

REGULATING THE FUTURE: THE AI ACT, EU PRINCIPLES, AND THE CHALLENGE OF MEMBER STATE EQUALITY



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Abstract

This chapter analyses the legal regulations regarding artificial intelligence (AI) adopted within the EU. The primary objective is to highlight the benefits and costs borne by EU Member States as they adapt to an increasingly unified EU legal system. The analysis examines AI-related EU secondary law through the lens of the legal principles of the EU's primary law, focusing on the principles of conferral, subsidiarity, proportionality and equality. The chapter investigates the compatibility of the newly adopted AI Act with the overarching legal principles, particularly the considerations concerning its legal basis in EU primary law. Hence, the conclusions are presented based on linguistic, systemic and teleological interpretations. The concluding section is divided into two segments. The first presents the core insights derived from the analysis, without reiterating each finding. The second offers observations on how the EU should approach AI regulation to ensure adherence to the equality principle among the Member States.

Keywords: artificial intelligence, European Union law, new technologies law, law unification, EU principles

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1. Introduction

The present chapter analyses the effects of the EU's legal framework on artificial intelligence (AI), weighing the attendant benefits and costs of legal unification following the principle of equality of the EU Member States. The central research question is whether the costs exceed the benefits. A related issue is whether such harmonisation furthers or undermines the equality principle.

EU's decision to regulate AI through Regulation (EU) 2024/1689 of the European Parliament and the Council of 13 June 2024, laying down harmonised rules on AI, and by 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 (AI Act)¹ inaugurated a new, albeit controversial, phase in the enduring tension between the drive to integrate the internal market and the duty to respect the diversity of the EU Member States. This chapter placed that tension within the broader framework of the monograph, which tracked the EU's responses to contemporary global challenges by resorting to increasingly uniform legal instruments. The point of departure was the equality clause of the EU primary law, which obliged the EU to accord all its Member States equal standing, irrespective of significant economic, technological and constitutional disparities.

The analysis proceeded along four closely connected lines. First, competence, that is, whether the existing treaty provisions truly empowered the EU to regulate AI extensively. Secondly, the choice of legal instrument, that is, whether scrutiny under the principles of subsidiarity and proportionality justified a directly applicable regulation or whether a directive would have sufficed. Thirdly, equality, that is, how the adopted measures affected the practical equality of the Member States, including who gained, bore the costs, and risked falling behind. Fourthly, policy guidance, that is, how the EU should approach the legal AI regulation in the future.

These lines prompted four corresponding research questions. First, on which precise legal bases does the AI Act rest, and are they adequate under the principle of conferral? Second, does the AI Act respect or bypass the safeguards of subsidiarity and proportionality that protect EU Member State autonomy? Third, how do its uniform and exacting standards (e.g., regulatory sandboxes, market-surveillance authorities) interact with the principle of equality among the EU Member States? Fourth, how should the EU regulate AI to conform with EU's primary law?

The above questions determined the five-part structure of the chapter, whereby the individual parts remained in a close logical relationship with one another. First, 'Introduction to AI and Justification for its Normatization in the EU' presents the definition and scope of the concept of AI, outlines the main regulatory challenges at the European level and indicates the normative needs. Second, 'Legal Form Selection: Struggle between EU Regulation and EU Directive' discusses the doctrinal

1 Regulation (EU) 2024/1689, Official Journal of the European Union, L 1689, 12 July 2024.

differences between a directive and a regulation, reconstructs the treaty-based criteria for the selection of a legal instrument and analyses the implications of the chosen form following the equality principle.

Third, ‘Legal Form Selection: AI Act Case’ presents the legislative process leading to the adoption of the AI Act, outlines the general competence of the EU and verifies the compliance of the chosen instrument with the principles of subsidiarity and proportionality, referring to personal data protection and the harmonisation of medical device regulations. Fourth, ‘AI Act: Legal Characterisation’ conducts a three-track (linguistic-logical, systemic and teleological) analysis of the EU’s specific competences in the light of EU primary law and assesses the indicated legal bases of the AI Act regarding their adequacy. Fifth, ‘AI Act vs. Principle of Equality’ presents the general arguments of a systemic nature, focusing on competence and arguments related to the potential effects of the AI Act’s practical application.

The chapter concludes with findings and recommendations. The overarching theme of the structure is the main aim of the chapter: to highlight the benefits and costs borne by EU Member States as they adapt to an increasingly unified EU legal system.

2. Introduction to AI and Justification for Its Normalization in the EU

2.1. Definition and Scope of AI

A review of AI technologies shows that it is a broad term encompassing several designations. It is a dynamic term, where its scope and the list of AI technology types are constantly changing and being updated. Nevertheless, establishing such a list is not impossible. However, this list will neither be closed-ended nor will it exhaustively represent all AI technology designations. Based on available sources, it is possible to determine that the subject matter of AI technologies includes Machine Learning (ML),² Natural Language Processing (NLP),³ Computer Vision,⁴ Deep Learning,⁵ Reinforcement Learning,⁶ Generative Adversarial Networks (GANs),⁷ Neural Networks,⁸

2 Janiesch, Zschech and Heinrich, 2021, pp. 685–695.

3 Khurana et al., 2023, pp. 3713–3744.

4 Sivkov et al., 2020, pp. 662–667.

5 Sarker, 2021, p. 420.

6 Cao, 2007, pp. 289–340.

7 Goodfellow et al., 2020, pp. 139–144.

8 Wun and Feng, 2018, pp. 1645–1656.

Automated Machine Learning (AutoML),⁹ Speech Recognition,¹⁰ Robotics,¹¹ AI Ethics and Bias Mitigation,¹² Explainable AI (XAI),¹³ Transfer Learning,¹⁴ Federated Learning,¹⁵ Quantum Machine Learning,¹⁶ Edge AI,¹⁷ AI in IoT (AIoT),¹⁸ Cognitive Computing,¹⁹ AI in Cybersecurity²⁰ and Data Mining.²¹ However, the presented list does not provide much information, merely indicating that the scope of AI technologies is extremely broad.

Each designation on the list has been the subject of numerous publications and practical issues, including from a legal perspective. This is a noticeable drawback of defining through division, where a logical error may occur by explaining the unknown through the unknown. Hence, it is better to refer to descriptive definitions. It is worth noting that organisations, such as the Organisation for Economic Cooperation and Development (OECD), the International Organization for Standardization (ISO), the United Nations (UN), the Institute of Electrical and Electronics Engineers (IEEE) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) have proposed their own definitions. For example, according to the ISO, AI is ‘a technical and scientific field devoted to engineered systems that generate outputs such as content, forecasts, recommendations, or decisions for a given set of human-defined objectives’.²² According to the UN:

AI is generally considered to be a discipline of computer science that is aimed at developing machines and systems that can carry out tasks considered to require human intelligence. Machine learning and deep learning are two subsets of AI. In recent years, with the development of new neural network techniques and hardware, AI is usually perceived as a synonym for ‘deep supervised machine learning’.²³

Meanwhile, according to the IEEE, ‘Artificial Intelligence is that activity devoted to making machines intelligent, and intelligence is that quality that enables an entity to function appropriately and with foresight in its environment’.²⁴ However, several definitions are preceded by the caveat that AI is either variously defined or possesses

9 Chauhan et al., 2020, pp. 205–212.

10 King et al., 2007, pp. 723–742.

11 Hofmann, Samp and Urbach, 2020, pp. 99–106.

12 O’Connor and Liu, 2024, pp. 2045–2057.

13 Holzinger et al., 2022, pp. 13–38.

14 Zhuang et al., 2020, pp. 43–76.

15 Xu et al., 2021, pp. 1–19.

16 Biamonte et al., 2017, pp. 195–202.

17 Li et al., 2019, pp. 447–457.

18 Baccour et al., 2022, pp. 2366–2418.

19 Modha et al., 2011, pp. 62–71.

20 Stevens, 2020, pp. 164–170.

21 Witten et al., 2005, pp. 403–413.

22 International Organization for Standardization, 2024.

23 United Nations Regional Information Centre for Western Europe, 2024.

24 Institute of Electrical and Electronics Engineers, 2024.

multiple definitions. This is a drawback of such definitions, as they are not binding in nature. Hence, they only stimulate discussion in this area, generating further and diverse definitions. Such a mechanism leads to terminological chaos, where almost every text about AI has its own definition.²⁵

A remedy would be the introduction of legal regulations that define the meaning and scope of AI in a binding manner.²⁶ One could argue that almost every legal definition is dangerous; however, a definition does not necessarily have to be closed-ended and is often essential for an approximate understanding of the subject of regulation. To date, two significant legal regulations concerning AI can be noted in international law. First, is the increasingly well-known AI Act, and second, is the not yet in force Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (AI Convention).²⁷ According to Art. 3 of the AI Act:

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

Meanwhile, according to Art. 2 of the AI Convention:

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

At first glance, both definitions seem similar, and the differences mainly arise from linguistic formulation. However, concluding that they have the same meaning is hasty. This meaning derives from the exegesis of the legal text and the application of appropriate interpretative techniques. Therefore, it is necessary to wait for competent entities to voice their opinions on this matter.

Regarding the AI Act, this would be the Court of Justice of the European Union (hereafter, CJEU), and regarding the AI Convention, according to its Arts. 23 and 29, it would be the Conference of the Parties. The statements of these entities would shape the actual definition of AI in Europe. This is because these definitions would

25 Stewart, Davis and Igoche, 2020, pp. 135–142; Corea, 2019, pp. 25–29; Modgil et al., 2022, pp. 130–149; Holmes, Sacchi and Bellazzi, 2004, pp. 334–338; Brunette, Flemmer and Flemmer, 2009, pp. 385–392; Adams, 2021, pp. 176–197.

26 Schuett, 2023, pp. 60–82; Leith, 1988, pp. 31–46; Greenstein, 2022, pp. 291–323; Hacker et al., 2020, pp. 415–439.

27 Council of Europe Treaty Series – No. 225.

be international in nature (region of application: Europe), and would directly affect national legal systems by introducing and imposing the terminology. Such actions are aimed at unifying the conceptual framework and eliminating diversity in defining AI in the literature (which will likely fail) and the national law. Such a move does not seem unreasonable, as, in principle, the national laws of European countries do not provide their own definitions of AI.²⁸ The actions of international bodies with a European scope, at least in the EU, where a Union regulation directly applicable in EU Member States has been issued, supplement their normative systems in this regard, irrespective of the will of these states.²⁹

It is noteworthy that the situation appears different outside the European continent, where attempts are being made within national laws to issue AI-related legal regulations.³⁰ For instance, in Brazil,³¹ the currently pending '*Senado Federal Projeto De Lei N° 2338, De 2023*',³² in its Art. 4(I), provides a definition, according to which an 'artificial intelligence system' is:

A computational system, with varying degrees of autonomy, designed to infer how to achieve a given set of objectives, using approaches based on machine learning and/or logic and knowledge representation, through input data originating from machines or humans, with the purpose of generating predictions, recommendations, or decisions that may influence the virtual or real environment.

This definition does not differ significantly from the AI Act or the one proposed in the AI Convention. However, their meanings are not identical. The Brazilian definition may be interpreted similarly; however, this is unlikely due to the lack of a direct connection between the country and the EU or the Council of Europe (hereafter, CoE). Brazil, a South American country not often cited as an example of avant-garde legal solutions,³³ highlights a currently noticeable global legal trend of normatively regulating AI. On the European continent, if not for the legislative initiatives, primarily by the EU, several countries would likely be proceeding with their own legislation in this area, without the possibility or obligation to consider common unification standards.

28 Martini, 2020, pp. 100–135.

29 Craig, Craig and de Búrca, 2020; Chalmers, Davies and Monti, 2019; Judgment of the Court of Justice of the European Union of 10 October 1973, C-34/73 (ECLI:EU:C:1973:101).

30 Surden, 2019, pp. 1306–1337; Verheij, 2020, pp. 181–206.

31 Belli, Curzi and Gaspar, 2023.

32 Projeto de Lei no. 2338, de 2023.

33 However, certain legal solutions that have proven effective should not be overlooked. de Oliveira Dias and Teles, 2019, pp. 1–12; Lopes and Freitas Filho, 2014, pp. 91–103.

2.2. *Regulatory AI Challenges in Europe*

As mentioned, in Europe, due to the activities of the EU and CoE, AI is being subjected to international and regional normative regulation to address the challenges or legal problems arising from the practical application of this new technology.³⁴ In the EU, the AI Act has been adopted, where its significance for the EU Member States, their national legal orders and the practice of applying and utilising AI can be assessed as having comparable, or even greater, importance than the already famous Regulation (EU) 2016/679 of the European Parliament and 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 (hereafter, GDPR).³⁵

The GDPR has shown, regarding personal data protection, the significant impact that an EU regulation can have on the national laws of its Member States and the principles governing the functioning of the internal market. It can be assumed that this scenario will, at least, repeat itself regarding the AI Act, whereby this act could exert an even greater influence on the legal systems of the EU Member States. Hence, it is worth noting that the intention of the EU legislator was to introduce harmonised AI standards as a legal model for AI throughout the EU and counteracting the particularism of the EU Member States, justified by AI's cross-border nature. A direct confirmation of such an intention is found in Recital 3 of the AI Act, according to which:

AI systems can be easily deployed in a large variety of sectors of the economy and many parts of society, including across borders, and can easily circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that AI is trustworthy and safe and is developed and used in accordance with fundamental rights obligations. Diverging national rules may lead to the fragmentation of the internal market and may decrease legal certainty for operators that develop, import or use AI systems...

Thus, since this is explicitly stated in the AI Act, it further justifies the prediction of a strong influence of this legal instrument on the national laws of the EU Member States, where even the form of the legal act has far-reaching consequences. However, the emphasised influence of the AI Act on national law is not limited to its direct application. This is because the adoption of the AI Act does not absolve the EU Member States from action. They cannot adopt the position that all issues are regulated in the EU regulation and its simple or mechanical application in the territory would be sufficient. It is the duty of the EU Member States to adapt their legal systems to

34 Feuerriegel, Dolata and Schwabe, 2020, pp. 379–384; Al Ridhawi et al., 2020, pp. 372–379; Kononova, 2023, pp. 520–530.

35 OJ L 119, 4 May 2016, pp. 1–88.

enable the effective enforcement of the AI Act.³⁶ For example, according to Art. 5(5) of the AI Act:

A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement within the limits and under the conditions listed in para. 1, first Subpara., Point (h), and paras. 2 and 3. Member States concerned shall lay down in their national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision and reporting relating to, the authorisations referred to in para. 3. Those rules shall also specify in respect of which of the objectives listed in para. 1, first Subpara., Point (h), including which of the criminal offences referred to in Point (h)(iii) thereof, the competent authorities may be authorised to use those systems for the purposes of law enforcement. Member States shall notify those rules to the Commission at the latest 30 days following the adoption thereof. Member States may introduce, in accordance with Union law, more restrictive laws on the use of remote biometric identification systems.

Thus, for Art. 5(5) to be effectively enforced, if specific EU Member States decide to do so due to its optional nature, it is necessary to adopt appropriate national measures. Another similar example is Art. 31(1) of the AI Act, which states: ‘A notified body shall be established under the national law of a Member State and shall have legal personality’. In this instance, it is necessary to issue appropriate national legal acts to establish the notifying body, with the distinction that the cited provision is obligatory.

These examples demonstrate that the issuance of the AI Act is a challenge in its application by EU Member States, referring to the daily application of this legal act by appropriate national authorities, and a legislative challenge, including institutional aspects. This situation may, in some ways, resemble the challenges that the EU Member States faced after the adoption of the GDPR. For example, in Poland, it was decided to enact the Personal Data Protection Act of 2018.³⁷ This act serves as the main legal instrument enabling the effective enforcement of GDPR provisions in Poland. A similar approach cannot be ruled out concerning the AI Act, where the Member States may decide to adopt particular legal measures and entire legal acts dedicated to adapting the national legal order for effective enforcement of the AI Act. In the future, this will be one of the greatest legal challenges for EU Member States, confirmed by the legislative actions being initiated in Poland for adopting the Act on Artificial Intelligence Systems.³⁸

36 This should not be confused with the obligation to implement into national law, as this obligation applies exclusively to the EU directives.

37 Act of 10 May 2018 on the Protection of Personal Data (Consolidated text: Journal of Laws from 2019, item 1781).

38 Draft Bill on Artificial Intelligence Systems (Project Number: UC71; Document Type: Draft Bills; Document Type: C – EU Implementing Drafts).

Conversely, within the CoE, the adoption of the AI Convention is underway. However, this convention has not yet entered into force, unlike the AI Act. Although it contains several significant AI-related legal norms, it is currently uncertain how many CoE members will accede to this Convention and how the follow-up mechanism and cooperation specified within it (Chapter VII of the AI Convention) will function in practice. In other words, the future territorial scope of applicability of this legal instrument and the effectiveness of its control mechanism are presently unknown, unlike the AI Act, which is an EU regulation applicable in all EU Member States, where CJEU ensures its correct application.

However, the current text of the AI Convention does not provide for the jurisdiction of the European Court of Human Rights (ECtHR), leaving this judicial body of the CoE dedicated exclusively to adjudicating matters related to the ECHR.³⁹ Additionally, it is worth considering the relationship that the simultaneous validity and application of the AI Convention will have with the AI Act's application. This will be a significant issue because all EU Member States are CoE members. Hence, the substantive compatibility of the simultaneous application of both legal acts, if a specific EU Member State accedes to the AI Convention, will become important for the practical interpretation of legal regulations applicable to AI in such a country, originating concurrently from the EU and the CoE.

A subtle hint in this regard may be the mild design of the control mechanism and conflict resolution in the AI Convention, as reflected in Arts. 23 and 29. This may suggest an auxiliary role of the CoE, supporting the EU's leading role. However, as exemplified by the current relationship of the ECtHR to the Charter of Fundamental Rights of the EU and the associated relationship between the CJEU and the ECtHR, this remains uncertain. Nonetheless, this example pertains to the protection of human rights, which is a fundamental objective of the CoE, justifying the assertion that the CoE's aspirations may not be as high in other areas. This is one of the regulatory challenges of AI that can currently be anticipated in Europe.

Other regulatory challenges of AI remain, which are no longer exclusively European but global in nature. These include challenges related to legal and ethical or moral aspects, such as the scope of decision-making by AI systems, the issue of AI replacing human labour (the impact of AI on human dignity) or the problem of the de-humanisation of interpersonal relationships. Although these issues do not originate in the legal sphere, law as a regulatory instrument should address such aspects of AI. Such regulatory challenges in Europe, if approached strictly, should be related to the AI Act, as it is a legal act already issued, in force in the EU, and subject to mandatory application by the EU Member States. The content of the AI Act is known and certain, unlike the AI Convention, which may be subject to modification. Hence, due to this reason, and given that the topic of this paper focuses on the orbit of EU law, the remainder of the study will concentrate on the EU's AI Act.

39 Convention for the Protection of Human Rights and Fundamental Freedoms.

2.3. Justification for EU Normalization

Regarding the justification for legal regulation by the EU, there are several reasons cited as benefits resulting from EU norm-setting. There are talks of harmonising legal standards across the EU and, consequently, building a coherent internal market.⁴⁰ Furthermore, consumer protection,⁴¹ sustainable development,⁴² safety and public health⁴³ and supporting innovation are mentioned.⁴⁴ These certainly are the advantages of EU norm-setting, whether as harmonisation (EU directives) or unification (EU regulations).

Moreover, one can mention the benefits for the functioning of the society and the institutional advantages for the EU. By issuing EU regulations in an increasing number of areas and more frequently, the EU gains significance. It becomes increasingly powerful in competencies and has a greater influence on the national laws of its Member States. From the EU's perspective, increasingly aspiring to the title of a super international organisation or a so-called *sui generis* international organisation, these beneficial aspects justify its active legislative actions. This is somewhat related to the increasingly advocated concept of federal integration of the EU.⁴⁵ For example, if the EU had not issued the AI Act, it would have become a passive observer of the issuance of AI legal standards by successive EU Member States. Instead, it is now in the role of the player and supervisor of the implementation of its standards.

However, from the perspective of EU Member States, this is not so straightforward. The norm-setting carried out by the EU, its harmonising or unifying actions, directly impacts the preservation of cultural diversity or constitutional identity and the scope of the Member States' sovereignty. Their sovereignty is diminished each time the EU issues its secondary legislation, particularly in areas previously unregulated by EU law, such as AI, and when the EU decides to issue an EU regulation, such as the AI Act. Another significant issue concerning the justification for EU normalization is the frequent breach of the equality principle among EU Member States in this context. This provides an impetus to evaluate the developmental trends in the unification of law within the EU and their outcomes. Hence, one must consider whether the fundamental loss of equality in the EU is a price worth paying for the benefits of a common EU regime. This is the main objective of this study.

40 de Vries, Kanevskaia and de Jager, 2023, pp. 583–610; Ferguson and David, 2022, pp. 51–114.

41 Graef, 2022, pp. 1–10; Llorente, 2020, pp. 169–193.

42 Constantin et al., 2021, pp. 948–963; Leitao, Ferreira and Santibanez-Gonzalez, 2021, pp. 2077–2090.

43 Greer and Jarman, 2021, pp. 23–47; Könönen, 2024, pp. 601–619.

44 Amann and Essig, 2015, pp. 282–292; Musch, Borrelli and Kerrigan, 2023, pp. 135–152.

45 In this context, the recently proposed treaty amendments by the European Parliament are noteworthy. European Parliament resolution of 22 November 2023 on proposals of the European Parliament for the amendment of the Treaties (2022/2051(INL)).

3. Legal Form Selection: Struggle Between EU Regulation and EU Directive

3.1. Definitions and Legal Implications

In the EU, there are two main types of secondary legislation. Therefore, when the EU decides to exercise its competence and regulate a certain area, it must choose whether to do so by means of an EU directive⁴⁶ or an EU regulation.⁴⁷ The difference between them is significant. An EU directive harmonises national law by indicating the objective that EU Member States must achieve, generally with the freedom regarding the means to achieve the objective.⁴⁸ An EU directive does not, in principle, have direct effect on the normative systems of the Member States.⁴⁹

An EU regulation, with direct effect on the national law of the Member States, unifies legal standards across the EU, leaving no discretion in terms of the objective or the means of achieving that objective.⁵⁰ However, this does not mean that EU Member States can remain passive regarding an EU regulation, because such acts entail a range of obligations to ensure effective enforcement, using their institutions and laws to uphold the unified EU legal standards. Hence, the Member States are the implementers of the legal standards enacted in the EU. It should be remembered, as mentioned, that secondary legislation negatively affects the sovereignty of the Member States and their competences to varying degrees, whereby, in the case of EU regulations, this impact is noticeable *prima facie*.

3.2. Rules of Selection EU Regulation vs. EU Directive

The EU is founded on three fundamental principles that define its role and the limits and use of its competences. The limit is the principle of conferral, which sets the boundaries of its competences. The use refers to the principles of proportionality and subsidiarity (only in areas of non-exclusive EU competences), which determine how the EU exercises its competences. All these principles are regulated by Art. 5 of the Treaty on European Union⁵¹ (hereafter, TEU), where para. 1 states: ‘The limits of Union competences are governed by the principle of conferral. The use of Union competences is governed by the principles of subsidiarity and proportionality’.

46 Haas, 1998, pp. 17–37; Dickson, 2011, pp. 190–212; Karayığit, 2016, pp. 59–95.

47 Rotondo, 2013, pp. 437–445; Blom-Hansen et al., 2023, pp. 2786–2806.

48 Hopwood, 1994, pp. 241–254; Givens and Luedtke, 2004, pp. 145–165.

49 However, sometimes, an EU directive, according to the case law of the CJEU, can produce direct effect (see CJEU judgments in the cases of *Ratti* (Case C-148/78), *Van Duyn* (Case C-41/74) and *Marks & Spencer* (Case C-62/00)).

50 Crettez and Deloche, 2006, pp. 203–214; Hugenholtz, 2012, pp. 4–16.

51 Consolidated version of the Treaty on European Union (OJ C 202, 7 June 2016, pp. 13–47).

According to Art. 5(2) of the TEU, the essence of the principle of conferral is that: ‘The Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein’.⁵² Although the wording of this provision is clear, meaning that linguistic interpretation (exegesis of the legal text) should suffice for understanding this legal norm, Art. 5(1) of the TEU emphasises that competences not conferred upon the EU under the Treaties remain under the jurisdiction of the Member States.⁵³ This principle, in conjunction with other relevant provisions of the TEU and the Treaty on the Functioning of the European Union (hereafter, TFEU), determines whether a specific field falls within the EU’s competences and, if so, whether the EU is empowered to issue secondary legislation in that field, that is, to adopt appropriate legal measures.

However, sometimes the situation is not so clear. For example, regarding AI, there is no explicit legal basis in the Treaties granting the EU legitimacy to act.⁵⁴ Nonetheless, the principles of proportionality and subsidiarity (concerning non-exclusive competences) define the rules according to which the EU should exercise its competences. This means they set out the principles guiding the choice of the appropriate form of secondary legislation, since each form differs in the degree of impact on the legislation of the EU Member States. The principle of subsidiarity (in areas which do not fall within its exclusive competence), following Art. 5(3), para. 1 of the TEU, states that the EU shall act only if and insofar as:

The objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.⁵⁵

Meanwhile, the principle of proportionality, according to Art. 5(4), para. 1 of the TEU, requires that ‘the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties’.⁵⁶ The exercise of the EU’s competences occurs mainly through the issuance of secondary legislation, among which EU directives and regulations are the most important. As noted, directives harmonise the provisions of the Member States, while regulations directly introduce uniform legal standards within the Member States. Therefore, the choice of legal act must comply with the principle of subsidiarity (the legal act should correspond to the difficulty of achieving objectives that the EU Member States cannot accomplish on their own or whose implementation would be less effective) and proportionality (the legal measure must not exceed what is necessary).

52 See, for example, Judgment of the Court of Justice of the European Union of 14 June 2016, C-361/14 P.; Judgment of the Court of Justice of the European Union of 5 December 2017, C-600/14.; Judgment of the Court of Justice of the European Union of 25 October 2017, C-687/15.

53 See, for example, Lohse, 2015, pp. 165–182; Żelazna, 2022, pp. 593–606.

54 The issue will be discussed in more detail in the later sections of this study.

55 Melé, 2005, pp. 293–305; Spicker, 1991, pp. 3–14; Follesdal, 2013, pp. 37–62.

56 Hermerén, 2012, pp. 373–382; Portuese, 2013, pp. 612–635; Poto, 2007, pp. 835–869.

Hence, the EU should first resort to directives as a less invasive measure towards the legal systems of the Member States. Issuing an EU directive in a specific area, aimed ‘only’ at harmonisation, would test whether unification is a necessary step, given that the unification of legal standards is not a normatively prescribed goal of the EU. Only after the failure to ensure a harmonised approach to legal regulations across the EU, the possibility or, in some cases, the necessity⁵⁷ of legal unification through EU regulations arises. These observations become more relevant when the EU addresses areas previously unregulated by its institutions, where the impact of the principles set out in Art. 5 of the TEU becomes more pronounced. Therefore, it is surprising to observe the EU’s legislative practice trending towards the unification of legal standards, with an increasing number of EU regulations being issued in ever-expanding areas.

This trend can only be justified if accompanied by a thorough rationale demonstrating compliance with the principles of proportionality and subsidiarity. Unfortunately, as illustrated by the AI Act, this requirement is often disregarded in the EU’s legislative practice.⁵⁸ This fact must be assessed negatively, as it often leads to conclusions about the arbitrariness of the EU’s decisions regarding the issuance of regulations unifying the legal standards across the EU. Furthermore, it sparks discussions about the true normative nature of EU regulations, particularly regarding their function of subordinating the Member States to their will and authority or of certain Member States that strongly influence the EU’s directions. Hence, EU regulations can be viewed as inappropriate instruments of authority.⁵⁹ This gives the impression that the decision of the choice of the secondary legislation is arbitrary and not based on substantive reasons, even though EU primary law explicitly requires it.

3.3. Legal Form Selection and Principle of Equality

It is noteworthy that the choice of the secondary legislation in the EU is influenced by Arts. 5 and 4(2) of the TEU. According to the latter provision:

The Union shall respect the equality of Member States before the Treaties as well as their national identities, inherent in their fundamental structures, political and constitutional, inclusive of regional and local self-government. It shall respect their essential State functions, including ensuring the territorial integrity of the State, maintaining law and order and safeguarding national security. In particular, national security remains the sole responsibility of each Member State.

57 The necessity indicator here refers rather to areas where, *prima facie*, there is an apparent advantage in using the same legal standards across the EU.

58 It will be further discussed below.

59 Minogue, 1998, pp. 17–37; Ackerman, 2017, pp. 395–490; Samuels, 2009, pp. 703–726.

This is a normatively defined principle of equality within the EU concerning its Member States. The Member States are equal before the Treaties; hence, equal under the EU law, in relation to the EU, and among themselves. Hence, there are no ‘better’ or ‘worse’ Member States. The EU respects their equality⁶⁰ and, as Art. 4(2) states, their diversity, as all the EU Member States are not identical. This observation is significant because, if the Treaties emphasise the diversity or specificity of the Member States, the question arises whether treating them equally will render them equal, given their cultural, national, constitutional, economic and technological differences.

Therefore, the principle of equality, in this case, must consider the diversity of the Member States and may conflict with the application of identical requirements for all. The inclusion of the equality principle in the same paragraph of Art. 4 of the TEU, where the diversity of the Member States is emphasised, is unlikely to be coincidental. These two elements are profoundly and strongly interconnected, whereby understanding one element influences the interpretation of the other. Hence, it should be advocated that, instead of imposing unified legal standards across the EU, compliance with the equality principle should involve efforts to introduce requirements tailored to the needs and developmental capacities of the Member States. This would ensure that, in the future, the EU becomes a conglomerate of states, representing comparable technological or economic levels, regardless of geographical location. Alternatively, compliance with the equality principle could involve introducing a fair mechanism for sharing resources, knowledge, experience and technology to support those Member States that demonstrate such a need. This argument leads to the conclusion, which is neither novel nor groundbreaking, that treating everyone equally may not always be the appropriate course of action if the goal is to achieve equality in practice. Under specific circumstances, particularly when dealing with inherently different entities, the only way to realise equality is to treat them according to their needs.

Furthermore, this discourse leads to a conclusion regarding the choice of the secondary legislation. Given the specificity and nature of EU directives and regulations, the selection of a particular legislative instrument significantly impacts the realisation of the equality principle. Issuing an EU directive assumes that the Member States will implement the directive within their legal systems. Hence, the Member States are bound by the directive’s objective, with discretion in selecting the means to achieve the objective. In contrast, an EU regulation does not afford such discretion.⁶¹ It has a direct effect through its objective and the set of provisions specifying the means to achieve the objective. The Member States have no discretion and are obliged to adapt their legal systems to the rigid provisions of the EU regulation. Hence, all Member States are treated the same.

60 Rossi, 2017, pp. 3–42; Bayefsky, 2017, pp. 71–104; Raz, 2018, pp. 37–58; Wouters and Schmitt, 2017, pp. 43–82.

61 De Witte, 2008, pp. 79–108; Chalmers, 2015, pp. 303–326.

This distinction highlights that, with an EU directive, the Member States play a decision-making role in determining how to achieve the objective, accounting for their diversity. However, an EU regulation, if it is a typical rigid regulation, has no room for considering such diversity. The Member States are merely executors of the EU's will, as they must adapt their legal systems to ensure the effective implementation of the directly applicable EU law, often, as practice shows, even through the adoption of dedicated national legislation. It is noteworthy that the content of EU law is significantly influenced by economically and politically powerful Member States. Hence, the choice of the secondary legislation is crucial from the perspective of the equality principle.

Choosing an EU directive should be favoured from the perspective of the significance of Art. 4(2) of the TEU. An EU regulation neither promotes the realisation of the equality principle nor accommodates the diversity of the Member States. However, objectively, this does not mean that such an accommodation is impossible. It is possible, yet it depends on the EU's willingness and inclusion within the specific regulation of legal instruments. Considering the diversity of the Member States while realising the equality principle is crucial because, when diversity is not considered, it is difficult to speak of true equality. Hence, the equality principle and the respect for the diversity of the Member States are closely linked in Art. 4(2).

However, a potential departure from the equality principle within the EU does not have universally adverse effects for all the Member States. The consequence of such inequality is that some Member States may find themselves in a disadvantaged position, while others may find themselves in a more favourable position. A situation in which a departure from the equality principle takes the form of assigning the EU a hierarchically superior position to the Member States does not imply that all the Member States will have the same practical position in relation to the EU. The EU's practical functioning demonstrates that some Member States, while seemingly agreeing to transfer sovereignty or take on a theoretically subordinate role, actively and effectively influence the direction of EU actions and policies. Therefore, for some Member States, departing from the equality principle and the respect for diversity among Member States becomes a pathway to achieving supremacy within the EU.

4. Legal Form Selection: AI Act

4.1. General EU Competence for AI Normalization

The starting point for AI regulatory actions in the EU was 2020, when, on 1–2 October, the European Council, during its Brussels summit, called on the European Commission to take appropriate measures to ensure that the EU becomes a global

leader in the development of safe, trustworthy and ethical AI (Conclusion No. 13).⁶² Subsequently, on 21 April 2021, the Commission proposed the AI Act as a legislative proposal for an EU regulation.⁶³ On 6 December 2021, the Council of the European Union (hereafter, the Council) adopted its position on the AI Act, emphasising the need for safe AI in compliance with fundamental rights.⁶⁴ On 26 January 2024, a preliminary agreement⁶⁵ between the Council and the European Parliament on the AI Act was issued, following negotiations held on 6–9 December 2023.⁶⁶ On 21 May 2024, the Council approved the AI Act,⁶⁷ which entered into force on 1 August 2024.

An important aspect of selecting the legal form for AI regulations in the EU is determining the nature of the EU's general competence to adopt AI-related legal measures. It is necessary to establish whether this is an exclusive competence of the EU following Art. 5 of the TEU, as it decides whether the principle of subsidiarity applies to this competence. According to Art. 5, the principle of subsidiarity applies to EU competences that are not exclusive. It is noteworthy that this issue has a different legal significance than identifying the legal bases in the EU Treaties for adopting the AI Act (discussed later), as it pertains to the already specified competence to adopt a particular EU secondary law act.

In contrast, general competences are outlined in Art. 4 of the TFEU. Art. 4(2) specifies that one of the shared competences is the area of freedom, security and justice, further specified in Arts. 77 and 78. Art. 4(2) refers to the EU's general competence, while Arts. 77 and 78 provide for the competence to adopt specific legal measures in the form of EU secondary law. Thus, regarding AI, it is necessary to determine the general competence, which poses little difficulty in light of the opening section of Recital 1 and Art. 1 of the AI Act, which emphasises that 'the purpose of this Regulation is to improve the functioning of the internal market...'. Hence, the EU derives its general competence to regulate AI under Art. 4(2)(a) of the TFEU, where the internal market is listed as a shared competence. Furthermore, since this is a shared competence, the principle of subsidiarity applies. Consequently, all the above considerations and observations regarding the selection of the legal form of EU secondary legislation apply to the AI Act.

62 European Council conclusions, 1–2 October 2020.

63 Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, COM/2021/206 final.

64 Artificial Intelligence Act: Council calls for promoting safe AI that respects fundamental rights.

65 Analysis of the final compromise text with a view to agreement.

66 Artificial Intelligence Act: Council and Parliament strike a deal on the first rules for AI in the world.

67 Artificial Intelligence (AI) Act: Council gives final green light to the first worldwide rules on AI.

4.2. Subsidiarity, Proportionality and Choice of Instrument

The AI Act was designed as an EU regulation, which was reflected in the legislative proposal of the European Commission.⁶⁸ In the justification of the legislative proposal, reference was made to the principles of proportionality and subsidiarity and the reasons for selecting a legal instrument as an EU regulation. Regarding the principle of subsidiarity, it was stated:

The nature of AI, which often relies on large and varied datasets and which may be embedded in any product or service circulating freely within the internal market, entails that the objectives of this proposal cannot be effectively achieved by Member States alone. Furthermore, an emerging patchwork of potentially divergent national rules will hamper the seamless circulation of products and services related to AI systems across the EU and will be ineffective in ensuring the safety and protection of fundamental rights and Union values across the different Member States. National approaches in addressing the problems will only create additional legal uncertainty and barriers, and will slow market uptake of AI. The objectives of this proposal can be better achieved at Union level to avoid a further fragmentation of the Single Market into potentially contradictory national frameworks preventing the free circulation of goods and services embedding AI. A solid European regulatory framework for trustworthy AI will also ensure a level playing field and protect all people, while strengthening Europe's competitiveness and industrial basis in AI. Only common action at Union level can also protect the Union's digital sovereignty and leverage its tools and regulatory powers to shape global rules and standards.⁶⁹

Regarding the principle of proportionality, the EU emphasised:

The proposal builds on existing legal frameworks and is proportionate and necessary to achieve its objectives, since it follows a risk-based approach and imposes regulatory burdens only when an AI system is likely to pose high risks to fundamental rights and safety. For other, non-high-risk AI systems, only very limited transparency obligations are imposed, for example in terms of the provision of information to flag the use of an AI system when interacting with humans. For high-risk AI systems, the requirements of high quality data, documentation and traceability, transparency, human oversight, accuracy and robustness, are strictly necessary to mitigate the risks to fundamental rights and safety posed by AI and that are not covered by other existing legal frameworks. Harmonised standards and supporting guidance and compliance tools will assist providers and users in complying with the requirements laid down by the proposal and minimise their costs. The costs incurred by operators are

68 Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence.

69 Ibid., Point 2.2.

proportionate to the objectives achieved and the economic and reputational benefits that operators can expect from this proposal.⁷⁰

Regarding the arguments supporting the use of an EU regulation as the legal form, it was noted:

The choice of a regulation as a legal instrument is justified by the need for a uniform application of the new rules, such as the definition of AI, the prohibition of certain harmful AI-enabled practices, and the classification of certain AI systems. The direct applicability of a Regulation, in accordance with Art. 288 TFEU, will reduce legal fragmentation and facilitate the development of a single market for lawful, safe, and trustworthy AI systems. It will do so, in particular, by introducing a harmonised set of core requirements with regard to AI systems classified as high-risk and obligations for providers and users of those systems, improving the protection of fundamental rights and providing legal certainty for operators and consumers alike. At the same time, the provisions of the regulation are not overly prescriptive and leave room for different levels of Member State action for elements that do not undermine the objectives of the initiative, in particular the internal organisation of the market surveillance system and the uptake of measures to foster innovation.⁷¹

It is noteworthy that the AI Act, in its current version, explicitly refers to the principles of subsidiarity and proportionality. Recital 176 of the AI Act states:

Since the objective of this Regulation, namely to improve the functioning of the internal market and to promote the uptake of human-centric and trustworthy AI, while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection against harmful effects of AI systems in the Union and supporting innovation, cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Art. 5 TEU. In accordance with the principle of proportionality as set out in that Art., this Regulation does not go beyond what is necessary in order to achieve that objective.⁷²

In this context, and in a form lacking substantiating arguments, assertions or claims are made that the objective of the AI Act cannot be sufficiently achieved by the Member States; due to the scale and effects of the action, the objective of the AI Act can be better achieved at the EU level; the AI Act does not go beyond what is necessary to achieve its objective; and the choice of an EU regulation is justified

70 Ibid., Point 2.3.

71 Ibid., Point 2.4.

72 Tacconi, 2017, pp. 23–41; Budianto, 2020, pp. 1339–1346.

by the need for unification. *Prima facie*, it is evident that these statements are not accidental, as under the EU primary law, they represent the conditions that must be met to comply with the principles of proportionality and subsidiarity.⁷³ To conclude that the specific conditions of these principles have been met, a thorough analysis and exhaustive evidence are necessary.

This requirement becomes even more critical when addressing an area previously unregulated by the EU, where efforts to justify any regulation should be rigorous and meticulous. However, the proponents or drafters of the AI Act deemed it sufficient to present arguments that were unsupported by analyses or studies. These arguments were based on the nature of AI, which prevents the Member States from sufficiently achieving the objectives of the Act, and the emergence of a ‘potentially’ divergent patchwork of national laws that could hinder the free circulation of AI-related products and services within the EU, while failing to ensure the protection of fundamental rights and EU values in individual Member States. Yet, no specific examples of such laws or evidence of their existence were provided, leaving an unsubstantiated claim. The assumption was that national approaches would result in additional legal uncertainty and barriers while slowing down AI’s market adoption.

Furthermore, it was forecasted that robust European regulatory AI frameworks would ensure a level playing field, protect all citizens and strengthen Europe’s competitiveness and industrial base in AI. They asserted that ‘only’ common EU action could protect its digital sovereignty⁷⁴ and leverage its regulatory tools to shape global rules and standards. The presumption was that the AI Act aligned with the principle of proportionality because it applied a risk-based approach, imposing regulatory burdens only when AI posed high risks to fundamental rights and safety. The term ‘strictly necessary’ was used to justify the legal requirements for high-risk AI systems, such as high-quality data and documentation, essential to mitigating risks to fundamental rights and safety not covered by the existing legal frameworks. However, no details were provided about which legal frameworks were being referenced.

These arguments were presented to justify compliance with the principles of proportionality and subsidiarity. Regarding the choice of an EU regulation as the legal instrument for the AI Act, additional arguments were used, which lacked substantiation as well. The need for the unification of EU law on AI was cited, which seemingly justified choosing a regulation over a directive. The role of a regulation in preventing legal diversity and ensuring a unified AI market was emphasised. It was argued that the AI Act, as a regulation, was not ‘overly prescriptive’, leaving room for multidimensional actions by the Member States, particularly regarding the internal organisation of monitoring systems and measures to support innovation. However, it was specified that these actions must not undermine the objectives of the AI Act, effectively requiring compliance with its provisions. Nonetheless, the last argument demonstrated that the Member States could not rely on the adoption of the AI Act by

73 Cannizzaro, 2002, pp. 889–916; Christodoulou, 2018, p. 16.

74 At this point, setting aside whether the EU has any sovereignty, including digital sovereignty.

the EU. Instead, they bore the responsibility to ensure its effective implementation within their national jurisdictions, including adapting their domestic laws to align with the AI Act. Thus, the last argument for choosing an EU regulation should be read through the lens of obligations imposed on the Member States rather than their legislative freedom.

The evaluation of the quality of the presented arguments highlights that they represent a low substantive standard, characteristic of a popularising publication rather than a legislative document⁷⁵ or a scientific article. All the mentions, assumptions, forecasts, premises, needs, theses and facts presented in the justification of the AI Act form a good starting point for a draft rationale; however, they should not constitute the final result. The arguments should have been supplemented with robust analyses that lent credibility to and proved their validity. Accepting the justification, as presented by the EU, would allow almost any objective to be simultaneously classified by the EU as achievable by the Member States and unachievable by them. The same applies to the principle of proportionality, as it becomes easy to state that any legal measure either goes beyond what is necessary or does not. Without thorough analysis and arguments, this justification becomes simplistic, exemplifying the Latin maxim *charta non erubescit* (paper does not blush).

This method of justifying the compliance of EU actions with the principles of proportionality and subsidiarity exhibits unacceptable arbitrariness. The arbitrariness, or even frivolity, lies in the fact that, under such rules, the EU can, at any time, issue a statement asserting that any of its actions fall within its scope and are compliant with the principles of subsidiarity, proportionality, or conferral, without presenting analyses, supporting arguments or evidence. The same applies to the reasoning behind the choice of a secondary legal act. The mechanism promoted in the AI Act appears to be insufficient and broad. Using an academic analogy, when a scholar wishes to publish their thesis in a scientific journal, they must conduct research or analysis to substantiate their claims. Without such evidence, the thesis would be deemed baseless and devoid of substantive merit. The standards that lawmakers should meet should be no lower than those applied to researchers. Therefore, if the EU declares that its actions comply with the principles outlined in Art. 5 of the TEU, it must provide proof to substantiate such a declaration.

This necessity arises because the EU, like the Member States, is bound by the primary EU law, which constitutes the foundation of its functioning. This explains why, before adopting the GDPR, the EU undertook several measures for harmonising national data protection laws, starting with an EU directive as a less intrusive measure.⁷⁶ This was intended to ensure that the EU could demonstrate its compliance with the principles of subsidiarity and proportionality. The Member States, as the creators and guardians of the EU primary law, incorporated the principles outlined in Art. 5 of the TEU into the Treaties to protect their sovereignty from unjustified

75 Staniszevska, 2019, pp. 119–128; Urbaniak, 2017, pp. 71–86.

76 Moerel, 2011a, pp. 92–110; Moerel, 2011b, pp. 28–46; Custers et al., 2018, pp. 234–243.

interference by the EU, particularly when such interference lacked supporting arguments, analyses or evidence.⁷⁷ Hence, the principles of subsidiarity and proportionality are protective in nature, outlining how the EU should exercise its competences. It is logical, purposeful and consistent with the function of these principles to assert that, since the EU is obliged under its primary law to ensure its activities comply with the principles of proportionality and subsidiarity, the burden of proving, or at least significantly substantiating or adequately justifying, this compliance lies with the EU. In other words, the burden of proof should rest with the EU, as it pertains to the actions it undertakes in the exercise of its competences.

This aligns with the general principle that the burden of proving a fact falls on the party relying on the fact to derive legal consequences.⁷⁸ Hence, when regulating AI at the EU level, the EU should conduct exhaustive analyses, present arguments, hold consultations, publish national reports and initiate discussions that are open to diverse perspectives. This is essential to comprehensively substantiate or prove that the EU's actions are justified, necessary and in compliance with the principles of proportionality and subsidiarity. Furthermore, the EU should justify the form of its potential legal acts, if issuing legal acts is indispensable in light of the need to harmonise or unify the Member States' regulations. If a legal act is warranted, the EU should assess whether a directive would suffice, as with the GDPR. Only after comprehensively substantiating or proving such necessity should the EU consider issuing a regulation, which would unify the national laws of the Member States.

In regulating AI, this process of deduction was missing. Instead, the EU directly issued a regulation (the AI Act) without substantiating or proving its compliance with the required principles. Such an approach should be negatively evaluated, despite the EU, in theory, having the authority to issue a regulation outright in certain areas. The justification for issuing an EU regulation, especially in a new regulatory area, is exceedingly challenging to substantiate concerning the compliance with the required principles. However, it is worth observing that while the issuance of an EU directive may be easier to justify, this does not mean that it can be taken lightly. In other words, issuing an EU directive must be thoroughly justified in light of the principles outlined in Art. 5 of the TEU, which cannot merely be based on the failure to meet the requirements for issuing a regulation.

The case of the AI Act illustrates a dangerous trend within the EU: the issuance of regulations without substantiating their compliance with the principles of subsidiarity and proportionality, arbitrarily unifying the Member States' laws. This is a tendency towards harmonising legal standards within the EU and a trend of unconditional unification. Hence, the issuance of the AI Act is one of the more concerning precedents, given the direct impact that EU regulations have on the sovereignty of the Member States.⁷⁹

77 Blanke and Mangiameli, 2013, pp. 255–286.

78 Adrych-Brzezińska, 2017, pp. 29–37; Ronald and Stein, 2013, p. 557.

79 Pavel, 2022, pp. 596–603; Bellamy, 2017, pp. 188–209; Mardanov, 2023, p. 128.

4.3. Lesson From History: Personal Data Protection and Medical Devices in EU

The case of regulating data protection and medical devices by the EU demonstrates a different approach to unifying legal standards across the Member States. The well-known and iconic GDPR unified data protection standards across the EU. However, before this regulation was issued and it was determined that such a measure was necessary and compliant with the principles of subsidiarity and proportionality, the area was governed by the EU's 1995 directive on the same subject (Directive 95/46/EC).⁸⁰ Hence, the EU initially issued a directive to harmonise the laws of the Member States, and after 21 years of efforts in this area, it decided to adopt a regulation as a more intrusive legal instrument. In other words, the EU tested the legal form and the provisions of Directive 95/46/EC in practice. As a result, it demonstrated that data protection required EU regulation because the objective could not be achieved by the Member States alone or because their efforts were insufficient.

To validate this justification, it was necessary to issue a less intrusive legal act, such as an EU directive, and allow sufficient time for its implementation and potential amendments. This aligned more closely with the principles of subsidiarity and proportionality. The adoption of the GDPR was further supported, albeit not primarily, by the growing importance and urgency of data protection, driven by the scale and pace of changes in the 21st century. While this was a secondary justification that supported the decision to issue an EU regulation, it was relevant and worth considering. Regarding AI, a similar rationale could apply, as the growing importance and transformative potential of AI systems provide a supporting argument. However, as with data protection, such considerations should complement, rather than replace, the substantive justification required to meet the principles of subsidiarity and proportionality.

The EU took a similar approach for regulating medical devices. Setting aside sectoral regulations, it issued a directive on active implantable medical devices on 20 June 1990.⁸¹ This was followed by a directive on medical devices on 14 June 1993, and another directive on in vitro diagnostic medical devices⁸² on 27 October 1998. These directives represented the initial step in regulating this area. After 27 years from the issuance of the first directive, on 5 April 2017, the EU adopted

80 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals regarding the processing of personal data and the free movement of such data. OJ L 281, 23 November 1995, pp. 31–50.

81 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. OJ L 189, 20 July 1990, pp. 17–36.

82 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ L 169, 12 July 1993, pp. 1–43.

two regulations repealing the aforementioned directives. The first regulation addressed medical devices,⁸³ while the second pertained to in vitro diagnostic medical devices.⁸⁴

This analysis reveals an established pattern within the EU. When the EU possesses competence and there is a necessity to regulate a specific area at the Union level, the initial approach is the adoption of an EU directive. Some directives would prove sufficient to achieve the objectives, eliminating the need for further, more intrusive legal acts. However, assuming that an EU directive will suffice is somewhat naive, as practice demonstrates that some directives fail to achieve the intended objectives. In such cases, the natural progression involves adopting a more robust legal act, including stricter regulations or an EU regulation, as a different form of secondary law. This pattern was guided by an underlying principle: not to pre-emptively issue regulations without thorough justification. Although this approach was not explicitly codified in the Treaties, it arose from the interpretation of the principles of subsidiarity and proportionality and became a customary practice.

However, in recent years, a notable shift has emerged within the EU – prioritising the unification of legal standards through regulations rather than harmonisation via directives. This is evident in new legislative areas where the EU is yet to issue secondary legal acts, such as AI. Furthermore, it extends to ‘older’ legislative areas, where directives are gradually being replaced by regulations. If this trend is not underpinned by substantive reasons, which seems difficult given its current scale, it contradicts the spirit of the Union enshrined in the Treaties.⁸⁵ It undermines the balance

83 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ L 117, 5 May 2017, pp. 1–175.

84 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. OJ L 117, 5 May 2017, pp. 176–332.

85 In addition to the previously presented examples related to data protection and medical devices, attention should be drawn to the harmonisation processes in most areas of EU legislation. For example: (1) Under the Dublin system, Regulation (EU) 2024/1351 of the European Parliament and of the Council of 14 May 2024, on asylum and migration management, amending Regulations (EU) 2021/1147 and (EU) 2021/1060 and repealing Regulation (EU) No 604/2013. OJ L, 2024/1351, 22 May 2024. (2) As part of the qualification system, Regulation (EU) 2024/1347 of the European Parliament and of the Council of 14 May 2024, on standards for the qualification of third-country nationals or stateless persons as beneficiaries of international protection, was issued. OJ L, 2024/1347, 22 May 2024. (3) As part of the procedural system, Regulation (EU) 2024/1348 of the European Parliament and of the Council of 14 May 2024, establishing a common procedure for international protection in the Union, was issued. OJ L, 2024/1348, 22 May 2024. However, while the trend towards unification applies to most areas of EU legislation, there are some exceptions. One such exception is the issuance of another directive within the reception system, where Directive (EU) 2024/1346 of the European Parliament and of the Council of 14 May 2024, laying down standards for the reception of applicants for international protection, was adopted. OJ L, 2024/1346, 22 May 2024.

between harmonisation and respect for the diversity and sovereignty of the Member States, which are protected by the principles of subsidiarity and proportionality.

5. AI Act: Legal Characterisation

5.1. Specific EU Competence – Linguistic-Logical Interpretation

As mentioned above, the EU, in adopting the AI Act, derives its general competence from Art. 4(2)(a) of the TFEU, which pertains to the internal market. However, the EU's possession of general competence in a specific area does not authorise it to adopt specific secondary legal acts. This is because the competences outlined in Art. 4 of the TFEU are of a general nature, preliminarily and abstractly indicating certain areas as being subject to the transfer of competences by the Member States. The normative nature of the TFEU's provisions concerning shared competences, interpreted through linguistic analysis based on the exegesis of the legal act and systemic and teleological interpretation, precludes the view that this abstract and general delimitation of areas results in their full transfer to the EU. A full transfer means that the EU, in such a case, would be legitimised to undertake any available activities within the subject matter of a specific area, limited only by the type of competence. However, accepting such a position appears inadmissible in light of the below-presented interpretation of Art. 4 of the TFEU.

According to Art. 4(1) of the TFEU, 'the Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Arts. 3 and 6'. The linguistic construction of this provision is intriguing, as it is based on conditional syntax. The norm in this provision, linguistically and logically, could mean that if the EU primary law confers competence on the EU in an area other than those specified in Arts. 3 and 6, such competence is shared with the Member States. If one were to assume that Art. 4(2) constitutes what Art. 4(1) defined as 'where the Treaties confer on it a competence', then Art. 4(1) would become meaningless and redundant, as a simple enumeration of shared competences would suffice. However, this approach was not taken. Instead, Art. 4(2) stated that 'shared competence between the Union and the Member States applies in the following principal areas:...', listing, for instance, the internal market, environment and area of freedom, security and justice.

Notably, the language emphasised that competences did not encompass these areas as a whole; instead, they were applied 'in the following principal areas'. Here, the use of 'in' indicated that something was contained within something else; in this context, shared competences were contained within the enumerated areas. If the Treaties drafters had intended to confer competence to the EU over the entire subject matter of the areas listed in Art. 4(2), they would likely have used a more

precise term, such as ‘within’ or ‘covering’. Moreover, the term ‘principal areas’ suggested that these were general, broad or abstractly defined domains, without specific subject-matter delineation within Art. 4. This interpretation effectively precluded treating this provision as an independent basis for detailed EU competences. The phrase ‘Shared competence [...] applies in the following principal areas: ...’ emphasised that shared competences applied to the principal areas listed in Art. 4(2); instead of the shared competences being those areas. Hence, linguistically and logically, the areas indicated in this provision are domains for the application of shared competences, framed as matrices for their potential use, and not competences in and of themselves.

Combining the observations concerning the terms ‘in’, ‘principal areas’ and ‘applies in’ concludes that the EU Treaty drafters constructed this provision with the linguistic and logical intent that shared competences do not encompass the areas listed in Art. 4(2) of the TFEU in their entirety. Instead, shared competences pertain to parts of those areas, which must be further specified in subsequent Treaty provisions concerning the subject matter of a particular shared competence applied within one of the principal areas of Art. 4(2). This interpretation is reinforced by the use of ‘competence’ twice in Art. 4(1). According to this provision, ‘The Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Arts. 3 and 6’. If the meaning of ‘competence’ were identical in both instances, the provision would not need to use the term twice. A simpler construction could either state, ‘The Union shall share competence with the Member States within areas indicated in para. 2’, or consolidate the paragraphs and declare that the EU has shared competences over the entirety of the listed areas.

However, this approach was not taken, and the current wording of Art. 4(1) included a condition. The provision explicitly states that the EU has shared competences on the condition that the Treaties confer such competences, while para. 2 of the same Art. specifies the principal areas in which such competences are applied. In other words, Art. 4(2) legitimises the potential for specifying the subject matter of detailed EU competences. Hence, the first use of ‘competence’ refers to the EU’s general competences, and the second use refers to its specific competences. Therefore, a linguistic-logical interpretation reveals that the EU Treaty drafters did not use the term ‘competence’ uniformly in Art. 4. Instead, the meaning of this provision should be as follows: the EU shares competences with the Member States in the principal areas listed in Art. 4(2) (general EU competences) provided that further Treaty provisions specify the subject matter of these general competences by conferring specific competences on the EU.

Considering that the objectivity of research and scientific analysis is paramount, additional steps should be undertaken to verify the result achieved through the linguistic-logical method. Given that the linguistic interpretation of Art. 4 may evoke strong reactions, mainly because it diverges from the mainstream interpretative approach commonly presented within the EU, it is necessary to refer to systemic and

teleological interpretations. These can either refute or reinforce the validity of the result obtained.

5.2. Specific EU Competence – Systematic Interpretation

Based on systemic interpretation, it is essential to refer to the structure of the TFEU as the EU treaty that contains the relevant provisions regarding the conferral of specific competences by the Member States in substantive areas. The systematic structure of the TFEU is organised as follows: Part One includes Title I, ‘Categories and Areas of Union Competence’, and Title II, ‘Provisions Having General Application’. Part Two addresses ‘Non-Discrimination and Citizenship of the Union’. Part Three is dedicated to ‘Union Policies and Internal Actions’ and is subdivided into 24 titles: The Internal Market; Free Movement of Goods; Agriculture and Fisheries; Free Movement of Persons, Services and Capital; Area of Freedom, Security and Justice; Transport; Common Rules on Competition, Taxation and Approximation of Laws; Economic and Monetary Policy; Employment; Social Policy; The European Social Fund; Education, Vocational Training, Youth and Sport; Culture; Public Health; Consumer Protection; Trans-European Networks; Industry; Economic, Social and Territorial Cohesion; Research and Technological Development and Space; Environment; Energy; Tourism; Civil Protection; and Administrative Cooperation.⁸⁶ Following Arts. 3, 4, 5 and 6 of the TFEU, it becomes clear that the titles correspond directly, or indirectly, to the areas indicated in these provisions, which characterise the categories and areas of EU competences.

The linguistic interpretation of Art. 4 of the TFEU suggests that the structure of the TFEU should be understood as Part One, Title I referring to general competences, while the subsequent parts and titles specify the ‘principal areas’ by setting out detailed competences. For instance, Art. 4(2)(j) states that one of the principal areas is the ‘area of freedom, security and justice’. This is also the title of Title V in Part Three, which contains Arts. 67 to 89. Hence, we understand that the competence referred to in Art. 4(2)(j) is confined to a specific subject matter that outlines the possible and concrete actions the EU may take in this area. These actions pertain to policies on border checks, asylum and immigration, judicial cooperation in civil matters, judicial cooperation in criminal matters and police cooperation. Hence, we understand the actual subject matter of the principal area referred to as the ‘area of freedom, security and justice’ and the specific actions for which the EU is empowered.

Furthermore, under Art. 77(2), the EU has been granted specific competence to adopt measures, acting under the ordinary legislative procedure, concerning the common policy on visas and other short-stay residence permits, the checks to

⁸⁶ Cherchye et al., 2007, pp. 749–779; Greer and Jarman, 2021, pp. 23–47; Vickerman, 1995, pp. 237–254; Giubboni, 2007, pp. 360–379; Hofmann, 2013, pp. 24–38; Minor, 2012, pp. 163–168; Ekengren et al., 2006, pp. 457–476.

which persons crossing external borders are subject, the conditions under which nationals of third countries shall have the freedom to travel within the Union for a short period, any measure necessary for the gradual establishment of an integrated management system for external borders and the absence of any controls on persons, irrespective of their nationality, when crossing internal borders. These EU competences are defined precisely and concretely. Without such specifications, the principal area indicated in Art. 4(2)(j) would lack the actual subject matter of EU competence, which should preclude the adoption of legal acts, as outlined in detailed provisions. Furthermore, without such specification, the areas listed in Art. 4(2) would have to be regarded merely as programmatic norms, lacking the element necessary to constitute a basis for the EU to take specific actions, particularly in the TFEU's current structure. In other words, without Art. 77(2), the EU would not be authorised to adopt, for instance, secondary legal acts relating to the checks to which persons crossing external borders are subject, even though 'area of freedom, security and justice' is listed as a principal area in Art. 4(2)(j). This is because, as confirmed by the linguistic-logical interpretation, the TFEU's structure indicates that the principal areas listed in Art. 4(2) require the EU to possess specific competences (detailed competences), as defined in subsequent treaty provisions, to act within those areas. Hence, the result of the systemic interpretation concerning the structure aligns with and supports the linguistic-logical interpretation.

5.3. Specific EU Competence – Teleological Interpretation

Accounting for the complementary linguistic-logical and systemic interpretations, it is possible to refer to the arguments based on teleological interpretation. This interpretation of Art. 4 of the TFEU is challenging, as it relies on the intent of the creators of the EU primary law. Legally, under international law, these creators are the Member States. Decoding their intent is difficult, as such analyses are based on assumptions. This approach seems inappropriate, mainly due to the interpretative difficulties that make such assumptions less reliable, and their scientific utility is often questioned. Therefore, would be more accurate to refer to the function that a particular legal norm is intended to serve. However, even in this case, we may encounter vague concepts with undefined scope, unless the function of the specific legal norm is indisputable.

Concerning Art. 4 of the TFEU, assumptions about an indisputable function could be considered hasty or biased. In such cases, it is necessary to rely on linguistic-logical and systemic interpretations. Since their results are known, the teleological interpretation would either definitively confirm their conclusions or cast doubt upon them. Therefore, it is necessary to refer to the function of another legal norm whose purpose is indisputable and try to infer, based on this, the function of Art. 4. In this context, it is noteworthy that the function of Art. 5 of the TEU is fundamentally clear. Its purpose is to guarantee, by the Member States for the Member States, that the EU will act only within the scope of the competences conferred upon it and, in cases

where such competences are conferred, it will act subsidiarily (except for exclusive competences) and proportionally. This raises the question whether the EU has competence to regulate AI, making the principle of conferral of central importance.

Concerning Art. 4(1) of the TFEU and Art. 5(2) of the TEU, the principle of conferral establishes that the EU ‘shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein’ and creates a legal presumption. This presumption holds that in cases of doubt as to whether a particular competence has been conferred upon the EU, it must be concluded that such competence has not been conferred. This would counteract the phenomenon of ‘competence creep’.⁸⁷ This presumption is based on the general principles of public international law concerning national sovereignty or conclusions regarding state sovereignty, tied to the natural prerogatives of exercising public authority. Furthermore, it rests on the rule repeated twice in the TEU, in Arts. 4 and 5, that ‘competences not conferred upon the Union in the Treaties remain with the Member States’.

Adopting the protective character of the principle of conferral and the legal presumption embedded within it is crucial for determining the function of Art. 4 of the TFEU, especially because the drafters of both the TEU and TFEU are the Member States, as a unified actor. Thus, assigning a specific function to Art. 4 of the TFEU must align with the unified spirit of the Treaties, as expressed in the legal norms crafted by the Member States. If the Member States chose to define Art. 5 of the TEU in a protective manner regarding themselves and framed the principle of conferral as a safeguard, then treating Art. 4 of the TFEU as an open gateway for competences, not requiring further specification in subsequent treaty provisions in the form of detailed competences, would be illogical. Moreover, this approach would undermine the real significance and impact of the principle of conferral. To interpret Art. 4 of the TFEU in a manner inconsistent with the linguistic-logical and systemic interpretations would lead to a fundamental inconsistency between Art. 5 of the TEU and Art. 4 of the TFEU. However, such inconsistency cannot exist, as the EU Treaties, forming a single legal framework, must be treated as a cohesive and consistent whole.⁸⁸ This coherence and consistency can only be achieved if the functions of Art. 5 of the TEU and Art. 4 of the TFEU complement each other. However, if one denies the protective and safeguarding nature of Art. 5 of the TEU, which influences the understanding of the function of Art. 4 of the TFEU, then either the function of Art. 5 must be interpreted through the lens of Art. 4, or vice versa. To resolve any doubts arising from such an interpretative dilemma, it is necessary to refer to the normative character of the TEU and TFEU. The TEU defines the foundations of the EU, as established in Art. 1:

87 Prechal, 2010, pp. 5–22; Fisicaro, 2022, pp. 334–356; Garben, 2020, pp. 429–447; De Witte, 2015, pp. 434–457.

88 Duic, 2015, p. 537; Gauttier, 2004, pp. 23–41; Franklin, 2011, pp. 42–85.

By this Treaty, the High Contracting Parties establish among themselves a European Union, hereinafter called 'the Union', on which the Member States confer competences to attain objectives they have in common. This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.

Hence, the TEU is constitutive for the entire EU. The TFEU defines far more procedural and formal aspects of the EU's functioning, as stated in Art. 1: 'This Treaty organises the functioning of the Union and determines the areas of, delimitation of, and arrangements for exercising its competences'. Thus, the TFEU has an executive character for the EU.

Nonetheless, to negate potential counterarguments, this does not conclude that these instruments have different legal weight. Such reasoning is excluded under Art. 1 of the TEU and TFEU, which contain the same provision: 'These two Treaties, which have the same legal value, shall be referred to as the Treaties'. However, there is a distinction between the legal value and method of interpreting the norms contained in the TEU and TFEU, which relies on their mutual coherence and consistency. Both treaties, with the same legal value, must be interpreted as a whole.

A comprehensive view of the EU's treaty system leads to the observation that Art. 5 of the TEU establishes legal principles, whereas Art. 4 of the TFEU does not possess such normative significance. Legal principles, by encapsulating a fundamental goal, establish guiding ideas for the legal system, determining the interpretation and meaning of other types of legal norms.⁸⁹ Such a perception of Art. 5 of the TEU aligns fully with its protective and safeguarding essence and constitutive nature. This unequivocally means that even if the argument about the protective and safeguarding character of Art. 5 of the TEU is not accepted, the function of Art. 4 of the TFEU, concerning shared competences, should be understood through the lens of the legal principles established in Art. 5 of the TEU, including the principle of conferral. This implies that the objectives of Art. 4 of the TFEU and Art. 5 of the TEU cannot conflict. This teleological interpretation provides compelling arguments that support the linguistic-logical and systemic interpretations of Art. 4 of the TFEU.

5.4. Legal Basis of the AI Act

The AI Act was adopted with reference to the TFEU, particularly Arts. 16 and 114. It is in these two provisions that the EU identifies its specific competence to regulate AI. This is legally significant because, as demonstrated above, the possession of general competence, such as that outlined in Art. 4(2)(a) of the TFEU, is insufficient.

⁸⁹ Akehurst, 1976, pp. 801–825; Goldman, 1987, pp. 113–125; Lammers, 1980, pp. 53–75.

Art. 16 relates to the protection of personal data within the EU.⁹⁰ It emphasises that everyone has the right to the protection of personal data and the EU has the competence to establish rules concerning the protection of individuals regarding the processing of personal data by EU institutions, bodies, offices and agencies, and by the Member States when carrying out activities within the scope of the EU law. It sets out principles for the free movement of such data, and stresses that compliance with these rules is subject to control by independent authorities. Art. 16 was the primary legal basis for adopting the GDPR. Regarding the AI Act, as the European Commission pointed out in its Explanatory Memorandum accompanying the legislative proposal for the AI Act:

In addition, considering that this proposal contains certain specific rules on the protection of individuals with regard to the processing of personal data, notably restrictions of the use of AI systems for ‘real-time’ remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this regulation, in as far as those specific rules are concerned, on Art. 16 of the TFEU.

Hence, within the scope indicated by the Commission, Art. 16 contains a specific EU competence to regulate issues related to data protection within a defined subject matter. Consequently, it can serve as the legal basis for any EU secondary law that includes data protection. Given that certain provisions of the AI Act pertain to data protection, citing Art. 16 as the specific legal basis for the AI Act appears justified.

However, Art. 114, as a legal basis for the AI Act, is particularly interesting.⁹¹ It pertains to the approximation of Member States’ legislation. According to Art. 114(1):

Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Art. 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

The referenced Art. 26 lays the groundwork for defining the EU’s specific competences in the area of ‘The Internal Market’. According to Art. 26, (1) The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties, (2) The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the

⁹⁰ Hijmans and Hijmans, 2016, pp. 511–564.

⁹¹ Van Cleynenbreugel, 2014, pp. 64–88; Varju, 2020, pp. 471–486.

provisions of the Treaties and (3) The Council, on a proposal from the Commission, shall determine the guidelines and conditions necessary to ensure balanced progress in all the sectors concerned.

Hence, the use of Art. 114 as the legal basis for the AI Act seems inappropriate. The Art. may serve as a subsidiary, yet not an independent, legal basis for adopting legislation on matters related to the internal market. This is only permissible to the extent that the Treaties, specifically through the existence of a specific competence, authorise the EU to do so. Similarly, Art. 26, referenced in Art. 114, cannot serve as an independent basis for adopting the legislation. The wording of these provisions indicates that they do not contain specific competences for concrete EU actions. Such provisions are important; however, they serve as a subsidiary basis for general competences, offering additional detail, yet not enough to constitute a source for adopting legislation on matters not specified in other primary EU law provisions. Accepting a different interpretation would encounter the same objections raised regarding the interpretation of Art. 4 of the TFEU as an open competence gateway.

Hence, Art. 26 should be understood as a provision initiating the specification of the scope of the EU's detailed competences in the area of the internal market. Art. 26(1) authorises the EU to adopt legal measures for the establishment and functioning of the internal market, while Art. 26(2) contains a legal definition of the internal market. This definition states that the internal market, in simplified terms, refers to the free movement of goods, persons, services and capital across national borders. However, both paras. 1 and 2 of Art. 26 refer to the necessary specification of competences through further treaty provisions. This specification occurs in Part Three of the TFEU, particularly in Title II: Free Movement of Goods⁹² and Title IV: Free Movement of Persons, Services and Capital,⁹³ which provides further examples of such provisions, including Arts. 34 and 47 of the TFEU.

Art. 34 prohibits quantitative restrictions on imports and any measures having an equivalent effect between the Member States. According to Art. 47, the Member States promote the exchange of young workers as part of a joint program. These provisions establish specific EU competences, yet do not directly confer authority on EU institutions to adopt secondary legislation. However, some provisions in the specified titles of the TFEU include such authorisation. For example, Art. 48 of the TFEU grants the EU a specific competence to adopt legislation in the field of social security. Assuming that only provisions like Art. 48 create specific EU competences enabling legislative action would render several provisions in Part Three, Titles II and IV incomplete specific competences. Such competences would not provide a basis for the EU's legislative action. Legally, this would indeed be the case if not for Art. 114 of the TFEU.

Art. 114 functions as a corrective provision, transforming incomplete specific competences into fully actionable ones, yet only within the strictly defined subject

92 Weatherill, 2012, pp. 541–550; Akkermans and Ramaekers, 2013, pp. 237–266.

93 Connor, 2010, pp. 159–209; Leemann, 2018, pp. 857–876.

matter of the internal market, as determined by the provisions in Part Three, Titles II and IV of the TFEU. An alternative interpretation would treat Art. 114 as an open competence gateway, which cannot be considered valid under Art. 5 of the TEU or the arguments previously presented regarding the interpretation of Art. 4 of the TFEU. Additionally, Art. 114 pertains to the approximation of the Member States' legislation rather than the unification of legal standards across the EU. Therefore, even if it applies under the Treaties, it leads to the adoption of directives rather than regulations, particularly in new areas without a legislative history in the EU.

Hence, the AI Act was issued on an incorrectly identified legal basis. This is not surprising, as the Treaties lack a provision authorising the EU to regulate AI, even if AI is treated as a service or a good. Although AI can be a good or a service, it can exist as intangible software, falling outside these categories. There is no suitable legal basis in Titles II or IV of Part Three of the TFEU granting the EU a specific competence to regulate AI. In other words, the Treaties do not provide a legal basis for the AI Act, meaning its adoption violated the principle of conferral, which, alongside the principles of subsidiarity and proportionality, forms one of the EU's foundational principles. This has implications for the equality principle outlined in Art. 4 of the TEU as well.

Additionally, the subject matter of the AI Act (as outlined in its table of contents: General Provisions; Prohibited AI Practices; High-Risk AI Systems; Transparency Obligations for Providers and Deployers of Certain AI Systems; General-Purpose AI Models; Measures in Support of Innovation; Governance; EU Database for High-Risk AI Systems; Post-Market Monitoring, Information Sharing, and Market Surveillance; Codes of Conduct and Guidelines; Delegation of Power and Committee Procedure; Penalties; and Final Provisions) demonstrates that it does not exclusively pertain to the area specified in Art. 4(2)(j) of the TFEU, which grants the EU general competence to regulate AI. This is because the AI Act addresses more than AI-related issues. From the perspective of the internal market, it touches on several other matters, including the protection of fundamental rights, ethics and morality. This observation aligns with the objectives of the AI Act, as stated in its Art. 1:

The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Hence, even if Art. 114 was considered an independent legal basis under the Treaties, it would remain insufficient for the AI Act. This conclusion does not change with the inclusion of Art. 16 of the TFEU as a part of the legal basis for the AI Act, as it pertains exclusively to the protection of personal data and does not extend to other issues addressed by the AI Act.

6. AI Act vs. Principle of Equality

6.1. Introduction

In light of all the above analyses and discussions, it is important to address the relationship between the AI Act and the principle of equality among the EU Member States. The considerations can be divided into two groups. The first group pertains to general arguments of a systemic nature, focusing on issues of competence. This analysis highlights the significance, role and impact of the AI Act on the current perception of the relationship between the EU and its Member States. However, these arguments will refer to the principles and essence of the EU law, including the EU's position as determined by public international law, notably the primary EU law. The demarcation in this case is the adoption of the AI Act, particularly its entry into force. The second group concerns arguments related to the potential effects of the AI Act's practical application. This group is significant for the relationships among the Member States. Hence, the first group can be referred to as systemic legal determinants, while the second group can be called operational effects of the application.

Although the equality principle in Art. 4(2) of the TEU has been discussed, it is necessary to recall its most important elements.⁹⁴ This principle obligates the EU, as is evident from its wording, which is clear and does not require additional legal interpretations.⁹⁵ The EU is obligated to respect the equality of the Member States concerning the Treaties, and their national identities, which are inextricably linked to their political and constitutional structures, including regional and local self-government. Hence, under this provision, the Member States are to be treated equally, instead of the Member States and the EU. As noted, the EU is not a beneficiary of Art. 4(2) but rather its addressee. Even if one were to accept that the EU has gradually, through treaty changes and in accordance with them,⁹⁶ evolved into a *sui generis* international organisation,⁹⁷ this does not alter the fact that its role should not be to lead or eliminate the diversity of the Member States. Rather, its role is to proportionately and subsidiarily support the development of the Member States according to the principles of conferral.

The EU must respect the fundamental functions of the Member States, particularly those ensuring territorial integrity, maintaining public order and protecting national security, with national security being the exclusive responsibility of each Member State. Therefore, it is clear that the EU is obligated to respect the fundamental

94 Wouters, Schmitt, 2017, pp. 43–82; Rossi, 2017, pp. 3–42.

95 Choduń, 2014, pp. 134–140; Grabowski, 2015, pp. 67–97.

96 This refers to amending treaties, such as Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts (OJ C 80, 10.3.2001, pp. 1–87); Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts (OJ C 340, 10.11.1997, pp. 1–144).

97 Klabbers, 2016, pp. 1–15.

functions of the Member States, which, in conjunction with the principles outlined in Art. 5 of the TEU, portrays the EU as an entity obliged to ensure equality while adhering to firmly established standards that set boundaries for its actions. Thus, while the equality principle, in its entirety, might suggest equality across the EU, the principle of equality among Member States, as defined in Art. 4(2), assigns specific roles and positions to the Member States and the EU separately. In this arrangement, the EU is the obligated entity serving the Member States, a view supported by Art. 4(1) of the TEU.

6.2. Group I: Systemic Legal Determinants

In the analysis of systemic legal determinants, and in light of a comprehensive evaluation, it is reasonable to assert that the AI Act does not uphold the equality principle in the EU as presented above, particularly regarding the relationship between the EU and its Member States. This excludes, in principle, its impact on the relationship among the Member States, where the analysis of operational effects of application will be more relevant. However, this division is not rigid, as the actual functioning of the EU indicates that some Member States exert a strong guiding influence on the forms, directions and values of EU actions. This can lead to the conclusions of the analysis of systemic legal determinants being applicable to the relationship among the Member States. This is because a strong guiding influence ties the relational position of the Member States to the EU's position and status. Hence, it is not surprising that, for some Member States, a strong EU represents a beneficial solution. Nonetheless, leaving aside this fact – mainly because, from a legal perspective, it remains imperceptible and unproven – it is necessary to present several arguments supporting the validity of the thesis proposed above.

It is undeniable that there is a need for legal regulation of AI.⁹⁸ The essence, definitions and subject matter of AI indicate the need for effective and well-thought-out legal solutions, particularly for cross-border situations.⁹⁹ However, the goal does not justify all the means, particularly actions that conflict with the principles and rules of the legal system in general and the EU legal system. The current EU legal framework is founded on and determined by the Lisbon Treaty,¹⁰⁰ which, on the one hand, opened the EU to a new stage of integration but, on the other hand, effectively halted changes to the primary EU law until the adoption of a new treaty or treaties.¹⁰¹ Hence, EU actions regarding AI that go beyond the boundaries of EU primary law, regardless of the existing need, constitute a violation of the equality principle

98 Selvakumar, 2022, pp. 186–195.

99 Regarding the cross-border case: Bu-Pasha, 2017, pp. 213–228.

100 Lisbon Treaty amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007 (OJ C 306, 17.12.2007, pp. 1–271); Reh, 2009, pp. 625–650; Biernat, 2011, pp. 279–296.

101 European Parliament, 2023, Resolution of 22 November 2023 on proposals of the European Parliament for the amendment of the Treaties.

of Art. 4(2) of the TEU. They undermine the autonomy and constitutional identity of the Member States by interfering in areas that, according to the treaties, remain within national competence. This encroachment can result in unequal treatment of the Member States concerning their sovereign right to regulate critical technological issues, such as AI, per their legal principles and constitutional values,¹⁰² which inherently require respect for diversity.¹⁰³

Directly connected to the first argument, the AI Act was adopted without the EU possessing a specific competence to do so. While the EU holds general competence to regulate the internal market, provisions such as Arts. 4, 26 and 114 of the TFEU do not grant it the authority to adopt secondary legislation concerning AI. Such authority can only be derived from explicit competences concretised in the EU primary law. The EU's adoption of the AI Act without a proper legal basis constitutes a blatant violation of EU law, particularly the principle of equality under Art. 4(2) and the principle of conferral in Arts. 4(1) and 5(2). The EU's reliance on false legal grounds to inadequately justify the adoption of the AI Act should be seen in the context of 'competence creep'. However, this does not mitigate the negative assessment and consequences of the EU's actions. The breach of the equality principle lies in the total disregard for the fundamental functions of the Member States and the limits of competences conferred on the EU by them. By undertaking such actions, the EU seeks to reverse the equality principle under Art. 4(2), attempting an extra-legal and *de facto* attribution of a leading role over the Member States. Such conduct must be deemed unacceptable and contrary to the rule of law.¹⁰⁴

The AI Act was issued as an EU regulation without complying with the principles of subsidiarity and proportionality. The lack of a well-founded and substantive analysis, providing arguments that either prove or strongly substantiate such compliance, results in a violation of Art. 5 of the TEU but renders the decision to adopt this form of legal act arbitrary. The legislative mechanism employed by the EU may justify the assertion that, by exhibiting an impermissible degree of discretion, it breached the treaty principles governing its use of competences. The adoption of a legal act as an EU regulation, particularly in a new legislative area, should be accompanied by compliance with the principle of subsidiarity (outside exclusive competences) and proportionality. In the AI Act, this essential element is missing. Given that the EU is obligated to demonstrate the compatibility of its actions with the limits and use of its competences, the absence of this justification results in the allegation of unlawful action and has significant implications for the equality principle. It breaches the fundamental functions of the state, one of which is the sovereign and autonomous determination of the scope and manner of the exercise of competences delegated to an international organisation.¹⁰⁵

102 Wielec, 2017, pp. 53-68.

103 Joos and Lang, 1994, pp. 141-168.

104 Varga, 1995, p. 183; Varga, 2021, pp. 245-278.

105 Tóth, 2023, pp. 175-195; Karakamisheva-Jovanovska, 2023, pp. 69-94.

EU activities that are inconsistent with, or unjustified in compliance with, the principles of proportionality and subsidiarity, such as the unjustified issuance of a legal act or the unwarranted adoption of a regulation instead of a directive, limit the manner in which Member States exercise their competences, indirectly affecting their scope. Such actions can result in a reversal of the intent behind the principles of proportionality and subsidiarity, as enshrined in Art. 5 of the TEU. These arguments conclude that, from the perspective of the systemic legal determinants, the adoption of the AI Act in this manner, form and on such a legal basis was legally inadmissible.

6.3. Group II: Operational Effects of the Application

Turning to the arguments belonging to the operational effects of the application, it should be noted that these will pertain to the potential consequences of applying the AI Act. This means that such arguments will not account for the arguments presented under the first group, systemic legal determinants. To discuss the operational effects of the application, it must be acknowledged that the AI Act has been adopted and is currently an operative piece of secondary EU legislation. In this context, considering the analysis conducted in this chapter, it is reasonable to assert that the application of the AI Act could have serious negative implications for the equality principle under Art. 4(2) of the TEU, particularly regarding ensuring equality among the Member States.

The regulations contained in the AI Act have been adopted as an EU regulation, constituting binding laws directly applicable in all the Member States. The Act applies uniformly to all the Member States, obligating them to comply and treating them equally. However, equal treatment in this context does not necessarily align with the equality principle.¹⁰⁶ This is because the Member States are not identical; in other words, they are diverse.¹⁰⁷ The AI Act's approach to treating the Member States equally fails to recognise their inherent diversity. Consequently, uniform treatment of diverse Member States may exacerbate existing inequalities. This outcome is unsurprising, as the AI Act was adopted as a binding EU regulation, devoid of compensatory mechanisms that account for varying economic and technological advancements across the Member States. Regulations, by their nature, do not favour the respect for diversity, which is a core component of the equality principle. An important related provision is Art. 27 of the TFEU, which mandates the European Commission, when drafting proposals to achieve the objectives outlined in Art. 26 of the TFEU, to consider the level of effort required from economies with varying levels of development to establish the internal market.

Had the AI Act been adopted as an EU directive, the diversity of the Member States would have been safeguarded through their own implementation of the directive's

¹⁰⁶ Callinicos, 2000; Williams, 2016, pp. 135–140.

¹⁰⁷ Cerna, 2013, pp. 180–200.

objectives, retaining flexibility in choosing the means to achieve them. However, since the AI Act was adopted as a binding EU regulation, directly effective in the Member States and not accommodating their diversity, it may lead to increasing disparities, particularly in economic and technological domains. In this context, the choice of legal instrument is crucial. While EU directives allow for the consideration of Member States' diversity, regulations do not inherently facilitate such consideration, though it is not impossible. Unfortunately, the AI Act, in its current form, does not incorporate these considerations.

Complementing the first argument, it is necessary to highlight specific provisions of the AI Act that may contribute to increasing inequalities. Art. 70 of the AI Act obliges the Member States to designate at least one notifying authority and one market surveillance authority. It further requires the Member States to provide these authorities with adequate technical, financial and human resources, and the infrastructure necessary to effectively carry out the tasks assigned under the AI Act. Art. 57 of the AI Act mandates that the Member States ensure that their competent authorities establish at least one regulatory sandbox for AI at the national level.¹⁰⁸ This sandbox must be operational by 2 August 2026. Although such regulatory sandboxes may be established jointly by more than one Member State, according to Art. 3, Point 55 of the AI Act, they should provide AI system providers or potential providers with the opportunity to develop, train, validate and test innovative AI systems based on a sandbox action plan, within a limited timeframe and under regulatory supervision.

Art. 62 of the AI Act outlines measures for providers and deployers, particularly small and medium enterprises, including start-ups. Under this regulation, the Member States are obligated to ensure that small and medium enterprises have access to regulatory sandboxes under the AI Act, provided they meet the qualification requirements and selection criteria. Moreover, it mandates the Member States to organise informational and training events tailored to the application of the Act's provisions, addressing the needs of small and medium enterprises, start-ups and local public authorities. Furthermore, it requires the Member States to utilise existing special communication channels or establish new ones as necessary to provide guidance and respond to small and medium enterprises' inquiries regarding the implementation of the AI Act. It obliges the Member States to facilitate small and medium enterprises and other relevant stakeholders in the development of standards.

Art. 71 of the AI Act obliges the European Commission, in cooperation with the Member States, to create and maintain an EU database containing information about high-risk AI systems registered under Arts. 49 and 60 of the AI Act, and AI systems not deemed high-risk under Art. 6(3) and registered under Arts. 6(4) and 49. While the European Commission is identified as the responsible entity, the obligation specifies that this task must be carried out in collaboration with the Member States, meaning that the national segment will lie with the Member States, from whom the

108 Buocz, Pfothenhauer and Eisenberger, 2023, pp. 357–389.

European Commission will require cooperation. This demonstrates the significant obligation foreseen for the Member States under this Art..

These examples lead to interesting conclusions about the practical implications of applying and implementing the AI Act concerning the equality principle. They raise concerns, as the AI Act lacks compensatory mechanisms that account for varying economic and technological advancement levels across the Member States. Addressing this issue requires answering the question of what the consequences might be of treating all the Member States uniformly, without considering their diversity. This uniform approach could exacerbate disparities in technological resources. Member States with higher economic and technological development will adapt more efficiently and swiftly to the AI requirements, while less advanced Member States may face significant difficulties in implementing the Act's full scope and meeting additional obligations.

Furthermore, it could hinder innovation in economically and technologically weaker Member States. The implementation of relatively stringent legal regulations might leave such Member States unable to provide the same level of financial, technological and advisory support as their more developed counterparts. This could influence entrepreneurs' decisions about where to launch their businesses and impact national technological advancements. It might lead to the centralisation of the AI market, negatively affecting the business competitiveness in certain Member States. Moreover, it could result in dependence on foreign technology providers. Member States unable to develop their own AI technologies may be forced to import solutions from technologically advanced Member States, potentially leading to dependency and, over time, a reduction in technological sovereignty. These considerations indicate that the equal treatment of the Member States may not necessarily ensure equality, given their cultural, national, constitutional, economic and technological differences.

In such cases, the equality principle must acknowledge diversity and avoid uniform standards. Instead, requirements should be tailored to developmental needs and capabilities to ensure a balanced technological and economic advancement across the EU, regardless of geography. The equality principle calls for sharing resources, knowledge, experience and technology to support the Member States in need, preventing them from falling behind. Hence, achieving true equality may require differentiated treatment based on developmental needs. Furthermore, the above examples of regulations imposing additional, albeit extensive, obligations on the Member States are just a part of their responsibilities. The fundamental duty of every Member State is to implement the AI Act by aligning national laws to ensure its effectiveness. For instance, in Poland, a draft law on AI systems is currently being processed. It aims to introduce regulations for applying the European Parliament and Council Regulation (EU) 2024/1689 of 13 June 2024 on harmonised rules concerning AI and amending related EU regulations, referred to as the '2024/1689 Regulation'

or the ‘AI Act’. The draft law is designed to enable the direct application of certain provisions (Chapters I, II, III (Section 4), V, VII, IX and XII) of the AI Act.¹⁰⁹

The AI Act grants the European Commission the authority to issue delegated acts, as provided in its Art. 6, paras. 6 and 7, Art. 7, paras. 1 and 3, Art. 11, para. 3, Art. 43, paras. 5 and 6, Art. 47, para. 5, Art. 51, para. 3, Art. 52, para. 4 and Art. 53, paras. 5 and 6. According to Art. 96, para. 2 of the AI Act, the European Commission has this authority for a period of five years, starting from 1 August 2024. However, pursuant to Art. 96, para. 3, this authority may be revoked at any time by the European Parliament or the Council through a decision. The mechanism for adopting delegated acts by the European Commission could lead to negative consequences concerning the principle of equality among the Member States. This is because it may result in the Member States losing control over the direction of changes in EU law and being deprived of the ability to represent their national interests. In practice, this could lead to the marginalisation of less politically influential Member States or those with lower economic or technological levels, where the possibility of opposition by the European Parliament or the Council, under Art. 97, para. 6, may prove insufficient. There is no equality mechanism ensuring that the European Commission exercises its powers in accordance with Art. 4, para. 2 of the TEU, particularly respecting national identity, which is closely linked to national interest. The risk of marginalisation of less influential Member States and the potential deepening of inequalities could raise doubts about the compliance of this mechanism with the equality principle and the EU’s fundamental values.¹¹⁰

7. Conclusions

It is not true that the AI Act lacks legislative measures that can be assessed in terms of benefits, including benefits for the Member States. For instance, the AI Act addresses threats specifically related to AI applications, prohibits AI practices that pose unacceptable risks, establishes requirements for high-risk AI systems, specifies detailed obligations for entities implementing and supplying high-risk AI applications, mandates conformity assessments before an AI system is deployed or placed on the market, introduces enforcement measures after an AI system is placed on the market and establishes governance structures at European and national levels. All of this constitutes the benefits of the AI Act for the EU Member States, including their citizens. However, as demonstrated, there are costs borne by the Member States for such a defined common legal regime.

109 Government of Poland, n.d., Draft Bill on Artificial Intelligence Systems (Project Number: UC71).

110 Williams, 2009, pp. 549–577.

One such cost is the deviation from or abandonment of the equality principle in Art. 4(2) of the TEU. Another significant cost is the EU's non-compliance with the protective principles in Art. 5 of the TEU, namely the principles of conferral, subsidiarity and proportionality. The adoption of the AI Act, in some instances, even leads to conclusions about a reversal of these principles. It is worth noting that this is not the case for the principle of equality and the principles under Art. 5. Their relationship is close; a violation of one of these provisions often results in a violation of the others as well. Therefore, by adopting the AI Act, the EU targeted its foundations, legal principles and values. Through the adoption of the AI Act, particularly regarding the rationality of the chosen legal instrument and the lack of a legal basis, the EU acts beyond its conferred competences, disproportionately, without regard for subsidiarity and in violation of the equality principle. This is the greatest cost that the Member States must bear for the establishment of a common AI regulatory regime.

The consequences appear even worse, as it would mean accepting that the EU can act in any area of competence of the Member States ('principle' of appropriation), not always adhering to the principles of proportionality and subsidiarity, without respect for their equality before the Treaties, their national identity, which is inseparably linked to their political and constitutional structures, including regional and local self-government, and respect for the essential functions of the Member States. Perhaps such a vision is exaggerated at this moment; however, an overt violation of the fundamental principles expressed in the EU primary law is a step towards recognising the supremacy of the EU and transforming it into an entity operating in the spirit of federalism,¹¹¹ without respect for the diversity and sovereignty of the Member States.

In this context, the AI Act represents another powerful measure in the EU's arsenal for subordinating the actions of the Member States to the dictates of the EU or certain Member States, which, by influencing EU operations, carry out their national functions through the Union's administration. Incidentally, for such Member States, the breach of the equality principle or the principles outlined in Art. 5 might not have negative consequences. On the contrary, it may positively influence their position within the EU. For example, a departure from the equality principle logically results in some Member States being placed higher than the others. Such a situation may resemble the concept of a multi-speed or a two-speed Europe.¹¹² Adopting a different interpretation seems challenging, particularly concerning the violation of EU primary law in the adoption of the AI Act. While answering the question of whether the loss of equality and other principles has been a fair price to pay for the benefits of a common EU AI regime, the analysis leads to a negative conclusion.

The EU, to regulate AI thoroughly and in compliance with its primary law, should notify the Member States of the need to amend the TFEU in a manner that the TFEU

¹¹¹ Loughlin, 1996, pp. 141–162.

¹¹² Prisecaru, 2017, pp. 54–61.

would foresee general and specific competences, authorising the issuance of a legal act concerning AI. In this way, the EU would expand the scope of its competences following the principle of conferral. Subsequently, it should conduct an in-depth analysis of the compatibility of the planned actions with the principles of subsidiarity and proportionality, including the selection of the appropriate secondary legal act. In such a case, if the TFEU's updated version does not provide direct authorisation for the adoption of an EU regulation, an EU directive would be the most likely option, though not the only one.

The selection of a specific secondary legislation would depend on the results of the analyses of compatibility with the principles of subsidiarity and proportionality, where the justification for choosing an EU regulation is not impossible; however, it is exceptionally challenging, particularly in a new legislative area. The next step would be an additional analysis of the compatibility of the content of the planned secondary legal act with the equality principle, especially through the lens of compensatory or adaptive mechanisms. Such an analysis would influence the choice of the legal instrument. The final step would be a comprehensive analysis of the compatibility of the content of the planned secondary legal act with the EU's legal system, particularly human rights, and the determination of the regulatory impacts. Only after following such a process would it be reasonable to initiate the procedure for adopting a secondary legal act concerning AI.

Nonetheless, this highlights an imperfection in the EU primary law, which currently does not provide mechanisms for adapting to emerging legislative needs without undergoing the formal treaty amendment process. It seems reasonable for the Member States to consider that, in situations such as the need for AI regulation, there should not be a necessity to follow the formal procedure for treaty amendments. This underscores the need for introducing an additional mechanism within the EU primary law to allow for adjustments to such requirements. A potential solution might involve a treaty amendment that authorises, as a justified exception, the European Council, acting unanimously, to create specific competences for the EU in new legislative areas. If the EU were to take such steps, particularly concerning the real need for AI regulation and ensuring effective international cooperation, it would be positively received by the Member States. Acting in the spirit of the principles of equality, conferral, subsidiarity and proportionality, the Member States would likely engage in cooperation, as they did when they originally established the EU or acceded to it.

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