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# Regulating by standards: current progress and main challenges in the standardisation of Artificial Intelligence in support of the AI Act.

## *Regolare con gli standard: gli attuali progressi e le sfide principali nella standardizzazione dell'intelligenza artificiale a sostegno dell'AI Act.*

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Abstract

The AI Act provides a risk-based framework for the regulation of Artificial Intelligence, delegating the implementation of essential requirements to harmonised standards. This regulatory approach raises several issues concerning the alignment of standards with regulation's requirements, the legitimacy of the European standardisation system, and the ability of harmonised standards to ensure fundamental rights protection. This paper discusses and analyses the regulatory approach underlying the AI Act, the main issues surrounding the proposed regulation, and the implications for the AI Act's ability to achieve its goals.

*L'AI Act propone un quadro legislativo basato sul rischio per la regolamentazione dell'IA, che delega l'attuazione dei requisiti essenziali alle norme armonizzate. Questo approccio solleva diverse questioni riguardanti l'allineamento degli standard ai requisiti del regolamento, la legittimità del sistema della standardizzazione europea e la capacità degli standard armonizzati di garantire la protezione dei diritti fondamentali. Il presente articolo discute e analizza l'approccio normativo alla base dell'AI Act, le principali questioni relative alla regolamentazione proposta e le implicazioni per la capacità dell'AI Act di*

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Keywords: AI Act; harmonised standards; European Standard Organisation; conformity assessment; legitimacy; fundamental rights.

Summary: Introduction. – 1. The European standardisation system. – 2. The role of standards in the AI Act. – 3. Main challenges. – 4. Discussion. – Conclusions.

## Introduction.

As the digital age progresses and artificial intelligence (AI) becomes increasingly integrated into various sectors of society, the need for comprehensive and effective regulation has emerged as a critical concern in Europe.[1] In response, the European Commission has proposed the AI Act,[2] a ground-breaking piece of legislation that is poised to shape the future of AI in Europe.[3] The AI Act establishes a risk-based regulatory framework to develop and use AI systems in Europe, providing different regulatory regimes for AI applications according to their category of risk.[4] The proposed regulation identifies four categories of risk, i.e., unacceptable risk, high risk, limited risk, and minimal risk, determined according to the impact of AI systems on health, safety, or fundamental rights of individuals.[5]

Unacceptable risk AI systems are forbidden under the proposed regulation.[6] AI systems that fall under the unacceptable risk category include those that can manipulate individuals through subliminal techniques or exploit vulnerabilities of particular groups, such as children or persons with disabilities. These practices may cause significant

[1] European Commission, 'On Artificial Intelligence - A European Approach to Excellence and Trust' (White Paper, COM(2020) 65 final).

2 Proposal for a Regulation of the European Parliament and of the Council Laying down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts.' COM/2021/206 final. At the time of penning this piece, the AI Act is currently in the 'trialogue' phase. This means that amendments suggested by the Council of the European Union and the European Parliament may alter the Commission's initial proposal. Upon examining these proposed amendments, it's evident that the principle of relying on harmonised standards for implementing the regulation's requirements and demonstrating compliance hasn't been challenged. Consequently, this aspect of the regulation will very likely remain unchanged. Regardless of any potential change during the trialogue stage, the analysis in this article will continue to hold relevance. We will focus on the European Commission's original proposal and any noteworthy amendments to other areas of the AI Act will be pointed out when necessary. For the general approach by the Council of the European Union, see Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - General approach, available at https://data.consilium.europa.eu/doc/document/ST-14954-2022-INIT/en/pdf. For the amendments proposed by the European Parliament, see 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)), available at https://www.europarl.europa.eu/doceo/document/TA-9-2023-0236_EN.html

3 For a high-level overview of the AI Act see G Resta, 'Cosa c'è di 'europeo' nella Proposta di Regolamento UE sull'intelligenza artificiale?' (2022) Diritto dell'Informazione e dell'Informatica (Il), fasc.2, 1.

[4] For an analysis of the risk-based approach in European digital technology regulation, including the AI Act, see G De Gregorio and P Dunn, 'The European risk-based approaches: connecting constitutional dots in the digital age' (2022) 59 Common Market Law Review.

5 The amendments made by the European Parliament include the protection of "democracy, rule of law, and the environment" as part of the overall objectives of the AI Act. See Amendments adopted by the European Parliament, Amendment 3, Recital 1.

6 See AI Act, Title II.

psychological or physical harm to the affected individuals. Furthermore, the regulation prohibits AI-based social scoring for general purposes by public authorities[7]. AI systems cannot be used for evaluating or classifying the trustworthiness of individuals based on their social behaviour, personal or personality characteristics, leading to detrimental or unfavourable treatment in unrelated social contexts or unjustified treatment disproportionate to their behaviour. This prohibition aims to prevent invasive and unjust social consequences that may result from AI-driven assessments. Lastly, the use of real-time remote biometric identification systems in public spaces for law enforcement purposes is also banned. However, there are some exceptions to this ban. Real-time remote biometric identification systems can be used under certain limited circumstances, such as searching for potential crime victims (e.g., missing children), preventing substantial and imminent threats to life or physical safety, or detecting and prosecuting perpetrators or suspects of severe criminal offenses. To ensure the rights and freedoms of individuals, the use of these systems must be necessary, proportionate, and subject to authorisation from a judicial or independent administrative authority of the Member States.[8]

AI systems that pose a serious risk to the health, safety, or fundamental rights of individuals fall under the category of "high risk".[9] These AI systems are allowed in the European market, provided they meet mandatory requirements and undergo ex-ante conformity assessment. The requirements cover the following areas: risk management, data quality and governance, technical documentation, record keeping, transparency and provision of information to users, human oversight, accuracy, robustness, and cybersecurity.[10] Aligning with existing product safety legislation, classification as high-risk depends on the AI system's intended purpose.[11] Based on the classification rules for high-risk AI systems,[12] the AI Act identifies two different types of high-risk AI systems. On the one hand, high-risk AI systems are those used as safety components in products,

7 Concerning prohibited AI practices, in Article 5 the compromise text of the Council contains the extension of the prohibition of using AI for social scoring also to private actors.

8 The European Parliament has significantly broadened the list of prohibited practices. The amendments further include the following banned applications: 1) Remote biometric identification systems that operate in "real-time" within publicly available spaces; 2) Remote biometric identification systems operating in "post" mode, with the only permissible use being by law enforcement in the investigation of severe crimes, subject to judicial approval; 3) Systems for biometric categorisation that utilise sensitive attributes such as gender, race, ethnicity, citizenship status, religion, and political inclination; 4) Predictive law enforcement systems that draw conclusions based on profiling, geographical location, or past criminal activity; 5) Systems for emotion recognition employed in law enforcement, border management, workplaces, and educational institutions; and 6) Unrestricted collection of biometric information from social media platforms or CCTV recordings to construct facial recognition databases, which infringes human rights and the right to privacy. See Amendments adopted by the European Parliament, Amendments 215-231, Article 5.

9 High-risk systems, according to the European Parliament, also include those that could potentially harm the environment. In addition, the European Parliament categorize AI systems used for manipulating voter preferences in political campaigns, and those used in social media platforms' recommendation algorithms, as high-risk. See Amendments adopted by the European Parliament, Amendment 234, Article 6, and Amendments 739-740, Annex III. The Council's general approach have deleted three high-risk applications (deep fake detection by law enforcement authorities, crime analytics, verification of the authenticity of travel documents), and added two new ones (critical digital infrastructure and life and health insurance).

10 See AI Act, arts. 9-15.

11 For an analysis of the relationship between the AI Act and safety legislation see T de Graaf and G Veldt, 'The AI Act and Its Impact on Product Safety, Contracts and
Liability' (2022) European Review of Private Law 5.

12 See AI Act, art. 6.

or are themselves products, covered by Union harmonisation legislation listed in Annex II and requiring third-party conformity assessment. On the other hand, stand-alone AI systems with significant health, safety and fundamental rights implications are also considered high-risk. They include, among others, those used in education and vocational training, employment, workers management and access to self-employment, law enforcement, administration of justice and democratic processes.[13]

AI systems that interact with humans (e.g., chatbots), detect emotions or determine association with social categories based on biometric data, generate or manipulate content, are considered limited-risk and are subject to transparency obligation.[14] These transparency measures ensure that individuals are aware when they interact with an AI system or when their emotions or characteristics are recognised automatically. When AI systems generate or manipulate content, such as image, audio, or video, that closely resembles authentic content, there is an obligation to disclose that the content is produced through automated means.[15] Exceptions apply for legitimate purposes, such as law enforcement or freedom of expression. Transparency enables individuals to make informed choices or disengage from a situation involving AI systems and AI-generated content.

Finally, all AI systems that do not fall into the previously mentioned categories are considered minimal risk and are not subject to any mandatory requirements. However, these systems can still adhere to voluntary measures, such as codes of conduct, aimed at enhancing excellence and trust in AI applications.[16] These codes are designed to encourage providers of non-high-risk AI systems to voluntarily adopt the mandatory requirements specified for high-risk AI systems. By adhering to these codes, providers can demonstrate their commitment to additional requirements related to environmental sustainability, accessibility for persons with disabilities, stakeholder participation in AI system design and development, and diversity within development teams. By integrating these aspects into their codes of conduct, providers can foster greater trust and confidence in their AI systems, ensuring that they not only adhere to high standards of safety and transparency but also contribute positively to society and the environment.

The AI Act is partially based on the regulatory approach outlined by the New Approach[17] and reinforced by the New Legislative Framework.[18] Both the New

13 See AI Act, Annex III for a complete list.

14 See AI Act, Title IV.

15 The European Parliament extends these transparency obligations also to general-purpose and generative AI systems. See Amendments adopted by the European Parliament, Amendment 399, Article 28b (new). The Council's general approach delegates the application of requirements for general purpose AI systems to implementing acts specifying how these requirements should be applied in relation to general purpose AI systems.

16 See AI Act, Title IX.

17 Council Resolution of 7 May 1985 on a New Approach to technical harmonisation and standards [1985] OJ C 136. For a detailed analysis of the "New Approach" see J Pelkmans, 'The New Approach to Technical Harmonization and Standardization', (1986-1987) 25 J. Common Mkt. Stud. 249.

18 The New Legislative Framework consists of:

a. Regulation (EC) No 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 [2008] OJ L 218/30.
b. Decision No 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 [2008] OJ L 218/82.

Approach and the New Legislative Framework aim at creating a more streamlined and effective regulatory environment for products and services within the single market. The New Approach, initiated in 1985, stipulates that harmonised legislation is limited to the definition of the essential requirements to which products must conform in order to be marketed and enjoy free movement within the European Union. Rather than establishing detailed technical specifications for implementing essential requirements in the legislation, the New Approach entrusts the task of developing harmonised standards to competent European standardisation organisations (ESOs), i.e., CEN, CENELEC and ETSI. While harmonised standards are voluntary, they play a crucial role in ensuring product safety and compliance. National authorities are obliged to recognise that products manufactured in conformity with harmonised standards are presumed to conform to the essential requirements established by the corresponding legislation. Since industry players are directly involved in the creation of harmonised standards, this approach amounts to a form of co-regulation that fosters close cooperation between public authorities and market operators. [19] By distinguishing between essential requirements and technical specifications, the New Approach has provided a more flexible and effective way to ensure product safety and compliance within the European Union, while promoting innovation and technological progress. In 2008, the New Approach was reinforced by the New Legislative Framework, which introduced a set of measures to improve market surveillance, strengthen the conformity assessment system and the accreditation of conformity assessment bodies, and clarify the roles and responsibilities of various economic operators.

The New Approach and the New Legislative Framework have been successful in achieving the European Union's policy objectives, including the promotion of consistency and coherence in EU harmonisation legislation, the enhancement of the conformity assessment system, and the reinforcement of the clarity and credibility of the CE marking. [20] Nevertheless, the application of this approach to the regulation of artificial intelligence raises several challenges. This paper discusses and analyses these challenges as follows. Section 1 provides background information on the European standardisation system. Section 2 outlines the role of standards in the AI Act. Section 3 examines the three primary challenges identified: 1) ensuring the implementation of standards aligned with the regulation's requirements; 2) evaluating the legitimacy of ESOs in determining how to implement these requirements; 3) assessing the capacity of the standards to provide adequate protection of fundamental rights, which is one of the specific objectives of the AI Act. Section 4 presents a discussion regarding these challenges. Finally, the conclusion summarises the main findings and suggests potential avenues for future research.

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c. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 [2019] OJ L 169/1.

For a detailed analysis of the "New Legislative Framework" see L Gorywoda, 'The New European Legislative Framework for the Marketing of Goods', (2009-2010) 16 Colum. J. Eur. L. 161.

19 For an analysis of the role of co-regulation in the AI Act see A Simoncini, 'La co-regolazione delle piattaforme digitali' (2022) Rivista Trimestrale di Diritto Pubblico, fasc.4, 1. For a more general analysis of the co-regulatory approach in European legislation see L A J Senden, 'Soft Law, Self-Regulation and Co-Regulation in European Law: Where Do They Meet?' (2005) 9(1) Electronic Journal of Comparative Law.

20 Evaluation of the New Legislative Framework, Commission Staff Working Document, SWD(2022)364, 2022.

## 1. The European standardisation system

The Regulation (EU) No 1025/2012 on European standardisation (henceforth, RES) establishes the main principles and procedures of European standardisation.[21] The regulation's primary objective is to ensure the effectiveness and efficiency of standards and standardisation as policy tools for the Union through cooperation between ESOs, national standardisation bodies, Member States, and the European Commission.

The principles guiding European standardisation are drawn from the standardisation principles of the World Trade Organisation.[22] They include coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency. To ensure ESOs adhere to these principles, the RES provides for specific measures to enhance transparency and participation in the standardisation process within ESOs. As part of these measures, ESOs are required to create and publicly share an annual Work Programme, which outlines the standards and standardisation deliverables they plan to develop or revise, are currently developing or revising, and have adopted during the previous Work Programme period. Moreover, ESOs are encouraged to promote and enable appropriate representation and active participation from all interested parties. This includes small and medium-sized enterprises (SMEs), consumer organisations, public authorities as well as environmental and social stakeholders, ensuring that their voices are heard and considered in standardisation activities.

In order to clarify how standards and standardisation are expected to support European legislation and policies, the RES mandates that the European Commission adopt an annual Union work programme for European standardisation. This program identifies strategic priorities, taking into account the Union's long-term growth strategies. Based on this, the Commission can then request ESOs to produce standards specified in the annual work programme. This process, called standardisation request, is outlined in Article 10 of the RSE and further detailed in the Vademecum on European standardisation.[23]The process includes four main steps: issuance of a standardisation request by the Commission, acceptance and execution of the standardisation request by the ESOs, assessment of ESOs documents, and adoption.

The Commission's standardisation request details the objectives, scope, and deadlines for drafting the standards. In certain situations, a standardisation request is necessary to ensure compliance with relevant legislation and maintain transparency in

21 Regulation (EU) No 1025/2012 on European standardisation [2012] OJ L316/12. The RES was recently amended by the Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 1025/2012 as regards decisions of European standardisation organisations concerning European standards and European standardisation deliverables [2022] OJ L 323/1. However, the amendments did not affect the fundamental principles of the European standardisation system discussed in this section and are therefore not discussed here.

22 WTO, 'Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement', Available at: https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm. For a detailed analysis of WTO principles for standardisation in the context of TBT agreements see Steve C 'International Standards and the WTO' (2005) GW Law Faculty Publications & Other Works, 394.

23 Vademecum on European standardisation in support of Union legislation and policies, Commission Staff Working Document, SWD(2015) 205.

the standard-setting process. For example, it is required in the case of harmonised standards, where legislation mandates the publication of references in the Official Journal of European Union (OJEU). Likewise, issuing a standardisation request is compulsory for European standards that offer a presumption of conformity or other legal effects under the applicable sectoral legislation. After the Commission issues a standardisation request, the ESOs must respond within one month, indicating whether it accepts the request. If the ESOs accept it, it begins its activities and keeps the Commission informed about the progress in developing the requested documents. The primary responsibility of ESOs is to guarantee that the request is carried out correctly, and that the subsequent harmonised standards adhere to it and the corresponding legislative act. Once the ESOs have developed the harmonised standard, it undergoes a series of checks and assessments before its reference is published in the OJEU. The assessment process may involve external third parties such as harmonised standards (HAS) consultants.[24]If the assessment is positive and a standard fulfils the requirements set out in the standardisation request and the corresponding Union harmonisation legislation, the Commission publishes a reference to that standard in the OJEU. A European standard adopted on the basis of a request submitted by the Commission is defined as a "harmonised standard".

When a harmonised standard is referenced in the OJEU, it can be used to demonstrate compliance with the relevant legislation. As detailed in the "Blue Guide" on the implementation of EU product rules 2022,[25]applying a harmonised standard provides a presumption that a product or service complies with the relevant essential or other legal requirements. This applies only if the harmonised standard matches the relevant requirements according to the standardisation request and if it is referenced in the OJEU. Since ESOs can produce harmonised standards based fully or partially on international ISO or IEC standards,[26] it is crucial to note that the presumption of conformity is only applicable when using the European version published by reference in the Official Journal. This is because the European version might require technical modifications to ensure compliance with the legal requirements. Furthermore, the ISO and IEC versions do not contain information about which clauses of the standard are relevant for which essential requirement, as this information is only included in their European version. These standards play a critical role in helping manufacturers and other economic operators demonstrate compliance with the applicable legal requirements. However, manufacturers and providers are not obliged to use

24 CEN, 'HAS Assessment Process', Available at: https://boss.cen.eu/developingdeliverables/pages/en/pages/has_assessment_process/

25 The Blue Guide is a crucial guidance document for EU product rules. It applies to a wide range of products covered by Union harmonisation legislation, including CE-marked products such as radio equipment, medical devices, toys, and machinery, among others. While not legally binding, it provides significant interpretative guidance on many areas of product regulation and is heavily relied upon by market surveillance authorities. The 2022 revision addresses new regulations, challenges of new technologies, and new marketing structures, including online sales. It also reinterprets some fundamental principles of European law, such as the "right to repair" and how software updates to products are handled under EU product safety regimes. See The 'Blue Guide' on the Implementation of EU Product Rules, Commission Notice, 2022/C 247/01, OJ C 247/1.

26 Today, out of around 3 500 CEN and CENELEC Standards cited in the Official Journal, 44% are based on International Standards. See Feedback from CEN-CENELEC to Standardisation strategy, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy/F2665566_en.

harmonised standards and can choose alternative means to demonstrate conformity with the essential requirements.

Since harmonised standards are instrumental to the presumption of conformity, this latter concept is intimately linked with this regulatory approach.[27] Presumption of conformity is a legal principle that arises from the assertion that a product adheres to harmonised standards published in the OJEU. This principle establishes that the product meets the essential requirements of an EU legislation based on that claim. When all relevant parties across Europe concur that a specific technical solution described in a harmonised standard represents the best practice for a certain essential requirement, authorities will generally accept this determination. In this way, harmonised standards promote product conformity and streamline the conformity assessment process. "Product conformity" under Union harmonisation legislation refers to a product's compliance with applicable essential requirements, as outlined in a relevant European directive or regulation. "Conformity assessment" is a procedure carried out under the manufacturer's responsibility, involving a choice among various optional or mandatory conformity assessment procedures during the design and production phases.[28] In some cases, manufactures may autonomously carry out all checks needed to ensure the conformity of the product. In other cases, this process may require the involvement of a third-party conformity assessment body, which is independent of the manufacturer, to examine the product and/or various phases of the manufacturer's design and production process. Although adopting standards is voluntary and alternative methods exist to benefit from the presumption of conformity, such as the certification of the product by an independent third party, adhering to harmonised standards is often the most convenient option for manufacturers and providers.

The presumption of conformity provides two key advantages. Firstly, it increases legal certainty. By adhering to harmonised standards, manufacturers gain a favourable opinion from market surveillance authorities. This confirmation of proper conduct is vital to manufacturers' business operations. In the *Global Garden Products Italy SpA (GGP Italy) v European Commission* case,[29] the European Court of Justice (ECJ) criticised the Commission for depriving economic operators of the benefits associated with using harmonised standards. The ECJ also underscored that corrective actions from competent authorities must always be based on established non-compliance with essential requirements. Secondly, the presumption of conformity partially reverses the burden of proof of non-compliance in favour of manufacturers. When manufacturers adhere to the specifications in the standard(s) addressing all the essential requirements of the applicable legislation, they can assume they have met those requirements, obliging enforcement authorities to prove otherwise.

However, the presumption of conformity also has some limitations that affect manufacturers claiming this benefit. While designing a product in compliance with harmonised standards enables the presumption of conformity to serve as a crucial

27 For a detailed analysis of "presumption of conformity" see P Portalier, 'Myths and realities of the presumption of conformity. Scope and relevance of the presumption of product conformity with Union harmonisation legislation in 10 questions and answers', version 1c of 15/5/2017.

28 For a detailed analysis of the functioning of conformity assessment processes under the New Approach see H Delaney and R van de Zande, 'A Guide to EU Standards and Conformity Assessment', NIST Special Publication 951.

29 Case T-474/15, Global Garden Products Italy SpA v. Commission, 2017 E.C.R. 36.

indicator of adherence to EU legislation, it does not constitute a definitive proof. It contributes to establishing the manufacturer's good faith but remains a rebuttable presumption, as market surveillance authorities and Member States can still act if risks arise. The legal effect of the presumption of conformity is also limited in terms of granting free circulation rights within all Member States without additional administrative burdens. Nonetheless, it does not guarantee safety or compliance. Manufacturers of products not covered by Union harmonisation legislation might be required to demonstrate an equivalent level of public interest protection in the target country compared to the country of origin. Additionally, conformity with a standard does not necessarily imply conformity with the law. The presumption of conformity represents a claim made by the manufacturer, not a guarantee that the harmonised standard meets the relevant request(s) from the European Commission and covers the essential requirements it claims to cover. Standards serve as useful indicators but are not infallible.

The legal status of harmonised standards remains contentious.[30] On one hand, they are voluntary, non-binding, tools established by private organisations, while on the other hand, they are referenced in European laws and produce legal effects, such as the presumption of conformity. These ambiguities are reflected in the judgment of the European Court of Justice in the case of James Elliott v. Irish Asphalt.[31] On that occasion, the Court regarded harmonised standards as "part of EU law", but simultaneously, it recognised that these measures are not acts of the institutions, bodies, offices, or agencies of the Union. Consequently, the Court integrated harmonised standards into the legal framework of the European Union, while maintaining the European Standardisation Organizations on the outskirts of the Union's institutional structure. This ambiguity, which has not yet been resolved at the legislative or jurisprudential level, underlies many of the legitimacy issues explored in Section 3.b.

### 2. The role of standards in the AI Act

The AI Act leverages the regulatory approach described in the previous section. It recognises that harmonised standards should play a key role in providing technical solutions to suppliers to implement the essential requirements and demonstrate compliance with the regulation.[32]This is explicitly provided for in Article 40, according to which high-risk AI systems that comply with harmonised standards, or parts thereof, are presumed to comply with the requirements of the regulation.[33] Since harmonised

30 See C Colombo and M Eliantonio, 'Harmonized Technical Standards as Part of EU Law: Juridification with a Number of Unresolved Legitimacy Concerns?: Case C-613/14 James Elliot Construction Limited v. Irish Asphalt Limited, EU:C:2016:821', (2017) 24 Maastricht Journal of European and Comparative Law 323.

31 Case C-613/14, James Elliott Constructiong Ltd. v. Irish Asphalt Ltd., 2016 E.C.R. I-821.

32 See AI Act, Recital 61.

33 The European Parliament has proposed minor amendments to Article 40 in order to clarify that actors involved in the standardisation process shall take into account the general principles for Trustworthy AI, shall seek to promote investment and innovation in IA and the competitiveness and growth of the Union market, contribute to strengthening global cooperation on standardisation and take into account existing international standards in the field of AI that are consistent with the fundamental values, rights and interests of the Union and ensure a balanced representation of interests and effective participation of all stakeholders, in accordance with Articles 5, 6 and 7 of Regulation (EU) No 1025/2012. The Council's general approach makes similar remarks.

standards play a key role in providing technical solutions that enable providers to implement the requirements of the regulation, they serve as a preferred, though not the only, means for suppliers to demonstrate compliance with the regulation.

This has practical implications for providers of high-risk AI systems. Once the AI Act becomes applicable, they will have to comply with the essential requirements before releasing high-risk AI systems on the market. One way to do this is to follow the guidance offered by the harmonised standards that implement the essential requirements. By following these standards, providers of high-risk AI systems can benefit from a presumption of conformity with the requirements of the regulation. Although this is not the only way to comply with the requirements and benefit from the presumption of conformity, it is particularly convenient for providers for several reasons. First, it is cheaper than other alternatives, such as the certification of the product by an independent third party. Furthermore, as discussed above, the presumption of conformity resulting from the application of harmonised standards provides greater legal certainty for providers, as they benefit from a favourable opinion from the market surveillance authorities. Finally, the presumption of conformity reverses the burden of proof of non-compliance to the benefit of providers.

The AI Act's dependence on harmonised standards highlights the necessity for their development. This is crucial to ensure that the regulation's requirements can be implemented by providers. To address this need, the Commission needs to issue a standardisation request to the ESOs. As the AI Act explicitly refers to harmonised standards, the Commission is, in fact, obligated to initiate a standardisation request, as discussed in the previous section. At the time of writing this article, the Commission has only submitted a draft standardisation request.[34] This is expected to be transformed into an official request in the near future. Since the AI Act is now in trialogue stage, it will likely undergo changes compared to the original Commission proposal. Consequently, the Commission may revise the standardisation request to accommodate any changes in the final text of the AI Act.

The draft standardisation request contains the rationale and terms of the request, a ten-item list of standards and standards deliverables to be drafted, and a set of requirements for the prospected standards. CEN and CENELEC are the primary recipients of the request, with ETSI mentioned as contributor to fulfil the request. The draft identifies ten areas on which CEN and CENELEC are to produce or adopt standards. They correspond to some of the requirements and obligations put forward in Chapters II and III of the AI Act. The following table shows the list of new European Standards and/or European standardisation deliverables to be drafted and maps them to the corresponding articles of the AI Act.[35]

| Standardisation area | AI Act | Standardisation area | AI Act |
|---|---|---|---|
| risk management system for AI systems | Art. 9 | accuracy specifications for AI systems | Art. 15 |

34 Draft Standardisation Request to the European Standardisation Organisations in Support of Safe and Trustworthy Artificial Intelligence, Available at: https://ec.europa.eu/docsroom/documents/52376.
35 *Ibid.*, Annex I.

| | | | |
|---|---|---|---|
| governance and quality of datasets used to build AI systems | Art. 10 | robustness specifications for AI systems | Art. 15 |
| record keeping through logging capabilities by AI systems | Art. 12 | cybersecurity specifications for AI systems | Art. 15 |
| transparency and information to the users | Art. 13 | quality management system for providers of AI systems, including post-market monitoring process | Art. 17 |
| human oversight of AI systems | Art. 14 | conformity assessment for AI systems | Art. 19 |

In the draft standardisation request, the Commission requires ESOs to involve SMEs and civil society organisations in the standardisation process and requires that the standards produced in response to the request should be aligned with the Commission's policy objectives in the field of AI. They include, in addition to the specific objectives of the AI Act, the safety of AI products and services, the respect of fundamental rights and European Values, the digital sovereignty of the Union, the growth of the AI market, the public interest, and the rights of persons with disabilities.

Finally, the Commission encourages collaboration between ESOs and International SDOs, and the possible adoption of standards by ISO/IEC on the basis of the Vienna and the Frankfurt agreements. The Vienna Agreement and the respective implementing guidelines set out the terms of technical cooperation between ISO and CEN.[36] The Frankfurt Agreement describes the cooperation arrangements between IEC and CENELEC.[37] Under the Vienna and Frankfurt Agreements, CEN and CENELEC can adopt ISO and IEC standards as European standards through a streamlined process, known as the "parallel procedure". Thanks to the parallel procedure, CEN and CENELEC can adopt an ISO and IEC standard respectively without the need to undertake a full standardisation process. The standards jointly developed by ISO and IEC in the joint technical committee ISO/IEC JTC 1 are covered by the Frankfurt and Vienna Agreements as well. These institutional arrangements will be crucial to avoid duplication of effort, reduce time, and bring together the expertise needed to realise AI standards.

Thanks to existing agreements, ESOs can leverage the proliferation of international standards in the field of artificial intelligence. Besides developing their own homegrown standards, ESOs can also adopt international standards to support the AI Act. At the international level, standardisation in the field of artificial intelligence has been progressing for several years. ISO/IEC JTC 1 established Subcommittee 42 on Artificial Intelligence in 2017. In 2016, IEEE launched the Global Initiative on Ethics of Autonomous and Intelligent Systems, which includes the P7000 series of standards.[38] ITU has focus groups dedicate to AI since 2017. According to AI Standard Hub,[39] a UK initiative dedicated to monitoring the field of standardisation for AI technologies, these

36 ISO, 'Agreement on Technical Co-Operation between ISO and CEN (Vienna Agreement)'.

37 CENELEC, 'Guide 13. IEC-CENELEC Agreement on Common Planning of New Work and Parallel Voting (the Frankfurt Agreement)'.

38 R Chatila and J C Havens, 'The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems' in MI Aldinhas Ferreira et al. (eds), Robotics and Well-Being (Springer International Publishing 2019).

39 Standards Database (AI Standards Hub), Available at: https://aistandardshub.org/ai-standards-search/.

three standard development organisations (SDOs) alone have published or are developing nearly 150 AI-related standards. Several of these international standards, especially by ISO/IEC and IEEE, could support the AI Act.

The significance of standards within the AI Act's regulatory framework cannot be overstated. In line with the New Approach and the New Legislative Framework, where legislative acts define only essential requirements, the requirements delineated in the AI Act are frequently expressed in a high-level and generic fashion. This necessitates the use of harmonised standards, which can provide a more precise interpretation of specific requirements and their practical implementation. For example, Article 10 of the AI Act establishes criteria for high-quality training datasets. However, as highlighted in some responses to the public consultation on the AI Act conducted by the European Commission,[40] the quality of a dataset is a normative concept, challenging to assess objectively. As a result, these stakeholders advocate for the establishment of EU standards to define what qualifies as 'high-quality' dataset and which desirable attributes it should have.

Because of this interplay between standards and regulation, it is reasonable to concur with Veale and Zuiderveen Borgesius' claim that "standardization is arguably where the real rule-making in the Draft AI Act will occur".[41] However, this introduces several challenges, which will be examined in the remainder of this paper. These challenges can be categorized into three groups. First, alignment challenges (Section 3.a) concern the ability to bring the content of the standards in line with the requirements of the regulation. Second, legitimacy issues (Section 3.b) address the appropriateness of ESOs - private entities - in producing documents that become part of EU law and carry legal implications, such as the presumption of conformity. Lastly, the protection of fundamental rights (Section 3.c) revolves around the ability of harmonised standards to adequately safeguard these rights.

## 3. Main challenges

### a. Alignment challenges

The development and adoption of harmonised standards brings forth the challenge of aligning their content with the requirements of the AI Act, in order to ensure that they effectively operationalise these requirements. The process described in previous sections, where legislative acts establish essential requirements and harmonised standards provide technical specifications for their implementation, is not as simple and straightforward as it may appear. Frequently, the standards proposed by ESOs for adoption as harmonised standards in support of European legislation do not align with the legislative acts they are intended to support. In the *Report on the Implementation*

40 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: OpenAI, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665231_en.

41 M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' (2021) 22 Computer Law Review International 97.

*of Regulation (EU) No 1025/2012 from 2016 to 2020,*[42] the European Commission revealed that only 27.58% of the HAS assessments were deemed positive, primarily due to inconsistencies with EU law and misalignment with policy and legal requirements. This resulted in over 50% of the harmonised standards proposed by ESOs being rejected by the European Commission. Furthermore, a small number of standards face formal objections in accordance with Article 11 of Regulation 1025/2012 on European standardisation. Under this provision, a Member State or the European Parliament may lodge an objection to withdraw or prevent the publication of a harmonised standard in the OJEU if they believe that the standard does not fully satisfy the requirements it aims to address and outlined in the relevant Union harmonisation legislation.

The issue of alignment is especially critical when considering the adoption of international standards as harmonised standards in the context of the AI Act. International standards are typically designed to be as neutral as possible with respect to national and regional interests, in compliance with the principle of impartiality outlined in the WTO's Principles for the Development of International Standards. As such, international standards may not be tailored to meet the specific requirements of the AI Act. Therefore, it is essential to address potential misalignments when adopting international standards as European harmonised standards. Harmonised standards should reinforce the objectives of the AI Act by providing comprehensive processes, procedures, and technical specifications to fulfil its requirements. Failure to adequately address these concerns may lead to the rejection of the harmonised standards by the European Commission, non-publication in the OJEU, and a subsequent unavailability of the presumption of conformity for providers of high-risk AI systems. Such an outcome would significantly complicate and increase the cost of compliance for providers, ultimately undermining the AI Act's effectiveness in safeguarding the health, safety, and fundamental rights of individuals while promoting responsible innovation in field of artificial intelligence.

A review of the existing international standardisation landscape indicates that some standards may effectively cover certain AI Act requirements, while others may not. To evaluate the appropriateness of a specific standard for a particular AI Act requirement, it is essential to conduct a comprehensive comparison between the requirement and the content of the standard in question.[43] This analysis, however, is currently limited to published standards. With this in mind, our illustrative examination will focus on two examples: ISO/IEC 23894:2023 in relation to Article 9 of the AI Act on risk management, and IEEE 7001 concerning Article 13 on transparency.

### i. Risk Management: Article 9 and ISO/IEC 23894:2023

Article 9 of the AI Act requires the establishment of a risk management system (RMS) for high-risk AI systems to be implemented, documented and maintained throughout their entire lifecycle. The RMS shall be a methodical process, comprising several steps.

42 Report from the Commission to the European Parliament and the Council on the Implementation of the Regulation (EU) No 1025/2012 from 2015 to 2020, COM(2022) 30.

43 This comparative analysis is conducted here according to the methodology outlined in J Soler Garrido et al., 'AI Watch: Artificial Intelligence Standardisation Landscape Update', JRC Publications Repository, Jan. 09, 2023.

It starts with identifying and analysing known and foreseeable risks associated with high-risk AI systems, followed by estimating and evaluating risks emerging from the intended use and any reasonably foreseeable misuse. The RMS shall also evaluate other possible risks based on data gathered from post-market monitoring. Upon completion of this analysis, suitable risk management measures shall be adopted.[44]

The goal of the RMS is to ensure that the overall residual risk is acceptable. These residual risks shall be communicated to the user. When implementing risk management measures, the focus should be on eliminating or reducing risks through appropriate design and development choices, implementation of mitigation and control measures for risks that cannot be eliminated, and provision of adequate information and training to users. Article 9 also provides that high-risk AI systems shall be tested to identify suitable risk management measures and ensure they perform consistently. The testing procedures shall be appropriate for the intended purpose of the high-risk AI system and performed at suitable points during the development process, before placing on the market.

Presently, the only published standard concerning AI risk management is ISO/IEC 23894.[45] An examination of this standard reveals that although it integrates certain aspects of Article 9 and the corresponding area of the draft standardisation request, it fails to incorporate others. On the one hand, the standard aligns with Article 9 by establishing that risk management is executed iteratively throughout the entire life cycle, documented comprehensively, and aimed at reducing risk to acceptable levels. On the other hand, it does not mandate communication of residual risks to users or consideration of risks associated with foreseeable misuses. Additionally, it lacks specific testing procedures for identifying risk management measures and does not provide metrics or probabilistic thresholds for conducting testing. Nevertheless, guidance on this matter may be found in standards for testing of AI system like ISO/IEC TR 29119-11.[46]

Another element that misaligns ISO/IEC 23894 from Article 9 is the different conception of risk that underlies the standard compared to the AI Act. The standard focuses on organisational risks, which are uncertainties that could impact an organisation's objectives, while the regulation considers risk as the combination of likelihood and magnitude of harm to individuals' health, safety, and fundamental rights. This factor limits the adequacy of ISO/IEC 23894 in operationalising the AI Act's RMS requirements.

Finally, a key limitation of the ISO/IEC 23894 is that it provides recommendations rather than requirements. In the standardisation field, the distinction between requirements, typically introduced by "shall", and recommendations, introduced by "should", is crucial because only standards containing requirements can be used for conformity assessment. Standards supporting the AI Act must be suitable for conformity assessment in order to verify that an AI system comply with the regulation's requirements. However, since it is not possible to demonstrate compliance with ISO/IEC

44 In addition to the risks for health, safety and fundamental rights, the European Parliament's amendments propose that risks for democracy and rule of law or the environment should also be taken into account when performing risk management under Article 9. See Amendments adopted by the European Parliament, Amendment 263, Article 9.
45 ISO/IEC 23894 - Information technology - Artificial intelligence - Guidance on risk management.
46 ISO/IEC AWI TS 29119-11 - Software and Systems Engineering - Software Testing - Part 11: Testing of AI Systems.

23894, this standard is not an appropriate solution for operationalising the requirements of the AI Act on risk management.

### ii. Transparency: Article 13 and IEEE 7001

Requirements on transparency and provisions of information to users are provided in Article 13 of the AI Act. It requires that high-risk AI systems be designed and developed to ensure a sufficient level of transparency that allows users to interpret the system's output and use it properly. High-risk AI systems shall also be accompanied by instructions providing concise, complete, correct, and clear information that is relevant, accessible, and easy for users to comprehend.

The information provided shall include several elements concerning the characteristics, capabilities, and performance limitations of the high-risk AI system, including its intended purpose, the level of accuracy, robustness, and cybersecurity tested and validated for the system, and any known or foreseeable circumstances that may impact these levels. The information shall also specify any known or foreseeable circumstances that could pose risks to health, safety, or fundamental rights. Moreover, the system's performance concerning the persons or groups it is intended to be used on shall be described. Additionally, Article 13 establishes that human oversight measures, including the technical measures implemented to facilitate users' interpretation of AI system outputs, be detailed. Lastly, the high-risk AI system's expected lifetime should be disclosed, along with necessary maintenance and care measures to ensure proper functioning, including software updates.

IEEE 7001 is pertinent to Article 13 of the AI Act and the corresponding area of the draft standardisation request. The standard defines six levels of transparency, ranging from level 0 (no transparency) to level 5 (highest attainable level), and specifies these levels for three stakeholder groups: users of autonomous systems, the general public and bystanders, and expert stakeholders. For each group, criteria are given to assess the transparency level of an AI system from 0 to 5. The standard can serve two purposes: evaluating the transparency of an existing AI system through a System Transparency Assessment (TSA) or guiding the design of a new system by addressing the transparency needs of each stakeholder group. However, IEEE 7001 does not provide specific guidance on incorporating transparency into AI systems.

IEEE 7001 aligns with Article 13 in multiple ways. Firstly, it considers transparency as the disclosure of information concerning the system's purpose, context of use, capabilities, and limitations. Secondly, the standard assumes that the goal of transparency is to enable users understand the AI system. Thirdly, it acknowledges the necessity to differentiate the type of information provided according to users. This is in line with the requirements of Article 13. In addition, IEEE 7001 explicitly mandates information disclosure on AI system performance, particularly for the expert stakeholder category at transparency level 3. As required by Article 13, IEEE 7001 also requires the release of information about data and maintenance instructions at transparency level 1 for the users stakeholder category. Accordingly, IEEE 7001 may be suitable for assessing whether an AI system is compliant with the requirements of Article 13 of the AI Act. To achieve this, it is essential to determine the appropriate level of

transparency required for each stakeholder category in accordance with the AI Act's requirements. The highest transparency levels in IEEE 7001, such as levels 4 and 5, establish requirements that go far beyond those of the AI Act, for example on explainability. In some cases, level 1 is sufficient for compliance with some of AI Act's requirements, while in other instances, it is necessary to reach level 3, depending on the stakeholder category.

### iii. Factors contributing to alignment challenges

These two examples enable us to pinpoint key challenges in ensuring that future harmonised standards align with the requirements of the AI Act.

First, the current alignment, or lack thereof, between international standards and the AI Act's requirements is coincidental. Both ISO 23894 and IEEE 7001 were being developed prior to the European Commission's release of the AI Act's initial draft. As a result, the alignment of IEEE 7001, for example, is unintentional. Nevertheless, IEEE 7001 demonstrates that international standards can be adopted as harmonised standards when their requirements are more stringent than those of the AI Act. In such instances, it is possible to identify which clauses of the standard are to be followed to meet the requirements.

Rather than adopting international standards, better alignment can be achieved through the development of new standards by ESOs, which can explicitly consider and operationalise the AI Act's requirements within the standards. Moreover, this approach promotes greater alignment with European specificities, such as EU policy objectives and European values and fundamental rights. However, this seemingly straightforward solution encounters significant practical obstacles, such as time constraints, lack of expertise, and market resistance to regional standards in favour of global ones.

Another challenge lies in linking the AI Act's requirements to appropriate standards or their respective sections. The complexity of this task arises from the low probability that a single standard will match exactly with one of the AI Act's requirements. Often, an article in the AI Act contains provisions that are operationalised across multiple standards. For example, Article 9, which focuses on risk management, also covers testing requirements that are separately dealt with in the standardisation process. On the other hand, a single standard may be relevant to several AI Act requirements, as illustrated by IEEE 7001's connection to parts of Articles 12, 13, and 14 of the AI Act.

When determining the compliance of ESOs' documents with the standardisation request and the AI Act's requirements, fundamental rights and European values will be of utmost importance. In areas where technical and value concerns intersect, such as risk management, data quality and governance, and human oversight, ensuring the adequacy of standards can be challenging. For example, Article 10 requires datasets to be complete and error-free.[47] This requirement, however, seems difficult if not

47 Both the Council and the European Parliament suggest modifications to this article, with the goal of enhancing the practicality of the implementation of these requirements. Their proposal is to add provisions stating that datasets should be free of errors and be as complete as is achievable. The Council suggests this should be done "to the best extent possible", whereas Amendment 278, Article 10, proposed by the European Parliament, prescribes that it should be done "as far as this is technically feasible".

impossible to implement.[48] In addition, Article 10 mandates an examination of training datasets for high-risk AI systems for potential bias. However, it is uncertain whether the technical specifications of the standards can provide a clear determination of what bias are and how to identify them, and especially whether they are entitled to do so.[49] This problem highlights broader issues: the capacity of standards to sufficiently protect fundamental rights and European values and their legitimacy in doing so. These topics are further explored in the subsequent sections.

### b. Legitimacy issues

The delegation of powers implied by the European standardisation system has raised a debate on the legitimacy of this regulatory approach.[50] Following the distinction proposed by Schmidt,[51] three types of issues can be identified: input, output, and throughput legitimacy issues.

#### i. Input legitimacy issues

Input legitimacy concerns the representativeness of the decision-making process to ensure responsiveness to people's preferences. It emphasises political participation, representation, and the responsiveness of government to the needs and desires of the citizens. In the context of standard-making, input legitimacy concerns the involvement of all affected stakeholders in the development of standards that directly impact them. This element ensures that their perspectives and interests are taken into consideration. This form of legitimacy necessitates the inclusion and protection of all citizens' interests in the establishment of private standards, as well as in the development of rules and procedures that ensure equal representation and balance competing interests.

Consequently, the input legitimacy of the European standardisation primarily concerns the inclusiveness of the standardisation process within the ESOs. This process is often dominated by industry large players. The European Commission acknowledges this when it states that the industry is “the key stakeholder in standardisation, the engine of all standardisation and the main influencer of European standardisation”.[52] As a result, large industry actors typically wield significantly more influence than other market participants. Small and medium-sized enterprises (SMEs) are often effectively excluded from participating due to financial and time constraints.[53] The standardisation process is generally organised into Technical Committees (TCs) comprised of Working

48 For a more detailed analysis on this topic see F F Liza, ‘Challenges of Enforcing Regulations in Artificial Intelligence Act - Analyzing Quantity Requirement in Data and Data Governance’, CEUR Workshop Proceedings, 2022.

49 See N Maccabiani, ‘The European path towards Data Quality and its standardisation in AI: a legal perspective’ (2022) 4 BioLaw Journal - Rivista di BioDiritto.

50 For an extended analysis of this debate see M Eliantonio and C Cauffman, ‘The Legitimacy of Standardisation as a Regulatory Technique: A Cross-Disciplinary and Multi-Level Analysis’ (Edward Elgar Publishing 2020).

51 See V A Schmidt, ‘Europe’s Crisis of Legitimacy: Governing by Rules and Ruling by Numbers in the Eurozone’ (Oxford University Press 2020).

52 Vademecum on European Standardisation in Support of Union Legislation and Policies. PART I - Role of the Commission’s Standardisation Requests to the European Standardisation Organisations, Commission Staff Working Document, SWD(2015) 205.

53 European Commission, Directorate-General for Enterprise and Industry, ‘Using standards to support growth, competitiveness and innovation’, Publications Office, 2014.

Groups (WGs). Each WG consists of a group of experts, and the time and financial costs of participation are substantial enough that only market players with adequate resources can actively engage in the process. This presents a barrier to the effective and efficient participation of other stakeholders, such as SMEs, which frequently lack the necessary funds and skilled personnel to influence the standardisation process. The situation is even more challenging for social stakeholders like civil society organisations.[54]

The underrepresentation of SMEs and civil society organisations results in their interests not being adequately represented in the standardisation process, and subsequently in the resulting standards, to the benefit of large industry players. The RSE includes explicit measures to encourage the participation of SMEs and civil society organisations, such as Annex III organisations representing consumers (ANEC), the environment (ECOS), trade unions (ETUC), and smaller companies (SBS). This demonstrates that the participation and representation of these stakeholders are recognised as issues and sources of concern within the European standardisation system. The *Report on the Implementation of Regulation (EU) No 1025/2012 from 2016 to 2020* also reveals shortcomings in terms of participation in the standardisation process, particularly within one of the ESOs, ETSI.

The input legitimacy issues raised by the lack of inclusiveness in the European standardisation system are further exacerbated when international standards not developed by the ESOs are adopted at the European level. As a matter of fact, these international standards are not required to comply with the procedural prerequisites outlined in the RES. When an international standard is adopted as a European standard, there is no guarantee that all stakeholders' interests have been considered in the process. However, when these standards are adopted as harmonised standards to implement European legislative acts, they produce legal effects, such as the presumption of conformity, which have public relevance and impact on all stakeholders.

Similar issues of input legitimacy are present in the standardisation of artificial intelligence. During the public consultations on the AI Act conducted by the European Commission, numerous SMEs and civil society stakeholders expressed concerns about their ability to participate in and influence the standardisation process. For instance, the Confederation of Laboratories for AI Research in Europe (CLAIRE) voiced concerns about the underrepresentation of SMEs, startups, and entrepreneurs in standardisation organisations due to insufficient resources (in terms of money, time, network, or expertise).[55] Consequently, standards are often primarily developed by large companies with limited understanding of the small business sector's needs and challenges. As a result, a standards-based conformity assessment scheme may further disadvantage SMEs and startups.

54 For an analysis on the topic of participation in European standardisation see M Kallestrup, 'Stakeholder Participation in European Standardization: A Mapping and an Assessment of Three Categories of Regulation' (2017) 4 Legal Issues of Economic Integration 44.

55 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Confederation of Laboratories for AI Research in Europe (CLAIRE), Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665643_en.

The Centre for Democracy & Technology shares this concern, suggesting that the draft AI Act disproportionately empowers private actors.[56] The self-assessment and standardisation approach could risk exempting public authorities from policymaking by transferring responsibilities to private SDOs. Similarly, Digital SME argues that SMEs are excluded from standards development due to their underrepresentation in standardisation organisations, often resulting in impractical and inapplicable standards for SMEs.[57] According to Digital SME, it is crucial to develop standards with the active participation of SMEs and avoid a one-size-fits-all approach frequently adopted by research organisations and large companies.

Small Business Standards, one of the Annex III organisations, echoes these sentiments, stating that SMEs are excluded from developing standards due to their underrepresentation in standards bodies, resulting in impractical and inapplicable standards.[58] Academics, such as those from the Legal, Ethical & Accountable Digital Society (LEADS) Lab at the University of Birmingham, have also expressed doubts about the legitimacy of the standardisation process, arguing for a democratic deficit in standard-setting and conformity assessment.[59] Unsurprisingly, major players like Huawei[60] and Facebook[61], as well as standards development organisations such as ETSI[62] and DIN,[63] welcome the AI Act's reliance on standards and the standards-based conformity assessment approach.

Concerns about the input legitimacy of the standardisation process are further substantiated by a recent report from the Ada Lovelace Institute on "Inclusive AI Governance"[64]. In the report, ANEC representatives express concerns that consumer perspectives are often absent and disregarded during standardisation processes. The report highlights that societal stakeholders face significant obstacles in effectively participating in CEN/CENELEC JTC 21, the technical committee responsible for AI

56 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Centre for Democracy & Technology, Europe, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665242_en.

57 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: European DIGITAL SME Alliance, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665574_en.

58 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Small Business Standards (SBS), Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665497_en.

59 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Legal, Ethical & Accountable Digital Society (LEADS) Lab, University of Birmingham, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665480_en.

60 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Huawei Technologies, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665442_en.

61 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Facebook Ireland Limited, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665607_en.

62 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: ETSI, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665289_en.

63 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: DIN Deutsches Institut Für Normung e.V., Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2635987_en.

64 C Galvagna, 'Discussion Paper: Inclusive AI Governance', Available at: https://www.adalovelaceinstitute.org/report/inclusive-ai-governance/.

standardisation. These challenges include factors such as the required time commitment, the opacity and complexity of the standardisation process, industry dominance in decision-making, and a general lack of awareness of the relevance of European standards for AI.

### ii. Throughput legitimacy issues

In Schmidt's definition, throughput legitimacy concerns the quality of policymaking processes. It encompasses the internal processes and practices of governance, the accountability of decision-makers, the transparency of information, and the openness to consultation with interest groups of civil society. Throughput legitimacy requires that rule-makers demonstrate trustworthiness, integrity, fairness, impartiality, and credibility, along with competence and respect for citizens' prerogatives.[65]

As private entities, ESOs are not subject to the same transparency requirements as public authorities, nor are they held to the same level of oversight and accountability as government bodies. While this is not inherently problematic, it raises concerns about throughput legitimacy, especially considering that these standards are part of EU law and produce legal effects. Therefore, it is essential to assess whether appropriate mechanisms are in place to ensure that ESOs' internal procedures satisfy the established criteria for throughput legitimacy. In this discussion, we will focus solely on oversight, accountability, and transparency, since the openness and inclusiveness of the standardisation process have already been addressed in terms of input legitimacy.

Appropriate oversight by public authorities, such as the European Commission, over the standardisation process could enhance throughput legitimacy of European standardisation, given that the ESOs are private organisation. As per RSE, "the Commission, in collaboration with the European standardisation organization, is responsible for evaluating the conformity of documents created by the European standardisation organisation with the initial request". As specified in the Vademecum on European Standardisation, the assessment of a document's compliance with the standardisation request and any related legal requirements should focus on two main issues: identifying and assessing the extent to which the document covers and addresses the requirements specified in the standardisation request, and evaluating whether the document thoroughly addresses the corresponding requirements of the legal act. This assessment should mainly occur during the drafting phase to ensure the draft standards align with the requirements established in the corresponding standardisation request. Based on this evaluation, the Commission has the final say on whether to include the references of harmonised standards, or portions of them, in the OJEU.

Before the Court of Justice ruling on the Elliot case, the European Commission, due to a lack of resources and expertise, often accepted the standards produced by the ESOs without additional scrutiny.[66] However, starting from 2018, the European Commission

65 For a reflection on good governance principles for standardisation bodies see P Verbruggen, 'Good Governance of Private Standardization and the Role of Tort Law' (2019) 27(2) European Review of Private Law.
66 M Eliantonio, 'Alternative Forms of Regulation: Are They Really "Better" Regulation?: A Case Study of the European Standardization Process' (2017) 19 European Journal of Law Reform 141.

introduced the Harmonised Standards (HAS) consultants system.[67] HAS consultants are a group of experts provided by a Contractor, currently Ernst & Young, with the purpose of implementing the assessment mechanisms stipulated by the RSE. The depth of this assessment, though, remains contested.[68] A strict control by the Commission over the standards produced by the ESOs would contradict the core philosophy of the New Approach and New Legislative Framework, which promotes public-private partnerships and co-regulation as a means to develop better policies. Consequently, the assessment remains at a formal level and appears to be inadequate for ensuring a proper *ex-ante* control over the standards that could strengthen the throughput legitimacy of the standardisation process.

Due to the limitations of ex-ante assessment, some scholars have called for increased ex-post control through judicial review.[69] However, despite calls for a more incisive role of the Court of Justice in technical standardisation,[70] harmonised standards are not subject to legality review under Article 263 TFEU. This is because the legality review applies to "legislative acts, of acts of the Council, of the Commission and of the European Central Bank, other than recommendations and opinions, and of acts of the European Parliament and of the European Council intended to produce legal effects vis-à-vis third parties", as well as "acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties". However, even if one were to accept the categorisation of harmonised standards as implementing acts, albeit atypical,[71] they would still not be subject to legality review under Article 263 TFEU, because harmonised standards do not autonomously produce legal effects, as they do only after being referenced in the OJEU. Other alternatives for judicial review, such as the preliminary reference procedure and the plea of illegality, involve complications that prevent them from offering a satisfactory alternative to legality review under Article 263 TFEU.[72] These issues highlight that ESOs lack accountability[73] and consequently weaken the throughput legitimacy of the standardisation process within ESOs.

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67 Technical Assistance to the Commission for the Assessment of Harmonised Standard, Available at: https://etendering.ted.europa.eu/document/document-old-versions.html?docId=110066.

68 K Dingemann and M Kottmann, 'Legal Opinion On the European System of Harmonised Standards Commissioned by the German Federal Ministry for Economic Affairs and Energy ("BMWi")', Available at: https://www.bmwk.de/Redaktion/EN/Downloads/L/legal-opinion-on-the-european-system-of-harmonised-standards.pdf?__blob=publicationFile&v=3.

69 M Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44 Legal Issues of Economic Integration. On the same topic see R Van gestel and HW Micklitz, 'European integration through standardization: How judicial review is breaking down the club house of private standardization bodies' (2013) Common Market Law Review 50. For an analysis of how judicial review can legitimise the delegation of power to standard bodies see M Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) Legal Issues of Economic Integration 44(4).

70 P Cuccuru, 'European Judiciary and Harmonised Standards: Which Intersection?', Available at: https://www.stals.santannapisa.it/sites/default/files/Cuccuru.pdf.

71 C Tovo, 'Judicial Review of Harmonized Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55 Common Market Law Review.

72 L Jung, 'Juridification of Harmonised Technical Standards Regarding the Aspect of Judicial Review' (2019), Available at: https://www.researchgate.net/publication/349947978_Juridification_of_harmonised_technical_standards_regarding_the_aspect_of_judicial_review.

73 A Volpato, 'Controlling the Invisible: Accountability Issues in the Exercise of Implementing Powers by EU Agencies and in Harmonised Standardisation' (2019) 1 (september) 1 Review of European Administrative Law (REALaw).

A final issue that raises concerns of throughput legitimacy involves the lack of transparency in the standardisation process. As a matter of fact, the standardisation process within the ESOs is almost entirely opaque to the public. Despite the measures provided by the RES, it is challenging to argue that the European standardisation process is transparent. No information is publicly available on the technical committees, the participants in the standardisation process, or the decisions made.[74] Questions about transparency have also been raised concerning the fact that harmonised standards are protected by copyright[75] and are therefore only accessible upon payment of a fee.[76]

These concerns apply to the standardisation of artificial intelligence as well. In the absence of oversight, accountability, and transparency, delegating powers to ESOs could result in the "regulatory capture" phenomenon.[77] Regulatory capture is the process by which interest groups, including industries, influence government regulations to benefit their own interests. Both public rule-making and standardisation are susceptible to this issue, but the latter is more at risk due to the openness of the standardisation procedures. For example, ETSI, one of the ESOs, was excluded from the European Commission's draft standardisation request on the AI Act on the grounds of being overly influenced by the private sector.[78] This situation could lead to standards that reflect private rather than public interests in the implementation of the AI Act.[79]

### iii. Output legitimacy issues

In Schmidt definition, output legitimacy describes the acceptance of coercive powers of government as long as their exercise serves the common good and is constrained by community norms. It focuses on the effectiveness of policies in solving problems and producing good results that serve not just individual interests but those of the public in general. Consequently, in the context of standardisation, the output legitimacy of standards and the standardisation process is to be assessed on the basis of their ability to meet political and economic objectives and to achieve positive results for the public.

The output legitimacy of standards is not questioned usually. Standards promote economic growth through the dissemination of technical knowledge and open access to this information, thus acting as a catalyst for innovation. Furthermore, the increase in productivity associated with the use of standards reinforces their positive impact on

74 M Eliantonio, 'Private Actors, Public Authorities and the Relevance of Public Law in the Process of European Standardization' (2018) 24 European Public Law 473.

75 For an analysis of intellectual property-related issues in European standardisation see M Granieri, 'Attività di standardizzazione, diritti di proprietà intellettuale e antitrust', (2004) Riv. dir. ind., fasc.4-5.

76 A Volpato, '"Part of EU Law" but only partially: The issue of accessibility of harmonised standards', *REALaw.blog*, Available at https://wp.me/pcQ0x2-7F.

77 M Ebers, 'Standardizing AI - The Case of the European Commission's Proposal for an Artificial Intelligence Act', in L A DiMatteom C Poncibò and M Cannarsa (eds), ' The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics' (Cambridge University Press 2022).

78 L Bertuzzi, 'Commission leaves European standardisation body out of AI standard-setting', December 2022., Available at: https://www.euractiv.com/section/artificial-intelligence/ news/commission-leaves-european-standardisation-body-out-of-ai-standard-setting/.

79 For an analysis of how standards are a crucial element in the establishment of global private governance see H Schepel 'The Constitution of Private Governance; Product Standards in the Regulation of Integrating Markets' (Oxford Hart Publishing 2005).

economic growth.[80] Additionally, common global standards can promote trade and lower trade barriers by creating internationally recognised product quality characteristics.[81] In the European context, standards are trade-enhancing because of their cost-decreasing effect and the reduction of information asymmetries between the supply and demand sides, especially in the case of cross-border transactions. According to the European Commission,[82] the impact of standards on annual GDP growth could range from 0.3 to 1 percentage point.

However, standardisation can also have disadvantages. Among these, lock-in effects have the most significant consequences. Once a standard for a product or service is set, the marketplace dynamics that result in one standardised version of the technology becoming the dominant solution do not guarantee that this version is the optimal one. When manufactures and providers conform to the standard, they invest substantial resources in learning to absorb and use the standardised technology as well as complementary technologies and infrastructures. These sunk costs create a reluctance to switch to a new standard and related cluster of technologies. Considerable resources are then allocated to a possibly inferior technology, which can extend over long periods of time.

Assessing whether the benefits of standards outweigh their negative effects is beyond the scope of this paper. However, it should be noted that the pros and cons of standardisation need to be considered in relation to the maturity of the technology being standardised. The field of AI is rapidly evolving, and it is difficult to determine the Technology Readiness Levels (TRL) of AI technologies. A study on the subject shows that the TRL for AI technologies decreases as the generality level of the AI technologies increases.[83] Therefore, low-generality technologies focusing on narrow or specific abilities achieve higher TRLs, while AI technologies with more general capabilities still have low TRLs. A low TRL is also correlated with a low standardisation readiness level, as discussed by the IEC in the context of the standardisation of quantum information technologies.[84] As a result, initiating and promoting standards activities before the technology has matured can lead to standards that lock in inferior and immature technologies.

While this raises a question about the appropriateness of standardising artificial intelligence at this time, the AI Act's choice to adopt the conformity assessment mechanism underlying the New Approach and the New Legislative Framework acts as a form of regulatory pressure for the realisation and adoption of these standards. Since conformity assessment for high-risk AI systems is based on standards, this will push

80 G Swann, 'The Economics of Standardization: An Update' (2010), Available at: https://www.semanticscholar.org/paper/The-Economics-of-Standardization%3A-An-Update-Swann/f4713176e30f5b241f7c2506f4e3b2d2dd52ac32.

81 P Swann, P Temple and M Shurmer, 'Standards and Trade Performance: The UK Experience' (1996) 106 The Economic Journal 1297.

82 Communication from the Commission to the European Parliament, the Council and the European economic and social committee, A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020.

83 F Martinez Plumed, E Gomez Gutierrez and J. Hernández-Orallo, 'AI Watch: Assessing Technology Readiness Levels for Artificial Intelligence', EUR 30401 EN, Publications Office of the European Union, Luxembourg, 2020.

84 Quantum Information Technology | IEC, Available at: https://www.iec.ch/basecamp/quantum-information-technology.

providers to adopt them and designate their AI products and services according to these standards. Whether this will have positive or negative effects on technology development cannot be determined a priori. These considerations, however, seem sufficient to question the success story of standards' benefits when applied to emerging technologies like artificial intelligence, making further investigation of the impact that standards will have on technology development needed.

Finally, the output legitimacy of standards and standardisation should also be evaluated based on their ability to meet policy goals. In the case of AI standards, this means assessing their ability to protect health, safety, and, most importantly, the fundamental rights of individuals, as these are the overall objectives of AI. Given the importance of this issue, it will be addressed separately in the next section.

### c. Fundamental rights protection

The potential adverse effects of artificial intelligence on fundamental rights have garnered the attention of academics, policymakers, and non-governmental organizations.[85] To address these concerns, the AI Act incorporates the protection of fundamental rights into two of its four specific objectives. The AI Act strives to, firstly, "ensure that AI systems placed on the Union market and used are safe and respect existing laws on fundamental rights and Union values", and secondly, to "enhance governance and effective enforcement of existing laws on fundamental rights and safety requirements applicable to AI systems". The potential impact of an AI system on fundamental rights serves as one of the critical factors in determining its classification as a high-risk system.[86] Moreover, certain requirements, such as those concerning human oversight, explicitly mention the protection of fundamental rights as a primary rationale.

While fundamental rights form the backbone of the AI Act, the regulation's ability to ensure their effective protection has been called into question.[87] Once again, the role of harmonised standards in implementing the AI Act's requirements has raised concerns in this context. Although the draft standardisation request mandates that ESOs adequately consider the protection of fundamental rights in their standards, this is a topic hitherto unknown to technical standardisation bodies. According to EDRI, fundamental rights are evidently beyond the expertise and authority of ESOs and should not be subjected to technical standardisation.[88] This position has been echoed by various stakeholders. According to BEUC, "harmonised standards must not be used to define or apply fundamental rights, legal or ethical principles. Their use should be limited to implement technical aspects. In this regard, a standard should, for example,

85 A common example in this context is discrimination produced by AI algorithms, see for example H Steege, 'Algorithm-based discrimination by using artificial intelligence. Comparative legal considerations and relevant areas of application' (2021) EJPLT 1.

86 See AI Act, Recital 28 and Article 7.

87 M Almada and N Petit, 'The EU AI Act: Between Product Safety and Fundamental Rights' (20 December 2022), Available at: https://papers.ssrn.com/abstract=4308072.

88 EDRI, 'The Role of Standards and Standardisation Processes in the EU's Artificial Intelligence (AI) Act', Available at: https://edri.org/wp-content/uploads/2022/05/The-role-of-standards-and-standardisation-processes-in-the-EUs-Artificial-Intelligence-AI-Act.pdf.

not be used to determine what types of biases are prohibited under Art. 10 (2) f".[89] According to Access Now, the significant role of ESOs and standards "risks undermining the fundamental rights protections' allowing a significant way for AI providers to lobby for weaker obligations that the Proposal itself mandates".[90] Similarly, the Center for AI and Digital Policy "is concerned that business interests will dominate these standard-setting organizations, and that the protection of fundamental rights and the voices and concerns of civil society and affected communities will not be effectively represented"[91]. In addition to NGOs and civil society organisations, academic scholars have also expressed concerns in this regard.[92]

These critical positions underscore three primary issues concerning the safeguarding of fundamental rights through harmonised standards. First, they emphasise the notable absence of expertise in fundamental rights within the ESOs. This deficiency can be attributed to the limited stakeholder involvement within these organisations, which predominantly consist of industry representatives. Second, the concerns raised by civil society organisations bring attention to the legitimacy deficit of private entities like ESOs when it comes to formulating rules that protect fundamental rights. In essence, these organisations may not be best suited for such responsibilities due to their inherently private nature and potential conflicts of interest. Lastly, the protection of fundamental rights cannot be a one-time, set-and-forget process, dependent solely on compliance with technical norms established within a standard. If so, the AI Act could be jeopardized by an overdependence on the efficacy of standards-based conformity assessments. We delve deeper into this issue in the subsequent section.

## 4. Discussion

The AI Act deserves credit for placing the need to regulate a technology with transformative potential, as well as significant risks to individual health, safety, and fundamental rights, at the forefront of public debate. The initiative's intentions have been largely well-received, with only a small minority arguing that regulating AI is unnecessary or even detrimental. This discuss begins by examining the objections raised by this minority and the arguments surrounding this contentious issue.

Some authors argue that the regulation of AI, driven by the precautionary principle, may stifle innovation in the field.[93] They contend that regulations slow down AI development and increase costs due to compliance, leading to higher prices for consumers, hampering adoption, and ultimately undermining potential benefits to

89 BEUC, 'Regulating AI to protect the consumer. Position Paper on the AI Act', Available at: https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-088_regulating_ai_to_protect_the_consumer.pdf.

90 Artificial Intelligence – Ethical and Legal Requirements. Feedback from: Access Now Europe, Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665462_en.

91 CAIDP, 'Statement on Proposed EU AI Regulation', Available at: https://www.caidp.org/resources/eu-ai-act/.

92 I Barkane, 'Questioning the EU Proposal for an Artificial Intelligence Act: The Need for Prohibitions and a Stricter Approach to Biometric Surveillance1' (2022) 27 Information Polity 147.

93 D Castro and M McLaughlin. 'Ten Ways the Precautionary Principle Undermines Progress in Artificial Intelligence', Available at: https://itif.org/publications/2019/02/04/ten-ways-precautionaryprinciple-undermines-progress-artificial-intelligence/.

society and the economy. However, such arguments often stem from a distorted laissez-faire program,[94] which perceives any regulatory interference in the market as inherently negative. Once this bias is set aside, it becomes clear that regulation is not only unlikely to produce such detrimental effects but could actually help minimise them by fostering a positive impact on innovation.[95] Indeed, these authors often assume that, in the absence of regulatory constraints, the resulting technology would be safe and devoid of negative consequences for consumers. This assumption, however, is flawed. Consider the development of automobiles as an example. Since their inception, cars have been accompanied by social concerns and calls for regulation.[96] It is reasonable to assume that without safety regulations such as speed limits, seat belts, and driving licenses, cars would have become so dangerous that public sentiment would eventually turn against their presence on the roads. This demonstrates how appropriate regulation can positively influence innovation, promoting its adoption and social acceptance.

While the regulation of AI is both welcome and necessary, the AI Act's reliance on the New Approach and the New Legislative Framework, commonly adopted in safety legislation, raises several concerns, as discussed in Sections 3.a, 3.b, and 3.c. Basing conformity assessment on harmonised standards may weaken the regulatory framework and undermine the positive intentions behind it.

First, the AI Act appears to reverse the relationship between standards and technical regulation. According to the WTO TBT agreement, "where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations".[97] However, the AI Act is not based on technical standards, but rather requires the standards to be based on the regulation's requirements. In other words, the AI Act sets regulatory requirements and then mandates standards to provide technical specifications for implementing these requirements. This could likely lead to misalignments between the regulation's requirements and the standards meant to implement them, as discussed in section 3.a. This is because the AI Act, while adopting the appearance of a technical regulation, addresses issues that extend far beyond this domain. For example, determining acceptable risk levels for fundamental rights posed by AI systems, the amount and type of bias permissible to avoid discrimination, and how to implement oversight are questions with a strong political and social dimension, not exclusively a technical one.

The type of questions that standardisation is now tasked with answering raises doubts about whether ESOs are legitimate providers of solutions to these issues. The discussion in section 3.b indicates that the short answer is "no", as legitimacy problems beset standardisation in support of the AI Act. Efforts to promote the participation of various stakeholders may mitigate these issues, but legitimacy concerns are likely to persist until the legal status of harmonised standards and the role of legitimate public authorities in their development and implementation are clarified.

94 JF Hanry, 'The Ideology of the Laissez Faire Program' (2008) Journal of Economic Issues, 42(1).
95 A Tartaro, AL Smith and P Shaw, 'Assessing the Impact of Regulations and Standards on Innovation in the Field of AI', Available at: http://arxiv.org/abs/2302.04110.
96 K Tranter, 'The history of the haste-wagons: the motor car act 1909, emergent technology and the call for law' 29 Melbourne University Law Review.
97 See Marrakesh Agreement, Available at: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.

Lastly, the question remains whether, aside from being legitimate, ESOs are capable of addressing these issues, as discussed in section 3.c. It is challenging to argue that harmonised standards are the most suitable instrument for enforcing the protection of fundamental rights. In addition, importing an instrument used in safety legislation into a regulation aimed at protecting fundamental rights may inadvertently reduce fundamental rights to a safety issue, as the AI Act seems to imply. The risk here is that the AI Act's conformity assessment mechanisms could permit systems with negative impacts on people's fundamental rights to be legally introduced to the EU market. This would create a clear disconnect between the Regulation's intentions and its practical effects.

## Conclusions.

The AI Act is currently at the trialogue stage, but the date of its final enactment remains uncertain. However, the regulation's core framework is unlikely to undergo substantial changes. This means that the European Union will regulate AI based on the New Approach and the New Legislative Framework, with the AI Act establishing essential requirements whose implementation relies on harmonised standards produced by CEN/CENELEC.

This approach raises several concerns, as explored in this paper. While using standards to harmonise the European market and ensure product safety and quality has been successful in other fields, this paper shows that this choice may not be optimal for artificial intelligence. Beyond the economic implications of using standards in an emerging field like AI, which warrant further investigation, the AI Act's regulatory approach appears inadequate for achieving some of its goals.

However, this pessimistic conclusion can be counterbalanced by more optimistic considerations. The effectiveness of European legislation in ensuring that innovation does not compromise health, safety, and fundamental rights of people should be evaluated holistically, considering all European policies and legislation in the digital sector. The AI Act, along with existing legislation such as the GDPR and the Digital Service Act, as well as new proposals like the AI liability directive and the Data Governance Act, could collectively guide technological development for the benefit of society and individuals. Moreover, just as technology evolves, so does the law. There remains ample opportunity and time for further regulatory interventions on AI that genuinely prioritise fundamental rights in both intent and practice, and that provide individuals with the tools to challenge and seek redress for rights violations perpetrated by some AI systems.