ARTICLES

FUTURE-PROOF REGULATION AND ENFORCEMENT FOR THE DIGITALISED AGE

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INTERNAL MARKET 3.0: THE OLD "NEW APPROACH" FOR HARMONISING AI REGULATION

SYBE DE VRIES*, OLIA KANEVSKAIA** AND RIK DE JAGER***

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ABSTRACT: In April 2021, the European Commission proposed a Regulation on Artificial Intelligence (AI) as part of a package of EU legislative harmonization measures that seek to tackle the societal challenges of digitalization and technological innovation. The proposed legislation draws heavily on the "New Approach" technique for the technical harmonization and standardization of goods. This raises several questions and concerns. Firstly, it can be questioned whether a harmonization technique that has been developed for health and safety standards in the offline, physical market, can be that easily transposed to the field of AI, where ethical and fundamental rights issues abound. Secondly, despite its success, the "New Approach" regulatory technique has been subject to much criticism, such as the responsibility of the manufacturers to carry out a conformity assessment, the role and decision-making powers of the private law standardization organizations and notified bodies, and the lack of public participation and public oversight in standardization and certification processes. These concerns are aggravated in the AI environment due to the pertaining legal, ethical and fundamental rights issues. This *Article* therefore seeks to explore the future-proofness of the proposed AI Act from three perspectives: *i)* the internal market; *ii)* protection of fundamental rights and *iii)* democratic legitimacy in the EU decision-making

* Professor of Public Economic Law, Utrecht University, s.a.devries@uu.nl.

** Assistant Professor of Public European Economic Law and Technology, Utrecht University, o.s.kanevskaia@uu.nl.

*** LLM Graduate in European Union Law, Utrecht University, rikdejager1@gmail.com.

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processes. Ultimately, it offers a broader reflection on the policy and legal implications of AI and proposes a number of recommendations on how to increase the fitness of the future AI Act, bearing in mind the balance between the economic and fundamental rights goals of the AI Regulation.

KEYWORDS: EU Digital Single Market – AI Act – standardisation – "New Approach" – harmonised standards – fundamental rights.

I. INTRODUCTION

On April 21, 2021, the European Commission published a proposal for a "Regulation laying down harmonised rules on artificial intelligence", also called the Artificial Intelligence Act ("Draft AI Act").[1] Being a core part of the EU Digital Market Strategy, this pioneering attempt to regulate AI in the EU aims to ensure the proper functioning of the European internal market by introducing harmonised rules on the use, development, and placement of AI systems in conformity with the Union values. The aim of the Draft AI Act is twofold: to ensure the free movement of AI-based goods and services in the EU internal market and to protect public interests such as health, safety and fundamental rights.[2]

While bringing positive solutions and benefits in multiple sectors, *e.g.*, finance, health care, transportation, and sustainability,[3] AI also carries many effects that are (potentially) disruptive for society, ranging from algorithmic bias enabling discriminatory practices[4] to the situation where we are unable to explain the rationale for an AI system's conclusions and actions (the so-called "black box" phenomenon).[5] Consequently, a wide range of fundamental rights and other values risk being negatively impacted by AI systems: to name a few, AI technologies may violate the rights to privacy and data protection, non-discrimination, human dignity and self-determination, the rights of effective judicial remedies and a fair trial, freedom of expression and consumer protection.[6] It is then not surprising that the use of AI technologies has fuelled concerns of policymakers and academics alike.

Regulating emerging technologies is not an easy task. Next to the question "how" such technologies should be regulated, there are also questions of "what" to regulate,

[1] Communication (COM)2021 206 final from the Commission of 21 April 2021 on a 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 (Draft AI Act).

[2] *Ibid*. recital 13.

[3] DM West and JR Allen, 'How Artificial Intelligence is Transforming the World' (24 April 2018) Brookings www.brookings.edu; G Misuraca and C van Noordt, 'AI Watch – Artificial Intelligence in Public Services' (Publication Office of the European Union 2020) publications.jrc.ec.europa.eu 40 ff.

[4] A Jobin, M Ienca and E Vayena, 'Artificial Intelligence: The Global Landscape of Ethics Guidelines' (2019) Nature Machine Intelligence 389, 390.

[5] Y Bathaee, 'The Artificial Intelligence Black Box and the Future of Intent and Causation' (2018) Harvard Journal of Law & Technology 890; M Ebers, 'Standardising AI – The Case of the European Commission's Proposal for an Artificial Intelligence Act' in L Di Matteo, C Poncibò and M Cannarsa (eds), *Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (Cambridge University Press 2022) 4.

[6] See for example M Ebers, 'Standardising AI' cit. 3.

and "when". Too tight, or too early a regulation may unduly restrict the development of new technologies, while regulating at the later stage risks not capturing the major risks brought by these technologies. This dilemma, also known as the "pacing problem", is very well familiar among law and technology scholars.[7]

Regulation of AI is no exception. Governments worldwide are still exploring the avenues for regulating this technological development. In this regard, the approach chosen by the EU represents an ambitious attempt that seeks to tackle the economic and societal challenges of digitalization and technological innovation through the adoption of a regulation and the use of a well-established harmonisation technique of internal market legislative harmonisation, *i.e.*, the "New Approach". Developed in the 1980s for the harmonization of rules on product safety, this approach entails in short that the Draft AI Act is confined to setting only essential safety and consumer protection standards which AI systems must comply with, whereas more detailed requirements for AI systems are developed and defined by private bodies.[8] This *Article* focuses on the regulatory regime of so-called high-risk AI systems, as only these systems are subject to the New Approach harmonisation technique and constitute the most impactful systems the Draft AI Act aims to regulate.[9]

The fact that the proposed act uses this regulatory technique for the regulation of AI raises several questions and concerns. First and foremost, it can be questioned whether a harmonization technique that is developed in the "offline market" can be that easily transposed to an online environment and to the field of AI, where ethical and fundamental rights issues are abound. Second, the "New Approach" has been frequently criticised for its perceived lack of democratic legitimisation and accountability and, related to this, the lack of public participation and public oversight in the standardization and certification processes.[10]

[7] For the literature overview, see A Butenko and P Larouche, 'Regulation for Innovativeness or Regulation of Innovation?' (2015) Law, Innovation and Technology 52. The critique of this theory has been, among others, that the law does not react on sociotechnical changes, but constructs them; see, among others, M Leta Jones, 'Does Technology Drive Law? The Dilemma of Technological Exceptionalism in Cyberlaw' (2018) Journal of Law, Technology and Policy 101. In this regard, Kamiski also argues that from the viewpoint of legal construction, the regulation of AI also creates the meaning of AI systems and the harms they bring, ME Kaminski, 'Regulating the Risks of AI' (forthcoming 2023) Boston University Law Review 5.

[8] By analogy, see Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, Annex II. See also H Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Bloomsbury 2005) and M Egan, *Constructing a European Market* (Oxford University Press 2001).

[9] It concerns, in short, AI systems that manipulate human (group) behaviour, enable the social scoring of people by public authorities, or use real-time and remote biometric identification systems, which the Commission considers to be at fundamental odds with Union values, see Communication (COM)2021 206 final (Draft AI Act) cit. 21.

[10] See, among many others, L Senden, 'Towards a More Holistic Legitimacy Approach to Technical Standardisation in the EU' in M Eliantonio and C Cauffman (ed), *The Legitimacy of Standardisation as a Regulatory Technique: A Cross-disciplinary and Multi-level Analysis* (Elgar Publishing 2020) 27.

Against this backdrop, we seek to explore whether the proposed use of the "New Approach" regulatory technique in the Draft AI Act is sufficiently future-proof, in the sense that it both enhances the EU internal market and other core values, including fundamental rights. The remainder of this *Article* is organized as follows. Section II provides a brief overview of the evolution of EU harmonization, from product safety to the Digital Single Market. Section III explains the main elements of the Draft AI Act, focusing specifically on its risk-based approach. Section IV dives into the "future-proofness" of the Draft AI Act in regulating AI in the current digitalised era from three perspectives, *i.e.*, the internal market, fundamental rights, and democracy and legitimacy. Section V provides several recommendations on future-proofing the Draft AI Act and places the Draft AI Act in the broader AI policy agenda at the EU level.

II. The evolution of the "New Approach" to harmonisation in the EU: setting the scene

Harmonisation of national laws is a crucial instrument for the realisation and functioning of the EU's internal market, next to the application of the Treaty rules on free movement and competition.[11] The last fifty years have marked a shift in the EU's legislative praxis, from merely harmonising product requirements, mainly through the adoption of directives, to adopting rules that span across many features of the digital world and cut through the arising concerns of fundamental rights. Here, the key legislative instrument seems to be the regulation, which is directly applicable, rather than the directive, which needs to be transposed into national law. To understand the embedment of the recent Draft AI Act into the EU legal system, this section broadly outlines the development of the EU harmonisation, focusing in particular on the New Approach technique that plays a central role in the European proposal for AI regulation.

II.1. The "New Approach" to technical harmonisation

Until the early1980s, technical harmonisation was carried out through the "traditional" approach: the Commission established detailed technical requirements in its Directives and issued the lists of products these requirements applied to.[12] Needless to say, this harmonization method was ill-equipped to deal with the ever-increasing variety of

[11] PJ Slot, 'Harmonisation' (1996) ELR 378-387. SA de Vries, *Tensions within the Internal Market: The Functioning of the Internal Market and the Development of Horizontal and Flanking Policies* (Europa Law Publishing 2006) 247.

[12] H Schepel, 'The New Approach to the New Approach: The Judification of Harmonized Standards in EU Law' (2013) Maastricht Journal of European and Comparative Law 521; J Pelkmans, 'The New Approach to Technical Harmonization and Standardization' (1987) JcomMarSt 249.

products and unpredictable technical developments due to its slow pace and lack of the necessary expertise in the Commission.[13]

The breakthrough came with the CJEU's landmark ruling in *Cassis de Dijon* that introduced the principle of mutual recognition to the EU acquis. In light of the Court's judgment, and to promote European integration by addressing the "impediments to the internal market that were not already neutralised by the application of the principle of mutual recognition",[14] the Commission introduced the "New Approach" framework in 1980.[15] Under the New Approach regulatory technique, the Commission's Directives set the essential requirements of health, safety, consumer protection or environmental protection,[16] while the methods of achieving these essential requirements were prescribed in harmonized standards adopted by the three European Standardisation Organisations ("ESOs") following the request of the Commission.[17] These harmonized standards are then endorsed by the Commission and their references are published in the Official Journal of the European Union ("OJEU").[18] Compliance with harmonized standards grants a presumption of compliance with the essential requirements.[19] The New Approach was amended in 2008 with the "New Legislative Framework", updating rules for certification and conformity assessment.[20]

In principle, harmonized standards are voluntary, meaning that manufacturers are free to pursue an alternative method to demonstrate conformity with the essential requirements of the Directives. In practice, however, compliance with harmonized standards is less costly and provides more (legal) certainty, making it the preferred option

[13] P Messerlin, 'The European Union Single Market in Goods: Between Mutual Recognition and Harmonisation' (2011) Australian Journal of International Affairs 412-413.

[14] Communication COM(1980) 256/3 from the Commission of 3 October 1980 concerning the consequences of the judgment given by the Court of Justice of 20 February 1979 in Case 120/78 ('Cassis de Dijon').

[15] Council Resolution of 7 May 1985 on a New Approach to Technical Harmonisation and Standards cit. See also I Govaere, '"*Ceci n'est pas... Cassis de Dijon*": Some Reflections on its Triple Regulatory Impact' in A Albors-Llorens, C Barnard and B Leucht (eds), *Cassis de Dijon 40 Years On* (Hart Publishing 2021) 105.

[16] PJ Slot, 'Harmonisation' cit.

[17] See, for example, Notice C/2016/1958 of the Commission of 26 July 2016 on the 'Blue Guide' on the implementation of EU products rules.

[18] Regulation 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, art. 10(6).

[19] Member States can still adopt legislation with additional requirements under certain conditions, see cases C-470/03 *A.G.M.-COS.MET Srl* ECLI:EU:C:2007:213 para. 53 and case T-474/15 *GGP Italy v Commission* ECLI:EU:T:2017:36.

[20] Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, art. 1 ff.

among most producers.[21] From this vantage point, the "voluntarism" of harmonized standards becomes somewhat debatable, with recent case law of the European Court of Justice (the Court or CJEU) adding confusion to whether harmonized standards, being subjected to the CJEU's jurisdiction, are indeed a part of European law,[22] and which legal consequences it would entail for both manufacturers and the ESOs.[23]

Compliance with harmonized standards is verified through conformity assessments, typically conducted in a testing house following the order of the manufacturer (also known as a "self-assessment") or by "notified bodies". These bodies are independent technical organisations, typically private sector certification firms or, more rarely, by public authorities,[24] that perform the required testing and certify products that successfully passed the testing requirements.[25] Once the conformity assessment is fulfilled, the producer issues a Declaration of Conformity (DoC) and affixes a *Conformité Européenne* (CE) marking to the product, which allows for free circulation of that product within the EU. Conformity assessments thus take place in the pre-marketing phase of the product to determine whether the product's safety and performance meet the applicable legal requirements.

The "New Approach" and later, the "New Legislative Framework", have brought substantial benefits to the integration of the EU market. Rooted in public-private partnership, these legislative techniques have contributed considerably to fostering the free movement of goods, while relieving the EU legislature from the onerous duty of issuing sector-specific technical specifications through the EU decision-making process.[26] Furthermore, it allows the EU legislator to balance the interest of free trade with public, non-economic interests, such as safety, health or environmental protection.[27] The ratio behind the New

[21] R van Gestel and H Micklitz, 'European Integration through Standardisation: How Judicial Review is Breaking Down the Club House of Private Standardisation Bodies' (2013) CMLRev 145, 157.

[22] Case C-613/14 *James Elliott Construction v Irish Asphalt Ltd* ECLI:EU:C:2016:821 para. 40; but also case T-185/19 *PRO and Right to Know v Commission* ECLI:EU:T:2021:445 paras 53-54.

[23] M Gerardy, 'The Use of Copyrighted Technical Standards in the Operationalisation of European Union Law: The Status Quo Position of the General Court in Public.Resources.Org (T-185/19)' (2022) European Journal of Risk Regulation 532; B Lundqvist, 'European Harmonized Standards as "Part of EU Law": The Implications of the *James Elliott* Case for Copyright Protection and, Possibly, for EU Competition Law' (2017) Legal Issues of Economic Integration 421; A Volpato, 'The Harmonized Standards before the ECJ: James Elliott Construction' (2017) CMLRev 591. See also CEN and CENELEC position on the consequences of the judgment of the European Court of Justice on James Elliott Construction Limited v Irish Asphalt Limited, available at opil-ouplaw-com.proxy.library.uu.nl.

[24] Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

[25] G Spina Alì and R Yu, 'Artificial Intelligence between Transparency and Secrecy: From the EC Whitepaper to the AIA and Beyond' (2021) European Journal of Law and Technology 15.

[26] See J Pelkmans, 'The New Approach to Technical Harmonization and Standardization' cit. 249.

[27] See also I Govaere, '"*Ceci n'est pas… Cassis de Dijon*"' cit. 106.

Approach seems also to stem from the aim to distinguish between law and technical expertise. The law merely sets the general framework and broad policy choices, while the exact technical details are fleshed out by the industry.[28]

Yet, next to generating efficiency in making and adopting harmonised rules with a view to the functioning of the internal market, the New Approach raises pertinent questions of legitimacy and accountability in European rulemaking. The actual standardisation work takes place in ESOs' technical committees and working groups predominantly consisting of national standards bodies,[29] but which also include representatives of commercial firms as well as trade associations or consumer groups, although the latter categories lack voting rights on adopting harmonized standards.[30] Given that participation in these committees, as well as in the national standards bodies representing the interests of the Member States in the ESOs, requires time and resources, in practice, key industry actors play a crucial agenda setting role.[31] This prevalence of commercial interests, together with the increased politization of standards development processes and the lack of democratic accountability of ESOs have been among many points of criticism against the New Approach, which will be discussed in section IV.[32] To address some of these concerns, the Commission issued a new Standardization Strategy in February 2022 which, among others, aims to improve governance and decision-making of the European standardization system.[33]

II.2. The Digital Single Market

As the digital transition drew closer, the Commission began to rethink its approach to legislative harmonisation within the context of the Digital Single Market. The EU Digital Single Market strategy (DSM) was adopted as one of the Commission's political priorities with a view to promote the digitalisation of European industry, incentivise investments in

[28] B van Leeuwen, 'Standardisation in the Internal Market for Services: An Effective Alternative to Harmonisation' (2018) Revue Internationale de Droit Économique 323.

[29] It should be noted, however, that while CEN/CENELEC and ETSI membership indeed consists of national bodies, ETSI also allows membership of private companies.

[30] M Egan, *Construction a European Market: Standards, Regulation, and Governance* (Oxford University Press 2001) 133.

[31] *Ibid*. 143.

[32] See, among others, H Schepel, 'The New Approach to the New Approach' cit. 521; C Frankel and E Hojbjerg, 'The Constitution of a Transnational Policy Field: Negotiating the EU Internal Market for Products' (2007) Journal of European Public Policy 96.

[33] Communication COM(2022) 31 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 2 February 2022, 'An EU Strategy on Standardisation Setting global standard in support of a resilient, green and digital EU single market'; M Gerardy, 'The New EU Strategy on Standardisation: Real Step Forward or Missed Opportunity?' (14 March 2022) EU Law Live eulawlive.com.

digital infrastructure and create fair(er) conditions on the emerging digital markets.[34] The DSM "is [a market] in which the free movement of persons, services and capital is ensured and where the individuals and businesses can seamlessly access and engage in online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence".[35] In other words, the DSM is about allowing the freedoms of Europe's Single Market to enter the digital age but also about taking account of public interests and fundamental rights.[36]

Although the DSM is clearly intertwined with the offline or physical internal market, it has certain distinctive characteristics, which primarily revolve around the strong role of private actors, the importance of data and fundamental rights, and the (initial) lack of a public economic law infrastructure at national level and the (consequential) use of the instrument of a regulation instead of a directive.[37] The strength and power of private actors has important ramifications, not only for market access of businesses and consumers but also for citizens' fundamental rights, public interests and social values. The DSM recognizes their often crucial role in the regulatory domain and of the breaking down of the tradition public-private divide.[38] For instance, the Draft AI Act illustrates how the EU legislator increasingly imposes direct obligations on private actors with art. 114 TFEU as the legal basis, just as is the case in for example the Digital Services Act (DSA) (*e.g.* measures to counter illegal content online), the Digital Markets Act (DMA) (obligations for platforms as gatekeepers) or the Roaming Regulation (a wholesale roaming access obligation imposed on roaming providers).[39]

Furthermore, data and information are at the centre of the digital economy, which emphasizes the importance of the political, non-market, next to economic, aspects of the

[34] Communication COM(2015) 192 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 6 May 2015 on A Digital Single Market Strategy for Europe.

[35] Commission Staff Working Document SWD(2015) 100 final of 6 May 2015 on A Digital Single Market Strategy for Europe - Analysis and Evidence Accompanying the document Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Digital Single Market Strategy for Europe.

[36] See S de Vries, 'The Resilience of the EU Single Market's Building Blocks in the Face of Digitalization' in U Bernitz and others (eds), *General Principles of EU Law and the EU Digital Order* (Kluwer Law International 2020).

[37] *Ibid*. 4-5.

[38] S de Vries, 'The Potential of Shaping a Comprehensive Digital Single Market with the Long Awaited Digital Single Market Act' (21 January 2021) Utrecht University www.uu.nl.

[39] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act); Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act); Regulation (EU) 2022/612 of the European Parliament and of the Council of 6 April 2022 on roaming on public mobile communications networks within the Union (recast). S de Vries, 'The Potential of Shaping a Comprehensive Digital Single Market with the Long Awaited Digital Single Market Act' cit.

internal market.[40] Whilst the process of digitalization enlarges the (commercial) space of the market, the boundaries between commercial and public spaces become increasingly blurred.[41] Examples are the position of Big Tech companies, whose power do not only impact market access but also the political and democratic processes.[42] In a similar vein, the content monetization business models used on social media blur the lines between commercial advertising and political speech.[43] Meanwhile, within the context of the EU's DSM and the internal market legal basis of art. 114 TFEU, the EU legislator seeks to protect and balance fundamental rights, such as the protection of personal data and privacy, the freedoms of expression and information, the rights to non-discrimination and human dignity and the freedom to conduct a business, which are all enshrined in the EU Charter of Fundamental Rights. This is inherent to legislative harmonisation within the context of the (digital) single market as it "sets common rules for the European market, but, against a background of diverse national sources of regulatory inspiration, it also involves a standard of re-regulatory protection [...]".[44] It makes internal market legislation by its very nature receptive to public and social policy interests. This approach, whereby the EU legislator seeks to give considerable weight to public, non-market values and fundamental rights vis-à-vis market interests has been endorsed by the CJEU. For instance, in cases like *Sky Österreich* and *Google Spain* the CJEU in balancing conflicting fundamental rights and market interests within the context of EU internal market legislation, recognised the importance of freedom of information, media plurality (Sky Österreich) and the right to be forgotten as part of data protection (Google Spain), vis-à-vis the economic interests of commercial broadcasters or Google.[45]

[40] MZ van Drunen, N Hellberger and RÖ Fathaigh, 'The Beginning of EU Political Advertising Law: Unifying Democratic Visions through the Internal Market' (2022) International Journal of Law and Information Technology 194.

[41] *Ibid*. 194; J Habermas, *Ein neuer Strukturwandel der Öffentlichkeit und die deliberative Politik* (Suhrkamp Verlag 2022).

[42] A Gerbrandy, 'General Principles of European Competition Law and the "Modern Bigness" of Digital Power: The Missing Link Between General Principles of Public Economic Law and Competition Law' in U Bernitz and others (eds), *General Principles of EU Law and the EU Digital Order* cit. 309.

[43] G De Gregorio and C Goanta, 'The Influencer Republic: Monetizing Political Speech on Social Media' (2022) German Law Journal 204-225.

[44] S Weatherill, 'Protecting the Internal Market from the Charter' in S de Vries, U Bernitz and S Weatherill (eds), *The EU Charter of Fundamental Rights as a Binding Instrument: Five Years Old and Growing* (Hart Publishing 2015) 228. See also S de Vries, *Tensions within the Internal Market: The Functioning of the Internal Market and the Development of Horizontal and Flanking Policies* (Europa Law Publishing 2006) 247-296.

[45] S de Vries, 'The Resilience of the EU Single Market's Building Blocks in the Face of Digitalization' cit. p. 22-23. In *Sky Österreich*, the Court interpreted the Audiovisual Media Services Directive and held that the EU legislator may give precedence to the protection of media pluralism over the free movement of services and the freedom to conduct business, see case C-283/11 *Sky Österreich* ECLI:EU:C:2013:28. In a similar vein, the Court held in *Google Spain* that the right to be forgotten as enshrined in the former Data protection directive overrides the economic interests of Google, see case C-131/12 *Google Spain and Google* ECLI:EU:C:2014:317.

Nevertheless, the extent to which non-market values and fundamental rights may constitute a counterweight to market values in EU internal market legislation is not always clear. There are also judgments where the Court in interpreting EU internal market legislation, sidelined public interests to the benefit of the internal market and business interests, sticking to the internal market rationale of the harmonization measure.[46] The chosen legal basis of the regulation or directive may thus inform the way in which this balance is carried out.[47] To further illustrate this, the General Data Protection Regulation ("GDPR"), adopted in 2016, is a prime example of protecting fundamental rights within the DSM based on the specific legal basis of art. 16 TFEU (protection of personal data). Like the DSA and the Draft AI Act, the GDPR aims to balance fundamental values and economic goals.[48] Yet, whereas the GDPR is based on a specific legal basis aimed at the protection of personal data, the other regulations as well as the Draft AI Act are based on the internal market legal basis of art. 114. It is then not surprising that the balance between the "economic" and "fundamental rights" objectives may be tilted towards the former in the Draft AI Act (see hereafter, section III).

Finally, with a view to realise a more comprehensive DSM, the EU legislator, as already observed above, shows an increasing preference for the instrument of a regulation instead of a directive, thereby achieving a higher "intensity" of EU legislation by directly intervening in all Member States' legal orders. Legislative harmonisation in the field of AI thereby follows other Regulations that were recently adopted within the context of the DSM, such as the above-mentioned DMA, the DSA and the Roaming Regulation. All these share a similar goal, *i.e.*, better access for consumers and businesses to online goods and services across Europe, creating the right environment for digital networks and services, and maximising the growth potential of the European Digital Economy.[49]

III. Harmonization in the Draft AI Act: old wine in a new bottle, or new wine?

With the proposed AI Act, the Commission's long-term plan to create a robust regulatory framework for addressing the ethical and legal concerns surrounding AI[50] was put into

[46] *E.g.*, case C-426/11 *Alemo-Herron and Others* ECLI:EU:C:2013:521 on the interpretation of the Transfer of Undertakings Directive, which is based on art. 94 EC (old).

[47] E Hirsch Balling and others (eds), *Variation in the European Union* (The Netherlands Scientific Council for Government Policy 2019) 84.

[48] G De Gregorio and P Dunn, 'The European Risk-based Approaches: Connecting Constitutional Dots in the Digital Age' (2022) CMLRev 473, 493.

[49] Communication COM(2015) 192 final cit.

[50] Communication COM(2019) 218 final from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions of 30 April 2019 on Preparing for a more united, stronger and more democratic Union in an increasingly uncertain world The European Commission's contribution to the informal EU27 leaders' meeting in Sibiu (Romania) on 9 May 2019, 33.

effect in April 2021. The Draft AI Act pursues four objectives. Firstly, it aims to ensure that AI systems that are placed on the Union market are safe and respect existing law on fundamental rights and Union values. Secondly, it aims to provide legal certainty to facilitate investment and innovation in AI. Thirdly, it strives to enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems. And finally, it intends to facilitate the development of a single market for lawful, safe and trustworthy AI applications and prevent market fragmentation.[51] Recall, however, that despite these variety of stated purposes, the legal basis of the Draft AI Act is art. 114 TFEU, meaning that the aim of ensuring the (AI) internal market and eliminating divergent national approaches to AI regulation should be viewed as prevailing.[52]

This section will examine the relevant provisions of the Draft AI Act, explaining how the draft legislation incorporates the New Approach technique and which roles it assigns to the different actors on the AI market, *i.e.*, ESOs, notified bodies, manufacturers, and the Commission.

III.1. Risk-based approach of the Draft AI Act

The Draft AI Act is a risk-based regulation with a multi-layered enforcement structure.[53] As such, it addresses two types of risks that stem from AI systems: product safety risks and risks to fundamental rights.[54] In its crux, the Draft AI Act introduces a wide range of mandatory requirements for designing and developing specific AI systems prior to their placement on the EU internal market. Since the Draft AI Act applies to private and public providers inside and outside the EU whose AI systems are put or used in the EU market,[55] it will also impact third-country businesses that are not legally present in the EU.

The Draft AI Act applies different legal regimes to AI systems with varying risks, differentiating between *i)* unacceptable risks (generally prohibited safe for some exceptions), *ii)* high risks, *iii)* limited risks and *iv)* minimal risks.[56] The larger the risk, the stricter the regulatory requirements. The Draft AI Act identifies two sub-categories of high-risk AI systems:[57] those that are (parts of) a product or a safety component already subject to

[51] Communication (COM)2021 206 final (Draft AI Act) cit. 3.

[52] *Ibid*. 6. See the established case law on the choice of legal basis for harmonisation, case C-58/08 *Vodafone and Others* ECLI:EU:C:2010:321 and case C-376/98 *Germany v Parliament and Council* ECLI:EU:C:2000:544.

[53] Communication (COM)2021 206 final (Draft AI Act) cit. recital 14. See further on whether risk regulation is an adequate mechanism to tackle AI Regulation, M Kaminski, 'Regulating the Risks of AI' cit. 103.

[54] See, for example, Communication (COM)2021 206 final (Draft AI Act) cit. 11.

[55] *Ibid*. art. 2.

[56] Upon the amendments of the Parliament in June 2023, the Draft AI Act also introduces requirements of transparency and conformity assessment for generative AI (art. 28(b)).

[57] Communication (COM)2021 206 final (Draft AI Act) cit. art. 6.

specific EU harmonisation legislation on health and safety;[58] and those that fall into one of the Annex III categories, such as educational and vocational training, employment and migration and asylum management.[59] Chapter 2 of Title III introduces various requirements and obligations to these high-risk AI systems,[60] most of which fall on the provider, *i.e.*, the entity that "develops the AI system or has an AI system developed to place it on the market or put it into service under its name or trademark".[61] These requirements can be broadly divided into *ex ante* (regulatory requirements that need to be complied with before the AI systems are placed on the market), and *ex post* (monitoring compliance with requirements once the AI systems are already on the market). The latter ranges from installing risk and quality management systems to identifying, estimating and evaluating the risks that may emerge during the use of AI systems.[62] In addition, they see to construct post-market monitoring systems that collect, document and analyse "relevant data" generated by the high-risk AI system throughout its lifetime in order to evaluate compliance with the essential requirements,[63] and to implement procedures for reporting incidents.[64] In turn, *ex ante* requirements for high-risk AI systems heavily rely on the New Approach harmonisation technique.

III.2. The "New Approach" technique in the Draft AI Act

The Draft AI Act follows the familiar logic of the New Approach. High-risk AI systems that comply with harmonised standards that are developed by ESOs upon the request of the Commission, and to which a reference is published in the OJEU, are presumed to conform

[58] Communication (COM)2021 206 final from the Commission of 21 April 2021 on Annexes to the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts 2 (Annex II). See also M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' (2021) Computer Law Review International 102.

[59] Examples of high-risk AI systems are the algorithmic-driven scoring of exams, CV sorting software for recruitment procedures, verification of travel documents' authenticity, and credit scoring to determine whether a citizen can obtain a loan. See also M Kop, 'EU Artificial Intelligence Act: The European Approach to AI' (2021) Vienna Transatlantic Technology Law Forum 1.

[60] M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' cit. 102.

[61] Communication (COM)2021 206 final (Draft AI Act) cit. arts 3(2) and 16(a), the latter stating that the providers must ensure the AI system's compliance with the requirements in Chapter II. Interestingly, the adopted text by the European Parliament speaks about "obligations of providers and deployers of high-risk AI systems and other parties" when describing the introduced requirements, see European Parliament, Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 - C9-0146/2021 - 2021/0106(COD)), 303 a.f.

[62] *Ibid*. arts 9 and 14(1).

[63] *Ibid*. art. 62(1).

[64] *Ibid*. arts 17(i) and 62.

to the requirements and obligations defined in the Draft AI Act.[65] The Draft AI Act thus sets high-level requirements regarding AI's desired objectives and outcomes, but leaves the technical solutions to implement the requirements to more flexible market-driven standards.[66]

The Draft AI Act provides several routes to conduct the required *ex ante* conformity assessment necessary to demonstrate compliance with harmonized standards. A first essential step is to determine whether the high-risk AI system is a component of a consumer product already covered by existing EU product harmonisation legislation. Is this the case, the AI system in question is covered by the conformity assessment procedures under the legislation that applies to that consumer product.[67] If, however, the high-risk AI system is a "stand-alone" system, art. 43 introduces different types of conformity assessment procedures that require either conformity assessment based on *internal control* or via a so-called *third-party notified body*.[68] The former category must be followed by providers of high-risk AI systems that affect fundamental rights and are set out in points 2 to 8 of Annex III; upon successful self-assessment, these producers may mark their systems as in conformity with the Draft AI Act.[69] The latter category applies to AI systems that may carry product safety concerns, and should be performed by the notified bodies.[70] This type of conformity assessment should also be followed by the AI-providers that have not (sufficiently) applied the applicable harmonised standards or when such harmonised standards or if common specifications[71] do not (yet) exist.[72]

After a successful conformity assessment procedure, the Draft AI Act requires the provider to draw up a written DoC for each AI system in question,[73] which must be kept at the disposal of the competent national authorities for ten years after the high-risk AI system was placed on the EU market. Importantly, by adopting the DoC, the provider assumes responsibility for compliance with the requirements for high-risk AI systems as set out in the Draft AI Act.[74] The high-risk AI system products that have passed the conformity assessment and are foreseen with a CE-marking that is affixed "visibly, legally and indelibly",[75] are then allowed to be deployed and traded freely within the EU internal market.[76]

[65] *Ibid*. art. 40.

[66] Communication COM(2021) 206 final from the Commission of 21 April 2021 on the Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative Acts, 52.

[67] Communication (COM)2021 206 final (Draft AI Act) cit. 13 and art. 43(1).

[68] *Ibid*. art. 43.

[69] *Ibid*. art. 43(2).

[70] *Ibid*. art. 43(3).

[71] See section IV.2 of this *Article*.

[72] Communication (COM)2021 206 final (Draft AI Act) cit. art. 43(1).

[73] *Ibid*. art. 48(1).

[74] *Ibid*. art. 48(4).

[75] *Ibid*. art. 49(1).

[76] *Ibid*. art. 44.

III.3. "Privatization" of AI regulation by ESOs and conformity assessment bodies

In AI technologies, standards as such are not a novelty. A great variety of standards and specifications developed by private standards bodies enable the technical functioning of AI products and interoperability of AI systems.[77] The Draft AI Act adds to this *technical* relevance also *legal, policy and market* relevance,[78] going beyond the typical use of standards in the AI industry. At the same time, the Draft AI Act practically outsources the development of the rules to be followed by producers of high-risk AI systems to industry driven ESOs. The same goes for the procedure to demonstrate conformity with the New Approach rules, which the Act outsources to private conformity assessment bodies or producers themselves, without any mandatory checks and reviews by public authorities.[79]

Indeed, as set out in section II.1, AI providers are not *required* to follow harmonised standards – after all, they may choose any other methods to demonstrate that their products comply with the essential requirements of the Draft AI Act. However, it is widely known that harmonized standards provide more legal certainty to producers and prove to be cheaper, compared to other means of interpreting the specific essential requirements.[80] Given the turbulent and rapid development in the AI market, these considerations will be even more prevalent as the use AI technologies unfolds.

It appears thus that harmonised standards developed by ESOs under the New Approach are to become the leading requirements that high-risk AI systems need to satisfy for conforming with the Draft AI Act and subsequently for being legally marketed in the EU. This, in turn, makes the private ESOs *de facto* AI regulators, wielding large and influential power over the specific regulation of high-risk AI systems.

IV. Future-proofing AI regulation through the "New Approach"

According to the Commission, reliance on harmonised standards allows the horizontal legal framework of the Draft AI Act to remain sufficiently agile to deal with the ever-increasing technological progress in AI.[81] However, the use of the New Approach regulatory technique in the Draft AI Act raises several questions and concerns, which relate to the fitness of the proposed regulatory regime for safeguarding both market access and core

[77] Examples include the recent ISO/IEC 23053:2022 standards establishing the framework for AI systems using Machine Learning. See further S Nativi and S De Nigris, 'AI Standardisation Landscape: State of Play and Link to the EC Proposal for an AI Regulatory Framework' (14 July 2021) Publications Office of the European Union publications.jrc.ec.europa.eu.

[78] M Cantero Gamito, 'The Role of ETSI in the EU's Regulation and Governance of Artificial Intelligence' (draft on file with the authors).

[79] That said, the decisions of notified bodies can in principle be appealed, see art. 45 Draft AI Act cit. It should also be noted that for self-assessment, there is in principle no control by an independent third party, and although regulators may check performance against such self-assessment, this type of conformity assessment is considered weaker than third party certification, M Kaminski, 'Regulating the Risks of AI' cit. 52.

[80] See R van Gestel and H Micklitz, 'European Integration through Standardisation' cit.

[81] Communication COM(2021) 206 final cit.

values and fundamental rights throughout the development and use of AI systems. Against this background, this section focuses on the "future-proofness" of the Draft AI Act in regulating (high-risk) AI systems from three perspectives: *i)* the internal market, *ii)* fundamental rights, and *iii)* legitimacy and democratic rule-making.

IV.1. The future-proofness from the perspective of the Internal Market

a) Benefits of the proposed AI Act for market integration

From the internal market perspective, introducing the New Approach for harmonising high-risk AI systems, combined with provisions on a presumption of conformity, benefits the internal market for trustworthy AI systems. Specific procedures apply to derogate from the conformity assessment, namely in exceptional cases of public security, the protection of life and health of persons, environmental protection, and the protection of key industrial and infrastructural assets.

Furthermore, the use of the instrument of a regulation rather than a directive is with a view to truly create a level playing field for an internal market in AI systems highly welcomed. Regulations by their very nature provide for a common, more uniform approach, thereby creating a level playing field for businesses and seeking to abolish barriers to trade within the internal market. In so far as it harmonises the field of AI exhaustively, the regulation pre-empts Member States from introducing and maintaining additional protective measures, which would otherwise lead to competitive disturbances in the DSM. It has been observed elsewhere, though, that the scope and thus exhaustive nature of the Draft AI Act in respect of all, not only high-risk AI systems, is still unclear, which means that that not all elements of AI technologies are entirely covered by the Draft AI Act.[82] Fragmentation, as a result, is lurking, which undermines legal certainty.

Another advantage of the choice for a regulation from the perspective of the DSM is the potential horizontal direct effect of the AI Act. As Directives only apply in vertical relations, the lack of horizontal direct effect may be problematic in case of conflicts between private parties, which are likely to arise in the DSM.[83]

b) Shortcomings of the proposed AI Act for market integration

However, there are also a few possible shortcomings of the New Approach in respect of AI that may jeopardise the future-proofness of the Draft AI Act with a view to the functioning of the internal market, which relate to *i)* risk-categorisation, *ii)* the application of the provisions of the Draft AI Act to the AI systems already in use and *iii)* the use of vague language.

[82] See also M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft Eu Artificial Intelligence Act' cit. 110. See also fn 58 in this *Article*.

[83] See also case C-261/20 *Thelen Technopark Berlin* ECLI:EU:C:2022:33. The Court takes a very different stance than AG Szpunar in his opinion.

Regarding risk-categorisation *i)* one of the main critiques on the current text of the Draft AI Act is its approach to categorizing the risk. For instance, Margot Kaminski argues that by subjecting different kinds of AI systems to different regulatory regimes, the Draft AI Act creates "sharp lines [...] between systems with similar risks that fall definitionally into different buckets".[84]

Furthermore, as it stands at the moment of writing, the proposed regulation substantially limits the possibilities to expand the list of high-risk AI systems covered by its provisions and to which the New Approach applies. New high-risk AI systems can only be added to the list of high-risk AI systems if they fall within the scope of the existing eight "categories" and pose a risk equivalent to or greater than the listed high-risk AI systems in Annex III.[85] The ratio behind this limitation primarily reflects the Commission's wish of creating certainty for the market and encouraging AI innovation.[86] At the same time, there are existing AI systems which do not fall within one of the eight areas but still have substantial risks. For instance, high-frequency trading algorithms or AI deployed for housing purposes are currently not covered by the Draft AI Act.[87] Given the rapid development of AI, it is conceivable that new AI systems will emerge which could also be unclassifiable under the eight specified areas, leading to a significant gap in EU harmonisation.[88] This poses the risk that providers may circumvent the requirements and obligations imposed on high-risk AI systems by arguing that their system does not fall within this rather static definition.[89]

It comes as no surprise that the insufficient possibilities to expand the list of high-risk AI systems came up in the discussions on the way forward for the Draft AI Act. In April 2022, the European Parliament proposed to extend the scope of delegated acts to allow

[84] M Kaminski, 'Regulating the Risks of AI' cit. 70. The adopted text by the European Parliament is an interesting development in this regard. Under the text, the European Commission is empowered to adopt delegated acts to add or modify areas or use-cases of high-risk AI systems where these "pose a significant risk of harm to health and safety, or an adverse impact on fundamental rights, to the environment, or to democracy". In addition, that risk must be "equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III", see art. 7(1). The requirement that the AI system is intended to be used in any of the areas already mentioned in Annex III has been left out of the text. contrary to art. 7(1)(a) of the European Commission's proposal.

[85] Communication (COM)2021 206 final (Draft AI Act) cit. art. 7(1).

[86] L Edwards, 'Regulating AI in Europe: Four Problems and Four Solutions' (1 March 2022) Ada Lovelace Institute www.adalovelaceinstitute.org.

[87] N Smuha and others, 'How the EU Can Achieve Legally Trustworthy AI: A Response to the European Commission's Proposal for an Artificial Intelligence Act' (5 August 2021) papers.ssrn.com 31.

[88] M Ebers and others, 'The European Commission's Proposal for an Artificial Intelligence Act: A Critical Assessment by Members of the Robotics and AI Law Society (RAILS)' (2021) Multidisciplinary Scientific Journal 594-595.

[89] N Smuha and others, 'How the EU Can Achieve Legally Trustworthy AI' cit. 13.

for modifying and expanding the current high-risk categories.[90] Concretely, the Parliament proposed to expand or modify several existing categories of high-risk AI systems, such as adding to the list AI systems that interact with children, make decisions regarding health or life insurance, or relate to voting and election.[91] The Parliament's considerations are in part echoed in the recent common position of the Council of the EU,[92] which suggested to add several categories to the list of high-risk AI-systems (*e.g.*, those used in life and health insurance and critical digital infrastructure)[93] and to add a "horizontal layer" to the high-risk classifications to ensure that the list does not capture AI systems that do not pot significant risks.[94]

These proposals, however, do not solve the main issue of high-risk classification. If new categories of high-risk AI systems cannot be added or current categories not modified, the Draft AI Act fails to become future-proof. New and unforeseen AI systems that cause equal (if not more) risks to fundamental rights and Union values would not fall under the imposed requirements and obligations. As a result, harmonising the rules on high-risk AI systems in the EU and achieving a comprehensive EU internal market for AI, both major goals of the Draft AI Act, would be difficult to achieve.

Regarding *ii)*, pursuant to art. 83(2), the Draft AI Act (and subsequently the New Approach) will only apply to high-risk AI systems already in use if those encounter significant changes in their design or intended purpose. Unfortunately, neither art. 83 nor the explanatory memorandum of the Draft AI Act provide further guidance or details on interpreting "significant changes". Art. 83(2) therefore lacks a clear and comprehensive interpretation.[95] While this legislative choice is understandable from the viewpoint of legal certainty, the current divide between high-risk AI systems marketed before or after the entry into force of the Draft AI Act does not sit well with its primary goal of preventing fragmentation of the internal market on essential requirements for AI products.[96]

[90] Draft Report COD(2021) 0106 of the European Parliament on the Proposal for a Regulation of the European Parliament and of the Council (April 2022) on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts.

[91] *Ibid*. amendments 289, 291 and 296.

[92] European Council COD(2021/0106) General Approach on the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, 5.

[93] *Ibid*. 5.

[94] *Ibid*. 5.

[95] J Mökander and others, 'Conformity Assessments and Post-market Monitoring: A Guide to the Role of Auditing in the Proposed European AI Regulation' (2022) Minds and Machines 241. The adopted amendments by the European Parliament in June 2023 removes the mention of "significant changes in their design or intended purpose", instead proposes to apply the obligation of art. 82 to "systems [that] are subject to substantial modifications as defined in Article 3(23)". Substantial modifications, in turn, are newly defined in art. 3(23) as "not foreseen or planned in the initial risk assessment by the provider as a result of which the compliance of the AI system" with the requirements of Title III, Chapter 2 of the AI Act is affected.

[96] Communication (COM)2021 206 final (Draft AI Act) cit. 6.

Arguably, harmonised rules on the marketing, use and supervision of high-risk AI systems that only apply to future high-risk AI systems will only worsen the fragmentation of the internal market on essential requirements for AI products. In addition, it may not lessen but increase legal uncertainty for providers of high-risk AI systems marketed before and after the proposed AI Act enters into force, given the various rules applicable to those AI systems. Additional guidance in the final text of the Draft AI Act regarding the extent to which it covers the existing AI systems is therefore much desired.

Regarding *iii)* a common concern of the Draft AI Act is its – often – vague and unspecified language, which arguably leaves ample room for interpretation, possibly undermining the intended regulatory effect. Commentators have voiced these concerns with respect to art. 47(1), which provides for a derogation from the conformity assessment procedure for certain reasons by national market surveillance authorities (MSAs).[97] Furthermore, art. 10, which mandates the requirements relating to data quality and governance, requires data sets to have "appropriate" statistical properties without specifying what "appropriate" entails,[98] while art. 10(2)(f) mandates an "examination in view of possible biases", without clarifying the notion of "bias".[99] In a similar vein, art. 13, requiring providers to design high-risk AI systems in way that is "sufficiently transparent to enable users to interpret the system's output and use it appropriately",[100] does not establish any threshold for "sufficiently" transparent and "appropriate" use. This lack of clarity may lead to differing interpretations of the providers obligations.

At the same time, specifying the requirements and obligations of the proposed AI Act in a (too) detailed manner may jeopardise the flexible character of the regulation and negatively impact its future-proofness. Leaving sufficient room for interpreting regulatory requirements may carry some substantial benefits for regulation of emerging technologies. In fact, the recourse to such uncertain and vague language is common in EU legislation, even in well-established regulatory domains. In this regard, such formulation may even contribute to future-proofness of the Draft AI Act by allowing the Court to

[97] J Mökander and others, 'Conformity Assessments and Post-market Monitoring' cit. 241; N Smuha and others, 'How the EU Can Achieve Legally Trustworthy AI' cit. 58. The Parliament proposed to remove this article from the draft, see Draft Report COD(2021) 0106 cit.

[98] Communication (COM)2021 206 final (Draft AI Act) cit. art. 10(3).

[99] M Ebers and others, 'The European Commission's Proposal for an Artificial Intelligence Act' cit. 596. The European Parliament describes biases in the sense of art. 10(2)(f) as biases "that are likely to affect the health and safety of persons, negatively impact fundamental rights of lead to discrimination prohibited under Union law", making explicit reference to so-called "feedback loops" where data outputs influence inputs for future operations, see amendment 285 of the adopted text. The European Council holds a more limited view, labeling "biases" as those "likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law", see European Council COD(2021/0106) General Approach on the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, 92.

[100] Communication (COM)2021 206 final (Draft AI Act) cit. art. 13(2).

interpret these terms in the light of the EU Charter, hence contributing to the protection of fundamental rights.

IV.2. Future-proofness from the perspective of fundamental rights and ethics

The Commission's choice for a relatively "old harmonisation technique" in the Draft AI Act can be interpreted as an important signal that the EU legislative praxis in the offline internal market for goods can easily be continued in a digital environment. But is this possible when ethical issues and fundamental rights are at stake? Apart from the apparent cases of safety of products that (will) use or rely on AI systems,[101] AI technologies involve a wide range of complex fundamental rights questions, which need to be carefully balanced with the economic goals pursued by regulating AI.

In this regard, some authors argue that in the Draft AI Act, this balance is (heavily) tilted towards market access rather than the protection of fundamental rights.[102] As stated above, the fact that art. 114 TFEU constitutes the legal basis of the proposed AI Act may explain why market interests are more dominant. Yet, at the same time, considering the inherently dual nature of harmonisation,[103] fundamental rights and public interests need to be protected by the EU legislator within the context of the internal market as well.[104] At the same time, this in no way implies that the two objectives are mutually exclusive: product safety regulation may cover fundamental rights,[105] and consumer protection – the ultimate goal of many safety regulations – is in itself a fundamental right according to the EU Charter.[106] But it has been rightly questioned whether the way in which the product safety legal framework regulates health and safety risks of "static products" can, considering the types of risks to fundamental rights that may be caused or amplified by the adoption of AI technologies, be transposed just like that to the field of AI. AI systems are complex, dynamic and changeable in nature, and fundamental rights are hard to measure in such relatively unstable systems.[107] In addition, as scholars have signaled, the Draft AI Act currently does

[101] See, *e.g.*, Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts and Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

[102] *E.g.*, M Almada and N Petit, 'The EU AI Act: A Medley of Product Safety and Fundamental Rights?' (2022) available at ssrn.com, comparing the fundamental rights protection in the Draft AI Act with the one in GDPR and DSA.

[103] See section II.2.

[104] See also S Weatherill, *The Internal Market as a Legal Concept* (Oxford University Press 2017) 152-166. See also S Weatherill, 'Protecting the Internal Market from the Charter' cit.

[105] M Almada and N Petit, 'The EU AI Act' cit., citing the Medical Device Regulation.

[106] Codified in art. 38 of the Charter of Fundamental Rights of the EU.

[107] M Almada and N Petit, 'The EU AI Act' cit. With a view to increase fundamental rights safeguards and risk management, the European Parliament proposed to include a new provision, Article 29a, which requires deployers of high-risk AI systems before they are put into use to conduct a fundamental rights impact assessment.

not provide any rights of redress for individuals nor a complaint mechanism, which absence could both weaken the fundamental rights protection offered by the legislation.[108] However, in September 2022, the Commission proposed the AI Liability Directive, which installs a fault-based liability regime for damage caused by high-risk AI systems.[109] Equally based on art. 114, the proposed Directive may potentially fill the gap left by the Draft AI Act regarding the enforcement of individual rights.

In addition, if it comes to that, the CJEU may, once the AI Act has been adopted, be asked to provide a Charter-conform interpretation of the provisions of the Draft AI Act, and thus perform its own balancing act between economic goals and fundamental rights protection. There are, however, two caveats for relying on the Court's interpretation to safeguard fundamental rights. Firstly, the Court proceedings tend to last for a long time which, in case of the fast-paced development of AI technologies, do not offer timely solutions. Secondly, many regulatory requirements will be established in harmonized standards, which the Court cannot interpret.[110]

This possible "fundamental rights deficit" is aggravated by the fact that fundamental rights and ethical aspects for harmonized standards will be defined by the ESOs. Being private bodies that are led by commercial companies, the ESOs are arguably ill-equipped to judge on these highly sensitive matters.[111] Engineers and other technical experts attending the meetings of standards development committees do not necessarily possess the knowledge and expertise necessary to embed ethical issues in technical discussions. And while ethics and fundamental rights experts may indeed be present in every large commercial company, these experts are typically involved in other standardization initiatives that pertain specifically the questions of ethics.[112] Even if such experts will eventually manage to have a seat at ESOs standardization committees, smaller stakeholders that do not have such an in-house expertise, and societal stakeholders that do not have an active voice in ESOs, remain disadvantaged. This expertise deficit is especially problematic in the field of AI, given its immensely complex nature that is often difficult to grasp for technology experts, let alone stakeholders with less technological expertise. Allowing large commercial players to define the requirements of fundamental rights and ethical

[108] See, for more in-depth, M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' cit.; N Smuha and others, 'How the EU Can Achieve Legally Trustworthy AI' cit. 44-46.

[109] Communication COM(2022) 496 final from the Commission of 28 September 2022 on a proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence.

[110] O Kanevskaia, *The Law and Practice of the Global ICT Standardization* (Cambridge University Press 2023) 87-93.

[111] See N ten Oever and S Milan, 'The Making of International Communication Standards: Towards a Theory of Power in Standardization' (2022) Journal of Standardization.

[112] One of such initiatives is the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems, of Standards Associations of the Institute of Electrical and Electronics Engineers.

aspects in AI is a dangerous precedent that can potentially result in a regulatory capture and the race to the bottom of harmonized standards.

A possible solution may be to leave the definition of issues related to fundamental rights and ethical concerns to the Commission acting through common specifications.[113] Such a common specification, which is explicitly not a standard, contains technical solutions to comply with the requirements set by the – in this case – Draft AI Act.[114] This relatively new method of restoring, albeit only in part, the Commission's power to define technical requirements is not uncommon in highly specific and narrowly focused areas, such as in the Machinery Directive.[115] Another example forms the In Vitro Diagnostic Regulation, in which the Commission established common specifications for certain high-risk *in vitro* diagnostics.[116]

However, the use of such common specifications in the Draft AI Act is still vague, and the current formulation of art. 41 potentially leaves the Commission with a huge discretionary power while imposing no obligation to state reasons for acting through common specifications. For instance, it remains unclear which process the Commission will follow when deciding that the existent harmonized standards are insufficient, and whether it will make any distinction between safety and fundamental rights concerns[117]. Without any further clarifications regarding the type of technical specifications that the Commission may issue under art. 41, this method is also likely not to sit well with the commercial stakeholders. They may see in the Commission a potential "competitor" in harmonized standards development, or even risk being deprived of the traditional industry-driven character of standardization.[118] The considerable discretion of the Commission is also problematic from the viewpoint of the Member States, since the level of protection of most (ethical) values and fundamental rights, which have not been subject to EU harmonization, is primarily determined at the national rather than the EU level.

On a positive note, if the final AI Act eventually results in the higher level of protection of fundamental rights, be it through harmonized standards, common specification or the

[113] Communication (COM)2021 206 final (Draft AI Act) cit. art. 41.

[114] *Ibid*. art. 3(28).

[115] See, for example, Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast), art. 9.

[116] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council.

[117] The amendments of the European Parliament of June 2023 have clarified some of these issues, if only in part, adding that the Commission should consult the AI Advisory Forum and listing conditions to be fulfilled in order for the Commission in order to invoke this provision (see the amended Article 41a). One may also argue that this provision is tilted towards fundamental rights, since following the amendemnt (proposed article 41b), the EC can act "when it wants to address specific fundamental rights concerns".

[118] DIN/DKE, Position Paper on the EU "Artificial Intelligence Act" (June 2021) www.din.de. Note that the Council proposal suggest that if the harmonized standards arise – or Commission considers them sufficient – they will replace common specifications.

CJEU's interpretation of the AI Act's provisions, this may signal a positive development towards the global enforcement of fundamental rights. Similarly to the GDPR, the AI Act is likely to set global rules for AI regulation, since the requirements of this legislation, including the New Approach framework implemented for high-risk AI systems, will need be adhered to by non-EU companies operating on the EU market. As Kop puts is, by embedding Union fundamental rights and values into the architecture and infrastructure of AI, the EU "provides direction and leads the world towards a meaningful direction".[119] From this perspective, the Draft AI Act could also play a valuable role in the development of so-called "values-based design" in AI,[120] contributing to its future-proofness. However, such a key role in the global AI regulation implies that the EU needs to actively embed norms, principles and values into the architecture of AI's technology, *i.e.*, a bottom-up design that focuses on incorporating fundamental rights into the earliest stages of AI design.[121] By imposing a wide variety of obligations on AI during the development of AI systems, the Draft AI Act forms a much welcome contribution in this regard. If the EU would *not* take a leading role in values-based AI design, the potential risk could be that other economies with less, or even absent, democratic and constitutional values and ethical norms, could design and distribute their AI technology in a way that imposes their values in the EU's "AI order".[122]

IV.3. The future-proofness from a democratic and legitimacy perspective

Several considerations regarding the "future-proofness" of the Draft AI Act can also be made from the viewpoint of the legitimacy and democratic character of the New Approach. Granting rule-making power to ESOs remains controversial. Long before the global world expressed the need to regulate AI, it was argued that the European standardisation regime lacks sufficient democratic oversight and adequate stakeholder participation.[123] According to McGee and Weatherill, there are "structural reasons why the [New Approach] might serve the European consumer ill".[124] In short, tensions exist regarding ESOs governed by private law but issued with public tasks and which do not have to comply with key public guarantees and can pursue commercial interests.[125] There is

[119] M Kop, 'EU Artificial Intelligence Act' cit. 10.

[120] *Ibid*. 10.

[121] See P Nemitz, 'Constitutional Democracy and Technology in the Age of Artificial Intelligence' (2018) Royal Society Philosophical Transactions 12;C Djeffal, 'AI, Democracy, and the Law' in A Sudmann (eds), *The Democratization of Artificial Intelligence: Net Policies in the Era of Learning Algorithms* (De Gruyter 2020) 255-284.

[122] M Kop, 'EU Artificial Intelligence Act' cit. 14. See Communication COM(2022) 31 final from the Commission of 2 February 2022 on a EU Strategy on Standardisation.

[123] A McGee and S Weatherill, 'The Evolution of the Single Market: Harmonisation or Liberalisation' (1990) The Modern Law Review cit. 585. See also H Schepel, *The Constitution of Private Governance* cit. 67.

[124] *Ibid*. 585.

[125] See also M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' cit. The recent ECJ case law confirmed that ESOs can pursue commercial goals, albeit the dispute was set

thus an imminent clash between private and public interests within the framework and practice of ESOs.

The EU legislation prescribes ESOs to adhere to certain good governance principles, such as transparency, openness, and participation.[126] In particular, art. 5(1) of Regulation 1025/2012 stipulates that each ESOs "shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities". However, whether stakeholder participation materializes in practice remains debatable,[127] especially since it is the national standards bodies – and not necessarily the ESOs, – that should guarantee stakeholder participation at the European level.[128] While this is generally a serious shortcoming of the New Approach standardisation technique,[129] insufficient stakeholder participation is especially problematic for AI due to its value-loaded choices. To incorporate fundamental rights and values in the harmonised standards, standardisation processes will need to include stakeholder representation from organisations that are usually unfamiliar with standardisation.

Furthermore, stakeholder participation in standardisation processes in the ESO's technical committees often seems unevenly balanced, which could have profound influence on the development of harmonised standards in AI. Non-technical stakeholders such as consumer or civil society organisations, as well as small and medium enterprises (SMEs), encounter *de facto* exclusion from participating in the technical committees preparing the harmonised standards, in part due to the lack of resources necessary to take part in standardization processes.[130] Active and meaningful participation in ESOs is time-consuming and generally subjected to a (substantive) fee.[131] As a result, large commercial stakeholders, possessing the required expertise and resources, play a disproportionately large role in providing input for harmonised standards. In addition, ESO's internal procedures are believed to fall short on safeguarding sufficient participation, transparency and

in the other context, see case T-185/19 *Public.Resource.Org and Right to Know v Commission*. ECLI:EU:T:2021:445 para. 73.

[126] O Kanevskaia, *The Law and Practice of the Global ICT Standardization* cit.; M Eliantonio and M Medzmariashvili, 'Hybridity under Scrutiny: How European Standardisation Shakes the Foundations of Constitutional and Internal Market Law' (2017) Legal Issues of Economic Integration 332.

[127] See M Kallestrup, 'Stakeholder Participation in European Standardisation: A Mapping and an Assessment of Three Categories of Regulation' (2017) Legal Issues of Economic Integration 381-393.

[128] The emphasis on national standards bodies appears from the new European standardization strategy.

[129] See, for a more in-depth contribution, M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique: A Cross-disciplinary and Multi-level Analysis* (Elgar Publishing 2020).

[130] M Eliantonio and C Cauffman, 'The Legitimacy of Standardisation as Regulatory Technique in the EU: A Cross-sector and Multi-level Analysis: An introduction' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* cit. 9.

[131] P Cuccuru, 'Interest Representation in European Standardisation: The Case of CEN and CENELEC' (2019) Amsterdam Law School Legal Studies 14.

accessibility.[132] Social stakeholders only enjoy an observer status, without voting rights. Although in theory, anyone may comment on the drafts discussed within the ESOs technical committees through the public enquiry procedure, in practice, awareness of every public enquiry remains a Herculean task.[133] Together with its ambiguous and fast-moving development, the possibility to safeguard 'all citizens' interests during AI standardisation process seems rather challenging. [134]

Given the lack of stakeholder participation, various organisations have advocated in recent years to improve participation of interest groups in the standardisation process.[135] In its recent Standardisation Strategy, the Commission acknowledged these concerns,[136] stating that the current decision-making processes within the ESOs allow for "uneven voting power to certain corporate interests",[137] and proposed to amend Regulation 1025/2012.[138] At its core, the proposed Regulation strengthens the role of national standardisation bodies in the decision-making process of the ESOs. For example, decisions on the adoption, revision and withdrawal of European standards need to be taken exclusively by national standardisation bodies.[139] The Commission considers the national standardisation bodies as best placed to make sure that the interests, policy objectives and values of the Union as well as public interests in general are duly considered in European standardisation organisations.[140]

However, it may also be argued that the Commission removes from ESOs any responsibility to ensure stakeholder participation, instead placing this responsibility on national bodies without providing for any penalties in case national bodies fail to ensure stakeholder representation. Furthermore, the question remains whether it is realistic to expect national standards bodies to protect *European* interests, let alone public interests, not least due to their often modest (human and financial) resources. At the same time,

[132] C Caufmann and M Gérardy, 'Competition Law as a Tool to Ensure the Legitimacy of Standard-setting by European Standardisation Organizations?' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* cit.

[133] M Eliantonio and C Cauffman, 'The Legitimacy of Standardisation as Regulatory Technique in the EU' cit. 9. The reports issued by the ESOs technical committees merely contain the outlines of the meetings, making it near-to-impossible to verify the negotiations and possible collusion between participants.

[134] See Senden who suggests that they should represent the interests of all citizens, L Senden, 'Towards a More Holistic Legitimacy Approach to Technical Standardisation in the EU' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* cit. 27.

[135] See for example European Association for the Co-ordination of Consumers Representation in Standardisation, Comments on the European Commission proposal for an Artificial Intelligence Act (ANEC 2021).

[136] Communication COM(2022) 31 final from the Commission of 2 February 2022 on an EU Strategy on Standardisation 4.

[137] *Ibid*. 4.

[138] Communication COM(2022) 32 final Proposal for a Regulation of the European Parliament and the Council of 2 February 2022 amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardization deliverables. Approved by European Parliament in October 2022.

[139] Communication COM(2022) 32 final cit. art. 2(a).

[140] Communication COM(2022) 32 final cit. recital 5.

shifting the balance to national standardisation bodies could lower the barrier for social stakeholders to, for example, raise concerns or exercise influence on the decision-making. As such, to increase and maintain trust in the EU standardisation process in the field of AI, as well as to enhance the legitimacy of this process, effective participation of affected stakeholders must be a prerequisite.

V. Conclusion and recommendations

This contribution examined whether the proposed use of the "New Approach" regulatory technique in the Draft AI Act is sufficiently future-proof, in the sense that it both enhances the EU internal market and other core values, including important fundamental rights that are at stake when developing and applying AI.

We found that the use of the New Approach in regulating (high-risk) AI systems has several important upsides. From the perspective of the internal market, the Draft AI Act brings substantial benefits, contributing to the free movement and market integration. Private regulation by means of standards and certification generally delivers a high level of expertise, which suits well with large and up-to-date knowledge of AI industry players in tackling technical, complex and detailed issue relating to AI. Because private regulation may lead to a broader ownership of AI's policies, as well to the involvement of private parties during the development of harmonised standards, the end-result could be a higher level of compliance with the AI Act.[141] The New Approach thus offers a flexible regulatory framework, especially compared to the traditional EU legislative process.

Furthermore, the use of a Regulation instead of a Directive is welcomed. By its regulatory nature, the Draft AI Act allows for a level playing field for providers placing AI systems on the EU market. Instead of having 27 Member States implementing the requirements and obligations of the Draft AI Act by themselves, the choice of a regulation ensures a uniform application and increased legal certainty of the Draft AI Act throughout the EU. The AI Act can also be applied directly in horizontal conflicts, which would have not been the case as a directive. Additionally, the impact of setting harmonised rules for AI systems will likely extend beyond the EU's borders, possibly creating a so-called "Brussels effect" and strengthening the EU's role as a global actor in safeguarding fundamental rights.[142]

At the same time, we have identified several shortcomings that affect the future-proofness of the Draft AI Act. From an internal market perspective, there are currently insufficient possibilities to expand the list of high-risk AI systems, which could severely limit the AI's Act adaptability to future, still unknown developments. In addition, the frequent use of vague wording and definitions in the Draft AI Act offers providers of AI

[141] M Eliantonio and C Cauffman, 'The Legitimacy of Standardisation as Regulatory Technique in the EU' cit. 9.

[142] A Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press 2020).

systems (too) much room for interpretation, for example when self-assessing the conformity of their high-risk AI systems with the harmonised standards.

With regard to the protection of fundamental rights, the question remains how suitable the New Approach, once developed for an "offline" world, is for the fast-evolving and complex "online" field of AI. The risk-based approach in the Draft AI Act means that providers need to evaluate their operational risks against *fundamental rights*. This suggested balancing exercise, however, ignores the often-non-negotiable character of fundamental rights, especially considering AI's potential adverse impact. The fact that the New Approach was particularly designed to speed-up the decision-making process, to protect the unity of the EU internal market and to enhance free movement, sits uneasily with the importance of fundamental rights' aspects of AI. In that light, endowing private standards bodies with ethical and fundamental rights decision-making is generally a worrisome development.

Finally, the "New Approach" raises questions from the perspective of democratic legitimacy. Social stakeholders, SMEs and Member States struggle for input in the standardisation process. However, precisely in the value-loaded field of AI, space for diverse opinion and the possibility to raise ethical concerns should not be lacking.

To mitigate these concerns, we propose several recommendations that would contribute to the future-proofness of the AI Act. Firstly, to better protect fundamental rights, we propose to provide more oversight from the European Commission and European Parliament over the standardization process when it comes to the issues of fundamental rights and ethical considerations taking into account the dynamic nature of AI systems, combined with the inclusion of a complaint and redress mechanism for individuals. This approach is to be preferred to the "decoupling" of economic and fundamental rights issues of the AI Act, by regulating fundamental rights aspects separately,[143] which is difficult due to the lack of a specific legal basis for such a regulation.[144] Furthermore, our proposal does not affect the innovative and market friendly character of the regulation, allowing for regulatory flexibility for the Member States.

Secondly, although oversight by the European Commission (and European Parliament) is desirable, this should go hand in hand with a clarification of the scope of art. 41 of the Draft AI Act, while the recent amendments of the European Parliament addressed some of the concerns raised by this provision, the extent of the discretionary power of the Commission to develop and issue common specifications, as well as the decision-making processes the Commission should follow when assessing whether such specifications are desired, should be (further) addressed. An interesting analogy can be made in that regard with how the Regulation for medical devices provides for common

[143] As suggested, for instance, by M Almada and N Petit, 'The EU AI Act: Between Product Safety and Fundamental Rights' (2022) available at ssrn.com. The amendment of the EP in the form of art. 29(a) to include a fundamental rights impact assessment is to be very much welcomed.

[144] The Charter of Fundamental Rights of the EU does not constitute a separate legal basis for invoking harmonisation legislation.

specifications.[145] Similar to the Draft AI Act, the Commission can lay down common specifications in areas where no harmonised standards exist or are insufficient. However, this possibility arises *only* after the Commission has consulted the expert committee called Medical Device Coordination Group (MDCG), which consists of experts representing the Member States and holding specific expertise in medical devices.[146] The MDCG, in turn, consists of several sub-groups that possess the necessary in-depth technical expertise. This approach forms a positive blueprint for the AI Act, which currently only states – rather vaguely – that the Commission shall "gather the views of relevant bodies or expert groups".[147] A, for example, Artificial Intelligence Coordination Group would create a more coherent framework of expertise the Commission needs to consult before issuing common specifications. In general, improving the current design of art. 41 would mitigate the risk of a "carte blanche" by the Commission in setting requirements for high-risk AI systems. An untransparent discretionary power by the Commission would have negative effects on the involvement of societal stakeholders and industry players, which in turn may undermine the quality of the requirements developed.

Thirdly, we encourage the ESOs and notified bodies to open up to non-technical expertise that can make a meaningful contribution in the area of ethics and fundamental rights. For example, granting societal stakeholders voting or approval rights in the ESOs technical committees could increase their participatory power and improve the overall quality of the harmonised standard. If a societal stakeholder, focussing on fundamental rights aspects of an AI harmonised standard, votes against the final draft standard, this could result in further action within the standardisation process, such as consulting an expert working in the specific field of the societal stakeholder.[148] In a more practical sense, the funding problems in both human and financial resources non-technical stakeholders face in the standard processes needs to be improved. If not, non-technical representation in setting harmonised standards in AI may end up playing second fiddle to the technical, Big Tech stakeholders.

Overall, "futureproofing" the regulation of a fast-paced, multifaced field as AI is not an easy task. With the inevitable regulatory and technical instability, it is difficult to predict what the future holds. Arguably, the use of AI in different sectors may require different regulatory approaches and strategies, which may include experimental legislation like

[145] 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.

[146] Art. 9(1) of Regulation (EU) 2017/745.

[147] Communication (COM)2021 206 final (Draft AI Act) cit. art. 41(2).

[148] See, for example, the recommendations made by the European Environmental Citizen's Organisation for Standardisation: European Environmental Citizen's Organisation for Standardisation, 'The Future of European Standardisation: ECOS' Recommendations for a Transparent and Inclusive Standardisation System, that can Effectively Support EU Legislation and Policies' (23 July 2015) ecostandard.org.

regulatory sandboxes, mechanisms for proactive legislative updates, or legislature allowing deviation and exceptions.[149] In this regard, the criticism on the risk-based nature of the AI Act seems justified. However, the many benefits for European integration that the proposed legislation aims to bring should not be forgotten. Future-proofness is about a legislation that is effective and adapt despite the legal, social and technical changes that come with time. Only time will tell whether the Draft AI Act has successfully anticipated these challenges and provided adequate mechanisms to address them. At least, the Draft AI Act forms a welcome starting point in the increasing policy need to regulate AI in a wide array of domains. Whether it concerns calls to set conditions for effective governance of AI in the military domain,[150] or a separate EU legal framework for AI in the employment context,[151] a successful balance between economic and fundamental rights objectives in the Draft AI Act could form a blueprint for the future AI policy agenda.

[149] See S Ranchordas and M van 't Schip, 'Future-Proofing Legislation for the Digital Age' in S Ranchordas and Y Roznai (eds), *Time, Law and Change: An Interdisciplinary Study* (Bloomsbury 2020) 347.

[150] See, for example, the recent Summit on the Responsible Artificial Intelligence in the Military Domain (REAIM), see Government of the Netherlands, *About REAIM 2023* www.government.nl.

[151] A Ponce del Castillo, 'Labour in the Age of AI: Why Regulation is Needed to Protect Workers' (2020) ETUI Policy Brief.