78] Hanns Peter Nehl, *Principles of Administrative Procedure in EC Law* (Hart Publishing 1999) 15; and Steve Peers et al, 'Article 41; in *The EU Charter of Fundamental Rights: A Commentary* (Hart Publishing 2021) 1125, 1126; and Case C-249/13 *Khaled Boudjlida* (n 77) paras 32-34 and case law cited.

[79] For instance, Case C-604/12 *H.N v Minister for Justice, Equality and Law Reform* EU:C:2014:302 para 49.

[80] Joined Cases C-141/12 and C-372/12 *YS v Minister voor Immigratie, Integratie en Asiel and Minister voor Immigratie, Integratie en Asiel v M and S* EU:C:2014:2081 para 68. The Court has clarified that the fact that Article 41 CFR represents a general principle of EU law does not imply that individuals can derive directly a national right from it.

[81] Or Brook and Katalin J Cseres, 'Priority Setting as the Blind Spot of Administrative Law Enforcement: A Theoretical, Conceptual, and Empirical Study of Competition Authorities in Europe (2024) 87(5) The Modern Law Review 1209, 1237.

[82] Joana Mendes, 'Good Administration in EU Law and the European Code of Good Administrative Behaviour', (2009) 9 EUI LAW <https://hdl.handle.net/1814/12101> accessed 30 October 2024, 5.

[83] Case C-446/18 *AGROBET CZ, s.r.o. v Finanční úřad pro Středočeský kraj* EU:C:2020:369 para 44; and Opinion of Advocate General Kokott in Case C-162/21 *Pesticide Action Network Europe and Others* EU:C:2022:650 para 39. On the use of scientific knowledge, Case T-13/99 *Pfizer Animal Health SA* (n 17) para 172. The Court states that 'It follows that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'.

[84] Hofmann and Mihaescu (n 75) 84; Ingrid Opdebeek and Stéphanie de Somer, 'The Duty to Give Reasons in the European Legal Area: a Mechanism for Transparent and Accountable Administrative Decision-Making? A Comparison of Belgian, Dutch, French and EU Administrative Law' (2016) 2 Rocznik Administracji Publicznej 97, 102.

[85] Ellen Vos, 'Independence, Accountability and Transparency of European Regulatory Agencies' in Damien Geradin, Rodolphe Muñoz, and Nicolas Petit (eds), *Regulation through agencies: A new Paradigm of European*

state reasons allows interested parties to have access to the reasons that led the authority to adopt a particular measure, enabling them to challenge that decision before the competent court, but also to enable the courts to review the legality of those decisions.[86] In this regard, it is quite usual that the Court connects the duty to state reasons to other fundamental principles. For instance, the Court has explained 'the obligation of the administration to state reasons for a decision which are sufficiently specific and concrete' is a corollary of the principle of respect for the rights of the defence.[87] Furthermore, the Court has also clarified that if the judicial review guaranteed by Article 47 CFR is to be effective, the person concerned must be able to ascertain, either by direct examination or request, the reasons upon which the decision is taken.[88]

4.2 THE PRECAUTIONARY PRINCIPLE

The EU has incorporated the precautionary principle into various EU policy areas, including environment, food safety, public health and consumer protection.[89] Regulation 1107/2009 also declares that the precautionary principle applies across the entire regulatory framework.[90]

Generally, scholars agree that the risk-averse approach of food-related policies represents a regulatory response to food safety crises, such as the bovine spongiform encephalopathy (BSE or mad cow disease) outbreak and to other public concerns about potential hazards associated with contemporary farming methods, among other factors.[91] In these areas of high scientific uncertainty, where 'there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation',[92] the precautionary principle operates as a risk management tool for decision-making at both the EU and Member State levels.[93] Precaution allows risk managers to take protective

Governance (Edward Elgar Publishing 2005) 120, 125; Opdebeek and de Somer (n 84) 97; Melanie Fink and Giulia Gentile, 'Article 41: the right to good administration' in Alexandra Giannopoulou (ed) *Digital rights are charter rights (*Amsterdam: Digital Freedom Fund 2023).

[86] Case C-46/16 *Valsts ieņēmumu dienests v 'LS Customs Services', SIA* EU:C:2017:839 paras 39 and 40; and Case C-721/21 *Eco Advocacy CLG v An Bord Pleanála and others* EU:C:2023:477 para 33 and case law cited. The Court recalls that 'the obligation to state reasons for decisions adopted by the national authorities is particularly important, since it puts their addressees in a position to defend their rights under the best possible conditions and decide in full knowledge of the circumstances whether it is worthwhile to bring an action against those decisions. It is also necessary in order to enable the courts to review the legality of those decisions'. Moreover, it must be mentioned that transparency is by itself a principle of EU law. In this regard, Koen Lenaerts, "'In the Union We Trust": Trust Enhancing Principles of Community Law' (2004) 41(2) Common Market Law Review 317, 320-321; and Paul Craig, 'Transparency' in Paul Craig, *EU Administrative Law* (Oxford University Press 2018) 400.

[87] Case C-230/18 *PI v Landespolizeidirektion Tirol* EU:C:2019:383 para 57 and case law cited.

[88] Case C-300/11 *ZZ v Secretary of State for the Home Department* EU:C:2013:363 para 53.

[89] Joanne Scott, *Legal Aspects of the Precautionary Principle: A British Academy Brexit Briefing* (The British Academy 2018) 9.

[90] Regulation 1107/2009 (n 3) recital 8 and Art 1(4).

[91] Joakim Zander, The Application of the Precautionary Principle in Practice: Comparative Dimensions (Cambridge University Press 2010) 77; Vogel (n 11) 63-66.

[92] Communication from the Commission on the precautionary principle, COMM(2000), 8.

[93] Nicolas de Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12(2) European Law Journal 139, 140-141; Zander (n 91) 79-92; Nicolas de Sadeleer, 'Precautionary principle in EU Law' (2010) AV&S, 173; and Didier Bourguignon, 'The Precautionary Principle—Definitions, Applications and Governance' (European Parliament Think Tank 2015)

measures when faced with plausible risks to human health or the environment, even in the absence of definitive scientific evidence.[94]

However, despite its widespread use as a regulatory tool in EU risk-oriented policies, the precautionary principle lacks a unified EU-wide definition. Furthermore, legal texts generally provide only a limited understanding of how the precautionary principle should be applied by risk managers.[95] Regulation 1107/2009 does not make an exception to that.

Against this background, the Court has provided considerable clarification on the application of the precautionary principle, including in the context of pesticide authorisations.[96] For instance, the *PAN Europe* case provides a relevant example of how the Court leverages the precautionary principle to enhance the standards of health and environmental protection in the context of Article 53's emergency authorisations.[97] More specifically, this case originates from a dispute over Belgium's temporary emergency approval of two pesticides containing the substances clothianidin and thiamethoxam for sugar beet seed protection. PAN Europe, the applicant in this case, argued that the use of these neonicotinoid insecticides has shifted towards a preventive approach known as seed coating or seed treatment. This method involves applying the insecticides to seeds before planting, rather than spraying crops after they have grown. Consequently, the applicant contended that this practice leads farmers to use treated seeds regardless of whether there is a demonstrated need or emergency for insect control in their fields. In addition, PAN Europe also noted that since 2013 the Commission has progressively restricted the use of the two insecticides due to their potential risks to bee populations. Under these circumstances, the Court unequivocally concludes that Article 53(1) must be interpreted as not permitting a Member State to authorise the placing on the market of plant protection products containing substances that have been expressly prohibited by an EU implementing regulation.[98] In its reasoning, the Court firmly embeds the precautionary principle as a fundamental basis for interpreting Regulation 1107/2009, emphasising its role in ensuring a high level of protection for human and animal health and the environment. By invoking this principle, it conclusively rejects any reading of the provisions of Regulation 1107/2009 that would undermine its objectives, i.e. authorising the placing on the market and use of products that have been expressly prohibited, and establishes a hierarchy of objectives where health and environmental protection takes precedence over improving plant production.[99] With this judgment, the Court underlines the importance of maintaining coherence between emergency measures and the broader regulatory framework for pesticides, underscoring that

<https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)573876> accessed 30 October 2024.

[94] Case C-236/01 *Monsanto Agricoltura Italia and Others* EU:C:2003:431 para 111; and Case C-487/17 *Criminal proceedings against Alfonso Verlezza and Other* EU:C:2019:270 para 57 and case law cited.

[95] Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing 2007) 211-212; and Maria Weimer and Gaia Pisani, 'Expertise as Justification: The Contested Legitimation of the EU "Risk Administration"' in Maria Weimer and Anniek de Ruijter (eds), *Regulating Risks in the European Union* (Hart Publishing 2017).

[96] Kristel De Smedt and Ellen Vos, 'The Application of the Precautionary Principle in the EU' in Harald A Mieg (ed), *The Responsibility of Science. Studies in History and Philosophy of Science* (Springer, 2022) 175-176.

[97] Case C-162/21 *Pesticide Action Network Europe* (n 1).

[98] ibid paras 50 and 54.

[99] ibid paras 48 and 50.

emergency authorisations under Article 53 must not undermine the core principles of EU pesticide legislation.

The Court's application of the precautionary principle not only underscores the obligation of national authorities to prioritise health and environmental concerns but also extends to other crucial aspects.

Together with using this principle as a substantive legal standard to interpret Regulation 1107/2009,[100] there is various evidence of how the Court has also used the precautionary principle as a procedural principle for guiding risk managers' decision-making.[101] The *Sweden v Commission (Paraquat)* case has served as an important reference point in this regard.[102] Asked to review the Commission's decision to include the active substance paraquat in Annex I to Directive 91/414 (now replaced by Regulation 1107/2009),[103] the Court declared that 'the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I'.[104] Furthermore, the Court, again invoking the precautionary principle, highlighted that before a substance can be included in Annex I, 'it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements' laid down in EU law.[105] Through its case law, the Court has subsequently further clarified that the application of the precautionary principle under Regulation 1107/2009 requires two key steps: first, identifying potential health risks associated with active substances and plant protection products; and second, conducting a thorough health risk assessment based on the most reliable and up-to-date scientific data available.[106] If and when one of these conditions is met, the precautionary principle allows protective measures to be taken without waiting for the reality and seriousness of the risks

[100] In this sense, see also Case C-616/17 *Blaise and Others* EU:C:2019:800.

[101] Emiliano Frediani, 'The Administrative Precautionary Approach at the Time of Covid-19: The Law of Uncertain Science and the Italian Answer to Emergency' (2021) 17(3) Utrecht Law Review 6. In this regard, evidence suggests strong similarities between the principle of good administration and the precautionary principle. For instance, European Ombudsman, 'Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides)' (2016) <https://www.ombudsman.europa.eu/en/decision/en/64069> accessed 30 October 2024. The Ombudsman was called to review the Commission's procedures for approving active substances in pesticides, particularly the 'confirmatory data procedure', which allows substances to be approved while additional data is requested to verify their safety. In this context, it asserts that the precautionary principle, being a principle of good administration, prevents the Commission from approving active substances in cases where there is a potential risk to public health or the environment. Furthermore, Opinion of Advocate General Kokott in Case C-436/22 *Asociación para la Conservación y Estudio del Lobo Ibérico (ASCEL) v Administración de la Comunidad Autónoma de Castilla y León* EU:C:2024:83 paras 79-82.

[102] Case T-229/04 *Kingdom of Sweden v Commission of the European Communities* EU:T:2007:217; Giulia Claudia Leonelli, 'Judicial Review of Compliance with the Precautionary Principle from Paraquat to Blaise: "Quantitative Thresholds," Risk Assessment, and the Gap Between Regulation and Regulatory Implementation' (2021) 22(2) German Law Journal 184, 195-96.

[103] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1991] OJ L230/1, Art. 5(1). This provision laid down the conditions for an active substance to be included in Annex I. A similar provision can now be found in Article 4 of Regulation 1107/2009.

[104] Case T-229/04 *Sweden v Commission* (n 102) para 161.

[105] ibid para 170.

[106] Case C-616/17 *Blaise* (n 100) para 46 and case law cited.

to become fully apparent.[107] In addition, these measures must be applied in accordance with the principle of proportionality.[108]

Most recently, in two judgments, *PAN Europe (Closer)* and *PAN Europe (Evaluation of Endocrine Perturbation Properties)*, the Court has also emphasised the importance of a scientifically rigorous approach to the authorisation of pesticides at the Member State level, with reference to the precautionary principle. Notably, it has pointed to the need to rely on the most relevant and reliable scientific and technical knowledge available at the time of the examination.[109] This position is maintained even in situations where such reliance might necessitate deviating either from the scientific risk assessment of a plant protection product conducted by another Member State, or from the EU level assessment of an active substance.[110] At the same time, in the *PAN Europe (Closer)* case, the Court has also used the precautionary principle in a manner that strengthens the capacity of individuals to challenge national competent authorities' plant protection product authorisations. In its ruling, the Court clarified that the most reliable scientific and technical data available constitutes admissible evidence for challenging the adequacy of plant protection product examinations. It declares that this possibility would be in line with the precautionary principle since it would allow for the attainment of the objective of Regulation 1107/2009, i.e. ensuring a high level of health and environmental protection.[111]

In conclusion, this section has illustrated, by reference to the Court of Justice case law on the principles of good administration and the precautionary principle, how both principles provide the conditions for realigning the application of Article 53 with the scope of the norm and the objective of Regulation 1107/2009. Firstly, drawing on the principles of good administration, the previous analysis has elucidated a series of obligations for the administrations of the Member States when enforcing EU law. These measures include the duty of national administrations to conduct a diligent and impartial examination of all the relevant matters using the most complete and reliable information, including scientific knowledge, to state the reasons for their decisions, and to provide access to information. Subsequently, the analysis has turned to the Court of Justice's application of the precautionary principle as both a condition to interpret the provisions of Regulation 1107/2009 and as a procedural principle to guide national competent authorities' discretion when authorising plant protection products, ultimately upholding high standards of health and environmental protection. In this respect, it is highlighted how the Court requires national competent authorities to conduct a thorough health risk assessment relying

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[107] Opinion of Advocate General Sharpston in Case C-616/17 *Blaise and Others* EU:C:2019:190 para 48.
[108] ibid; and Pavel Ondřejek and Filip Horák, 'Proportionality during Times of Crisis: Precautionary Application of Proportionality Analysis in the Judicial Review of Emergency Measures' (2024) 20 European Constitutional Law Review 27, 45-49.
[109] Case C-308/22 *Pesticide Action Network Europe (PAN Europe) v College voor de toelating van gewasbeschermingsmiddelen en biociden* EU:C:2024:350 para 70; and Joined Cases C-309/22 and C-310/22 *Pesticide Action Network Europe (PAN Europe) v College voor de toelating van gewasbeschermingsmiddelen en biociden* EU:C:2024:356 para 100.
[110] Joined Cases C-309/22 and C-310/22 *PAN Europe (Evaluation of Endocrine Perturbation Properties)* (n 109) para 97.
[111] Case C-308/22 *PAN Europe (Closer)* (n 109) paras 88 and 103. In more detail, Pietro Mattioli, 'How Can New Scientific and Technical Knowledge Affect the Authorisation of Plant Protection Products at Member State Level? Some Clarifications from the Court of Justice' [2025] European Journal of Risk Regulation 1, 3.

on the most relevant and reliable scientific knowledge available at the time of the examination.

However, the potential of these principles to function as EU tools for the institutional design of Member States' administrations when operating within the scope of EU law still faces significant limitations. The following section will specifically discuss how a persistently fragmented administrative law landscape across Member States jeopardises the effectiveness of these principles.

5 THE PRINCIPLES OF GOOD ADMINISTRATION AND THE PRECAUTIONARY PRINCIPLE IN ACTION

This section builds upon the previous analysis, which has highlighted that the principles of good administration and the precautionary principle, as interpreted and applied by the Court of Justice, mandate specific measures for national authorities in their enforcement of EU law. If effectively applied, these measures have the potential to realign the use of Article 53 with the scope and objectives of Regulation 1107/2009. Against this backdrop, this section first outlines the limitations of an approach that relies on these principles to effect changes in the administrative practices of the Member States. Subsequently, it suggests possible pathways to operationalise these principles.

5.1 MEMBER STATES' ADMINISTRATION AND EU LAW

The main problem with an approach that simply relies on the principles of good administration and the precautionary principle as EU tools of institutional design for national administrations enforcing EU law is related to the still diversified administrative systems of the Member States. The development of the Member States' administrations and administrative law reflects the distinct historical trajectories of each country, shaped by their unique state structures and tailored to address specific societal needs.[112] Under these circumstances, the administrations of the Member States generally follow their own administrative practices, which might not necessarily correspond to EU standards of good administration.[113]

At the same time, while Member States' administrative systems have developed as products of the nation-state, European integration has certainly contributed to their evolution.[114] For instance, the expansion in the number of interventions falling within the scope of the EU as 'a regulatory state', an idea first introduced by Giandomenico Majone,

[112] Sabino Cassese, *Il diritto amministrative: storie e prospettive* (Giuffre' editore 2010) 6-8; European Commission, Enora Palaric, Nick Thijs, and Gerhard Hammerschmid, 'A comparative overview of public administration characteristics and performance in EU28' (2018) <https://data.europa.eu/doi/10.2767/13319> accessed 30 October 2024, 36; and B Guy Peters, 'The Administrative Tradition Approach to Public Bureaucracy' in B Guy Peters, *Administrative Traditions: Understanding the Roots of Contemporary Administrative Behavior* (Oxford University Press 2021) 23.

[113] In more detail, Statskontoret, 'Good administration in European countries' (Statskontoret, 2023) <https://www.statskontoret.se/en/publications/publikationer/publikationer-2023/good-administration-in-european-countries/> accessed 15 October 2024.

[114] Sabino Cassese, 'New paths for administrative law: A manifesto' (2012) 10 International Journal of Constitutional Law 603, 605.

has had a significant impact on the role of the Member States' administrations.[115] While at the very beginning of its regulatory intervention, the EU started simply borrowing national independent agencies for the implementation of its market liberalisation policies, contemporary EU legislation routinely impacts the administrative organisation of the Member States.[116] Through expanding policy competences, the Union increasingly permeates sectors traditionally governed by domestic administrative law, necessitating structural, functional, and procedural adaptations at the national level.[117]

Considering this evolution, scholars generally agree that a body of administrative law in Europe has developed.[118] European administrative law is considered to encompass three main components. First, it includes rules and principles governing the execution of EU law by EU institutions. Second, it comprises the 'Europeanised' administrative law of the Member States, which involves national rules governing the enforcement of European law by national authorities. These rules are adapted to meet the requirements stipulated in EU law. Third, it includes rules that apply to cases even when they have no direct relation to EU law.[119] However, despite these significant developments, European administrative law does not yet encompass the entirety of the administrative law of the Member States. A comprehensive and uniform body of EU administrative law that applies to national administrations when enforcing EU law remains absent.[120] As a result, in the absence of Union law, Member States retain autonomy in determining the regulatory framework for implementing and enforcing EU law.[121]

Within this framework, one can assume that without EU law binding and uniform standards reflecting good administration principles applicable to national administrations in their execution of EU law, national administrations continue to follow their own practices

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115 Giandomenico Majone, 'The rise of statutory regulation in Europe' in Giandomenico Majone (ed), *Regulating Europe* (Routledge 1966) 40; Giandomenico Majone, 'Regulating Europe: Problems and Prospects' (1989) EUI Working papers No. 89/405, 8.

116 De Somer, 'EU impulse' (n 50); and Mattioli, 'The Quasi-Judicial Role of National Competent Authorities: (n 50).

117 Herwig C H Hofmann, Gerard C Rowe, and Alexander H Türk, 'The Idea of European Union Administration – Its Nature and Development' in Herwig C H Hofmann, Gerard C Rowe, and Alexander H Türk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011).

118 Kadelbach (n 45); Edoardo Chiti and Joana Mendes, 'The Evolution of EU Administrative Law' in Paul Craig and Gráinne de Búrca (eds), *The Evolution of EU Law* (3rd edn, Oxford University Press 2021) 339; and Joana Mendes, 'Administrative law in the EU: the liberal constitutional paradigm and institutionalism as an imperfect alternative' in Carol Harlow, *A Research Agenda for Administrative Law* (Edward Elgar Publishing 2023) 283.

119 Kadelbach (n 45) 167.

120 To address the lack of a coherent legal framework governing administrative procedures in EU law, scholars have advocated for harmonised administrative procedural rules binding both EU institutions and Member State authorities when implementing EU law. In particular, Herwig C H Hofmann and Alexander H Türk, 'Legal Challenges in EU Administrative Law by the Move to an Integrated Administration' in Herwig C H Hofmann and Alexander H Türk (eds), *Legal Challenges in EU Administrative Law* (Edward Elgar Publishing 2009) 378. This call aligns with a broader academic proposal for the codification of rules on administrative procedures concerning the implementation of EU law. Paul Craig et al, *ReNEUAL Model Rules on EU Administrative Procedure* (Oxford University Press 2017). More generally, on the codification of EU administrative law, Carol Harlow 'Codification of EC Administrative Procedures? Fitting the Foot to the Shoe or the Shoe to the Foot' (1996) 2(1) European Law Journal 3, 19-22; Sabino Cassese, 'Shrimps, Turtles and Procedure: Global Standards for National Administrations' (2004) NYU IILJ Working Paper No. 2004/4.

121 Kadelbach (n 45) 169-170. On the relationship between institutional autonomy and EU administrative intervention, see Section 3.

and standards, which might not necessarily be aligned with the EU standards of good administration. In this regard, the EU sources of good administration primarily include Article 41 CFR and the European Code of Good Administrative Behaviour.[122] However, both sources formally apply to EU institutions and bodies, extending to national administrations only when they reflect general principles of EU law.[123] While national authorities are bound by the EU principles of good administration when acting in the scope of EU law,[124] this is not sufficient to harmonise administrative practices across the Member States. Therefore, it is not surprising that significant variations persist among Member States in areas such as impartiality, transparency and democratic participation with respect to the decentralised administrative enforcement of EU law, as well as in the application of the precautionary principle.[125] For instance, the misapplications of Article 53 illustrate how national authorities normally act irrespective of the good administration and precautionary principles as interpreted by the Court.[126] In this regard, despite the Court's efforts to clarify the scope of the precautionary principle, the threshold of scientific uncertainty for precaution continues to be decided on a case-by-case basis by the competent authorities.[127]

Nevertheless, while obstacles persist to a coherent application of the good administration and the precautionary principles, it has also been illustrated that the EU possesses the capacity to influence the administrative practices of the Member States.[128] Considering these circumstances, the next subsection argues for proceduralising these principles within EU law. This approach could address their inconsistent application across national pesticide authorisation procedures and thereby the persistent misuse of Article 53. Ultimately, this section concludes by underlining how the Court of Justice has also provided the foundations for increased scrutiny by interested parties of the pesticide authorisations of national competent authorities.

5.2 OPERATIONALISING EU PRINCIPLES

The principles of good administration and the precautionary principle, as emerging from the Court of Justice case law, require national authorities to implement specific measures when operating within the scope of EU law. However, obstacles still impede the effective and uniform application of these principles across Member States, consequently affecting the

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122 European Parliament, 'European Code of Good Administrative Behaviour' [2001]. For a broader overview of the role of the Code, see Mendes, 'Good Administration in EU Law' (n 82) 5-6.
123 Statskontoret, 'Good administration in European countries' (n 113) 15-18.
124 Sacha Prechal, 'Competence Creep and General Principles of Law' (2010) 3(1) Review of European Administrative Law 5, 11.
125 In particular, Statskontoret, 'Good administration in European countries' (n 113) 31. More generally, regarding national administrations' variations across the EU, see European Commission, Palaric, Thijs, and Hammerschmid (n 112).
126 The current uses of Article 53 stand in direct contradiction to the Court of Justice's jurisprudence, which affirms that 'when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should 'take priority' over the objective of improving plant production'. For instance, Case C-308/22 *PAN Europe (Closer)* (n 109) para 68.
127 Case T-13/99 *Pfizer Animal Health SA* (n 17) para 151.
128 In more details, on the limits of the EU regulatory intervention, i.e. national institutional autonomy, subsidiarity and proportionality, see Section 3. In this regard, the Court of Justice has also clarified that institutional autonomy as regards the organisation and the structuring of regulatory authorities must be exercised in accordance with the objectives and obligations laid down by EU law. Case C-424/15 *Ormaetxea Garai and Lorenzo Almendros* EU:C:2016:780 para 30 and the case-law cited.

implementation of these measures by national administrative authorities. To address this issue, this section argues that these principles should be codified in EU law, particularly through soft law instruments.[129] This codification should also be accompanied by increased oversight by the Commission. Additionally, this section considers a complementary approach. It emphasises the potential role of interested parties in challenging national competent authorities' pesticide authorisations. This claim is grounded in the most recent Court of Justice case law, which may provide new avenues for stakeholders' ability to challenge pesticide authorisations.

Regarding the first possibility, there are various ways for the EU to proceduralise the measures required by the principles of good administration and the precautionary principle. The most direct approach to addressing inconsistencies in the application of these EU principles would be through an amendment of Regulation 1107/2009, which would directly incorporate the necessary administrative rules into the Regulation.[130] Specifically, this could be achieved by utilising the second paragraph of Article 78 of Regulation 1107/2009, which pertains to amendments and implementing measures, thereby avoiding an overhaul of the entire existing framework of Regulation 1107/2009. While such legislative intervention might successfully pass the proportionality test[131] and the scrutiny of the Court, which in areas such as health and agricultural policy often affords a wide margin of discretion to the EU legislator,[132] this approach might be unrealistic in the near future. The EU's political agenda has witnessed a clear shift away from its previously robust green ambitions, suggesting a diminished commitment to environmental regulatory reforms, particularly in areas such as pesticide regulation.[133] Additionally, a deregulatory trend has gained prominence across the entire EU policy landscape.[134]

Considering these circumstances, this article proposes resorting to soft law instruments to introduce the necessary measures: for instance, the Commission's ongoing revision of the guidance document concerning emergency authorisations under Article 53 of Regulation

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[129] The term soft law is generally employed to denote non-binding instruments like recommendations, opinions, communications, guidelines, and other quasi-legal tools that lack formal binding nature and are not subject to judicial enforcement. For more details, see Linda Senden, *Soft Law in European Community Law* (Hart Publishing 2004) 55-56.

[130] Regulation 1107/2009 (n 3) Art 78(2). This provision states that 'any further measures necessary for the implementation of this Regulation may be adopted in accordance with the regulatory procedure referred to in Article 79(3)'.

[131] Takis Tridimas, 'The Principle of Proportionality: Review of Community Measures' in Takis Tridimas, *The General Principles of EU Law* (Oxford University Press 2006) 136.

[132] The Court has affirmed that measures adopted in policy areas like environment, health, and consumer protection are in breach of the proportionality principle only if the measure is 'manifestly inappropriate' having regard to the objective which the competent institution is seeking to pursue. For instance, Case C-331/88 *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte: Fedesa and others* EU:C:1990:391 para 14.

[133] For instance, the European Commission officially withdrew the Sustainable Use of Pesticides Regulation (SUR) proposal after its rejection by the European Parliament and a lack of consensus in the Council. European Commission, Withdrawal of Commission proposals PUB/2024/302 [2024] OJ C, C/2024/3117. Furthermore, the new agriculture Commissioner Christophe Hansen affirmed that there is no intention of reviving pesticide reduction targets. More information – <https://www.euronews.com/my-europe/2025/02/20/pesticide-cuts-are-off-the-table-says-eu-agriculture-commissioner> accessed 20 February 2025.

[134] European Commission, 'A simpler and faster Europe: Communication on implementation and simplification' (2025) <https://commission.europa.eu/law/law-making-process/better-regulation/simplification-and-implementation_en> accessed 20 February 2025.

1107/2009.[135] In terms of necessary intervention, a crucial measure would be to establish a systematic requirement for uploading all supporting materials to the E-Submission Food Chain (ESFC) Platform.[136] While the current ESFC Platform requires applicants to submit basic information, such as type of danger and justification for necessity, it does not mandate the inclusion of supporting documents such as risk assessments, scientific studies or product-specific analyses,[137] limiting the possibility for interested parties to access relevant information concerning authorisations. This proposed intervention holds significant potential to enhance the transparency of national competent authorities' decision-making processes, which is widely recognised as a crucial counterweight to industry influence in regulatory procedures. It also serves as a fundamental element in reinforcing the democratic legitimacy of these processes by providing increased visibility and accountability.[138] Moreover, it is crucial that the Commission intensifies its efforts to ensure that Member States comply with Article 53's notification requirements. For instance, considering that informing the Commission and the other Member States is an obligation directly stemming from Article 53, the Commission could establish automated alerts for delayed submissions and periodic compliance reviews. Such measures would address the current practice of retroactive notifications.

At the same time, the Commission should develop binding templates for conflict-of-interest statements for the members of national authorities involved in authorisation decisions. This requirement could be operationalised by integrating these standardised declarations into the existing ESFC Platform. Such a measure would address the absence of explicit independence safeguards under Regulation 1107/2009 and counterbalance the disproportionate industry influence over pesticide authorisation procedures.[139]

In addition to these much-needed reforms, this Section also brings attention to the fact that the Court of Justice has recently established a possible pathway for stakeholders to contest insufficiently reasoned risk assessments under Regulation 1107/2009. In the *PAN Europe (Closer)* case, the Court has affirmed that interested parties have the possibility of raising any new scientific or technical knowledge that is relevant and reliable before the authorities and courts of the Member State concerned in order to challenge the authorisation

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[135] European Commission, 'Guidance on Emergency Authorisations According to Article 53 of Regulation (EC) No 1107/2009' (SANCO/10087/2013 rev 1, 2021).

[136] The ESFC has replaced the Plant Protection Products Application Management System (PPPAMS) since January 2023. However, the current guidance document does not acknowledge the replacement of the PPPAMS with the ESFC. More information on the ESFC system is available at <http://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/pppams_en> accessed 12 February 2025.

[137] More information on the guidance for applicants is available at <http://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/pppams_en> accessed 12 February 2025.

[138] Juli Ponce, 'Good Administration and Administrative Procedures' (2005) 12 Indiana Journal of Global Legal Studies 551, 554; Deirdre Curtin and Joana Mendes, 'Transparence et participation : des principes démocratiques pour l'administration de l'union européenne' (2011) 137 Revue française d'administration publique 101; and Craig, 'Transparency' (n 86) 356.

[139] Similarly, the European Ombudsman has recommended that if the Commission continues to rely on the European and Mediterranean Plant Protection Organization (EPPO), it should advocate for more rigorous conflict of interest policies and broader stakeholder participation beyond the pesticide industry. European Ombudsman, 'Decision on how the European Commission adopted a guidance document on comparative assessment in the context of the substitution of hazardous substances in pesticides' (case 177/2023/VB).

of a plant protection product in the territory of that Member State.[140] This approach, which is in line with the precautionary principle, contributes to the attainment of the objectives of Regulation 1107/2009.[141] With this ruling, the Court has not only underlined an obligation for national authorities to demonstrate they have evaluated all available most reliable scientific and technical data before granting authorisations but also highlighted a possible right for stakeholders to leverage scientific knowledge to demand an administrative or judicial review of pesticide authorisations.[142] By allowing stakeholders to introduce new evidence, the Court makes authorisations contingent on continuous scientific scrutiny, rather than one-time evaluations. Yet, the effectiveness of this pathway might also depend on improved transparency in national authorities' decision-making processes.[143]

6 CONCLUSIONS

This article has two objectives. Firstly, it intends to raise awareness of the use of emergency authorisations against the scope and objectives of Regulation 1107/2009. To that end, the first two sections are essentially focused on describing the procedures for placing plant protection products on the market as prescribed by Regulation 1107/2009 (section 2) and exposing systemic weaknesses in the current framework that have led to various misapplications of Article 53's emergency authorisation procedures (section 3).

Secondly, this article discusses legal solutions to address these misapplications of Article 53. As this article demonstrates, the EU legal order possesses the necessary tools to address the lack of independence and transparency safeguards under Article 53 of Regulation 1107/2009, notably the principles of good administration and precaution. By imposing obligations of conducting a diligent and impartial examination of all the relevant matters using the most complete and reliable information, including the most updated scientific knowledge, stating reasons for the decisions, providing access to information, and prioritising health and environmental protection, these principles have the potential to recalibrate the practices of national authorities competent to authorise pesticides.

At the same time, section 5 has also shown that simply formulating principles of good administration does not guarantee their uniform application across Member States. Therefore, the last section of this article argues that to ensure compliance with these principles, the EU must translate and proceduralise them into specific obligations. To that end, specific regulatory interventions are proposed in order to reinforce the independence and transparency of the Member States' pesticide emergency authorisation process. Ultimately, it is also highlighted how the Court of Justice has opened an important new avenue for challenging inadequately justified pesticide authorisations under Regulation 1107/2009. However, while this development represents a crucial advancement in ensuring the proper implementation of EU pesticide legislation, efforts are still needed to enhance transparency in pesticide authorisations across the Member States, ensuring that the

[140] Case C-308/22 *PAN Europe (Closer)* (n 109) para 110.
[141] ibid para 103.
[142] ibid paras 90 and 110.
[143] Mattioli, 'How Can New Scientific and Technical Knowledge Affect the Authorisation of Plant Protection Products at Member State Level?' (n 111) 7.

interested parties can access the necessary information to scrutinise and, when appropriate, challenge pesticide authorisations.

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EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIUMS AND ECONOMIC ACTIVITY: TO WHAT EXTENT (IF ANY) SHOULD ERICS BE SUBJECTED TO RULES THAT RESTRICT THEIR ECONOMIC ACTIVITY?

ARNLJOTUR ASTVALDSSON*

In 2009, the European Union introduced the European Research Infrastructure Consortium (ERIC) to provide a legal framework for organisations in which EU Member States and other countries could collaborate on the establishment and operation of research infrastructures. Today, 30 ERICs have been set up and operate with headquarters in various European countries. As ERICs' primary task is to conduct research activities, they are subject to rules limiting their ability to engage in economic activity. This article examines these rules in light of recent Commission statements regarding the concept of economic activity under the regulation that established the ERIC (the ERIC Regulation) and offers suggestions for amending the regulation's rules on economic activity.

1 INTRODUCTION

This article discusses the rules governing European Research Infrastructure Consortiums (ERICs), which are entities that operate within a legal form established under European Union (EU) law by Council Regulation (EC) No 723/2009 of 25 June 2009 (the ERIC Regulation).[1] The article focuses on rules governing the economic activity of ERICs.

In 2023, the Commission published its third report on the application of the ERIC Regulation (the Third ERIC Report), addressing 'remaining challenges and potential solutions for the effective financing and operation of ERICs'.[2] One key challenge identified was how ERICs define their activities, particularly economic activity, which had also been briefly addressed by the Commission in its first and second reports on the ERIC Regulation.[3] The third report provided the following considerations on this matter:

*Assistant Professor (lektor) at Reykjavik University (Iceland) and lecturer at Lund University (Sweden).

[1] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) [2009] OJ L206/1.

[2] See European Commission, 'Report from the Commission to the Council and the European Parliament – Third Report on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) of August 14 2023' COM(2023) 488 final (the Third ERIC Report), 1.

[3] See European Commission, 'Report from the Commission to the European Parliament and the Council – Second Report on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) of July 6 2018' COM(2018) 523 final, 8; and European Commission, 'Report from the Commission to the European Parliament and the Council on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) of July 14 2014' COM(2014) 460 final, 8.

> Under certain conditions, an ERIC can have limited economic activities by offering goods and/or services on a given market. Such activities can positively address the increasing demands for 'innovative' and 'socio-economic' impacts and therefore enhance the ERIC sustainability. However, only a limited number of ERICs have such activities on a regular basis. Uncertainty on the real meaning of 'limited economic activities' as well as on compliance with state aid rules and conditions for VAT exemptions are likely at stake. This question […] also includes other aspects such as how ERICs can develop (and then participate in) spin-offs, technology transfers and receive revenues from services, without weakening their ERIC status. […] Further and specific guidance on the meaning of 'limited economic activities' in the context of state aid rules should be provided for a consistent implementation, to enhance the broader impact of ERICs and therefore their sustainability.[4]

This article examines these Commission statements in the light of how economic activities of ERICs are regulated in the ERIC Regulation and in the statutes of ERICs that have been established at the time of writing. The aim of the article is to clarify how economic activity is regulated in the regulation and ERIC statutes – which includes clarifying the meaning of the concept *economic activity* – and discuss to what extent ERICs *should be* subject to a rule limiting their economic activity considering the purpose of the ERIC legal form, its structural characteristics and the overall objective of EU involvement in advancing research and technology.

The article begins by describing the ERIC legal form and the main interests pursued and protected by the ERIC Regulation (section 2). Subsequently, section 3 discusses the rules governing the economic activities of ERICs, primarily rules in the ERIC Regulation and in the statutes of established ERICs. Section 4 discusses the rule on limited economic activity in light of the objectives behind the ERIC Regulation, the scope of interest it seeks to protect and the structural characteristics of established ERICs. Section 5 offers concluding remarks.

Although the article necessarily mentions the rules in the Treaty on the functioning of the European Union (TFEU) related to competition matters, in particular Article 107 on State aid, detailed discussion of these rules is outside the scope of the article.

2 THE ERIC LEGAL FORM

2.1 ERICS ARE ENTITES THAT PURSUE EU OBJECTIVES

The ERIC Regulation grants the Commission the competence to establish a legal entity for setting up and operating a research infrastructure[5] upon application by one EU Member State

[4] The Third ERIC Report (n 2) 11-12.

[5] The ERIC Regulation, Article 2(1)(a), defines research infrastructure as: '[…] facilities, resources and related services that are used by the scientific community to conduct top-level research in their respective fields and covers major scientific equipment or sets of instruments; knowledge-based resources such as collections, archives or structures for scientific information; enabling Information and Communications Technology-based

and at least two other countries that are either EU Member States or countries associated with the EU (associated countries).[6] Other countries (third countries) and intergovernmental organisations can also become ERIC members at a later date if approved by decision of the highest ranking ERIC organ – the assembly of members.[7] At the time of writing, 30 entities have been established as ERICs, with statutory seats in 12 different European countries.[8]

The ERIC Regulation is adopted in pursuit of a specific Treaty objective, namely to strengthen the scientific and technological bases of the EU by achieving a European research area, as laid down in Article 179 TFEU and further outlined in other provisions of Title XIX TFEU (Articles 179-190). For these purposes, Article 179(2) provides that the EU shall:

> encourage undertakings, including small and medium-sized undertakings, research centres and universities in their research and technological development activities of high quality; it shall support their efforts to cooperate with one another, aiming, notably, at permitting researchers to cooperate freely across borders and at enabling undertakings to exploit the internal market potential to the full, in particular through the opening-up of national public contracts, the definition of common standards and the removal of legal and fiscal obstacles to that cooperation.

As can be seen, the objective is to facilitate research activity and, in particular, cross-border cooperation of parties of different nature in order to take full advantage of the internal market. There is therefore a clear link between the economic objective of the internal market and facilitating research activity. As a result, rules in national law that restrict, e.g. the freedom to provide services, can generally not be justified solely based on the objective of advancing *national* research interest, as advancing such interests is an EU objective, and the rules on freedom to provide service are one of the tools to achieve this objective.[9]

The legal base of the ERIC Regulation is Article 187 TFEU, in which the EU is given the competence to establish a legal structure that its institutions deem necessary for the 'efficient execution of Union research, technological and demonstration programmes'.[10] Accordingly, the main objective of the Regulation is to provide a legal form allowing countries to collaborate in establishing and operating a research infrastructure 'for the efficient execution of Community research, technological development and demonstration programmes'.[11] ERICs are thus legal entities that are set up for executing EU programs in the field of research and technological development and contribute to the development of science in the EU and the competitiveness

infrastructures such as Grid, computing, software and communication, or any other entity of a unique nature essential to achieve excellence in research. Such infrastructures may be 'single-sited' or 'distributed' (an organised network of resources)'.

[6] See ERIC Regulation, Articles 5, 6 and 9(2).

[7] See ibid Article 9(2).

[8] According to information retrieved through the European Commission website on ERICs, <https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/our-digital-future/european-research-infrastructures/eric/eric-landscape_en> accessed 5 March 2025.

[9] See, in this regard, Case C-39/04 *Laboratoires Fournier SA v Direction des vérifications nationales et internationales* EU:C:2005:161.

[10] See ERIC Regulation recital 5.

[11] See ibid recitals 3 and 24-25.

of the EU economy.[12] What kind of research activity each ERIC is to carry out is dependent on how members formulate their intended collaboration in ERIC statutes and the Commission approving the same.[13] The approval is dependent on the Commission determining that establishing the ERIC is necessary for the development of European research, including that it is necessary for European research programmes.[14]

As can be derived from the discussion above, the overall purpose of the ERIC legal form and established ERICs is to advance science and research in the EU in order to increase economic growth and social well-being in the EU and improve the competitiveness of the EU economic vis-à-vis other markets. The EU is thus an ERIC stakeholder, which is reflected in the fact that decision on whether an ERIC is established is based on Commission assessment on whether the ERIC is likely to contribute to the fulfilment of these goals. The regulation provides rules that are expressly aimed at strengthening the position of members that are EU Member States and associated countries.[15] These rules are intended to protect the research and scientific environment in the EU.

2.2 ERICS ARE MEMBER-BASED ORGANISATIONS

2.2[a] General

An ERIC is a member-based organisation in the sense that it is based on two or more (prospective) members agreeing to set up and collaborate in an ERIC. If the Commission accepts their application and decides to set up an ERIC, a legal entity is established that has legal capacity[16] and that is based on delegated management structure. The latter entails that the members are not involved in day-to-day operations but have the ultimate control rights over an ERIC – notwithstanding the control powers of the Commission[17] – which they exercise in the assembly of members.

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[12] See ERIC Regulation, *inter alia* recitals 1 and 9.

[13] Commission approval of the proposed statutes of the ERIC-to-be by is a condition for Commission decision, setting up the ERIC. Further, amendments of description of tasks and activities in statutes can only be adopted upon Commission approval, see ERIC Regulation, Articles 5 and 10-11.

[14] See ERIC Regulation, Article 5(1)(c), in conjunction with Article 4.

[15] See, e.g., ERIC Regulation, Article 9(3), which provides that the Member States and associated countries 'shall hold jointly the majority of the voting rights in the assembly of members'. See also Council Regulation (EU) No 1261/2013 of 2 December 2013 amending Regulation (EC) No 723/2009 concerning the Community legal framework for a European Research Infrastructures Consortium (ERIC) [2013] OJ L326/1, Article 1.

[16] See ERIC Regulation, Article 7(1)-(2).

[17] Aside the fact that the setting up of an ERIC is dependent upon a Commission decision, after the Commission has reviewed and accepted the objective and statutes of the prospective ERIC (see ERIC Regulation, Articles 5-6 and 10-11), ERICs are under a reporting obligation towards the Commission and the Commission has the competence to repeal its decision, on setting up the ERIC, if an ERIC has breached the regulation and such breach is not remedied (see ERIC Regulation, Article 17).

2.2[b] Members finance an ERIC

The financing of an ERIC is based on contributions from members – in cash or by contributing other assets (in-kind contributions).[18] ERIC statutes must contain a rule that obliges members to make contributions to the ERIC budget.[19] Most ERIC statutes oblige members to provide contributions for a period of 5 years after the establishment of an ERIC.[20] As contributions from members are the core of ERIC financing the Commission has also required, when assessing ERIC statutes, an obligation from members that they will not relinquish their membership for a certain period after ERIC establishment.[21]

Other forms of financing are not precluded, including external credit financing. However, one of the rationales behind the ERIC Regulation was to avoid a situation where the EU itself finances ERICs.[22] Yet the financing of some ERICs is – to a different extent – based on grants received from EU funds.[23] Additionally, ERICs can receive income from their own activity (operations), as will be further discussed below.

2.2[c] Members have a socio-economic interest in an ERIC

Although ERICs are entities based on member collaboration, the fact that EU objectives are part of their (mandatory) purpose means that they pursue objectives and interests outside the interests of their members. This does not mean that members do not have an interest in an ERIC. To the contrary, members have both social and economic interests in ERICs that partly – but not wholly – overlaps with the interests of the EU. No established ERIC covers the whole of EU in the sense that it has all EU Member States as its members.

ERIC members are primarily sovereign states, representing the interests of their respective citizens and financing ERICs through public funds. As a result, an ERIC member has a clear interest in ensuring that its expenditure of public funds is not more than necessary, which can be described as direct and individual economic interest. Further, the state in question has an

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[18] See also European Commission, 'Commission Staff Working Document Accompanying document to the Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI) Impact Assessment' COM (2008) 467 final, 36.

[19] See ERIC Regulation, Article 10(1)(h).

[20] See Arnljotur Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law: A study on a European Union legal form within the Swedish legal system* (Lund University, Media-Tryck 2022) 170-171.

[21] See European Commission (Directorate-General for Research and Innovation Research Infrastructures), 'ERIC Practical Guidelines Legal framework for a European Research Infrastructure Consortium' (Publications Office of the European Union 2015) (the ERIC Guidelines), 12; and European Commission (Directorate-General for Research), 'Legal framework for a European Research Infrastructure Consortium – ERIC Practical Guidelines' (Publications Office of the European Union 2010) (the 2010 ERIC Guidelines), 22.

[22] ERICs are, for example, not to be viewed as EU bodies, see e.g. ERIC Regulation recital 6.

[23] As also envisioned in the ERIC Regulation recitals 6 and 19. See also European Commission Press Release MEMO/13/1073 on 29 November 2013 (Brussels) on the setting up of European Social Survey ERIC, EATRIS ERIC, BBMRI ERIC, and ECRIN-ERIC <https://ec.europa.eu/commission/presscorner/detail/en/memo_13_1073> accessed 6 March 2025: 'Although Member States remain the main contributors to the setting up and operation of these transnational bodies, up to €37.5 million has been provided in support of the preparation of those four facilities under the EU's Seventh Framework Programme (FP7)'.

interest in ensuring *its* scientific community, consisting of both public and private actors, has sufficient access to the research infrastructure of the ERIC in question, with the resulting socio-economic benefits for the state in question (which can be described as an indirect individual socio-economic interest).[24]

2.3 KEY STRUCTURAL CHARACTERICS OF ERICS

2.3[a] Self-standing legal entities

The ERIC Regulation provides a legal form setting up self-standing entities that have full legal capacity and that shall be solely liable for their own debts. Members enjoy flexibility in terms of how they structure their own liability,[25] but statutes of many established ERICs provide a rule stipulating limited member liability.[26] This means that the only liability members have towards an ERIC is to provide the financial contributions to the ERIC, in accordance with their respective commitment in ERIC statutes. In accordance with these characteristics, the ERIC Regulation provides a mandatory rule on organisational structure, based on members delegating the day-to-day running of the ERIC to a board of directors and/or a director general (the executive organs of an ERIC).[27]

The structural characteristics are similar to key characteristics of private law legal forms for organisation, such as the company limited by shares.[28] A key factor that distinguishes ERICs from such legal forms is the fact that ERICs are *not* based on a rule which gives members right to share in economic surpluses, i.e. the profit of operations.

2.3[b] ERICs and the concept of non-profit

In for-profit (business) entities, such as the company limited by shares, those financing the entity can be said to *own* the entity through their investment, which gives them a right to both receive residual earnings and control the entity.[29] On the other hand, a prohibition or limitation on distributing economic surpluses from the entity and to those outside the entity, including its members or others has been viewed as an essential characteristic of non-profit entities

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[24] For further outlining of members interest in an ERIC, see Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 197-200.

[25] See ERIC Regulation, Article 14.

[26] See Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 191-192. This is in accordance with the Commission's proposal for the ERIC Regulation, see Commission, 'Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI) COM(2008) 467 final, 6, 10 and 12.

[27] See ERIC Regulation, Article 12.

[28] The company limited by shares – and its characteristic of limited member (shareholder) liability – was one of the main models behind the ERIC legal form, see e.g. European Strategy Forum on Research Infrastructures *Report of the Workshop on the Legal forms of research infrastructures of pan-European interests* (23 March 2006, Brussels) (ESFRI Workshop Report), in particular 4-7. See also Commission Staff Working Document, 'Accompanying document to the Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI)' SEC(2008) 2278, 12 and 18.

[29] See e.g. Reinier Kraakman et al, *The Anatomy of Corporate Law: A Comparative and Functional Approach* (3rd edn, Oxford University Press 2017) 13.

(a non-distribution constraint).[30] Importantly, the existence of a non-profit purpose and/or non-distribution constraint does not mean that a non-profit entity is not allowed to operate on a for-profit basis, in the sense of generating income and incurring expenses (for example in the form of compensation to employees and contractors) and making an economic surplus at the end of its financial year.[31] It primarily means that such surplus cannot be transferred *out of* the entity *to those that control the entity* – the use of the surplus is confined to financing the operations of the entity in accordance with its purpose.[32]

The ERIC Regulation does not provide any rule that clearly provides a non-distribution constraint in the aforementioned sense, i.e. a rule that lays down that the assets of an ERIC are to be solely used to further its research activities and that prohibits the distribution of assets to ERIC members. However, *the statutes* of several ERICs provide a non-distribution constraint in the form of rules stipulating that all resources shall only be used to carry out the main research activity of an ERIC[33] and the preamble of the regulation states that an ERIC should 'devote *most* of its resources to this principal tas[k]', i.e. for carrying out research activity.[34]

In statutes of other ERICs, examples can be found of rules that allow for the possibility of partial distribution of ERIC assets to ERIC members, both during the time of membership[35] and in relation to withdrawal of membership.[36] As with other parts of ERIC statutes, these rules have been subjected to Commission review and approval.[37] Further, as part of their control rights, ERIC members have the competence to initiate (voluntary) liquidation of an ERIC and the regulation does not mandate that remaining net assets are to be transferred to an entity

[30] See Henry B Hansmann, 'The Role of Nonprofit Enterprise' (1980) 89(5) The Yale Law Journal 835, 836; Henry B Hansmann, *The Ownership of Enterprise* (Harvard University Press, Belknap Press 1996), 11 and 35; and Kraakman et al (n 29) 13-14. Non-distribution constraint, as a concept and a constitutive element of non-profit entities, has also been found to be a constitutive element for foundations, as a legal form for non-profit entities, in most EU Member States, see Klaus J Hopt et al, *Feasibility Study on a European Foundation Statute Final Report* (European Commission 2009), 33 and 60 <https://efc.issuelab.org/resources/15835/15835.pdf> accessed 10 March 2025.

[31] See e.g. Hansmann, *The Ownership of Enterprise* (n 30) 17; Katarina Olsson, *Näringsdrivande stiftelser : en rättslig studie över ändamål, förmögenhet och förvaltning* (Nerenius & Santérus 1996) (with regard to the legal position of foundations, which carry out economic activity, under Swedish law), e.g. pages 183-202 and 211-215; and Hopt et al (n 30) in particular 86-89.

[32] See Hansmann, *The Ownership of Enterprise* (n 30) 61, and Henry B Hansmann, 'Reforming Nonprofit Corporation Law' (1981) 129(3) University of Pennsylvania Law Review 497, 501.

[33] See Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 231-232 and 243-245.

[34] See ERIC Regulation recital 8. Emphasis added.

[35] See e.g. Statutes of the European Infrastructure of Open Screening Platforms for Chemical Biology — European Research Infrastructure Consortium (EU-OPENSCREEN ERIC) [2018] OJ C111/1, Article 25(3): 'Income generated by intellectual property produced by EU-OPENSCREEN ERIC shall be used for the operations of EU-OPENSCREEN ERIC up to a threshold laid down in the Rules of Procedure. The use of income above this threshold *shall be subject to a decision of the Assembly of Members*'. Emphasis added.

[36] See e.g. STATUTES OF Euro-Argo ERIC [2014] OJ L136/36, Article 9(3): 'The Council shall determine if the Member is entitled to any sums upon withdrawal. If the Member is so entitled, the Council shall determine the value of the rights and obligations of such Member taking into account the assets and liabilities of Euro-Argo ERIC as they stand on the date on which such Member ceases to be part of Euro-Argo ERIC'.

[37] As required by the ERIC Regulation, see in particular Articles 5 and 11.

carrying out the same, or similar, activities.[38] Examination of statutes of established ERICs reveals that a majority of ERIC statutes grant members the right to net assets upon the winding-up of an ERIC, which is in line with Commission guidelines on the ERIC legal form.[39]

3 ERICS AND ECONOMIC ACTIVITY

3.1 ECONOMIC ACTIVITY AS EU LAW CONCEPT

Under the ERIC Regulation, ERICs are only allowed to carry out limited economic activity, as discussed in detail below. When determining whether an ERIC carries out economic activity the Commission has laid down that it will rely on the definition of *economic activity* under EU competition law.[40] According to established case law of the Court of Justice of the European Union (CJEU) the term 'undertaking', in Treaty articles concerning competition in the internal market,[41] refers to an entity that is involved in economic activity, which again means the offering of goods or services on a given market.[42]

The activities of both non-profit entities and entities that carry out public administration can fall within this definition of economic activity and thus under the application of competition law rules.[43] Further, it is not a requirement that the entity *itself* needs to be directly involved in carrying out economic activity.[44] As ERICs are (primarily) publicly funded entities whose objective is to produce new knowledge and technology – for which there might be no direct market – it is arguably most likely that there activities come into contact with *economic activity*, in the aforementioned sense, through engaging with private actors who operate commercially in a market. This will be discussed further below.

3.2 TREATY RULES ON COMPETITION IN THE INTERNAL MARKET

The TFEU provides certain rules on competition in the internal market of the EU. Articles 101 and 102 TFEU provide rules that prohibit concerted practices and abuse of dominant position, respectively. Article 107(1) provides the following rule intended to prevent state funding private actors to the detriment of competition in the internal market:

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[38] The lack of non-distribution constraint upon liquidation is, in and of itself, not alien to the notion of a non-profit entity, see e.g. the legal position of foundations in EU Member States in Hopt et al (n 30) 60 and 84.
[39] See Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 234-236 and 244-245; and ERIC Guidelines (n 21) 43.
[40] See ERIC Guidelines (n 21) 15.
[41] See rules in Title VII TFEU on competition in the internal market of the EU, in particular Articles 101 and 102 TFEU, which provide rules that prohibit concerted practices and abuse of dominant position, respectively, and Article 107(1), which provides rules on State aid.
[42] See e.g. case C-35/96 *Commission v Italy* EU:C:1998:303 paras 36-38.
[43] See e.g. Case C-41/90 *Höfner and Elser v Macrotron* EU:C:1991:161 e.g. paras 20-24; C-49/07 *Motosykletistiki Omospondia Ellados NPID (MOTOE) v Elliniko Dimosio* EU:C:2008:376 paras 27-28; and C-262/18 P *Commission v Dôvera zdravotná poist'ovňa* EU:C:2020:450 para 49.
[44] See e.g. C-222/04 *Cassa di Risparmio di Firenze and Others* EU:C:2006:8 paras 109-114.

> Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market.

Article 107(3) subsequently lists types of aid that *may*, notwithstanding the rule in Article 107(1), be seen as compatible with the internal market. Among such aid is 'aid to promote the execution of an important project of common European interest […]'.[45]

The ERIC Regulation does not directly refer to these TFEU rules on competition. However, the fact that ERICs are primarily financed by states and thereby public funds is liable to raise issues related to competition in the internal market of the EU, primarily the issue of whether the relationship between and ERIC and a private actor might result in State aid within the meaning of EU competition law.[46] In its most recent report on the ERIC Regulation – the Third ERIC Report – the Commission states that further guidance is needed on 'the meaning of "limited economic activities" in the context of state aid rules'[47] without offering further discussion from the perspective of EU competition law or reference to its statements in earlier guidelines in relation thereto.

As the EU institution responsible for monitoring State aid schemes and enforcing Article 107, the Commission has issued a communication on State aid in relation to research, development and innovation[48] and guidelines on the notion of State aid in relation to research infrastructures.[49] One of the points of departure of the guidelines and the communication is that while public funding of research infrastructure might amount to State aid that is prohibited under certain circumstances, using such funding in tandem with operations of private parties can contribute positively to the advancement of science and technology.[50]

One of the key elements of the Commission's assessment of an ERIC matter would presumably be to ascertain whether the ERIC in question had favoured certain private parties at the expense of others, for example when granting access to its resources (e.g. facilities and/or personnel) and deciding to enter into commercial relationships.[51] If an ERIC is using its state funded resources to aid the operation of *certain* – selected – undertakings, i.e. private actors offering products or services in a market, and thus not *all* undertakings, then its economic activity

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[45] See TFEU, Article 107(3)(b).

[46] See e.g. European Commission, 'Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI)' COM (2008) 467 final, Preamble, para 9, 11. See also Commission Staff Working Document, 'Accompanying document to the Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI)' COM (2008) 467 final, para 5.4.

[47] The Third ERIC Report (n 2) 12.

[48] See European Commission, 'Communication from the Commission: Framework for State aid for research and development and innovation' [2014] OJ C198/1, in particular pages 10-12.

[49] See European Commission, 'Guidance on the Notion of State Aid' on the European Commission website dedicated to State aid <https://competition-policy.ec.europa.eu/document/download/3c15ab87-4521-45af-a3ce-dbde55ee025b_en?filename=notion_of_aid_grid_research_en.pdf> accessed 5 March 2025, in particular pages 3-4.

[50] ibid 2-3.

[51] See ibid.

is liable to amount to State aid within the meaning of Article 107(1) TFEU, as the selected undertakings are provided with an economic advantage. One of the ways of avoiding this is to grant equal access on market terms to all potential undertakings, as indicated by the Commission in its communication and guidelines (aforementioned).[52]

Further discussion on the conditions of Article 107(1) and how they would be applied in a situation concerning an ERIC is outside the scope of this Article.

3.3 ARTICLE 3 OF THE ERIC REGULATION

3.3[a] Article 3(2): Economic activity must be limited

The ERIC Regulation provides mandatory rules on the purpose of an ERIC. Under Article 3(1) of the regulation, the main activity of an ERIC shall be to establish and operate a research infrastructure. Article 3(2) provides a rule on the extent to which an ERIC is allowed to engage in economic activity:

> An ERIC shall pursue its principal task on a noneconomic basis. However, it may carry out limited economic activities, provided that they are closely related to its principal task and that they do not jeopardise the achievement thereof.

By its wording, Article 3(2) provides an exemption rule on ERIC purpose, i.e. a rule that allows ERICs to carry out economic activity as an exemption to the main activity, which is to engage in research activities on a non-economic basis. It follows that ERICs are allowed – to a certain extent – to carry out economic activity irrespective of whether their statutes provide any rules in this regard. As shown in later parts of this article, some ERIC statutes provide rules that describe a source of income from a particular type of economic activity.

For the exemption in Article 3(2) to apply, the following conditions need to be fulfilled: (i) the activity in question falls under the definition of *economic activity* within the meaning of the regulation; (ii) the activity is *limited*; (iii) the activity is *closely related to the main research activity* of an ERIC; and (iv) the activity *does not risk achieving the objectives of the research activity*. If the activity in questions fulfils these conditions, then such activity is in accordance with the ERIC Regulation and thus allowed.

In its guidelines on the ERIC Regulation the Commission provides several parameters to assess whether a matter falls under Article 3(2) of the Regulation and whether its conditions are fulfilled, including whether the activity is *limited* within the meaning of the article. First, regarding the definition of *economic activity* the Commission reiterates that for Article 3(2) to be applicable there needs to be a *market* for the product or service in question, which '[…] depends on the organisation of the activity by the Member State concerned and can therefore differ from one Member State to another'.[53] Further, the Commission notes that the fact that an ERIC charges

[52] See Commission, 'Communication from the Commission: Framework for State aid for research and development and innovation', in particular pages 10-12; and Guidance on the Notion of State Aid (n 49) in particular pages 3-4 and para 17.
[53] See ERIC Guidelines (n 21) 15.

fees in its operations – for example when granting access to its facilities or resources (e.g. services) – does not constitute an *economic activity* 'if the access and related services do not correspond to what the market can provide'.[54]

Secondly, if an activity constitutes an *economic activity*, the Commission offers indications on how it would assess whether the activity is *limited* within the meaning of Article 3(2), including by stating that an any economic activity 'must remain secondary and not prevail over the execution of its main tas[k]'[55] and that one way of assessing this is to compare the volume of different activities based on '[q]uantifiable elements […] such the respective costs and income, use of human resources or the share of access to the facility for economic and non-economic purposes'.[56] In terms of use of resources specifically it should be recalled that the preamble of the ERIC Regulation states that an ERIC 'should devote most of its resources' to its principal, non-economic, task.[57] Seemingly, the main point is to protect the non-economic part of ERIC operations. However, the Commission also acknowledges that the scope of economic activity can expand and overtake the main, non-economic activity, in terms of quantity so that it becomes the primary activity. Instead of the ERIC being required to take action to minimise such activity – and thus comply with the mandatory rule in Article 3(2) – the Commission suggests that such situations may be remedied by 'creating a spin-off company'.[58] While this suggestion is in conformity with the socio-economic objectives behind the ERIC legal form, it raises questions as to whether such practices would simply amount to circumvention of the rule in Article 3(2).

3.3[b] Article 3(2) as a rule protecting the interests of members

The question arises whether the finding of State aid under Article 107(1) TFEU (or not) impacts the application of Article 3(2) of the ERIC Regulation. If the scope of interests protected by Article 107(1) TFEU and Article 3(2) of the ERIC Regulation are the same, i.e. preventing state resources from distorting competition in the internal market, then it can be argued that it is unnecessary to assess whether Article 3(2) has been breached *if* the Commission has found the existence of a prohibited State aid within the meaning of Article 107(1). To counter this statement two arguments can be put forward. First, Article 3(2) can be viewed as setting further limitations on economic activity *for the protection of competition in the internal market*, in addition to the requirements of Article 107(1). The fact that Article 3(2) has its own conditions, which are different from the conditions of Article 107(1), supports such conclusion. Based on this, the assessment carried out under Article 3(2) is different from the assessment under Article 107(1) even if it is accepted that the articles seek to protect the same interests. Secondly, as Article 3(2) concerns the purpose of ERICs it should also be viewed as a rule protecting *the interest of an ERIC*

[54] ibid.
[55] ibid.
[56] ibid. See also guidelines from 2010 where the Commission stated the following: 'On the basis of a combination of various quantifiable elements available, the Commission will generally assume that a share of economic activities below 25 % of total annual activities is limited'. See 2010 ERIC Guidelines (n 21) 13.
[57] See ERIC Regulation recital 8, and also discussion in Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 164-165.
[58] ibid.

member as a self-standing interest, distinct from the interest of protecting competition in the internal market.

Regarding the second argument it should be recalled that Article 3(2) of the ERIC Regulation provides a mandatory rule on the purpose of ERIC.[59] As a rule on the purpose of an organisation, it serves not only to protect the interest of the EU as a stakeholder but also – and perhaps primarily – the interests of ERIC members, which finance the ERIC and hold the ultimate right to control its operations (in the assembly of members). An ERIC member provides financing to an ERIC based on the purpose of ERIC collaboration. The outer limits of the purpose are laid down in the ERIC Regulation, with members agreeing on the more precise purpose in statutes.

It follows that, if countries and intergovernmental organisations have agreed to collaborate in the ERIC legal form, it can be assumed that they do so in order to create a legal entity that engages in research activity with the objective of advancing the development of research and technology within their respective territories and the EU (as a whole), with resultant socio-economic benefits (collective and individual). Further, as an ERIC is an entity that is based on free and voluntary agreement by ERIC members on achieving a common (scientific research) purpose, it can be assumed that *members'* participation in an ERIC is based on the premise: that ERIC organs will, when making decisions and undertaking action act: (i) within the scope of the purpose of the ERIC, as laid down by the ERIC Regulation and respective statutes; and (ii) in the collective interest of *all* members, as opposed to the interest of one or more members at the expense of other members.[60] It follows that the rule on limited economic activities in Article 3(2) is an integrated part of the *mandatory* purpose structure of ERICs, which *shall* establish and operate research infrastructure and only engage in economic activity to a limited extent. The organs of an ERIC are bound by this rule on purpose structure when taking decisions and actions. In that way, the purpose structure functions as a protection for the ERIC and its members, which have agreed to join an ERIC and, crucially, provide it with financing based on certain premises – primarily the fact that the entity they join operates in accordance with its mandatory purpose structure.

In the light of the above there are strong arguments for viewing Article 3(2) as a rule protecting the socio-economic interests of members *in addition to* any EU interest related to protecting competition in the internal market. This means that assessment of the economic activity of ERICs cannot be isolated to whether competition in the internal market is liable to be distorted, e.g. because of an ERIC providing State aid to a private actor. It also needs to cover assessment on whether an ERIC carries out economic activity in excess of what is allowed under Article 3(2) of the regulation, independent of any competition concerns. Yet, the question remains whether it is desirable for an ERIC to be bound by such mandatory rule on the scope

[59] For a discussion on mandatory rules in the ERIC Regulation see Arnljotur Astvaldsson, 'Construing the ERIC Legal Form From the Perspective of the Swedish legislator' in Ulf Maunsbach and Axel Hilling (eds), *Big Science and the Law* (Ex Tuto Publishing 2021), in particular pages 113-115.

[60] See Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 533-534.

of purpose, i.e. whether such rule advances the interests of ERIC members (and the EU). This will be addressed specifically in Section 4 below.

3.3[c] Article 3(3): Economic activity must be priced on market terms

The economic activity of an ERIC is subject to a further rule in Article 3(3) of the regulation, which reads as follows:

> An ERIC shall record the costs and revenues of its economic activities separately and shall charge market prices for them, or, if these cannot be ascertained, full costs plus a reasonable margin.

By its wording, Article 3(3) provides at least two different rules: (i) a rule providing that economic activities should be held separate from the non-economic activities with respect to accounting for revenues and costs; and (ii) a rule providing a limit on how much an ERIC can charge for its economic activities. The second rule contains two separate rules based on two different scenarios. If the economic activity is carried out on a *market,* then an ERIC is not allowed to charge more than *market price*. If, on the other hand, the activity is not carried out on a market, with the consequence that no market price can be established, then an ERIC is not allowed to charge more than the full cost (of making a product or providing a service) in addition to a 'reasonable margin'. The rules provided in Article 3(3) reflect the Commission's view on the notion of State aid in relation to research infrastructures, as put forward in its guidelines.[61]

It follows that Article 3(3) distinguishes between whether the economic activity of an ERIC is carried out on a market or not. However, the Commission guidelines on the ERIC legal form seem to connect both scenarios to the existence of a market, when stating that reasonable margin may be 'established by reference to margins commonly applied by undertakings for the same activity'.[62] This serves as a further indication that the Commission views ERIC engagement in economic activity – including the prices charges when carrying out such activity – primarily from the perspective of interests protected by EU competition law. The thinking seems to be that ERICs are prohibited from distorting competition by using their publicly funded operations to lower prices to the detriment of other actors operating on a given market and, thus, to competition on the market with the eventual negative effects on consumers. The rule intended to prevent such distortion of competition is Article 107 TFEU on State aid.

3.3[d] Applying the rules in article 3(2)-(3) to the economic activity of an ERIC

Based on the arguments above, Article 3(2) should be viewed as a rule that is separate from any assessment of whether an ERIC's collaboration with a private actor amounts to State aid within the meaning of Article 107(1) TFEU. It follows that if the *economic activity* of an ERIC is (i) closely related to its the main research task and (ii) and *limited* when compared to its main research task

[61] See European Commission, 'Communication from the Commission: Framework for State aid for research and development and innovation' [2014] OJ C198/1, in particular Section 2.2. on pages 10-11; and Guidance on the Notion of State Aid (n 49), in particular section 2. on pages 2-3.
[62] See ERIC Guidelines (n 21) 15.

– so that achieving the main task is not put at risk – then the activity is allowed *under the ERIC Regulation*. The activity must be subordinated to the research activity of an ERIC and that quantifiable elements may be used to assess this,[63] including numbers on use of resources.

Article 3(3) provides an additional (and final) restriction on ERIC economic activity under the ERIC Regulation. If the economic activity of an ERIC neither amounts to prohibited State aid under Article 107(1) TFEU nor in breach of Article 3(2) of the ERIC Regulation – as it is closely related to its main research task and limited vis-à-vis the main task – the remaining part of the test revolves around whether its economic activity is provided on terms that are compatible with Article 3(3) of the regulation. It follows that even though an economic activity of an ERIC is limited vis-à-vis its research activity it still needs to be carried out in accordance with the conditions of Article 3(3). This means that an ERIC is not at liberty in terms of pricing its products or services. To the contrary it must either price its economic activities at a *market price* or, if such price cannot be ascertained, a price that equals *full costs plus reasonable margin*. The rule in Article 3(3) has clear connection with the interests protected by Article 107(1) TFEU, i.e. one of the aims of the rule is to prevent an ERIC from using its public funds to subsidize the products and services is offers on a market.

3.4 THE ECONOMIC ACTIVITY OF ERICS IN PRACTICE

3.4[a] General

Strictly speaking it follows from the discussion above, that if the concept of economic activity in the ERIC Regulation has the same constitutive elements as the concept of economic activity in EU competition law, then an ERIC activity is not economic unless it consists of the ERIC *itself* offering products or services *on a market*. However, given the purpose of ERICs, which is to carry out research activity with the activity of producing *new* knowledge and technology,[64] it is arguably unlikely that such strict interpretation of the concept *economic activity* would be applied vis-à-vis ERICs, with the effect that their operations are *excluded* from the scope of EU competition law. Regarding the concept of *economic activity* – and the interests protected by EU competition law – the main issue seems to be determining under what circumstances ERIC activity can overlap with the activity of private actors operating in a (private) market. This section offers some examples of such overlap based on examination of ERIC statutes. More precisely, this section offers examples of how several ERICs regulate income from their own operations, including operations that can be defined as economic activity.[65]

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[63] See discussion in Section 3.3[a].

[64] The uniqueness of ERICs and their resources is arguably likely to result in a situation where there is not definable market regarding the service they can offer, including in the form of granting access to unique research infrastructures.

[65] The intention is by no means to offer an exhaustive account of how ERICs regulate income from their own (economic) activity in statutes. For a more comprehensive account see Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) Chapter 4.4.2.5, in particular pages 176-183, on which the descriptions of ERICs in this section are based.

When describing the precise nature of their activity in ERIC statutes, many ERICs also address the issue of economic activity. This is in line with the Commission guidelines on the ERIC legal form.[66] However, the text of ERIC statutes on economic activities is commonly limited to restating the language of Articles 3(2) and 3(3) of the regulation,[67] following the template for ERIC statutes provided by the Commission.[68] Based on examination of ERIC statutes, financial income because of an ERIC's *own activities* can be categorised into two main categories. First, there is income related to (i) *granting access* to the research infrastructure and its resources[69] and (ii) *providing services* in relation thereto.[70] Secondly, several ERICs foresee generating income by developing intellectual property.[71]

3.4[b] Commercial relationships with private actors[72]

The nature of the activities of several ERICs is amenable to collaboration with private industry, for example ERICS within the field of biological and medical sciences. EATRIS ERIC is, as an example, operational within the field of transnational medicine, forming a central research hub for research on medicines and vaccines,[73] a field with a high potential for industrial application and commercialisation of resources and services. Accordingly, the Statutes of EATRIS ERIC provide several indications of what such activity might consist of, including commercial relations with industrial third parties as to intellectual property rights,[74] and potential income stemming from user fees.[75]

The statutes of EU-OPENSCREEN ERIC, a research infrastructure that connects chemistry and biological facilities, cite the strengthening of academia-industry collaboration as one of its foundational objectives and list exchanges with industry among activities.[76] Foreseen

[66] See ERIC Guidelines (n 21) 11.
[67] Another common feature of ERIC statutes is to restate the language of recital 8 in the preamble to the ERIC Regulation: 'In order to promote innovation and knowledge and technology transfer, the ERIC should be allowed to carry out some limited economic activities if they are closely related to its principal task and they do not jeopardise its achievement'.
[68] See ERIC Guidelines (n 21) 25.
[69] In ERICs where research is not carried out on single (physical) site but through an organised network of resources, i.e. distributed ERICs (see definition of 'research infrastructure' in Article 2(1)(a) of the ERIC Regulation), such access can, for example, be in the form of online access to consolidated research results of the ERIC network. In single-site ERICs such as European Spallation Source ERIC, access is (primarily) in the form of allocated experimental time at a physical research facility.
[70] For example, services provided by the personnel of the relevant ERIC in relation to third party use (access) of the infrastructure, which may be part of a partnership formed with the private actor that receives the services.
[71] See also the account offered in Ana Nordberg, 'Big Science, Big Data, Big Innovation? ERIC Policies on IP, Data and Technology Transfer' in Ulf Maunsbach and Axel Hilling (eds), *Big Science and the Law* (Ex Tuto Publishing 2021) 95.
[72] The descriptions of ERICs in this section are primarily based on discussion in Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) in particular pages 177-180.
[73] See Statutes of the European Advanced Translational Research Infrastructure in Medicine as a European Research Infrastructure Consortium (EATRIS ERIC) [2013] OJ L 298/38, e.g. Article 2.
[74] See ibid, e.g. Articles 20(3), 22(1), and 27.
[75] See ibid, Appendix 2, para c.
[76] See Statutes of the European Infrastructure of Open Screening Platforms for Chemical Biology — European Research Infrastructure Consortium (EU-OPENSCREEN ERIC) [2018] OJ C111/1, Preamble, recital e, Article 3(3)(h), and Annex 3, 6 b.

income is in the form of payment for access to EU-OPENSCREEN ERIC services and resources.[77] ECRIN-ERIC – a research infrastructure supporting and coordinating the carrying out of multinational clinical trials, to advance research on the diagnosis, prevention and treatment of disease – is another ERIC whose statutes place significant emphasis on the relationship with industry. Its statutes distinguish between economic and non-economic activity based on the recipient of services, i.e. the user of the research infrastructure and not the nature of the activity.[78] The statutes stipulate that 'ECRIN-ERIC shall provide services at a not-for-profit rate for non-economic activities'.[79]

The statutes of Instruct-ERIC and BBMRI-ERIC can be described as providing a clear mandate in terms of commercialisation of the research activity carried out within their respective distributed research infrastructures, by collaborating with private industry.[80] The statutes of Instruct-ERIC[81] offer guidance on how the fee for access shall be determined. Access to researchers from 'institutions' located within Instruct-ERIC members shall be 'funded' by Instruct-ERIC. Access for users from 'non-members' for 'academic or pre-competitive research' shall be granted in return for 'an academic fee' while users from non-members, which request access 'for proprietary research shall be charged a commercial fee for access' with the proviso that 'the data arising from access will belong to the user and there shall be no obligation to disclose or publish it'.[82] It follows that, in terms of determining rate of access fee, the statutes of Instruct-ERIC distinguish between, firstly, whether the use in question is by a member or a non-member and secondly, whether the use is for academic or commercial purposes. As with the statutes of ECRIN-ERIC (discussed above), it is the nature of the activity of the ERIC *user* that determines the level of payment demanded for access.

The scientific field of marine biology and ocean sciences is another field suited to industrial application of research. Accordingly, the statutes of all three ERICs operating within that field regulate economic activities. EMBRC-ERIC lists income from service provision and commercialisation of intellectual property rights as a part of its resources,[83] while Euro-Argo ERIC can derive income from remuneration for services provided to third parties and income from commercialisation of its intellectual property rights.[84] EMBRC-ERIC is an ERIC with a

[77] See ibid Article 22 and Annex 3, para 9.
[78] See Statutes of the European Clinical Research Infrastructure Network (ECRIN-ERIC) [2013] OJ L324/8 (Statutes of ECRIN-ERIC), e.g. Article 2(2)(b), which states that ECRIN-ERIC shall 'be primarily accessible to investigator-initiated clinical research, but also open to industry sponsored clinical research projects, originating from any country'.
[79] Statutes of ECRIN-ERIC, Article 11(4).
[80] The Statutes of the Biobanking Biobanks and Biomolecular Resources Research Infrastructures European Research Infrastructure Consortium (BBMRI-ERIC) [2013] OJ L320/63 (Statutes of BBMRI-ERIC) list the performance of 'research services for public and private institutions' as one of its core activities, see Statutes of BBMRI-ERIC, Article 3(1) and (3)(3)(f) and Article 5(11).
[81] Instruct-ERIC is a distributed research infrastructure coordinating and granting access to research on structural cell biology, see Statutes of Instruct European Research Infrastructure Consortium (Instruct-ERIC) as of 15 July 2017 ([2017] OJ C230/01) (Statutes of Instruct-ERIC), in particular Article 4.
[82] See Statutes of Instruct-ERIC, Article 25(3)-(8).
[83] See Statutes of the European Marine Biological Resource Centre — European Research Infrastructure Consortium (EMBRC-ERIC) [2018] OJ C69/1 (Statutes of EMBRC-ERIC), Article 11.1(b).
[84] See Statutes of Euro-Argo ERIC, Article 19(1)(c).

relatively high level of foreseen commercial relationship with private industry, in particular in the form of technology transfer.[85] EMSO-ERIC lists income from provision of services to third parties, and third party exploitation of its intellectual property rights, as part of its resources and expressly mentions private users as 'stakeholders', which it shall serve by developing 'added-value data products' as well as by granting access to its research resources in return for payment.[86]

In bringing together top material science research facilities in Central and Eastern Europe, a part of the core mission of CERIC-ERIC is to stimulate 'industrial and economic development'.[87] Accordingly, its statutes include a provision specifically dedicated to technology transfer and relationship with industry, stating that CERIC-ERIC 'shall act as a focal point for European industry'.[88] This is to be achieved through research and development collaborations,[89] technology transfer, putting emphasis on involving industry in its operations and by facilitating the creation of 'spin-off industries' deriving from its research activities.[90]

3.4[c] Summary of economic activities of established ERICs

From the discussion above, it follows that several ERICs are structured to foster collaboration with private industry, especially in fields like biological, medical and marine sciences. The ERICs in question offer opportunities for industrial applications, commercialisation and technology transfer. For example, user fees, payments for access and revenue from IP exploitation are common methods for generating income.

The statutes of different ERICs distinguish between economic and non-economic activities based on the nature of the users, e.g. whether the user is *academic* or *commercial*. This assists the ERICs in determining appropriate access fees charged for accessing their research infrastructures and using the services they provide. If the user is a private actor that intends to commercialise the results of its use, then a higher fee is charged. This is broadly in line with rules of Article 3(3) of the ERIC Regulation, with the caveat that the fee charged *can never be lower* than market price or a fee that is equivalent to full cost (of granting access and providing services) plus a reasonable margin. This follows from the fact that Article 3(3) is a mandatory rule which ERICs cannot deviate by providing a different rule in statutes. Charging those using the research infrastructure for *academic* purposes a lower fee should also be in conformity with the ERIC Regulation if the academic user in question is not operating on a market and thereby not engaging in *economic activity*. If the academic user does not carry out economic activity in this sense, then the activity in question falls outside the scope of Article 3(3) and its mandatory rule on pricing.

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[85] See Statutes of EMBRC-ERIC, Article 4(2)(e).
[86] See Statutes of the European Multidisciplinary Seafloor and Water Column Observatory — European Research Infrastructure Consortium (EMSO ERIC) [2016] OJ C363/1 (Statutes of EMSO ERIC), Article 16(1)(c) and 22(2),(6).
[87] See Statutes of Central European Research Infrastructure Consortium (CERIC-ERIC) [2014] OJ L184/51 (Statutes of CERIC-ERIC), Article 5(1).
[88] See ibid Article 20.
[89] For example, joint development arrangements. CERIC-ERIC lists income from services related to such arrangements as part of its potential financial resources, see Statutes of CERIC-ERIC, Article 6(1)(d).
[90] See Statutes of CERIC-ERIC, Article 20.

4 SHOULD ERICS BE SUJBECT TO A SPECIFIC RULE LIMITING THEIR ECONOMIC ACTIVITY?

4.1 FRAMING THE ISSUE

As this article has laid out, under EU law the economic activity of ERICs is restricted by several rules that protect different interests. Competition in the internal market is protected by ERICs being – in principle – subject to Article 107(1) TFEU and other rules on State aid and Article 3(3) of the ERIC Regulation. The aim of both rules is to prevent an ERIC from using state funds to subsidise the operations of one or more private actor or subsidising the pricing of its own products or services when the same is offered on a market and thus in competition with other (private) actors.

In addition to these rules, an ERIC is subject to a specific rule in Article 3(2) that limits its economic activity. Although the scope of application of that rule is determined by way of a competition law concept, i.e. *economic activity*, the rule is not solely aimed at protecting competition in the internal market. As a rule on ERIC *purpose*, the rule is also aimed at protecting ERIC members from ERIC organs taking decisions that lie outside the purpose of an ERIC. The members have an individual socio-economic interest in the operations of the ERIC they have financed.

In its Third ERIC Report the Commission raises the issue of defining 'limited economic activities' and states that a '[f]urther and specific guidance on the meaning of "limited economic activities" in the context of state aid rules should be provided for a consistent implementation, to enhance the broader impact of ERICs and therefore their sustainability'.[91]

This section examines the way in which the Commission frames issues concerning limited economic activity considering the general purpose of the ERIC legal form and the structural characteristics of ERICs. In particular, the section raises and discusses the question of whether it is necessary or desirable that ERICs should be subject to a specific restriction on their economic activities – as laid down in Article 3(2) – in addition to restrictions following from rules protecting competition in the internal market, in particular Article 107(1) TFEU and Article 3(3) of the ERIC Regulation.

4.2 ASSESSING THE RULE ON LIMITING ECONOMIC ACTIVITY IN LIGHT OF THE INTERESTS OF EU AND MEMBERS

The ERIC legal form is intended as a vehicle for combing research efforts and resources with the objective of advancing scientific development in the EU[92] and strengthening the EU economy.[93] The idea of realising socio-economic benefits by generating economic value through

[91] The Third ERIC Report (n 2) 12.
[92] ERIC Regulation, preamble, for example recitals 5 and 9.
[93] See Commission Staff Working Document, 'Accompanying document to the Proposal for a Council Regulation on the Community legal framework for a European Research Infrastructure (ERI)' COM (2008) 467 final, para 6.1. See also discussion in Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 166-169.

connecting with private actors was put forward prior to the introduction of the ERIC[94] and at later points, e.g. as a justification for the public financing of ERICs.[95] A related argument for using public funds to finance ERICs is that the results of research can be applied in practice,[96] e.g. by private actors providing goods and/or services for the benefit of consumers (and thus society in general). As regards producing new knowledge in the form of intellectual property, the observation has been made that it is difficult to align a restriction on economic activity with the way in which intellectual property law is structured, i.e. how it connects economic incentives to innovation.[97] Further, while ERICs are not precluded from transferring intellectual property rights – including to a self-standing ('spin off') entity – it has been pointed out that the activities leading up to the creation of such an entity (and subsequent transfer of rights) might amount to economic activity that exceeds the notion of *limited* within the meaning of Article 3(2) of the regulation.[98] In this context it should be recalled that Article 3(2) is a *mandatory* rule on ERIC purpose, which means that an ERIC is in breach of the regulation if its activities go beyond *limited economic activities*, irrespective of whether that breach is remedied at a later point by transferring the activities to another entity.[99] A separate issue in this regard is whether the practice of remedying a breach of the regulation in this manner is consistent with the mandatory nature of Article 3(2) or whether it would be construed as a circumvention of the rules. This matter will not be discussed further here.

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[94] As noted by ESFRI in its *Report of the Workshop on the Legal forms of research infrastructures of pan-European interests* (n 28) 14: 'Research Infrastructures clearly stimulate industrial impacts. Pan-European Research facilities play an outstanding role in building the interface between science and industry. They also contribute to many other socio-economic impacts. The landscape of Europe shows that, where pan-European Research Infrastructures have their site, often "technology clusters" of associated industry or so-called technology parks can be found. Such strategic centres for transfer of knowledge offer either better possibilities for interdisciplinary research contacts or greater attraction to high-tech firms. As a result, this can be an opportunity to increase the public-private interaction also in the funding of research activities'.

[95] A point that was raised in both Commission reports on the application of the ERIC Regulation, see European Commission, 'Report from the Commission to the European Parliament and the Council on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC)' COM(2014) 460 final, 8, and European Commission, 'Report from the Commission to the European Parliament and the Council Second Report on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC)' COM(2018) 523 final, 8-9, with the latter stating the following: 'The question of economic-versus non-economic activities remains also to be further clarified as there are increasing demands for "innovative" and "socio-economic" impacts of the activities of the research infrastructures justifying the investments to be made by the members'. See also Helen Yu, Jakob Blak Wested, and Timo Minssen, 'Innovation and Intellectual Property Policies in European Research Infrastructure Consortia-Part I: The Case of the European Spallation Source ERIC' (2017) 12(5) Journal of Intellectual Property Law & Practice 384, 384-385.

[96] See e.g. Thomas Kaiserfeld and Tom O'Dell (eds), *Legitimizing ESS: Big Science as a Collaboration across Boundaries* (Nordic Academic Press 2013) 27.

[97] See Nordberg (n 70) 77, who, however, subsequently notes that ERICs are, in this regard, in a position that is not significantly different from other publicly funded research institutions, such as universities: 'Despite their non-commercial nature, large research facilities contribute to big science and big data and thus often, directly or indirectly, big science translates into big innovation'.

[98] See Yu, Wested, and Minssen (n 95) 385

[99] The argument has been made that the possibility of transferring ERIC activities to another entity, i.e. creating a spin-off, means that the mandatory rule in Article 3(2) on limited economic activity is not an issue as such. See European Strategy Forum on Research Infrastructures Innovation Working Group ESFRI, *Innovation-oriented cooperation of Research Infrastructures* (Dipartimento di Fisica - Università degli Studi di Milano 2018) 113.

While contributions from members form the basis of ERIC financing, it can be argued that a rule that limits the economic activity of ERICs – for purposes other than the protection of competition in the internal market – undermines the ability of ERICs to establish themselves as entities that can sustain themselves based on their own income, thus minimising the need for public funding from its members (or, potentially, the EU).[100] The rule consequently undermines the realisation of the structural characteristics ERICs are to have according to the ERIC Regulation and statutes of established ERIC, i.e. legal capacity – including an ERIC's liability for its own debts – and limited member liability (as generally envisaged by statutes of established ERICs). Further, the rule sits oddly with the objectives underlying the TFEU articles from which the ERIC Regulation – and by extension individual ERICs – derive its legal base. For example, Article 179 envisions the freedoms of the internal market as a facilitator for creating European Research Area in which public and private actors collaborate.

Based on the considerations above, it can be argued that it is counter-productive to the overall aims of operating ERICs, as self-standing legal entities to enhance socio-economic development, to have a mandatory rule on ERIC purpose which curbs the operations of an ERIC that successfully commercialises its research in collaboration with private industry, *provided the activities do not distort market conditions and lead to unfair competition terms of other market actors.* A rule on limited economic activity in Article 3(2) – in addition to State aid rules and Article 3(3) – is from this viewpoint liable to add further complications to the mandate on which ERIC organs operate. This may in turn hinder the ability of organs in taking decisions and actions in an effective manner.

4.3 PROTECTING COMPETITION IN THE INTERNAL MARKET

As previously discussed, both Article 107(1) TFEU and Article 3(3) of the ERIC Regulation provide rules for the protection of competition in the internal market. In other words, in so far as ERICs encounter private marketplaces, they are prohibited from using their publicly funded resources to subsidise the operations of private actors to the detriment of competition, i.e. the interests of other actors in the market and, eventually, consumers.

It follows that if the rule on limited economic activity in Article 3(2) is construed as a rule protecting competition in the internal market it can be argued that the rule is superfluous, as such interests are already protected by Article 107(1) TFEU and Article 3(3) of the ERIC Regulation, notwithstanding whether it might be necessary or desirable to offer additional clarifications of how rules on State aid would be applied in the case of ERICs.

4.4 SUGGESTED AMENDMENTS TO ARTICLE 3(2)

In the light of the discussion above it can be argued that, as presently formulated, the rule on limited economic activity in Article 3(2) creates complications to the purpose structure of ERICs

[100] See also discussion in Astvaldsson, *The European Research Infrastructure Consortium (ERIC) as governed by EU law and Swedish law* (n 20) 168.

which are unnecessary from a competition law perspective and undesirable in terms of pursuing the interests of ERIC members and the EU.

If the aim of Article 3(2) is to prevent an ERIC from becoming an entity that is driven by profit motives and thus no longer driven by contributing to the development of research and technological developments, then the author submits that such an aim is more likely to be achieved by simplifying the rule on purpose structure in Article 3(2) by removing references to *non-economic* and *limited economic activity* and adding a mandatory rule on prohibiting the distribution of ERIC assets to ERIC members, i.e. a rule that stipulates that *all* ERIC resources shall be *solely* used for financing its operation in accordance with its purpose (a mandatory non-distribution constraint rule).

An amended article 3 *could* read as follows:

1. The principal task of an ERIC shall be to establish and operate a research infrastructure. Any economic activity of an ERIC shall be closely related to its principal task and not jeopardise the achievement thereof.
2. All ERIC resources shall be devoted to its principal task and related economic activities. Any economic surplus from ERIC activity shall be used solely to finance its operations and cannot be distributed to members or external actors, save for distribution upon winding-up and insolvency in accordance with Article 16.
3. An ERIC shall record the costs and revenues of its economic activities separately and shall charge market prices for them, or, if these cannot be ascertained, full costs plus a reasonable margin.

Article 107(1) TFEU applies to ERICs, if the activity in question falls within its scope, as a Treaty rule, irrespective of whether the ERIC Regulation refers to the rules on State aid or not. Additionally, the Commission has issued a communication and guidelines on how it will assess whether research infrastructures have provided prohibited State aid, as previously discussed.[101] It follows that it is debatable whether there is an apparent need to directly refer to Article 107(1) in the ERIC Regulation or provide a rule restricting economic activity, in addition to the Treaty State aid regime. Whether or not it is desirable for the Commission to issue *a separate* or more complete guidance on how it would approach an ERIC matter in relation to State aid matters is outside the scope of this article. This notwithstanding, it is submitted that it might be advisable to consider adding a specific rule to the regulation, which expressly obliges ERICs to deliver a report on the scope of their *economic activities* to the Commission.[102] In that way the Commission would have a clearer mandate in terms of monitoring this part of ERIC activity, for example with regard to assessing whether the activity is in conformity with Article 107(1) TFEU and/or Article 3(3) of the ERIC Regulation based on its own communications and guidelines on State aid and research infrastructures, as the case may be.

[101] See discussion in Sections 3.3.2 and 3.3.3.
[102] Rules on ERIC reporting obligations are in Article 17 of the ERIC Regulation.

5 CONCLUDING REMARKS

This article has discussed the rules governing the extent to which entities operating within a European Union legal form – the European Research Infrastructure Consortium – are allowed to carry out economic activities. The roots of the article lie in the Commission's third report on the application of the ERIC Regulation and its views on the need to clarify the concept of economic activities. The aim of the article was to offer clarifications of the rules governing the economic activity of ERICs and, subsequently, discuss to whether the rules should be amended, given the core rationale behind the ERIC Regulation and the structure of established ERICs.

It can be argued that the current rule on limiting economic activity in Article 3(2) of the ERIC Regulation creates unnecessary complexity that hinders the ability of ERICs to fully achieve their potential in fostering socio-economic development within the EU. While the protection of competition within the internal market is undoubtedly important, existing EU rules, such as Article 107(1) TFEU and Article 3(3) of the ERIC Regulation, already address these concerns. As such, the restriction on economic activity under Article 3(2) may be redundant and counterproductive to the overarching goals of ERICs – namely, enhancing scientific excellence, technological innovation and economic competitiveness across the EU to improve both socio-economic standards within the EU and the competitiveness of the EU vis-à-vis other markets.

Rather than offering further clarifications on the meaning of *limited economic activities*, including in relation to the concept of State aid, as the Commission suggests, the author suggests amending Article 3 of the ERIC Regulation by removing its references to non-economic activity and limited economic activity. The objective should not be to curb the possibility of an ERIC to engage in economic activity *as such* but rather to make sure that when engaging in economic activity an ERIC does not use its public funds to distort competition.

A more simplified rule on ERIC purpose – along with a rule clearly stipulates the way in which ERIC resources should be used (including a distribution constraint) – would allow ERICs the flexibility to engage in economic activities that contribute to their financial sustainability and technological impact, without distorting competition. This approach would also be in line with structural characteristics of ERICs, which are based on the idea of creating a self-standing legal entity that is not dependent on member financing in perpetuity. The author submits that simplifying the rule on limited economic activity and ensuring that all ERIC resources are directed toward their research and technological objectives, with appropriate safeguards for competition, would strengthen the ability of ERICs to fulfil their dual role as hubs of scientific collaboration and engines of innovation, contributing significantly to the advancement of both knowledge and the economic strength of the EU.

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