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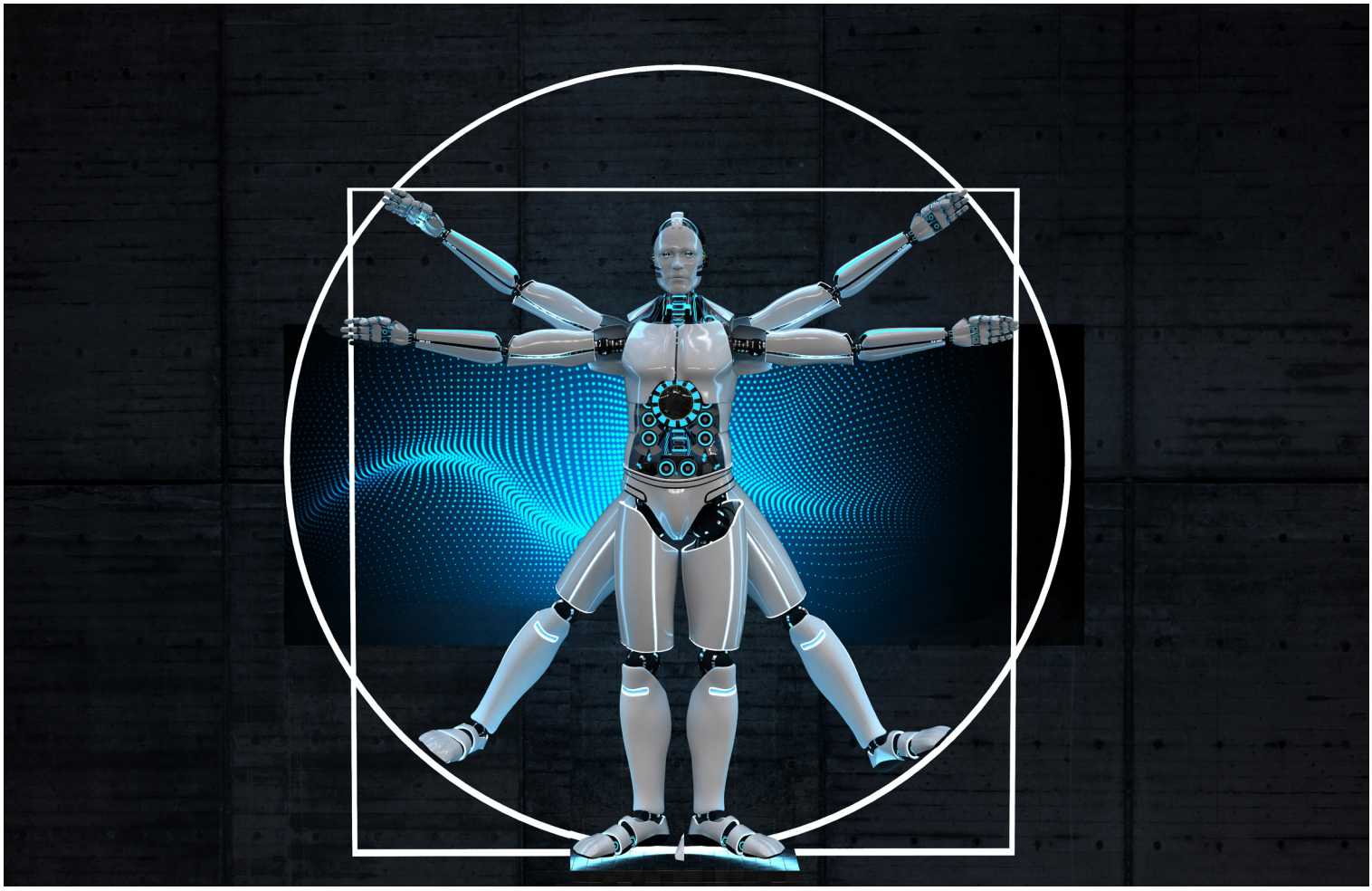

Harmonising Artificial Intelligence:

The role of standards in the EU AI Regulation

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EXECUTIVE SUMMARY

The draft EU AI Regulation is a far-reaching attempt to provide a regulatory foundation for the safe, fair, and innovative development of Artificial Intelligence in the European Union and is likely to have consequences across the globe. An important feature of the Regulation, which has so far provoked little academic debate, is its use of technical standards to help achieve its goals. However, standardisation is complicated and the nexus between standards and the European Commission's goals is a challenging intersection of stakeholders, economic interests, and established standards development organizations.

Building on extensive research and stakeholder consultation, the draft Regulation sets out a comprehensive framework for AI governance and standards. The large number of comments from stakeholders the draft Regulation has received reflect both the significance of such a proposed regulatory framework, and its anticipated global influence. It borrows mechanisms from the GDPR, but it also recognizes the unique role and challenges that AI presents. In addition, the EU itself is reconsidering its model for standardisation and is in the process of gathering input to a revised approach to European standardisation.

This paper focuses on the role that the draft Regulation gives to standards for AI. Specifically, conformance with harmonised standards will create a presumption of conformity for high-risk AI applications and services – lending a level of confidence that they are in compliance with the onerous and complex requirements of the proposed Regulation and creating strong incentives for industry to comply with European standards.

The Regulation has two important Articles that detail the role of standards in the AI landscape. The first, Article 40, discusses the role that harmonised standards play in assuring compliance with the intent and letter of the Regulation. The second, Article 41, discusses the use of common specifications in situations where harmonised standards may not exist or may not apply. These two articles are supplemented by an existing EU Regulation on Standardisation from 2012. Common specifications have been used in other fields, such as medical devices, with mixed results.

The number of standards bodies interested in AI is large and diverse. One group of standards bodies have a special status as European Standards Organizations (ESOs). Other standards bodies are global in their reach. Each standards body has its own, particular and often separate, interests in standardisation for AI. It is possible to clearly document the benefits of standardisation, but the AI ecosystem is so recent that standards bodies are just beginning to lay out their plans for standards activity.

There are clear strengths to the European approach but some notable challenges as well. We document those strengths and challenges. The study concludes with concrete recommendations for further action as the EU AI Regulation and standards reform proposals continue their legislative journeys:

- A mechanism must be in place to address the gulf between the ambition of the ESOs in the context of AI standards and the resources they have available to develop the standards.

- A mechanism must be in place to ensure meaningful, substantive participation in standards development by those most interested in protecting fundamental human rights and the public interest. Standardisation roadmaps, published well in advance, as well as national AI standards hubs could provide practical ways to involve such stakeholders early in relevant AI standardisation processes and at strategic points prior to the adoption of standards by international bodies.

- The proposed EU AI Regulation is flexible legally and procedurally. Standards developed in support of Clause 40 and 41 must also be flexible enough to reflect the rapid evolution of AI technology and products. A fast-track process could be developed to improve on the timeliness of adoption for standards. Another practical approach could be to review and eliminate the distinction between ESOs and international standards organisations, substituting more relevant tests such as the equity of stakeholder representation and adherence to international frameworks such as human rights instruments and/or the WTO principles for standardisation.

- Education and training, specifically for non-expert AI stakeholders, must be available that facilitates understanding of and participation in ESOs. Such training should be tailored to a wide variety of

stakeholder groups that need to understand the strategic importance of standards and be focused on developing the capacity and skills needed to participate effectively in standards organisations. Women and girls should be targeted with early interventions to redress the gender deficit in standards participation.

- Once effective operational standards are in place, compliance tools must be developed in close cooperation with industry and standards experts that help regulators, NGOs, industry, and product developers ensure that their products are compliant with the standards and the Regulation.

- Recognising the continued interplay between ESOs and international SDOs, there needs to be a mechanism for appropriate balancing of two imperatives: on the one hand, the need to devise European standards that specifically embed European rules and values; on the other, the need for global open, interoperable, standards that facilitate international trade between the EU and rest of world, rather than acting as barriers to global.

- Cooperation between business, particularly between SMEs, must be scaled to maximise participation while minimizing the costs of engagement and reducing the inefficiency of duplicate voices. Similarly, scaling of cooperation between civil society members is necessary to maximise participation and impact while reducing potential inefficiency of duplicate voices.

1 INTRODUCTION

The study provides an analysis of the draft EU AI Regulation's envisioned role for technical standards in the governance of AI. As well as exploring the EU AI draft Regulation's fitness for purpose as a template for engagement in standards, the study will also provide critiques and recommendations for suggested improvements for the draft Regulation.

The paper begins with an overview of the proposed EU AI Regulation as a whole, followed by a more detailed analysis of how the regulatory framework seeks to motivate conformance with certain technical standards. There follows a comparative analysis of the two instruments – harmonised standards and common specifications – which can be relied on by producers of 'high risk' AI as a way of minimising the compliance burden.

Next, there is an introduction to the world of technical standards and a brief overview of the standardisation work and roadmaps relating to AI across both European and international standards organisations. Given the EU AI Regulation's reliance on standards, the section concludes with an overview of the Commission's ongoing review of the European standardisation system, and what it highlights in relation to the strengths and weaknesses of the current environment.

The study goes on to provide an analysis of the benefits and risks of the proposed regulatory framework in relation to standards, including mismatches between the expectations of regulators, industry, and the standards bodies themselves, as well as the need for timeliness and effective use of limited resources. It provides some recommendations, addressed to both policymakers and standards organisations, intended to accentuate the benefits, and minimise the risks created by the interplay of EU AI regulation and global standardisation.

This has been a desk-based study based on publicly available sources. Key sources have been documents relating to the EU AI Regulation, especially the draft text of the proposed Regulation and consultation responses, the Commission's proposals to update its standardisation roadmap including consultation responses, and public documents relating to the European and international standards organisations, their governance and work relating to AI standards.

2 THE EU AI REGULATION—WHAT WOULD IT DO?

2.1 The interplay between AI governance and standards

The European Union has recognised the strategic importance of technical standards in emerging technologies with wide societal impact, such as artificial intelligence. In recent years, the EU and its member states have taken steps to develop a coherent European approach to the emerging field of AI governance and standards. Initiatives since 2018 have included a "Declaration of Cooperation on Artificial Intelligence" which describes a pan-European approach to policy, governance, and standardisation for AI;[1] a rolling plan for reform of ICT standardization,[2] which aims to foster coordination of standardisation efforts on AI both within Europe and with other international standardisation efforts, especially ISO's dedicated group on AI; and the formation of a European High-Level Expert Group (HLEG) on AI.[3] The HLEG's key objective was to support the implementation of the European strategy on AI and to develop recommendations on future-related policy developments on ethical, and societal issues related to AI, including socio-economic challenges.

The EU has long harnessed the interplay between regulation and standards as an important aspect of both the internal market and international trade, and the same is true in the field of AI. Thus, the interplay between standards and regulation is recognised by the EU, and the steps being taken to reform European standardisation in parallel to the higher profile proposals for an EU AI Regulation should be seen as integral to the future governance of AI both within the European Union and globally.

2.2 Overview of the regulation

On 21 April 2021, the European Commission published its proposal for the Artificial Intelligence Regulation (the draft EU AI Regulation).[4]

The draft EU AI Regulation borrows two elements from the General Data Protection Regulation 2016 (GDPR) which have now become the norm in the way that the EU regulates technology. The draft EU AI Regulation has extraterritorial effect (art 2) and turnover based fines -- up to €30m or 6% of total worldwide annual turnover (art 71). Thanks to those elements, the GPDR has become an international regulatory framework. Organisations that market AI systems to users in

the EU will be within scope of the Regulation, regardless of where the provider is located. The draft AI Regulation extends the level of fines and territorial scope further, in that it covers output produced by the system that is used in the EU.

The Regulation categorises three main categories of risk relevant to AI systems that are within scope: (i) unacceptable risk, (ii) high risk, (iii) low risk. The categories determine the regulatory consequences for the individual systems. Unacceptable risk AI will be banned – it covers systems considered a clear threat to the safety, livelihoods and rights of people and includes systems that manipulate human behaviour or allow 'social scoring' by governments. High risk AI will be highly monitored. AI systems with low or minimal risk AI will, with some exceptions, escape most regulatory obligations, save for obligations to inform individuals that they are interacting with AI systems. As most AI is low risk, this gives businesses wishing to provide or adopt such applications confidence that they may do so without complying with onerous regulatory requirements.

The majority of the draft AI Regulation concerns the framework that applies to high-risk systems, and this is also the focus for our paper.

The Regulation (Article 6) classifies two types of AI system as high risk:

- Systems that are intended to be used as safety components of a product, or are themselves a product, covered by listed Union harmonisation legislation and required by that legislation to undergo a third-party conformity assessment. This includes machinery, toys, radio equipment, medical devices, aviation equipment, motor vehicles and other products that are required by European law to be assessed for safety before use.
- Types of AI systems listed in Annex III to the Regulation. The common feature of such systems is that they pose a risk of harm to health and safety, or a risk of adverse impact on fundamental rights. They include systems concerned with biometric identification, evaluating creditworthiness, immigration assessments, access to education or employment, law enforcement, and as safety components for critical infrastructure (road traffic, water, gas, heating, electricity). By Article 7, the Commission, following stipulated criteria, may add similar systems to that list if they pose an equivalent or greater risk of harm to health and safety, or of adverse impact on fundamental rights, than the systems already listed in the Appendix.

High-risk AI systems will have to meet strict requirements before they can be put on the market in EU. The Regulation outlines detailed requirements for high-risk AI systems to be able to operate, set out across Chapters 2 and 3 of the draft Regulation, a detailed review of which is beyond the scope of this paper. Examples of the requirements include, but are not limited to, continuous iterative risk assessment and mitigation systems, use of high quality datasets to minimise risks and discriminatory outcomes, logging of activity to ensure traceability of results, detailed documentation requirements, provision of clear and adequate information to the user, appropriate human oversight, a high level of robustness, security and accuracy,[5] as well as numerous requirements relating to CE marking.

High-risk AI systems are presumed to comply with the requirements of the Regulation if they are in conformity with harmonised standards published in the Official Journal of the European Union (Article 40) or common specifications adopted by the European Commission (Article 41). Overall, conformance with established standards or common specifications is a way of cutting down the draft Regulation's significant compliance burdens for providers of high-risk AI. In some instances, compliance with harmonised standards or common specifications permits conformity assessment based on internal control rather than external assessment.

2.3 The role that the Regulation would give to standardisation

As above, there is a recognition that 'harmonised standards and supporting guidance and compliance tools will assist providers and users in complying with the requirements laid down by the proposal and minimise their costs'. [6] In other words, conformance with technical standards and common specifications should give providers of high-risk AI a level of confidence that they are compliant with the mandatory requirements of the proposed EU AI Regulation as well as significantly cutting the cost of compliance for business. In turn, this should create a virtuous circle, by incentivising conformance with technical standards by high-risk AI providers.

This section will examine key provisions of the draft EU AI Regulation relating to standards and common specifications, namely articles 40 and 41. It will explain the role that the

draft legislation gives both to the European Commission and to standards development organisations.

2.3.1 Article 40: Harmonized Standards

Article 40 is a key provision of the draft Regulation, as it is the mechanism that provides the presumption of conformity with regulatory requirements for providers of high-risk AI systems. The effect of Article 40 is that providers of high-risk AI systems may demonstrate compliance with the onerous set of requirements listed in Chapters 2 and 3 of the Regulation by complying with officially adopted "harmonised standards" that cover them.

The use of harmonised standards, prepared by the European Standards Organisations, as technical specifications meeting the requirements of European Directives, has been a common practice since 1985.[7] Currently, around 20% of European standards have been adopted in this way; 80% are not, and in the opinion of a co-author of this paper who has been engaged in international standards organisations for thirty years, awareness of them is patchy among the engineering communities that typically engage in standards. This points to gaps between the ambitions of policymakers for cohesion between the Commission and ESOs, and the reality on the ground.

Harmonised standards are adopted following a standardisation request (mandate) from the Commission to the ESOs (CEN, CENELEC, ETSI) for the application of Union harmonisation legislation.[6] The process entails the Commission drawing up a draft standardisation request through consultation with interested parties including social partners, consumers, SMEs, industry associations and the EU Member States. Before being sent formally to an ESO, the draft request is sent to the Committee on Standards (a committee of EU Member States) for a vote. The Commission keeps a database of standardisation requests it has made.

Once standardisation is complete, the standards are evaluated by the Commission against the original request. An EU member state or the European Parliament may object to a proposed harmonised standard on the basis that it does not fully meet the requirements it aims to cover.[6] Those standards that meet the requirements of the Commission's requests are then published in the Official Journal of the European Union (OJEU). Only standards published in the Official Journal can provide product developers with a view of whether their products meet the legal requirements of the EU harmonisation legislation in question.

2.3.2 Article 41: Common Specifications

The draft EU AI Regulation provides specific powers for the Commission to 'adopt common technical specifications, in areas where no harmonised standards exist or where they are insufficient.' (rec 61).

Art 3 (28) of the draft Regulation defines 'common specification' as '*a document, other than a standard, containing technical solutions providing a means to comply with certain requirements and obligations established under this Regulation*'. In other words, common specifications are not standardised in ESOs. They are technical solutions created by the Commission, albeit there is a requirement for consultation with expert approval by Member States.

Common Specifications for Medical Devices: Not Plain Sailing

The common specifications framework set out in art 41 of the draft EU AI Regulation was introduced in 2017 in another field—that of medical devices—by the Regulations on Medical Devices (Regulation (EU) 2017/745) and on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746) (MDR/IVDR). They have also been proposed as a means of implementing the proposed Batteries Regulation.[9] The adoption of common specifications for medical devices has not been free of controversy. Some stakeholders have complained that the common specifications have attempted to impose more onerous requirements than the framework legislation, suggesting a lack of understanding of current practices and legal obligations on the part of the Commission,[10] and that their implementation depends on bodies and databases which have not been established in a timely manner.[11]

The Commission has attributed to the common specifications framework improvements in the quality of regulation for medical devices to patient safety and to the credibility and reputation of Europe's medical device system. Some commentators have criticised the use of common specifications in the single-use medical devices field as increasing bureaucracy for manufacturers - the opposite of the regulatory intent of the presumption of conformity, which ought to reduce the compliance burden for vendors.[12]

Article 41 empowers the Commission to adopt common specifications covering the requirements that high-risk AI

systems must meet. It may do this when relevant harmonised standards do not exist, where the Commission considers the existing standards inadequate, or where it identifies a need to address specific safety or fundamental rights concerns. For the providers of high-risk AI systems, compliance with common specifications offers (like compliance with harmonised standards) a presumption of conformity with the Regulation's requirements.

When preparing common specifications, the Commission must gather the views of relevant bodies or expert groups established under relevant sectoral law. Before adopting common specifications, the Commission must put them to a committee composed of representatives of EU Member State.[4,n.Article 74] It must not adopt them unless the committee approves them.

It is not compulsory for providers of high-risk AI systems to comply with adopted common specifications; but where they do not, they must be able to justify that they have adopted equivalent technical solutions – a comply or explain obligation.

Recital 61 to the draft EU AI Regulation gives a hint on the intended interplay between adopted standards and the Commission's own 'common specifications.' On one view, common specifications act as a safety net or backstop, enabling the Commission to step in where there is a lacuna in the technical standards space. On another view, common specifications provide an opportunity for the European Commission to override or 'improve' on global technical standards as it sees fit, bypassing existing organisations and transparent processes, and substituting its own expert consultations.[8]

Ideally, common specifications in AI could also offer the same assurances of safety to users as harmonised standards. However, this is the first time that common specifications have been applied to technology with the complexity of AI. They risk giving great discretion to the Commission, bypassing the expertise and process requirements of the ESOs.

3 HOW DO TECHNICAL STANDARDS WORK?

3.1 Introduction to Technical Standards

Technical standards were originally devised to assure safety, quality, and interoperability. For industry players that seek to operate globally, international standards are preferred over national or regional standards because they create a level playing field in markets throughout the world. Older standards focused historically on interoperability as the key benefit to society. Today, many contemporary standards also have social, economic, and political intentions or effects, creating contemporary norms.

The Benefits of Standardisation: Two Contrasting Examples

The benefits of standardisation can be illustrated with two contrasting examples.

The foundational protocols on which the internet's architecture is built are lightweight, open and guarantee interoperability. So, TCP/IP, the open protocols that were standardised by the Internet Engineering Task Force, ensure that two completely heterogenous networks can interact. The standards behind email technologies guarantee that an email can be sent between two people who are on different networks, using different email clients and different devices.

On the other hand, international plug sockets are an example of fragmented standards where there is no single, interoperable plug shape. That failure leads to additional cost for every individual who travels with computers or other devices that need to be plugged into an electrical socket. This example also illustrates another aspect of standards - once infrastructures have been developed with fragmentary standards it can be near impossible to roll back to a single, unified framework. It would take substantial time and investment to cover the cost of replacing every single plug socket in the world with a unified version. These brief examples illustrate how standards, when they work successfully, can be an enabler of innovation through openness and interoperability and when they fail to deliver, can lead to substantial costs for indefinite periods of time.

Robust standards for AI may provide assurance that the new technology meets policy goals of security and develops consistently with norms and values, beyond simply providing functionality and interoperability. Ideally, standards are an enabler of robust competition, flourishing innovation, and global deployment of emerging technologies.

Standards are usually the collaborative effort of an engaged set of stakeholders. Typically, those who are involved in developing technical standards tend to be engineers within industry, whose organisations have a direct economic stake

in the outcome. Several important standards development organisations are global, but some are specific to a region (as we will see below) and some are specific to a vertical market. In the case of AI, standards activity has been taking place deep in industry verticals, such as autonomous vehicles and healthcare.

Technical standards can range from documents of best practice, guidance for deployment, to specifications for interoperability at the physical, network or application level. In most cases, use of the standard is voluntary.

There are commercial and strategic dimensions to standardisation. For example, China's Standards 2035 strategy articulates the interplay between domestic standards and the benefits to international trade arising from the legitimacy that international adoption of standards can bring.[13], [14] Thus, engineers and scientists who have historically engaged in standardisation as a technical process now find themselves engaged with an eye to the commercial, geopolitical and societal impacts of technical standards.

3.2 How do Technical Standards work for Artificial Intelligence

AI is already in widespread use today. However, technical standardisation for AI is in its infancy. In Europe, ETSI and CENELEC have published ambitious agendas for standardisation, in part stimulated by the proposed EU AI Regulation's framework for standards. ETSI has focused on security issues surrounding AI and machine learning, while CENELEC has a strong focus on trustworthiness and ethics (see appendix). European-focused standardisation organisations are of particular importance to both the Commission and the draft Regulation because they are the only ones capable of developing 'harmonised standards' as defined in the draft Regulation, a process in which the Commission is in the driving seat and would therefore have the greatest influence.

3.3 Dimensions of Technical Standardisation for Artificial Intelligence

Besides security, trust and ethics, AI standardisation is likely to have a significant impact on cross-sector use of AI. Many of the solutions now used in AI affect a single sector (such as healthcare or intelligent transportation). Being able to use large data sets across sectors will open the market to even greater innovation in AI. The safe and ethical sharing of data across sectors is likely to become one of the most significant developments in AI in the near future. Standards for the safe, ethical, efficient, and reliable exchange of information will be one of the most significant developments for AI in the coming years. ETSI currently has workstreams dedicated to the data supply chain and availability of training data, while ISO has several projects on AI and big data (see appendix).

AI Watch, the European Commission's knowledge service on the development, uptake and impact of AI in Europe, is preparing an iterative mapping of ongoing AI standardisation activities of the European and international standards development organisations on to the requirements of the draft AI Regulation.[15] To date, AI Watch has mapped ISO/IEC and ETSI standards by reference to the draft Regulation. AI Watch finds that in the eight principal areas for standardisation in the draft AI Regulation, many relevant standards have already been published or are under development. AI Watch identifies a core group of standards on which it recommends there be focus in implementing the Regulation; this group is likely to expand in later iterations of the report, both as AI standardisation is expected to develop apace and as AI Watch maps the work of further organisations (IEEE and ITU-T are to be covered next). AI Watch has, however, identified significant gaps in current standardisation efforts relevant to the Regulation, notably in the fields of data and data governance; technical documentation; and on appropriate "testing" of AI.

3.4 The AI Standards Landscape

The following sections briefly summarise the AI standards work that is ongoing across the principal standards development organisations. Reflecting the language of the draft EU AI Regulation, these sections include both international SDOs, namely ISO, IEEE, IETF and ITU, as well as the European Standards Organisations ETSI and CEN/CENELEC.

Of the international standards organisations, ISO/IEC has a special status within the European standards framework. Not only does ISO/IEC conform with WTO principles on standards, but there are specific agreements in place to ensure harmonisation between ISO/IEC and European standards — the Vienna and Frankfurt agreements. These agreements foster closer cooperation between ISO/IEC and CEN/CENELEC, including mechanisms for the parallel approval of standards at the international and European levels. The intent of the Vienna and Frankfurt agreements is to underline the primacy of international standards over those developed at national or regional levels.[16] The

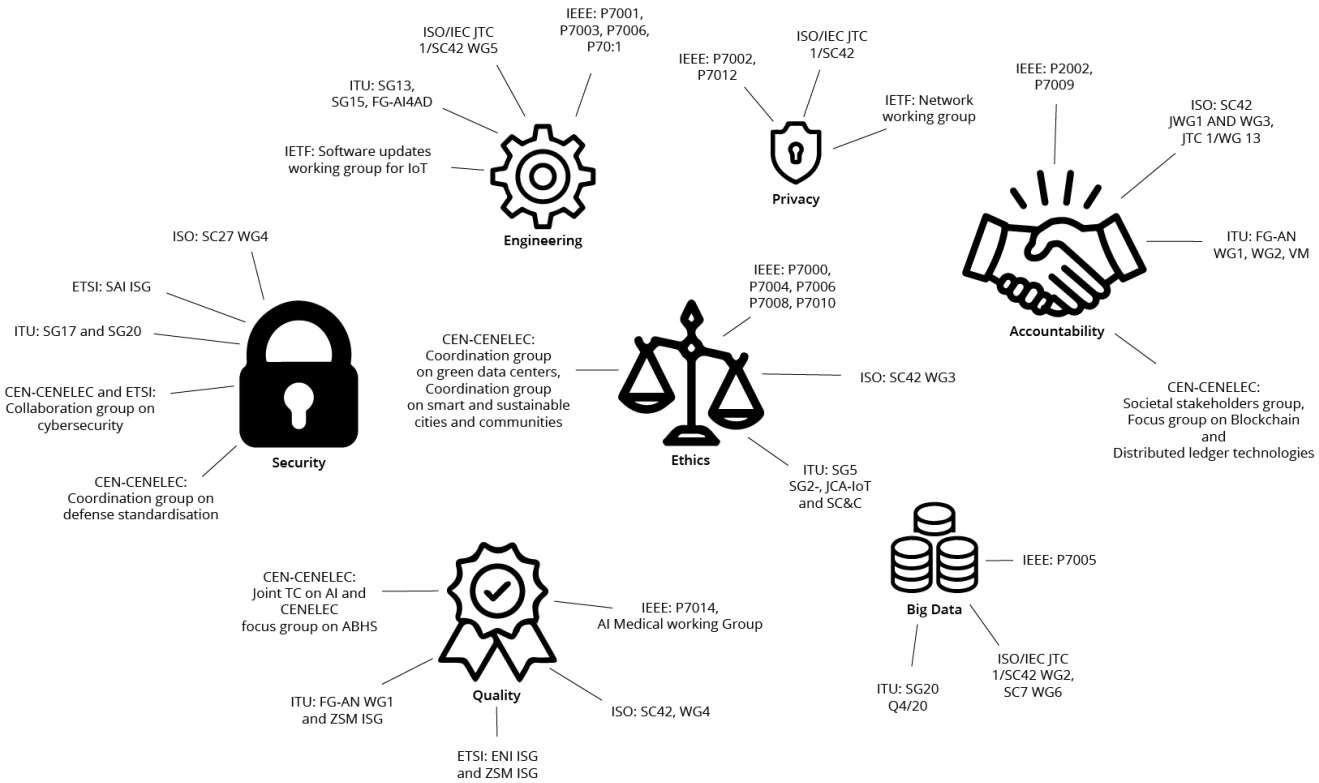

Figure 1 – Standards Development Organisations' activity on AI 2020

Source: Authors

agreements provide for ISO/IEC to take the lead in standards processes, although in limited circumstances CEN / CENELEC may perform this task.[17] In an unrelated field, that of geomatics, an ISO resolution highlights the need to 'avoid a random set of standards becoming European standards',[18] suggesting that the purposes of mechanisms intended to align the European and international standards processes are not as fully understood by standards participants, leading to potentially anomalous outcomes.

Further Information relating to each of the standards organisations and their activities on AI are contained in the appendix.

3.4.1 ETSI

ETSI is one of the two SDOs capable of creating 'harmonised standards'. Therefore, their work on AI standards is of particular relevance to this study.

Currently, the primary focus of ETSI in relation to AI is on security. This stems from the recognition that AI has the potential to create new attack vectors and defeat existing security measures. In 2018, ETSI formed an Industry Specification Group on Securing Artificial Intelligence(ISG SAI).[19] Founder members of the group were BT, Cadzow Communications, Huawei Technologies, the UK's National Cybersecurity Centre (NCSC) and Telefónica — the inclusion of Huawei emphasising the global participation in this European Standards Organisation.[20]

3.4.2 The European Committees for Standardisation (CEN) and for Electrotechnical Standardisation (CENELEC)

CEN/CENELEC is another SDO capable of generating 'harmonised standards' for the European Union. CENELEC's focus has been on mapping the work of other SDOs in the field of AI, and in articulating a work programme focusing on trustworthiness and ethics.

In 2019, CEN/CENELEC established a Joint Technical Committee 21 on Artificial Intelligence. This was based on the recommendations presented in the CEN/CENELEC response to the EC White Paper on AI and the German standardisation Roadmap for Artificial Intelligence.[21], [22] The work of the joint committee includes identifying and adopting external international standards already available or under development from other organisations like ISO/IEC JTC 1 and its subcommittees, such as SC 42 on Artificial Intelligence.

The joint committee's role includes supporting EU legislation, policies, principles, and values.[21]

In CEN/CENELEC's Work Programme for 2021, the Focus Group is directed to address European use cases, monitor the activities of ISO/IEC JTC 1 SC 42 and coordinate with European policymakers as well as ETSI. The Focus Group is also directed to follow-up and implement the CEN-CENELEC Roadmap on AI and has identified several areas for European standardisation, namely, accountability, quality, data for AI, security and privacy, ethics, engineering and safety of AI systems.[23]

3.4.3 The International Standards Organisation, or ISO

The ISO/IEC JTC 1/SC 42 standards, both published and those being developed, are important to the draft Regulation because they represent the foundation of what the European Standards Organisations will use for AI standardisation, given than 44% of standards cited in the Official Journal are based on international standards.[24] The standards under development at SC 42 will be adopted and not duplicated by CENELEC. However, there is a process requirement before such standards would be adopted by CENELEC, leading to potential delay and duplication of resources.

No other standards body has an equally rich and comprehensive approach to AI standards. It is worth noting that SC 42 has standards under development that address ethics and societal concerns. This will be of particular interest to CENELEC as it attempts to discern whether the global approach is consistent with the approach imagined in the draft Regulation by the European Commission, given the draft EU AI Regulation's stated ambition to 'shape global norms and standards and promote trustworthy AI that is consistent with Union values and interests.' [6,p.5]

3.4.4 The International Telecommunication Union's standardisation unit, ITU-T

The International Telecommunications Union Telecommunications Standardisation Sector has commissioned work in specific sectors through multiple Focus Groups e.g., on AI for Health, on Environmental Efficiency for AI and other Emerging Technologies, and on Machine Learning for Future Networks including 5G.

None of the ITU-T's Focus Groups are standardisation bodies. Instead, that work falls to Study Groups inside the ITU-T. In recent months, several study groups have embraced AI as a tool for managing telecommunications networks. Most notably Study Group 13 on Future Networks has a question devoted to networks beyond 5G and the use of machine learning in those networks. In addition, Study Group 13 is also working on using AI as a tool to improve Quality of Service in telecommunications networks.

3.4.5 The World Wide Web Consortium, or W3C

The World Wide Web Consortium uses the term "Semantic Web" to refer to a vision of linked technologies that allow organisations to create data stores on the Web, build vocabularies for those stores and then write rules for manipulating that data. The W3C also has an Artificial Intelligence Knowledge Representation group that is intended to identify the requirements, best practices, and implementation options for the specification of domain knowledge in AI.[25]

The W3C also has a group called Machine Learning for the Web Community which is incubating and developing a dedicated low-level Web API for machine learning inference in a web browser.

Most of the W3C's work in AI takes place in non-standardisation Interest Groups, which are fora for the exchange of ideas but not for standardisation.

4 EUROPEAN HARMONIZED STANDARDS – ARE THEY UP TO THE TASK?

4.1 How the System Works

The EU's new legislative framework (NLF) entails a partnership between legislation and standards. Following the procedure established by EU Regulation 1025/2012, the European Commission mandates the European Standardisation Organisations (ESOs) to prepare standards that meet the requirements of framing European legislation. Once adopted, harmonised standards are approved by the Commission and then published in the Official Journal of the European Union. Harmonised standards are widely viewed as an important building block of the European single market. They complement the framing requirements of EU legislation with technical requirements for manufacturers providing products for the European common market. The resulting standards are voluntary but tend to be widely adopted because compliance allows suppliers to self-declare that they

meet the legal requirements of the legislation and therefore have the right to supply goods into the EU market.

Regulation 1025/2012 establishes the ground rules for the ESOs: that they shall publish annual work programmes and shall encourage broad participation in European standardisation (including by SMEs, social stakeholders, and researchers), with free access to SMEs.

The ESOs do not comprise all the international standards development bodies, nor even all the European ones. They are CEN, CENELEC and ETSI, who entered a cooperation agreement with the European Commission in 1984.[26] The recitals to the 2012 regulation make it clear that the choice is deliberate (see rec 31), on the basis that European standards bodies are based on national representation (rec 2) and that, unlike European standards, 'some ICT technical specifications are not developed in accordance with the [World Trade Organisation's] founding principles,' (rec 31). The founding principles are 'coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency.' Even some standards bodies that are located in Europe, such as the W3C, and some international SDOs that do uphold the WTO principles, like IEEE,[27] do not fall within the 2012 Regulation's definition of an ESO and are therefore incapable of creating 'harmonised standards'.

The voluntary status of harmonised standards is in some doubt since 2016, when the European Court of Justice, in the case of *James Elliott Construction*, took the view that harmonised standards, although voluntary, are part of European legislation.[28] Since then, the European Commission has extended its processes for review of draft harmonised standards to ensure their compliance with standardisation requests before they are published in the Official Journal of the European Union. In 2018, the Commission introduced an expiry date to its standardisation requests and a list of detailed requirements to be developed by ESOs. Once prepared, draft standards are subject to a lengthy compliance procedure, first by HAS consultants (Harmonised Standards consultants) contracted by the Commission to perform a review, and then by officials of the European Commission. These developments have led both to significant delays and to the rejection of the ESOs' work by the Commission, putting pressure on the system and leading to a decline of trust between ESOs, the Commission, and industry stakeholders.

4.1.1 The Commission's Plans for Reform

The 2019 Bildt report on EU standardisation highlighted the need to refresh the EU's standardisation machinery and its use of the new legislative framework, not least to maintain the bloc's competitive position against the standardisation strategies of the United States and China.[29] In 2021, 17 EU Member States circulated a joint-non-paper on harmonised standards in which they called for improvements to the system for production of European harmonised standards including a commitment to flexibility and greater alignment between the Commission and ESOs and the need for speed.[30]

Following these calls for action, in June 2021 the European Commission issued a Roadmap for a new European standardisation strategy for public consultation. The Roadmap identifies problems with the existing European standardisation system, most fundamentally that it is "currently not sufficiently equipped to anticipate future standardisation needs".[23] It notes the challenge of striking the right balance between speed and quality; that stakeholders perceive new standardisation requests as too prescriptive; and the need for improved coordination of stakeholders and resources. It also notes the need for more formal education on or vocational training in standardisation, and for more standardisation around services (currently representing a mere 2% of European standardisation activities).

The Commission indicates that it is keen to consolidate and improve the EU standardisation system, for example through:

- Anticipating and defining standardisation priorities at political level and with stakeholders.
- Addressing bottlenecks within the standardisation system, including procedural aspects.
- Introducing more agile working methods and developing closer cooperation between national standardisation bodies and the relevant European organisations; and
- Incentivizing coordination, efficiency, and flexibility.

The Commission also states that it wishes to "develop a more strategic and coordinated approach to global standards-setting in areas of strategic EU interest",[23] make full use of EU industrial resources to support standardisation and pre-

standardisation activities (such as research and development, and address standards-related education, skills and expertise.

The Commission's more developed plans, taking account of consultation responses it has received, are due to be released in coming months.

4.1.2 Reaction to the Commission's Proposals

Review of the responses to the Commission's consultation on its proposals reveal the following themes.

Support for the system of global voluntary standards and the harmonised standards' presumption of conformity: Among the 138 responses to the Commission's consultation there is overwhelming support for the European approach of the new legislative framework, i.e., regulation supported by voluntary harmonised standards. Many respondents recognise that the European standardisation system in general, and Regulation 1025/2012 in particular, are fundamentally fit for purpose.[31], [32], [33], [34] To quote Nokia, "Voluntary global standards are the foundation for interoperability and have created significant benefits for the European economy and society and are critical for the EU's green and digital transformation."[35] In the words of a business association, "Harmonised Standards serve as a compliance demonstration tool as they grant their users presumption of conformity. They also enable market surveillance authorities to verify the conformity of products vis-a-vis the law."[36]

International cooperation: In the words of the Swedish National Board of Trade, "It is crucial that the European standardisation initiatives, to the largest possible degree, comply with international standards and take into account any international standardisation activities and only strictly apply the possibilities to deviate as stipulated in the Vienna and Frankfurt agreements." Many respondents call for more European leadership in international SDOs,[35], [37], [38] for Europe to adopt international standards where possible so as to avoid creating barriers to global trade and operability, and for ESOs to avoid duplicating work that is progressing well in international SDOs.[39], [40], [41]

There is support for CEN/ISO links through the Vienna Agreement, and CENELEC/IEC links through the Frankfurt Agreement.[40], [42] However, there are calls for connections with ISO/IEC to be deepened,[43] and concern is expressed that since the 2016 *James Elliott* judgment, it has become rare for harmonised standards to be based on international standards without deviation, leading to more fragmentation of standardisation as a whole.[44] COCIR calls for ISO and IEC to be seen as partners of ESOs rather than competitors.[45] The IEEE is keen to be more involved in the European standardisation system.[46] ANEC proposes that a standardisation request from the Commission should state whether a harmonised standard can be offered to ISO/IEC for development at international level (with responsibility for compliance with Regulation 1025/2012 remaining with the ESOs), or is to be developed within ESOs in order to safeguard European values or ethics.[47]

In contrast, some concerns are expressed about over-reliance on international standards. Some stakeholders question reliance on international standards as there is no guarantee that they comply with EU rights and values, and the processes for their elaboration may be less consultative - for example with civil society - than those of the ESOs.[48] ANEC observes a paradox between the EU on the one hand leading the development of international standards, and on the other ensuring and reinforcing its strategic autonomy; and expresses concern about the adopting in Europe of standards in which non-European countries or companies participated in sectors where cybersecurity is paramount.[47] X-Change AG notes repeated cases of tension between global standardisation processes and European stakeholder needs, citing the example of IETF's encrypted standard for DNS-over-HTTPS as one which placed European companies at a competitive disadvantage.[49]

There are calls for more international cooperation on standardisation at a political level,[50] including through fora such as the EU-US Trade and Technology Council,[51] and through cooperation with the "standardisation superpower China" to mitigate risks to multilateralism and avoid any prospects of damage to global trade through unilateralism.[52]

Common specifications: Although not mentioned in the Roadmap, some respondents express concern or wariness at the increasing provision for Common Specifications in new draft laws, not only in the draft AI Regulation but also in the Commission's proposal for a new Batteries Regulation.[41], [53], [54], [55] In the words of one business association, "Whereas the option of resorting to Common Specifications might be an appropriate solution in some cases, there is a possibility that it undermines work in the field of standardisation. The new standardisation strategy should reflect on this and provide further clarity on the possible development of Common Specifications."[36] Questions are

raised about how to guarantee stakeholder involvement in the development of common specifications, how to make sure common specifications are fit for purpose and meet market needs, how they will be aligned with standards and how they will be integrated and updated within the existing body of standards.[32] ANEC proposes that when the Commission decides to adopt Common Specifications, it should itself comply with the process requirements of Regulation 1025/2012.[47] By analogy with Technical Specifications, the term used for specifications similar to Common Specifications in some other European Regulations.

Concerns over timeliness and process: At the same time, there is equally wide appreciation of current problems with the process for adoption of harmonised standards and an urgent need to restore confidence. There is widespread concern at significant delays in the system, particularly in the interval between conclusion of work on a standard by an ESO and its publication in the Official Journal.[56], [57], [33], [58], [59], [52] This means that European standards are lagging behind international standards.[60] ANEC expresses concern that the loss of confidence resulting from delays in citation may lead the industry no longer to invest in European standardisation.[47]

There are calls for the Commission to re-assess the role it has adopted since the *James Elliott* judgment,[40], [39], [60] with some pointing out that Regulation 1025/2012 does not anticipate the treatment of harmonised standards as legally binding text.[61] Several stakeholders call for flexibility to be built into the requests made of the ESOs by the Commission,[36], [62], [59], [54] TE for the HAS consultancy system to be improved and for the criteria by which the Commission will evaluate proposed standards to be clear to all stakeholders.[58], [50], [63], [64] ETSI calls for increased engagement between ESOs and the Commission at the time of elaborating legislation and standardisation requests,[59] while OpenForum Europe calls for feedback from the Commission to ESOs on a rolling basis if an emerging standard may not meet its criteria.[41] Some argue that the Commission should develop further internal expertise, such that there would no longer be a need to engage HAS consultants.[65], [66] Some call for a more transparent working process during the development of a standardisation request.[55] Some support the creation of a high-level group to build and maintain dialogue between the Commission and stakeholders in standards.[47] ETSI also proposes a presumption of conformity: that harmonised standards elaborated by ESOs are consistent with their commissioning requests.[59]

More resource: Beyond these specific process concerns, there are calls for a significant strengthening of the European standards system, given its vital role (albeit with some sounding a note of caution, that "premature standardisation can hinder innovation").[39] The importance of standardisation for new technologies is stressed as a key mechanism for ensuring interoperability, with calls for every strategy for funding future technologies to include standardisation as a key component.[67] "Failing to maintain proactive standardisation activities would lead to less European-developed technology being adopted in important non-European markets".[67] There are calls for more funding and for the attraction of more expertise.[52]

Speed and priorities: Overall, there are calls for an "agile, efficient system".[32], [55] But this is accompanied by a recognition that rigour in adopting suitable technical requirements through consensus is more important than speed.[47] Prioritisation is widely seen as key.[32], [68], [24] The IEEE calls for a "needs-focused approach", by which standards should respond to societal and market needs to facilitate trade.[46] There is support for the Commission's plans to strengthen its processes to identify current and future priorities for standardisation, and to identify, discuss and push forward standardisation priorities with international partners.[39]

Limits of standards: The consultation responses include some discussion of the proper role of standards. A few respondents consider that standardisation is wrongly straying beyond a proper focus on scientific and technical procedures and materials to encompass matters defining professional activities and behaviour, or socio-political issues, which should properly be for the democratic legislative system.[69], [70] "Standards should not be instrumentalised to shift regulatory power to private actors".[48]

Transparency: Some respondents call for more transparency in processes: in the words of the FarmTech Society, "The methods for standard setting, reporting and monitoring no longer meet the expected 'radical transparency' of the digital age".[71] The possibility of taking account of open source solutions is mooted or encouraged by some.[32], [41] Some stakeholders called for avoidance of proprietary closed standards, seeing them as hindering the development of the Digital Single Market,[72] and note that CEN/CENELEC standards are not currently freely available (however all harmonised standards are freely available through citation in the OJEU). Others call for maintenance of intellectual

property protections that fund reinvestment in R&D and the retention of know-how and skills in Europe.[35], [67]

Similarly, some identify challenges caused by the different ways of working between different ESOs. ETSI's model of allowing direct industry participation, with one membership fee allowing open access to all activities, is praised;[65] in contrast, CEN/CENELEC operate on the basis of participation by national delegations, which each have different models for participation. Some national delegations require separate payment for participation in different classes of activity, therefore making participation overall more costly for SMEs.[73] But there is recognition that the ESOs, as private bodies, should be left to establish their own internal procedures.[35]

Education and engagement: There is widespread support for the Commission's proposal to include standardisation in education,[39], [32], [43], [37] for the promotion of a "standards-literate workforce",[8] and for young professionals to become more involved in standards development.[74] Some note the need to attract more experts to participate in standardisation.[52]

Further, some call for strengthening of links between European standardisation and innovation support tools such as R&D,[69], [67] tax incentives and economic support tools, with more support for SMEs, [75] start-ups, social partners, NGOs and consumers.[43] It is argued that there should be more participation of scientists in standardisation, and more uptake of research results.[32]

Stakeholder engagement: There are calls for broadened stakeholder engagement.[34] Some call for improved funding of experts and standards bodies at national level, as being key for stakeholder involvement.[76] Some call for the Commission to maintain attention to protection of the role of SMEs in standards development.[77] Concern is raised that SMEs have no realistic prospect of having their own innovations standardised.[78] It is suggested that further digitalisation of the standardisation process could increase its accessibility for diverse stakeholders.[60] Given the potential impact of standards on business activity, there are calls for impact assessment to be conducted by ESOs as part of the standardisation process.[31] Silence is also significant here: it is notable that few NGOs, and no human rights NGOs, participated in this consultation despite the increasing reliance being placed on standardisation for the protection of European fundamental rights and values, particularly in the field of AI.

5 STRENGTHS AND CHALLENGES OF THE PROPOSED EU APPROACH

5.1 Strengths of the Proposed EU Approach

While the EU AI Regulation overall is lengthy and detailed, key terms and concepts are defined broadly. This allows for a flexible approach and future adaptation of the Regulation in the face of evolving and emerging technology.
The Regulation follows the approach of the EU's "new legislative framework" (NLF), discussed above. The use of NLF in the draft AI Regulation has been broadly welcomed by stakeholders because, as with NLF generally, it allows for the requirements of Regulation to be given practical effect through a consensus-driven process that can take account of the views of multiple stakeholders and technical experts.[41], [59], [52]

While harmonised standards are developed by European standards organizations, the Vienna and Frankfurt agreements between those organizations and International Standardisation Organizations (such as ISO or IEC) seek to align international and European standards and recognise the leading role of ISO/IEC in standards formulation. This is another key strength of the current approach: ideally, duplication of effort is minimized and, where relevant, global standards can be adopted by the Commission with the cooperation of CEN/CENELEC. This is sensible because it ensures compliance with important international standards and reduces workload for the ESOs. In the field of AI, as with other technology whose application is not limited by physical boundaries, many developers are looking for international rather than merely European markets. Consequently, and particularly as these markets are developing rapidly, continuous vigilance is needed to avoid fragmentation between European and international standards, or the imposition of additional bureaucratic hurdles on the path towards compliance.

We have examined, in Section 3 and the appendix, the roadmaps of key standards organizations. In particular, the ETSI, ISO/IEC JTC1/SC42 and CEN/CENELEC roadmaps are detailed and ambitious. However, the combined number of standards produced and published by these organizations remains low: nine in 2019 and 2020.

It is also noteworthy that the ETSI, ISO/IEC JTC1/SC42 and CEN/CENELEC roadmaps have many operational standards

rather than frameworks or discussions of meta-AI topics. This can only help with the implementation of the EU AI Regulation when it becomes law – developers of AI products and services will have clear specification on which to judge their products' applicability to the Act. Again, very few of these standards have been published.

This may be a virtue in disguise. Given that the draft of the EU AI Regulation was released in April 2021, and the regulatory framework will likely not be adopted before 2023, it is reasonable to conclude that the currently published standards will not be essential to the implementation of the Regulation. In fact, requirements from the Regulation are useful as input to current deliberations of ESOs given that according to ISO, "from first proposal to final publication, developing a standard usually takes about 3 years".[79]

While, as discussed below, there are risks to common specifications devised by the Commission, these also have potential strengths. They allow the Commission to plug gaps not yet filled by the standards bodies. And they may provide a mechanism to set aside or bypass standards that do not meet European safety or human rights standards. One of the aspects of standardisation that has come to the fore in light of Chinese proposals to develop standards for what has been termed 'New IP' is that the international system affords asymmetric protection for standards in relation to trade and human rights.[80] Standards that have been adopted through international processes such as ITU or ISO are protected against trade bans through WTO rules, but there are no mechanisms enabling standards to be set aside on human rights grounds. The draft EU AI Regulation may provide such a mechanism, at least the level of products/services within the EU region.

The draft Regulation includes further protection for human rights in the form of Article 67. That provision allows a national authority to require an AI provider to modify, withdraw or recall its service to address a risk to health or safety, compliance with fundamental rights or to protect the public interest - even if the AI system complies with the Regulation and by implication may conform with harmonised standards or common specifications.

5.2 Challenges Posed by the Proposed EU Approach

5.2.1 Differentiation between standards bodies based on geography

The draft EU AI regulation's provisions relating to harmonised standards draw a line between European standards bodies on the one hand and international SDOs on the other, with only ETSI and CEN/CENELEC being capable of creating European standards. This distinction creates several anomalies.

First, the need for cooperation on standards goes wider than the EU alone if future technological standards are to reflect democratic values and respect fundamental rights. The need for international cooperation is recognised both in the 2021 EU-US Summit outcome and the G7 declaration,[81] which emphasises the need for cooperation on standards between like-minded states to 'ensure digital ecosystems evolve in a way that reflects our shared values'.[82] The proposed division between European standards organisations and international processes seems somewhat incongruous in that context.

The operation of the Vienna and Frankfurt agreements further undermines the distinction between European and international standards organisations, as in effect CEN /CENELEC's work programme in relation to AI standards is that of ISO. Responses to the Commission's consultation on its proposed standardisation strategy highlight the relevance of the international standards organisations for European competitiveness.

A further risk is that, because of the presumption of compliance arising from harmonised standards and the market access that brings for AI providers, the balance of power envisioned in the Vienna and Frankfurt agreements—namely, the leadership role of ISO/IEC—would be reverse, with CEN/CENELEC instead driving the standards agenda from a top-down political perspective, rather than the industry-led expertise offered by ISO/IEC.

Finally, the influence of non-EU participants in ETSI (e.g. Huawei is a founder member of ETSI's ISG SAI) blurs the boundaries between the European and international standards bodies, making it inappropriate to exclude or include certain bodies based on their geographical location or supposed conformity with WTO principles on standards.

5.2.2 Timeliness

There is a mismatch between the speed of deployment of AI-based products and services and the development of standards. The development of AI tools is rapidly accelerating and is increasingly affecting more areas of society. Standards move at a much slower pace. Once adopted, their review by the Commission and publication in the Official Journal can take further time. As highlighted by the Bildt report, on occasion a standard agreed by an ESO has been rejected by the Commission for non-compliance with instructions, setting the whole process back by years.

The Commission is currently consulting on a new Standardisation Strategy, with the aim in part of addressing timing issues. However, it should not be assumed that speed should be prioritized in standards development. While additional resources (expertise and funding, see below) will help, the time taken for adoption of new standards does not depend entirely on their availability. Engaging with diverse stakeholders to reach consensus on complex issues is a lengthy process; undue haste would likely result in compromises on the quality of standards achieved. It is important to achieve a balance that allows for appropriate consideration of, and compromise between, all relevant voices and perspectives without getting bogged down.

Stakeholders have called for the timely issue of standardisation requests by the Commission to SDOs.[83] Picking up tensions on the notification process, and its rigidity, in particular several SDOs call for more 'simple, agile' solutions for the finalization of standards with HAS consultants,[24] and the need for the process to avoid restricting participants into yes/no outcomes – providing instead the means for earlier involvement of SDO experts.[59]

5.2.3 Resources

The roadmaps for ETSI and CEN/CENELEC around AI are ambitious and aspirational. There is a significant difference between what these ESOs envisage as AI standards and what has been delivered. Part of the problem is lack of available resources to deliver the standard.

First, there is a noticeable mismatch between the size of the standardisation agenda and the number of industry experts available to work on those standards. One of the challenges for the Commission is that the development of European Standards presupposes the availability of experts to develop the standards. Even in the case of adopted standards (for instance in the CEN/CENELEC adoption of ISO/IEC standards under the Vienna and Frankfurt agreements) there is a requirement to assess whether those standards meet the requirements of formal requests from the Commission. The roadmaps for the standardisation work are detailed and extensive but give little information on how the necessary staffing resources will be found.

Secondly, staffing for the standardisation effort is not the only resource problem. The standardisation effort requires funding – no matter whether it is done at ESOs or at global standards organizations. While some excellent preliminary work has already been done around standards and AI (for instance, the EU AI Standardisation Landscape), the budgetary picture for standards work on AI in CEN/CENELEC, ETSI and global standards bodies remains unclear. In the absence of a funding strategy, the ESOs are left to alternative funding sources – for instance, national standards bodies, private sector funding and industry self-funding of standards participation. These alternative funding sources are not a stable or sustainable set of resources for the significant work that is promised in the overall standardisation agenda.

5.2.4 Compliance Tools

Noticeable in the work being done on standards and their intersection with the draft EU AI Regulation is the absence of compliance tools for assessing AI products and services against approved European Standards. While it might be argued that it is too early in the implementation to ask the Commission for compliance tools, it is also noticeable that there are many AI products and services already implemented. Making already established commercial implementations of AI products and services compliant with emerging European Standards may simply be impossible.

Still, there needs to be some way to measure and assess compliance with operational European Standards, and this is particularly vital given the broad, effects-based definitions in the draft EU AI Regulation for high-risk AI systems which will bear the main compliance burden. While the ETSI and CEN/CENELEC roadmaps have clear approaches to best practices, they see compliance with standards as voluntary. As a result, they have no need to develop compliance tools for themselves. However, the Regulation envisions that there will be a mechanism to assess compliance with European Standards and organizations will need tools for that assessment once the standards are in place.

An example of this is ISO/IEC TR 24027: a Technical Report on bias in AI systems and AI-aided decision making. It proposes to establish measurement techniques and methods for assessing bias, with the aim to address and treat bias-related vulnerabilities. All AI system lifecycle phases are in scope, including but not limited to data collection, training, continual learning, design, testing, evaluation, and use. The Technical Report is still at the Committee stage (under development), but it could be used as input to the development of a compliance tool that assessed bias. Other inputs would be needed to address issues such as transparency, explainability, or trustworthiness.

5.2.5 Protecting fundamental rights through standards

The draft Regulation recognises the potential impact of technical standards on human rights, by calling for the establishment of common normative standards for all high-risk AI systems, which are consistent with the Charter of Fundamental Rights (rec. 13).[6]

The draft Regulation lists certain AI systems as high-risk, and allows the Commission to add further AI systems as high-risk when they pose a risk of harm to health and safety, or of adverse impact on fundamental rights, equivalent to or greater than that posed by the high-risk AI systems already listed. Draft Regulation Articles 6 and 7, Appendix III. The Regulation also specifies as high-risk any AI system which is the safety component of, or is itself, a product covered by EU harmonisation legislation requiring a third-party conformity assessment before it is put into service (such as certain machinery, toys, medical devices). The listed AI systems include, for example, remote biometric identification systems; safety components in the management of road traffic and the supply of water, gas, heating and electricity; systems used by education providers to select students and to assess them; employment recruitment systems; systems assessing eligibility for social benefits. They are systems that can potentially have a major impact on aspects of people's lives.

It follows that the aim of the Regulation's requirements for high-risk AI systems, and therefore the aim of harmonised standards by which AI providers may demonstrate compliance with these requirements, is to mitigate risks of harm to health and safety or adverse impact on fundamental rights. While the Regulation's requirements generally focus on systems and processes rather than substantive rights and health requirements, they will only be effective if they successfully mitigate risks to those substantive rights. And, as ANEC observes, standards can be a tool by which to introduce values or principles – such as privacy by design - into the development and implementation of AI.[84]

For example, Article 9 of the draft Regulation requires the provider of a high-risk AI system to maintain a risk management system. While Article 9 focuses on the processes that must be followed—such as identification, evaluation and mitigation of risks and testing procedures—harmonised standards embodying these requirements will be more effective if prepared with some knowledge of the nature of the risks to be identified, tested for and mitigated against.

It follows that the harmonised standards giving effect to the requirements of the Regulation will be more effective if prepared with input from experts on health and safety and fundamental rights. Indeed, harmonised standards may be more effective if they draw on other legal protections of rights and safety. At the same time, it is arguable that standards that protect fundamental rights need to be sufficiently flexible to address a wide range of use case specific risks. Arguably, standardisation in the AI field has to address a much wider field of risks than it typically does in managing product-related health and safety issues.[85] The risks are more challenging to identify in the field of AI than that of products. Not only are the use cases for AI harder to predict than those of physical objects, but AI applications are typically embedded within complex systems—so it is difficult for the creator of the AI application to predict all the ways in which that software could be used or could impact fundamental rights.

These challenges raise the question of whether the ESOs are equipped to protect fundamental rights and the public interest. This is partly a matter of stakeholder involvement—see discussion below—but also a question of whether ESO processes lend themselves to discussion of fundamental rights and their jurisprudence.

5.2.6 Ensuring Protection of European Rights and Values

Not only is it challenging for standards to protect rights, but the different interrelationships between European and international standards bodies as compared to human rights jurisdictions means that it may be challenging for standards to protect specifically European rights and values. While many elements of human rights are universal, the boundaries of rights protection and the relative protection given to competing rights and other interests differ between

jurisdictions: it is no exaggeration, therefore, to refer to European rights and values. If international standards are adopted by ESOs and vice versa, there is a risk of losing these specificities of protection. Hence, for example, the European Association for Coordination of Consumer Representation in Standardisation (ANEC) has called for European standards specifically to address European values and fundamental rights, including consumer protection principles, rather than merely adopting international standards which may not reflect them.[84]

5.2.7 Mismatch between stakeholders currently working on standards and stakeholders on AI

The legal requirements for European Standards Organisations (ESOs), namely the CEN/CENELEC and ETSI, are clearly set out in law, through Regulation 1025/2012. The ESOs' obligations include the involvement of all relevant stakeholders in their work.[6] ESOs are required to encourage and facilitate representation and participation of SMEs, consumer organisations and environmental and social stakeholders at all stages of the standardisation process. Commission research facilities and EU-funded organisations are to encourage and facilitate appropriate representation in standardisation. ESOs are also required by Regulation 1025/2012 to publish annual work programmes and to give SMEs (but not 'social stakeholders') access to standardisation activities with participation for free or at special rates.[6]

In practice, however, there are mismatches and challenges concerning stakeholder engagement. The first is a perennial one raised by SMEs and consumer groups: that the standardisation process is not sufficiently inclusive. Hence both SMEs and consumer associations argue that there should be more steps taken in standardisation processes to enable SMEs/consumers of all ages and capacities to participate more effectively than at present.[84]

The practical challenge of inclusivity for SDOs is daunting. The method of operation of a SDO is often difficult for new participants to comprehend – there is a significant barrier to participation for newcomers in simply learning how to have an impact on standardisation processes. While the challenge of inclusivity may stem in part from lack of awareness of standardisation processes, it is also a question of available resources. For example, SMEs may wish to participate in standardisation to ensure the process is not captured by larger companies. But participation is time- and cost-intensive, and participation with a view to safeguarding their options in respect of products that do not yet exist is particularly challenging. The distribution of expertise in AI specifically does not favour SMEs in standardisation activities.

Consultation responses to the EU standardisation strategy from CEN-CENELEC point out the value of standardisation roadmaps in providing early warning of what is ahead, and of enabling the timely coordination of affected stakeholders.

The second challenge concerns standardisation in respect of AI more specifically. The draft AI Regulation relies on use of standards to help ensure that core European values are preserved by the Regulation. For this to be achieved, standards development will have to incorporate those values. This requires stakeholder participation from sectors not traditionally involved in standards development.

The SDOs identified in Section 4 and the appendix typically have subject matter experts in the areas that the standardisation is taking place. For instance, the IETF's Working Groups are dominated by engineers whose interests are the engineering of Internet protocols and services. Standards work is typically dominated by commercial engineering interests. While those engineers are supposed to leave their economic interests at the door, in practice engineers tend to advocate for protocols and services that reflect the interests of the companies for which they work. To give a different example, the same thing happens with the ITU-T. Here, national interests are expressed through nation states attempting to promulgate standards that are "friendly" to state interests. In both examples, participation by experts who could address the protection of fundamental rights is largely non-existent.

One of the challenges for the Commission is providing a platform for sustainable and meaningful participation by non-technical organizations and experts in standards development. Some standards bodies are simply not oriented, or not open, to the participation of non-experts and welcome them with a spectrum of understanding and receptiveness. In other cases, the engineers themselves attempt to address rights-based issues with predictable consequences. Other standards bodies (notably the ITU-T and ISO/IEC) need to make accommodations for expert help on rights-based issues. In many cases, experts in fairness, human rights and ethics, rather than in technical aspects of AI, do not feel welcome in technical standards organizations. In short, even if stakeholders had the awareness, resources and capacity to participate, they may find it difficult to do so

in practice. If standards are to protect rights effectively, this challenge urgently needs to be addressed.

5.2.8 Dependence on parameters set by the legislation

Many of the consultation responses on the draft Regulation raise substantive concerns about the overall content of the Regulation, discussion of which is outside the scope of this paper. However, it is significant to note that as standardisation must take place within the parameters set by the legislation, any deficiencies in the legislation cannot be remedied through standardisation.

By way of concrete example, some large industry players, including Microsoft and Google, argue that the Regulation puts too much onus on the manufacturers of AI systems.[86], [87] They argue that there should be a new designation of "deployer", representing the entity which purchases an AI system from a manufacturer and makes its own decision to deploy it in a high-risk scenario. In Microsoft's view, some of the compliance burden should fall on deployers rather than manufacturers. On this issue, standardisation will only be able to follow the parameters set by the legislation: the ESOs would not be able to prepare harmonised standards for deployers unless the Regulation permits this, and the Commission issues a standardisation request accordingly.

5.2.9 Training

At the intersection between the draft EU AI Regulation and standards bodies is the common understanding of how each are intended to work. Specifically, training, education and orientation to standards work – specific to AI standards and rights protection – is absent. While each standards organization has orientation materials for new participants, none are specific to a particular sector or area of interest.

As a result, those who have an interest in using the EU AI regulation to ensure fairness, transparency, ethics, and rights protection, have no specific training or education available. This creates a barrier to entry for those who would be otherwise willing to participate in standards work. It is almost never the case that standards work is simply a matter of turning up for a meeting on a topic of interest. Instead, the culture, procedures and makeup of the standards body makes a difference in how non-experts can meaningfully participate and influence the development of the standards. The need for standards-specific education and training is advocated by ISO, ETSI and CEN-CENELEC in their responses to the EU's ongoing standards strategy consultation.

5.2.10 Other Practical Constraints

The European Standards Organisations may be capable of producing the deliverables envisioned in the EU AI Regulation. However, ruthless prioritization of tasks will be needed, in addition to significant increases of expertise and funding, to address resource constraints. The Commission and ESOs should identify the key issues and threats, as well as areas which attract widespread common views, and focus standardisation areas on these topics.

The Commission will likely find that the CEN/CENELEC, ISO and ETSI AI standardisation roadmaps are good foundations on which to build. They have only minor overlaps. The natural linkage between ISO/IEC and CEN/CENELEC means that the Commission will be able to take advantage of global resources for standards development. Those areas of standardisation where CEN/CENELEC needs to act independently could benefit from robust prioritization. The goal of the prioritization would be to identify which standards should be worked on first – in order to further the objectives of the Regulation.

A natural approach here is to have the Commission focus on horizontal, foundational standards which will support sector-specific work. Areas that could be addressed immediately are standards for data exchange and transparency, metrics for trust and explainability, and related, horizontal standards. Once in place, these standards could be used as a standard set of baselines for sector-based standards; for example e-Health data collection and monitoring which is already a subject of an ETSI standard.[88]

While the Vienna and Frankfurt agreements give primacy to ISO/IEC over CEN/CENELEC in the promulgation of standards, the EU AI Regulation may change that in practice, putting CEN/CENELEC in the driving seat. Several factors might contribute to this, including the Commission's drive for values-respecting standards and the strong incentives for businesses to follow harmonised standards to reduce compliance costs and gain access to valuable EU markets.

5.3 Can the ESOs Produce Deliverables as the AI Regulation Envisages?

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While the Vienna and Frankfurt agreements give primacy to ISO/IEC over CEN/CENELEC in the promulgation of standards, the EU AI Regulation may change that in practice, putting CEN/CENELEC in the driving seat. Several factors might contribute to this, including the Commission's drive for values-respecting standards and the strong incentives for businesses to follow harmonised standards to reduce compliance costs and gain access to valuable EU markets.

5.4 Is the Commission Equipped to Produce Common Specifications?

Some stakeholders have argued that there should be more clarity as to when common specifications will be deployed, and that they should be avoided where possible as they will not engage the expertise and consultation embedded in standardisation processes.[83] Others have argued that common specifications should only be deployed in exceptional cases, and that the Commission should consult and involve all stakeholders in their elaboration.[89]

ETSI argues that the Commission should not need to deploy common specifications, because it should actively participate in standards committees and therefore play a role in shaping resulting standards.[90]

In summary, there may be gaps between the Commission's policy ambitions in relation to common specifications and its access to the necessary expertise and transparent processes in adopting them.

6 RECOMMENDATIONS

1. A mechanism must be in place to address the gulf between the ambition of the ESOs in the context of AI standards and the resources they have available to develop the standards.

2. A mechanism must be in place to ensure meaningful, substantive participation in standards development by those most interested in protecting fundamental human rights and the public interest. Standardisation roadmaps, published well in advance, as well as national AI standards hubs could provide practical ways to involve such stakeholders early in relevant AI standardisation processes and at strategic points prior to the adoption of standards by international bodies.

3. The proposed EU AI Regulation is flexible legally and procedurally. Standards developed in support of Clause 40 and 41 must also be flexible enough to reflect the quick evolution of AI technology and products. A fast-track process could be developed to improve on the timeliness of adoption for standards. Another practical approach could be to review and eliminate the distinction between ESOs and international standards organisations, substituting more relevant tests such as the equity of stakeholder representation and adherence to international frameworks such as human rights instruments and/or the WTO principles for standardisation.

4. Education and training, specifically for non-expert AI stakeholders, must be available that facilitates understanding of and participation in ESOs. Such training should be tailored to a wide variety of stakeholder groups that need to understand the strategic importance of standards and be focused on developing the capacity and skills needed to participate effectively in standards organisations.

Women and girls should be targeted with early interventions to redress the gender deficit in standards participation.

5. Once effective operational standards are in place, compliance tools must be developed in close cooperation with industry and standards experts that help regulators, NGOs, industry and product developers ensure that their products are compliant with the standards and the Regulation.

6. Recognising the continued interplay between ESOs and international SDOs, there needs to be a mechanism for appropriate balancing of two imperatives: on the one hand, the need to devise European standards that specifically embed European rules and values; on the other, the need for global open, interoperable, standards that facilitate international trade between the EU and rest of world, rather than acting as barriers to global.

7. Cooperation between business, particularly between SMEs, must be scaled to maximise participation while minimizing the costs of engagement and reducing the inefficiency of duplicate voices. Similarly, scaling of cooperation between civil society members is necessary to maximise participation and impact while reducing potential inefficiency of duplicate voices.

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APPENDIX: OVERVIEW OF PRINCIPAL STANDARDS DEVELOPMENT ORGANISATIONS AND THEIR ACTIVITIES

ETSI

ETSI is a global standards development organisation with more than 900 members in more than 60 countries.[91] ETSI has an extremely diverse portfolio, but its primary focus is on computing and networking. As a European Telecommunications standards body, in the last decade its remit has gradually expanded to emerging technologies and expansions on established technologies. ETSI's work is made up of a series of technical groups:

- Technical Committee (TC)
- ETSI Project (EP)
- ETSI Partnership Project (EPP)
- Industry Specification Group (ISG)
- Special Committee (SC)
- Specialist Task Force (STF) As European Standards (ENs)

ETSI and AI

In 2019, ETSI held a summit on AI including presentations that did not focus specifically on standardisation but with a note in the summary on the AI in telecommunications sessions: "We should standardise the interfaces between AI systems (for interoperability) but not the AI systems themselves".[92] In addition, the manufacturing session highlighted that "Standards can be of help both in contexts of technical regulation and for enabling interoperability around AI," as well as recommendations not to "treat AI different from other technologies, no special standardisation is required".[93]

The ISG SAI first outputs intended to discuss six key topics:[94]

- Problem Statement, that will guide the work of the group
- Threat Ontology for AI, to align terminology
- Data Supply Chain, focused on data issues and risks in for training AI
- Mitigation Strategy, with guidance to mitigate the impact of AI threats
- Security testing of AI
- Role of hardware in security of AI

ETSI has published three separate documents so far:

- Securing Artificial Intelligence (SAI); Problem Statement, published in December of 2020;[95]

- Securing Artificial Intelligence (SAI); Mitigation Strategy Report, published in March of 2021;[96]
- Securing Artificial Intelligence (SAI); Data Supply Chain Security.[97]

This list reflects the fact that ETSI's engagement with AI standardisation is relatively recent. ETSI's ISG SAI recognises this and has publicly suggested future areas for standardisation:

- Data security, integrity and privacy
- Training data: quality, quantity, confidentiality and labelling
- Transferability (re-use of models across tasks and industries)
- Transparency
- Explainability (for regulation purposes)
- Ethics and misuse
- Bias
- Unintended consequences.[94]

What is clear from this list is that ETSI has significant ambitions for producing standards in the area of AI. However, the tight focus on security – so far – has meant that the remainder of the ETSI standards agenda for AI is aspirational. This has an impact on the ability for ETSI to respond to the regulatory requirements surrounding AI.

SDO Name	**ETSI – European Telecommunications Standards Institute**
Standards Framework	ETSI works through direct participation of its members. Members choose for themselves what contributions and proposals to make. The decision-making process is through consensus. ETSI's standardization work is carried out in different technical groups: · Technical Committee (TC) · ETSI Project (EP) · ETSI Partnership Project (EPP) · Industry Specification Group (ISG) · Special Committee (SC) · Specialist Task Force (STF)d as European Standards (ENs).
Implications to the Regulation	ETSI has a special role as it is identified in EU regulation 1025/2012 as a European Standards Organisation, capable of developing 'harmonised standards' at the instigation of the European Commission. Only standards developed by the three ESOs (CEN, CENELEC and ETSI) are recognized as harmonised standards.

ETSI's reaction to the draft Regulation and EU standards strategy consultation [98]	ETSI submitted a consultation response which welcomes the early introduction of standards and the integration of European and International standards. It focuses on making harmonized European Standards a focus of demonstrating compliance with regulatory requirements, in line with ETSI's view that the New Legislative Framework should be used for technical regulation in new areas including AI and data.[90] ETSI's input into the ongoing consultation on the EU Standards Strategy describes education on standards as 'essential', calls for the active participation of the European Commission in standards development, and for more inclusiveness and better coordination with international standards organisations.[98]

Table 1 - ETSI Standards Organisation Framework

CEN/CENELEC

CEN / CENELEC has a focus on electrotechnology and includes sectors such as Defense and Security, Electric Equipment and Apparatus, Electronic, Electromechanical and Electro-Technical Supplies, Household Appliances, Energy and Utilities, and Transport and Packaging. As CEN/CENELEC is made up of European National standards organisations that focus on this kind of standardisation, CEN/CENELEC acts as a regional standards body with links to the global ISO and IEC bodies through the Vienna and Frankfurt Agreements. Of around 3,500 CEN / CENELEC standards cited in the Official Journal, 44% are based on international standards.[24]

One of its core functions is to develop harmonised standards across the European region based on requests from the European Commission and the European Free Trade Association.

The process for creating a European standard from a request from the European Commission or the European Free Trade Association consists of a series of distinct steps:

1. *The European Commission sends a provisional draft standardization request to CEN and/or CENELEC.*
2. *The text is examined by the relevant Technical Body/Bodies within CEN and/or CENELEC.*
3. *CEN and/or CENELEC provides comments to the European Commission, including proposals for specific modifications to the text (with explanatory notes).*
4. *A draft standardization request is submitted to the Standing Committee responsible for implementing the procedure described in Directive 98/34/EC, which ensures a wide consultation of national authorities and national standardization bodies in the EU Member States.*
5. *A standardization request is formally submitted to CEN and/or CENELEC and examined by the relevant Technical Body or Bodies.*
6. *The CEN and/or CENELEC Technical Board makes a decision on whether or not to accept the standardization request (with or without restrictions), taking into account the views of the relevant Technical Body or Bodies.*
7. *Once the Technical Board has made a decision, CEN and/or CENELEC informs the European Commission.*[99]

The Focus Group also made three key recommendations for future action in this area:

1. The European handling of AI standardisation requires a dedicated CEN / CENELEC group to be set up for the long term. A JTC (similar to the JTC for Cybersecurity) might be the most appropriate structure.

2. An initial proposal for a scope for such a JTC should be prepared by the AI Focus Group before the end of 2020. As soon as a JTC is operational, the AI Focus Group can conclude its work. It is anticipated that a number of AI Focus Group members will also play a role in a JTC.

3. The JTC should also act as a contact point for the European Commission as well as for other SDOs active in Europe in the field of AI standardisation.

CENELEC has yet to publish standards or specifications, but the roadmap shows CENELEC's ambition in the area of standardisation. Annex D of the Roadmap contains a list of standardisation work on which the Focus Group achieved consensus.[100]

The significant list below shows that CENELEC will attempt to work cooperatively with ISO/IEC on some issues, while other issues are specific to Europe. The recognition that there is work to be done in support of European legislation shows the importance of CEN and CENELEC's role in addressing the standardisation requirements of the draft legislation.

CENELEC's advantage is to leverage the global work going on at ISO / IET / JTC 1 / SC42 while separately addressing those requirements that are specific to Europe. Clearly, the establishment of a full-time group within CENELEC is appropriate for addressing those needs.

Area	Name of item	Standardisation body	Comments
Terminology/ Foundations	Description of scopes of AI standardization and regulation	New TC under CEN-CENELEC	In support of EU regulation
Terminology/ Foundations	Horizontal levels of automation/autonomy	To be determined	In support of EU regulation
Trustworthiness	AI and Data Management System	Already covered in SC42	Follow SC42 work
Trustworthiness	Quality and accuracy of training data	Partly covered in SC42	Follow SC42 work
Trustworthiness	Trusted Data Space	New TC under CEN- CENELEC	Coordinate with GAIA-X, Industrial Data Spaces etc.
Trustworthiness	Assessment list(s) for aspects of trustworthiness	New TC under CEN-CENELEC	Starting from AI HLEG work (ALTAI)
Trustworthiness	Ontology of Trustworthiness	ISO-IEC/JTC1/WG13	Follow JTC1 work and verify whether it is covering European needs
Trustworthiness	Explainability, verifiability	To be guided from a standardization perspective by CEN- CENLEC JTC	Pre-standardization R&D to be funded by EU
Trustworthiness	Robustness	Already covered in SC42	Follow SC42 work
Trustworthiness	Data quality management	Already covered in SC42	Follow SC42 work

Ethics	Summary description of the ethical properties of AI systems	New TC under CEN-CENELEC	Alternatively: Reference to IEC SEG 10
Ethics	Categorisation of ethical risk levels of AI application scenarios	New TC under CEN- CENELEC	
Security	(several items)	To be addressed in CEN-CENELEC JTC	

Table 2 – List of CENELEC standardisation work that has achieved consensus from the Focus Group.

SDO Name	**CEN / CENELEC - European Committee for Electrotechnical Standardisation**
Standards Framework	CEN / CENELEC is a non-profit organisation based in Brussels. The members of CEN / CENELEC are the national electrotechnical standardisation bodies of most European countries. CEN / CENELEC is made up of members and affiliate members. CEN / CENELEC works through the Dresden process using weighted voting among the members.[101] CEN / CENELEC also has strong links to ISO and IEC for global standards setting.
Implications to the Regulation	CEN / CENELEC has a strong link to the European Commission. This includes supporting European regulations and legislation through the creation of Harmonised European Standards. Only standards developed by ESOs (CEN / CENELEC and ETSI) are recognised as European Standards (ENs).
CENELEC reaction EU standards strategy consultation	Input includes support for standards roadmaps, and that timeliness of standards is essential: “In the absence of harmonized standards, manufacturers are not able to benefit in time from presumption of conformity using the standards and must assume extra costs for complying with the relevant legal requirements.” Supports standards education, and the extension of cooperation with international bodies such as ISO. It calls for a simple, agile solution for finalisation of standards with HAS consultants, and for the creation of a common framework for tracking environmental impact.[24]

Table 3 - CENELEC Standards Organisation Framework

International SDOs

International Telecommunications Union, ITU-T

The ITU intends to carve out a standardisation role as a neutral platform for government, industry, and academia. It is the only standardisation venue where governments have the final say in the adoption of standards through their national delegations. Participation in ITU-T comprises industry experts, government representatives and other stakeholders. It is governed by a World Telecommunication Standardisation Assembly (WTSA) which sets the overall direction and structure for ITU-T. It meets every four years and defines the general policy for the Sector, establishes the study groups, approves their expected work programme for the next four-year period, and appoints their chairmen and vice-chairmen.

The operational part of the ITU-T is governed by a Telecommunication Standardisation Advisory Group (TSAG). TSAG manages priorities, programmes, operations, financial matters and strategies for the ITU-T. It also establishes ITU-T study groups, provides guidelines to the study groups, advises the Director of the Telecommunication Standardisation Bureau (TSB), and produces organisation and working procedures.

Standards are produced by a set of eleven Study Groups with a diverse set of interest areas:

- Operational aspects
- Economic and policy issues
- Environment and circular economy
- Broadband and cable/TV
- Protocols and test specifications
- Performance, Qos and QoE
- Future networks (and cloud)
- Transport, access and smart home devices
- Multimedia
- Security
- IoT, smart cities and communities

SDO Name	**ITU-T, ITU's Telecommunication Standardisation Sector**
Standards Framework	ITU-T is responsible for standardisation for telecommunications and Information Communication Technology (ICT). The ITU is a treaty-based organisation and part of the United Nations. Its membership includes national delegations and sector members, however sector members are

	only allowed to participate in the development of standards, not their approval. The standardisation work of the ITU is largely carried out by Study Groups that focus on particular issues. Inside each Study Group, Questions Under Study focus the work. Standards are most often developed in the questions and then approved for consideration of global governments. ITU-T does some work in the area of Artificial Intelligence – especially in the area of machine learning for telecommunications applications. IT also convenes AI for Good, a United Nations program for sustainable development of Artificial Intelligence.
Implications to the Regulation	ITU-T is likely to have a marginal role for standardisation related to the draft regulation as the ITU is classified as an 'international' standards organisation, excluded from the 'harmonised standards' framework. The ITU-T's work on Artificial Intelligence is primarily in the area of telecommunications applications of AI. There is much work on Machine Learning applications – once again almost exclusively related to telecommunications settings. While ITU-T cooperates with ISO/IEC – and, thus, has a connection to CENELEC – this connection is very limited in the area of AI.

Table 4 – ITU-T Standards Organisation Framework

International Standards Organisation, ISO

SC 42 serves as the focus and proponent for ISO's work on artificial intelligence.[102] No other standards development organisation has as rich a portfolio of AI standardisation activities as the ISO. While there is little protocol standardisation, there is significant technical standardisation. In effect, this has given the ISO a "first mover" advantage over other standards organisations. In the event that a standards organisation uses a "gap analysis" to determine whether or not new standardisation work should proceed, it is very likely to find that ISO has similar or equivalent underway.

The process for standardisation in ISO/IEC JTC 1 proceeds through a series of steps:

- PWI – Preliminary Work Item
- NP or NWIP – New Proposal / New Work Item Proposal
- AWI – Approved new Work Item
- WD – Working Draft
- CD – Committee Draft

- FCD – Final Committee Draft
- DIS – Draft International Standard
- FDIS – Final Draft International Standard
- PRF – Proof of a new International Standard
- IS – International Standard

In the European context, the relationship between SC42 and any future CEN-CENELEC JTC would mean that CENELEC – and, by definition, the European Commission – would have access to globally developed AI standards. As we have seen previously in the CENELEC section above, this frees CENELEC to concentrate on European-specific AI standardisation issues while allowing CENELEC and Europe to take advantage of the rich set of AI standards already under development at SC 42.

While ISO's standardisation repertoire is seemingly comprehensive, it does have gaps. Data trusts are not to be found in ISO's work and standards specific to individual sectors are not part of SC 42's activity.

ISO/IEC JTC 1/SC 42 and AI

Title	Standard	Publication Date
Information technology — Big data — Overview and vocabulary	ISO/IEC 20546[103]	2019
Information technology — Big data reference architecture — Part 1: Framework and application process	ISO/IEC 20547-1 (Technical Report)[104]	2020
Information technology — Big data reference architecture — Part 2: Use cases and derived requirements	ISO/IEC 20547-2 (Technical Report)[105]	2018
Information technology — Big data reference architecture — Part 3: Reference architecture	ISO/IEC 20547-3[106]	2020
Information technology — Big data reference architecture — Part 5: Standards roadmap	ISO/IEC 20547-5 (Technical Report)[107]	2018
Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence	ISO/IEC 24028 (Technical Report)[108]	2020
Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview	ISO/IEC 24029-1 (Technical Report)[109]	2021
Information technology — Artificial intelligence (AI) — Use cases	ISO/IEC 24030 (Technical Report)[110]	2021

Table 5 – Published standards related to AI

ISO/IEC JTC 1/SC 25 - work in progress

ISO/IEC JTC 1/SC 25 has 23 standards under development and in various stages of progress:[102]

1. Information technology — Artificial Intelligence — Assessment of machine learning classification performance

2. Data quality for analytics and ML — Part 1: Overview, terminology, and examples
3. Data quality for analytics and ML — Part 2: Data quality measures
4. Data quality for analytics and ML — Part 3: Data quality management requirements and guidelines
5. Data quality for analytics and ML — Part 4: Data quality process framework
6. Information technology — Artificial intelligence — AI system life cycle processes
7. Information Technology — Artificial Intelligence — Guidelines for AI applications
8. Information technology — Artificial intelligence — Reference architecture of knowledge engineering
9. Artificial intelligence — Functional safety and AI systems
10. Artificial intelligence — Quality evaluation guidelines for AI systems
11. Information technology — Artificial intelligence — Objectives and approaches for explainability of ML models and AI systems
12. Information technology — Artificial intelligence — Controllability of automated artificial intelligence systems
13. Information technology — Artificial intelligence — Artificial intelligence concepts and terminology
14. Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)
15. Information Technology — Artificial Intelligence — Risk Management
16. Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
17. Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
18. Information technology — Artificial intelligence — Overview of ethical and societal concerns
19. Information technology — Artificial intelligence (AI) — Overview of computational approaches for AI systems
20. Information technology — Artificial intelligence — Process management framework for big data analytics
21. Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI-based systems
22. Information technology — Governance of IT — Governance implications of the use of artificial intelligence by organizations
23. Information Technology — Artificial intelligence — Management system

ISO/IEC JTC 1/SC 42

SDO Name	ISO – International Organisation for Standardisation
Standards Framework	Currently, there are 165 member countries in ISO. ISO has a "joint technical committee" with the International Electrotechnical Commission known as JTC 1. JTC1 is made up of a series of "technical committees" which focus on standardisation for specific technologies. Subcommittees are abbreviated SC and, as a result, SC 42 is the subcommittee on AI. Members of the subcommittees are technical experts nominated by participating national standards bodies. ISO is important to regional standards bodies such as CENELEC and national standards bodies, because these organisations often adopt ISO standards as their own. ISO also works jointly with the ITU and the two standards bodies sometimes product "common text" – standards agreed, with common language, in both ISO and the ITU. Its standards are not freely available. However, SC 42 has membership from a variety of sectors including academia, NGOs, governments and industry organisations.
Implications to the Regulation	JTC 1/SC 42 is crucial to the regulation as CENELEC is likely to use many of the standards that ISO produces on AI. CENELC's own standardization roadmap indicates that, where ISO is doing standards work, CENELEC will not duplicate that work. ISO is also important to the standards work because it has the broadest approach to AI standardisation. It is also worth noting that ISO standards are often adopted as national standards by European national standards bodies.

Table 6 – ISO/IEC JTC 1/SC 42 Standards Organisation Framework

IEEE and IEEE P700

The IEEE, unlike ISO or the ITU-T, is made up of individual members who work together to propose areas of standardisation, collaborate on the development of the standards and then publish and maintain the standards. IEEE has developed some of today's most influential standards including the IEEE 802 standard for Ethernet networking and the series of IEEE 802.11 standard for wireless networks.

Standardisation in IEEE takes place in six steps:

1. Initiating the project
2. Mobilising the Working Group
3. Drafting the standard
4. Balloting the standard
5. Gaining final approval
6. Maintaining the standard

P70000 is the IEEE's working group on ethical issues in artificial intelligence.

IEEE P7000 Standards under development in the P7000 series include:

P7000 - Model Process for Addressing Ethical Concerns During System Design	P7001 - Transparency of Autonomous Systems

P7002 - Data Privacy Process	P7003 - Algorithmic Bias Considerations
P7004 - Standard for Child and Student Data Governance	P7005 - Standard for Transparent Employer Data Governance
P7006 - Standard for Personal Data Artificial Intelligence (AI) Agent	P7007 - Ontological Standard for Ethically Driven Robotics and Automation Systems
P7008 - Standard for Ethically Driven Nudging for Robotic, Intelligent and Autonomous Systems	P7009 - Standard for Fail-Safe Design of Autonomous and Semi-Autonomous Systems
P7010 - Wellbeing Metrics Standard for Ethical Artificial Intelligence and Autonomous Systems	P7011 - Standard for the Process of Identifying and Rating the Trustworthiness of News Sources
P7012 - Standard for Machine Readable Personal Privacy Terms	P7013 - Inclusion and Application Standards for Automated Facial Analysis Technology
P7014 - Standard for Ethical considerations in Emulated Empathy in Autonomous and Intelligent Systems	

Table 7 – IEEE Standards under development in the P7000 Series

The IEEE also has two other groups worthy of attention. IEEE ECPAIS (Ethics Certification Program for Autonomous and Intelligent Systems) has the goal to create specifications for certification and marking processes that advance transparency, accountability, and reduction in algorithmic bias in Autonomous and Intelligent Systems (A/IS).

IEEE A-IS is the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems and has the mission to ensure every stakeholder involved in the design and development of autonomous and intelligent systems is educated, trained, and empowered to prioritise ethical considerations.

SDO Name	**Institute of Electrical and Electronics Engineers**
Standards Framework	IEEE is an association of individuals who have expertise in electronic and electrical engineering. Professionals join in regional organisations to participate and can also work in "communities" of common interest. The IEEE Standards Association is an operating unit inside of the IEEE.
Implications to the Regulation	At first glance, IEEE would not appear to have much relevance to the draft regulation. However, it is the one standards development organization working very actively on ethical issues related to AI. While there is limited cooperation between IEEE and ISO, this might be a standards body that informs CENELEC on issues related to ethics, policy and social issues in AI.
IEEE's reaction to the standards strategy	While ESOs are defined in regulation 1025/2012, there is a broader standardisation system addressing European needs. It is in Europe's strategic interest to cooperate with a broader set of SDOs, particularly in internet standards, and new technologies such as AI and blockchain.[46]

Table 8 – IEEE Standards Organisation Framework

W3C

The W3C was founded by Sir Tim Berners Lee, who invented the world wide web. It is a membership organisation that focuses entirely on standardisation for web technologies. Members can be individuals, organisations, NGOs and governments. The W3C works through a consensus process that allows any member to propose a particular topic for investigation and potential standardisation.

If there is enough interest in the topic, an Interest Group or Working Group is created. The membership is allowed to vote on the proposed initiation of the work and, if approved, the Director of the W3C initiates work.

The Working Groups include member representatives, invited experts and team representatives. A set of deliverables are agreed and an iterative process of developing specifications is used to move toward and W3C Recommendation which is the final stage of the standards process.

SDO Name	**World Wide Web Consortium**
Standards Framework	The W3C is a membership organisation with a very fluid structure that concentrates on standardization for the World Wide Web.
Implications to the Regulation	Minimal. W3C does not fall within the definition of a European Standards Organisation in regulation 1025/2012, and therefore is not capable of developing harmonised standards for the purpose of the regulation. If any relationship exists between the draft regulation and W3C, it would be through CENELEC standardisation that used the W3C as a source of information.

Table 9 – W3C Standards Organisation Framework

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ABOUT THE OXFORD COMMISSION ON AI AND GOOD GOVERNANCE

The mission of the Oxford Commission on AI and Good Governance (OxCAIGG) is to investigate the artificial intelligence implementation challenges faced by governments around the world, identify best practices for evaluating and managing risks and benefits, and recommend strategies for taking full advantage of technical capacities while mitigating potential harms of AI-enabled public policy. Drawing from input from experts across a wide range of geographic regions and areas of expertise, including stakeholders from government, industry, and technical and civil society, OxCAIGG will bring forward applicable and relevant recommendations for the use of AI for good governance.

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