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Regulation through standardisation: the legitimacy issue of European AI standards

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Abstract

In December 2023, the European institutions reached a political agreement on the AI Act, a new regulation on artificial intelligence. The AI Act will require providers of high-risk AI systems to test their products against harmonised standards (hENs) before affixing a European Conformity (CE) mark to allow AI products to circulate freely on the European market.

However, the current EU standardisation system faces a number of problems, such as the business model for selling standards, the EU's lack of sovereignty in its own standardisation processes and the possible emergence of conflicts of interest with industry, which raise questions about the legitimacy of the standardisation bodies. Is this system sufficient to protect us from the harms caused by AI?

In this work, we examine the existing problems with the standardisation system in Europe and how they are being accentuated in the context of the AI Act. We notably examine the international and industrial influences on European standards and show that the tight schedule imposed by the Commission with the AI Act is likely to intensify them. In addition to their lack of democratic processes, the European Standardisation Organisations (ESOs) do not have the competence to properly address fundamental rights issues, although they are encouraged by the European Commission to diversify their field of expertise. Transparency and contestability of standards will play a crucial role if the European Commission is to avoid the last resort of developing standards itself.

1 Introduction

In April 2021, the European Commission revealed its first draft for the future regulation laying down harmonised rules on artificial intelligence (AI), also known as the AI Act ([European Commission, 2021](#)). The text proposed a legal framework to regulate AI systems and laid down requirements that they should meet. The AI Act has since been adopted by the European institutions and will gradually apply across the European Union from 2025 onwards.

The AI Act is not the first law on digital technologies in Europe, it follows, notably, the adoption of data protection regulations such as the General Data Protection Regulation (GDPR) in 2016 ([European Parliament and Council, 2016](#)), the Data Governance Act ([European Parliament and Council, 2022c](#)) in 2022, and the Data Act ([European Parliament and Council, 2023](#)) in 2023. The Digital Markets Act (DMA) ([European Parliament and Council, 2022](#)) and the Digital Services Act (DSA) ([European Parliament and Council, 2022a](#)) were also adopted in 2022 for the regulation of online platforms. However, the AI Act takes a different route from these texts, choosing to draw inspiration from European product safety rules. In particular, AI systems will require a conformity assessment that will be based on harmonised standards (hENs), i.e. technical specifications drawn up by European Standardisation Organisations (ESOs) and possessing various legal properties, such

as generating a presumption of conformity with the legislation. This conformity assessment procedure will then lead to the European Conformity (CE) marking of the AI product, a seal affixed to show compliance to EU regulations.

However, hENs and CE marking are tools which have already been examined by the academic literature and face numerous criticisms. In particular, the lack of transparency, the involvement of the industry and the legitimacy problem faced by the ESOs weaken the European standardisation system and call into question the suitability of standards as a regulatory tool. In this work, we analyse all these issues and look at how they translate into AI standardisation.

We first recap in Section 2 the role that standards will play in the AI Act. In Section 3 we show that standards can be seen as a delegation of power from the Commission to the ESOs, but a delegation that lacks control and supervision. We further show in Section 4 that the ESOs are subject to international influences, even for standards meant to support European law, which calls into question European sovereignty¹ in standardisation. In Section 5, we show that this problem is likely to accelerate with AI because of the dependence of the AI Act on hENs and the tight schedule imposed by the European Commission. The ESOs also face criticisms as regard to the participation of the industry, which we develop in Section 6. In addition to the usual criticisms about their lack of transparency, with AI, the ESOs will now have to deal with fundamental rights issues for which they are not equipped. We show in Section 7 that these concerns ultimately create a lack of legitimacy that the ESOs struggle to overcome. Finally, in Section 8, we show that the European institutions are in fact highly critical of the current standardisation system and are planning for alternatives to the ESOs' standards. In particular, in the context of AI, common specifications will provide a safety net in case standards fail.

2 The AI Act strongly relies on standards for conformity assessment

2.1 The AI Act is based on product safety

The AI Act is part of the New Legislative Framework (NLF) for product safety. Under the NLF, European legislation² does not directly define technical specifications, but rather sets out the “essential requirements” that products must meet, leaving providers and manufacturers some flexibility as to the means of achieving compliance (CEN, 2019). One of the main tool of the NLF is harmonised standards (hENs) (European Commission, n.d.c) which define the technical requirements that would enable a product to comply with the essential requirements set out in a specific product directive or regulation. EU legislation sets what goals to reach, and hENs define how to reach them (Hernalsteen and Kohler, 2022). A harmonised standard is only one possible way to comply with a legal requirement (European Commission, 2022a, p.50) and is thus intended to be voluntary like any other standard, as stated by Article 2(1) of Regulation 1025/2012 (European Parliament and Council, 2012). However, it is in practice the most important pathway for compliance.

hENs are developed by one of the three ESOs: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), or the European Telecommunications Standards Institute (ETSI). If a directive or regulation needs to be supported by hENs, the European Commission issues a standardisation request to one or more ESOs, describing the main topics the standards should cover³. Once the standards have been drafted by

¹A “sovereign” state or entity, is one that enjoys autonomy and governs itself.

²Directives and Regulations.

³Not all standards developed by ESOs, are hENs, only those following a request from the Commission (art. 2(1)(b)&(c), Reg. 1025/2012).

the ESOs and approved, they are generally published in the Official Journal of the European Union (OJEU)⁴, therefore benefiting from some legal effects such as a presumption of conformity. This means that when a manufacturer of a product covered by NLF legislation has followed hENs, the product will automatically be considered compliant with the corresponding legislation.

hENs are particularly useful in conformity assessment procedures, where a manufacturer or third party assesses compliance with legislation and, if hENs are used to demonstrate compliance, procedures can be simplified. Once the conformity assessment has been completed, the manufacturer affixes a CE mark to the product, indicating that it complies with current legislation and can be sold in the EU⁵ without restrictions. The AI Act uses this product-based approach, as AI systems considered “high-risk” must go through this conformity assessment procedure and receive a CE mark before being put on the European market.

2.2 Private organisations draft harmonised standards

European and international standardisation organisations are private associations that are tasked to develop technical standards. They are composed of experts which have signed a service contract with a National Standardisation Body (NSB), another private entity gathering experts from the same country. Experts can come from private companies, research institutes, public establishments, or work on their own behalf. Anyone can apply to join a NSB to take part in standards development and committee voting, generally in exchange for a membership fee⁶, paid by the expert’s institution. However, because of the cost of sending experts to work on standardisation, industry is often over-represented (Morikawa and Morrison, 2004)⁷.

Once experts are part of their NSB, they can ask to join the working groups at European or international level. This includes the three ESOs and the three international standardisation bodies: the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU).

The various NSBs and standardisation organisations at international or European levels may have different legal statuses⁸ and business plans. However, they generally depend on income from membership fees, the sale of standards and, sometimes, certification schemes for these standards. NSBs and standards bodies also work together to ensure that standards developed at international or European level are adopted and sold at national level. With a few exceptions, access to these standards is therefore subject to a fee, and organisations retain copyright over the standards, even though they are written by external experts. Standards can even have different prices depending on which NSB sales them. For Gestel and Micklitz (2013), this is proof that they are trying to make the most of their position in the market.

2.3 Conformity assessments are mostly be carried out by providers themselves

Products that fall under the NLF, such as high-risk AI systems, need to undergo a conformity assessment procedure. To this end, manufacturers can choose to rely on any technical specifications, including hENs. For certain products, the conformity assessment must be carried out by a notified body, which are often private entities. But for many products, recourse to a notified body is not even necessary. For AI, a third-party audit will only be required for high-risk systems covered by existing

⁴Not all harmonised standards are cited in the OJEU. Some might be requested by the European Commission to address standardisation gaps, without supporting a specific legislation (Hernalsteen and Kohler, 2022).

⁵More precisely in the European Economic Area (EEA).

⁶Some NSBs do not require experts to pay a membership fee, for instance in Austria.

⁷See Section 6.

⁸Some of them are non-profit organisations, other are for-profit organisations.

NLF regulations and for biometric systems under certain conditions. But for the “new” areas of application introduced by the AI Act in Annex III, where the use of AI means it is automatically considered high-risk, such as education, employment or justice, providers will simply have to rely on internal control.

The entire compliance control chain, from the development of standards to support legislation to the auditing of systems against these standards, is therefore carried out entirely in the private sector. The European institutions have only the right to approve and supervise the work of these private entities. This excessive presence of the private sector may prove to be a flaw in the AI Act. Indeed, for some systems, companies will develop standards in standardisation organisations and will themselves carry out the conformity assessment using these same standards. This creates a loophole insofar as providers of high-risk AI systems, who are supposed to be regulated, will instead hold the keys to regulatory compliance with the rules they have established for themselves (Wachter, 2024).

3 There is a lack of control over standards

3.1 Standardisation as a delegation of power

Since the James Eliott case law (CJEU, 2016a), hENs are to be regarded as EU legal acts. The Public.Resource.Org case law (CJEU, 2024) has further shown that while the Commission is to be held responsible for the political dimension of hENs, the ESOs are responsible for the technical content (Gornet and Maxwell, 2024).

The term “delegation” of power is never used directly in CJEU ruling, as the court prefers to say that the Commission “*entrusts*” the development of harmonised standards to private bodies (CJEU, 2016a). But in various cases, Advocate Generals are more direct, speaking of a “*controlled’ legislative delegation in favour of a private standardisation body*” (CJEU, 2016b) or a *de facto* transfer of competence to private associations (CJEU, 2012). It is therefore clear that, in the context of harmonised standards, the European Commission delegates part of its power to the ESOs to draw up these legal acts. However, the CJEU sets narrow limits for the delegation of powers under the Meroni doctrine (ECJ, 1958b,a): only clearly defined powers, which are the result of an express delegation, and which are subject to strict reviews, can be delegated. But this doctrine might no longer hold since the European Securities and Markets Authority (ESMA) case (Scholten and van Rijsbergen, 2014), where the Court loosened these requirements by concluding that delegation of power is possible when there is an adequate judicial supervision (CJEU, 2014).

Despite the Commission involvement, democratic oversight of hENs is still lacking, as neither the European Parliament nor the Member States have a right to veto standards. Additionally, the Commission’s right to refuse publication of a hENs is burdened by technical limitations and human resources costs that prevent it from carrying out a comprehensive examination (Ebers, 2022). As a result, the Commission can refuse to publish standards in the OJEU, but this assessment is only based on a strict comparison between the contents of the standard, the SR items and the requirements of the law (Ebers, 2022). Scholars therefore believe that the delegation of power from the Commission to the ESOs in the case of standardisation is permitted under EU constitutional law, if the absence of control prior to the publication of standards can be compensated by an ex post judicial review (Eliantonio, 2017).

3.2 Contestability of standards might not be enough

Although the Commission is politically responsible for standards, its control prior to the publication of harmonised standards is limited. But even after publication, according to Ebers (2022) it is unlikely that the Court would be willing to rule on the validity of a harmonised standard, either in an annulment action⁹ or a preliminary ruling procedure¹⁰. Even if it were, the CJEU is unlikely to review and invalidate its substantive content: its jurisdiction would be limited to reviewing whether the Commission made an error in making the decision to publish a harmonised standard in the OJEU (Ebers, 2022). This pushes Ebers (2022) to affirm that hENs are “*currently in essence immune from judicial review*”.

However, this is not entirely true. The current Regulation on standardisation (European Parliament and Council, 2012) provides Member States with the power to oppose hEN when they do not provide a sufficient level of conformity with essential requirements (art. 11 Reg. 1025/2012). This opposition is called “formal objections”. France used this mechanism, for example, for standard EN 50566:2013 in July 2014. The standard was supposed to cover Article 3 of Directive 1999/5/CE on hertz equipments (European Parliament and Council, 1999) – which was later repealed by the Radio Equipment Directive (RED) directive (European Parliament and Council, 2014). At the time, France estimated that the recommended standards for the specific absorption rate (SAR), a measure of the rate of energy absorbed by the human body, did not correspond to the actual conditions under which phones and other mobile devices were used. Indeed, while the standard recommended measuring SAR at a maximum distance of 25mm, it was more common to have a device within 5mm of the body. Measures conducted by the French National Frequencies Agency (ANFR) confirmed these claims (ANFR, n.d.) and the Commission subsequently decided, by an implementing decision to change the content of the standard. The reference of standard EN 50566:2013 is now published in the OJEU with a warning explaining that for trunk SAR measurements, “*a separation distance of not more than a few millimetres may be used*” (European Commission, 2016). The changes was justifies as regard to the safety objectives of the corresponding Directive. However, such objections are unlikely to succeed in the event of a challenge to fundamental rights. To the best of our knowledge, this has, at least, never been the case.

4 European standards face international influences

4.1 The necessary alignment between European and international standards

The processes followed by standardisation organisations are inherited from international agreements, that are adopted at a larger scale than Europe. Indeed, in all their activities, ESOs and international SDOs follow the “core principles for standardisation” (WTO, 2000), and the “code of good practice for the preparation, adoption and application of standards” (WTO, 1995, Annex 3), set out by the World Trade Organisation (WTO). Both the principles and the code of practice are part of a broader agreement, called the “WTO Technical Barriers to Trade” (TBT) agreement (WTO, 1995). The WTO code of good practices is notably said to be applied by over 200 standards-setting bodies world-wide (WTO, n.d.).

The aim of the TBT agreement is to “*ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles*” (WTO, n.d.). As such, the WTO TBT agreement pushes the use of international standards as a basis for regulation, even if it leaves a degree of flexibility with respect to the choice of standard and the manner of its use (Wijkström and Mc-

⁹Per article 264 of the Treaty on the Functioning of the European Union (TFEU) (European Commission, 2012).

¹⁰Per article 267 TFEU.

Daniels, 2013). The agreement notably encourages countries to recognise each other’s procedures to avoid the duplication of standards and tests that have to be carried out from one country to the other. ISO and IEC play a big role as they notably compile which country participate in the agreements, and their terms and definitions are directly used in the TBT agreement¹¹. Under this agreement, regional standards and regulations are therefore forced to align with international standards, particularly those of ISO and IEC.

4.2 International standards have priority over European ones

This approach of convergence of standards encouraged by the TBT agreement pushes standardisation organisations to put in place mechanisms to favour international standards. In Europe for instance, the ESOs can collaborate with international SDOs and directly adopt their standards to make them “European standards”, even though these international bodies are not made up entirely of European members. For instance, the Vienna and Frankfurt agreements, concluded respectively between CEN and ISO, and between CENELEC and IEC, facilitate the exchange of information between the bodies and avoid duplication of work (ISO and CEN, 2016b; CENELEC, 2017). This collaboration extends to the adoption of standards, since ISO and IEC standards can be incorporated into the catalogue of European standards by ratification by CEN-CENELEC. At present, nearly 35% of CEN publications come from ISO, and 81% of CENELEC publications come from IEC (CEN-CENELEC, 2024). These figures seem to have increased in recent years compared with previous studies (Cuccuru, 2019). Furthermore, this adoption extends to hENs: 28% of all CEN deliverables which are offered for citation in the OJEU¹² come from ISO, respectively 69% for CEN-ELEC and IEC (CEN-CENELEC, 2024). The Vienna agreements state that ISO standards should be adopted by CEN “if possible” without change (ISO and CEN, 2016a). This could compromise the process of re-examining the suitability and legitimacy of a standard for a given task, and lead ESOs to adopt ill-suited international standards.

These agreements also allow expertise to be shared between SDOs, with members participating in several organisations and sometimes collaborating on the development of standards which could be adopted by both ISO and CEN, respectively IEC and CENELEC. In the Vienna agreements, this possibility of developing “common ISO/CEN standards” requires that the work that result from the collaboration be subject to “parallel approval procedures in both organisations” (ISO and CEN, 2016a). This parallel development notably requires one organisation to take the lead in standardisation work. However, the agreements stipulate that an ISO-lead standard is the preferred option, and that a CEN-lead standard is only possible if it is supported by committee members who are from ISO. As far as hENs are concerned, ISO and IEC standards take precedence where they exist, unless it can be proved that the Commission’s request cannot be met by standards issued by these international (Cuccuru, 2019). In order for CEN to take the lead in the development of hENs, ISO has to “agree that the project should advance under CEN lead based on clear documentation that the ISO committee cannot meet the EC Standardisation Request” (ISO and CEN, 2016a).

This collaboration makes the composition of international standards organisations even more relevant to European issues, since their standards are likely to become hENs. Indeed, international organisations encompass a much wider range of stakeholders than just the European players. For instance, while a large proportion of ISO members come from Western Europe, almost half come from elsewhere in the world, particularly Asia and North America (Morikawa and Morrison, 2004)¹³.

¹¹Annex 1 of the TBT on “terms and their definitions” is partly extracted from the ISO/IEC Guide 2 (1991).

¹²i.e. harmonised standards which benefit from a presumption of conformity.

¹³It should be noted however, that this study looks at participation in ISO in the late 90s. Participation has probably evolved since then.

With regard to AI in particular, the secretariat of ISO/IEC SC 42 – the sub-committee in charge of AI standards – is based in the US, as it is held by the American National Standards Institute (ANSI) (ISO, n.d.).

Furthermore, it is not only ISO/IEC standards that can be technically adopted by ESOs and become hENs. To meet regulatory expectations in accordance with the request for standardisation, ESOs may rely on existing products from any organisation, provided that there is “*no suitable ISO, IEC or ITU deliverable or activity likely to meet the need*”. This means that standards developed entirely outside Europe, such as the US standards developed by the American National Standards Institute (ANSI) or the US National Institute of Standards and Technology (NIST), could eventually become hENs (CEN et al., 2021). However, this is not the preferred option, and contrary to ISO/IEC standards, American standards such as the AI Risk Management Framework (AI RMF) (NIST, 2023), will likely not become hENs.

4.3 Some European stakeholders do not have a say in the development of international standards

All SDOs are structured around NSBs, as experts must first register with their national body in order to take part in standardisation discussions in international and European working groups. However, at European level, there are some exceptions to this system as some specific stakeholders have the right to participate in the ESOs working groups without registering first with a NSB. This is notably the case of associations representing societal interests – i.e. every non-business organisations – as well as associations representing the interests of small-medium sized enterprises (SMEs). CEN-CENELEC calls such stakeholders “Partner organisations” (CEN-CENELEC, 2021). Some of these organisations are also entitled to funding from the European Commission. They are called Annex III organisations (A3Os) as the criteria for receiving funding are listed in Annex III of Regulation 1025/2012 (European Parliament and Council, 2012). These include organisations representing European SMEs, consumers, environmental interests and social interests (Annex III, Reg. 1025/2012). Four organisations were identified by the Commission to represent these interests: (i) Small Business Standards (SBS) representing SMEs; (ii) European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC) representing consumers; (iii) European Environmental Citizens’ Organisation for Standardisation (ECOS) representing environmental interests; and (iv) European Trade Union Confederation (ETUC) representing workers (Ernst & Young, 2020).

The added value of the participation of these stakeholders in European standardisation is recognised by both the European Commission and the ESOs. In particular, CEN-CENELEC has stated that they help “*provid[e] expertise*”, “*contribut[e] to balanced representation*” and “*legitimis[e] the standardisation system*” (CEN-CENELEC, 2017). However, these A3Os, and more generally the partner organisations, do not necessarily have the right to participate in the work of ISO and IEC, since these SDOs remain based on the participation of national bodies. This means that these organisations have no say in the development of international standards, even if they are subsequently adopted as European standards (Cuccuru, 2019). The adoption of international standards as European standards as a result of the TBT and Vienna agreements helps to converge the work of different bodies, but nevertheless restricts the voice of civil society, which is more present at EU level (Cuccuru, 2019).

4.4 Even when standards are developed within the ESOs, European actors are not the only ones to participate

Questions of international influences are also raised when it comes to which countries participate in the discussions, even when the standards are developed exclusively by the ESOs. Indeed, the ESOs welcome various NSBs beyond the borders of the European Union. Different countries can benefit from different levels of inclusion in ESO standardisation work, from simple observer to full member with voting rights. In particular, in addition to the twenty seven members of the EU, seven other countries are full members of CEN-CENELEC. This includes, for instance, the British Standards Institute (BSI), the UK’s NSB. As there is no difference between these seven countries and the rest of the NSBs, experts can also occupy leadership positions. Examples include leading a standard project in working groups¹⁴ or hosting the secretariat of technical bodies within the ESO. With the BSI, the UK is the third country with the most secretariats at CEN-CENELEC, behind Germany and France (CEN-CENELEC, 2024).

In addition to the country leading the discussions, the question of the nationality of the companies taking part is also of the utmost importance. While experts participate as individuals when they are registered in a NSB, they may represent the interests of transnational companies, sometimes even based outside Europe. This is particularly true of American BigTech companies, such as the GAFAMI¹⁵, which have branches in European countries and whose experts are therefore directly involved in European standardisation work in the ESOs.

5 European standards are in a race for sovereignty

5.1 Timing issues are due to a lengthy European standardisation process

Although the European standardisation system is regularly praised in European official communications¹⁶, European institutions have admitted on several occasions that the current system has some flaws, in particular regarding the amount of time it takes to publish standards (European Commission, 2011b). The first criticisms of the slowness of the European standardisation process date back to the EU Commission’s “Green paper on the development of European standardisation” in 1990 (European Commission, 1990), and have been repeated ever since (Hesser and Czaya, 2010). The Commission is aware that this long timeline often puts at risk the implementation of laws that are directly supported by these standards and that must subsequently wait for their development. To counter this, the Commission explains having negotiated in the early 2000s with the ESOs to reduce the time taken by internal processes to accept and publish hENs. As such, according to a study conducted by the Commission, the time taken by hENs to be developed went from eight years in 2003 to three in 2008 on average (European Commission, 2011a).

But years after years, the length of development of standards, although getting better, is still cited as an important issue, even as of today¹⁷. The Commission therefore seems well aware that “*the success of the implementation of the European standards will depend on the legitimacy and the efficiency of their adoption processes*” (European Commission, 2011b).

¹⁴For example, obtaining the role of convenor or editor.

¹⁵Google, Amazon, Facebook (Meta), Apple, Microsoft and IBM.

¹⁶In a communication from 2011, the Commission says that “*European standardisation was extremely successful and one of the driving factors of the creation of the internal market for goods*” (European Commission, 2011b).

¹⁷In the recent EU strategy on standardisation (European Commission, 2022b), the Commission stated that “*European standardisation must respond to an increasingly rapid innovation pace and needs to deliver standards fast [...]. In particular in new and emerging technologies, the European standardisation system often fails to deliver in a timely manner and hence loses the important ‘first mover’ advantage through standardisation*”.

As a result, the adoption of international standards is sometimes presented as the solution to timing issues. The European Parliament notably recognises that *“the broader uptake of existing standards rather than the drafting of new ones would [...] have positive effects on timing”*. It further recommends taking the time to prepare new standards as *“the unduly rushed preparation or deployment of standards creates challenges for all stakeholders”* (European Parliament, 2023b). This injunction to the ESOs is, however, at odds with recent developments in standardisation, where the European Commission is pressing for standards, particularly in the field of AI, to be developed more quickly.

5.2 There is a gold rush to determine who will draft AI standards

The time constraint of AI standards is their greatest obstacle. To begin with, there is a gap between the speed of deployment of AI-based products and services and the development of standards. This creates pressure on standards bodies to publish standards as quickly as possible, otherwise they run the risk of incorporating technical elements that are already obsolete.

For the moment, European AI standards are lagging behind their international counterparts. Calls have therefore been made for closer links with ISO (NEN, 2021) and convergence with international standards (JBCE, 2021). Indeed, ISO is ahead of the game in developing technical standards for AI: at the time of writing¹⁸, SC 42 already published 31 standards and 36 more are currently under development (ISO, n.d.). On the contrary, CEN-CENELEC has yet to publish its own standards on AI (Gornet and Maxwell, 2024).

There is therefore considerable tensions as regard to which of the European or international bodies will develop the standards that will shape AI in Europe. This tension is even more important when it comes to standards relating to the ethical aspects of AI systems, where visions may diverge between the European Union and other regions of the world. Some societal stakeholders question whether Europe should trust international standards to incorporate these elements, arguing that there is no guarantee that these standards are consistent with EU rights and values (ETUC, 2021). ANEC has notably expressed its concerns about the adoption in Europe of standards in which non-European countries or companies have participated (Russell, 2021) and calling for the ESOs to address EU values and *“not just adopt international standards which might not reflect our values and principles”* (Giovannini, 2021). They propose that the Commission should clarify whether a harmonised standard can be entrusted to ISO, or whether it should be developed within the ESOs (Russell, 2021).

This ongoing competition is reinforced by the tight schedule imposed by the AI Act. European standards need to be quickly available for the AI Act to be properly enforced. Indeed, the text relies heavily on the subsequent publication of these technical documents, which currently do not exist (Pouget, 2023). Although the Commission has requested standards by April 2025, many believe that this deadline is impossible to meet (Perarnaud, 2023). Yet, if the ESOs fall too far behind the deadlines imposed by the European Commission, they may be tempted to adopt international standards that are already ready, instead of developing their own. The urgent need for European AI standards therefore raises issues of both correct implementation of the regulation and European sovereignty.

5.3 Europe needs its own definitions

Ideally, it is better to align the definitions of different frameworks that deal with the same topic. For instance, EU institutions and the Organisation for Economic Co-operation and Development

¹⁸November 2024.

(OECD) have converged on definition of AI¹⁹, so has the Council of Europe²⁰, and the US are in the process of doing the same. Aligning definitions enables the various stakeholders to communicate and implement rules effectively. For legislation and standards, alignment is all the more important as different definitions could lead to poor implementation or regulatory loopholes. However, in the context of the Vienna agreements, alignment of European standards with definitions emanating from international stakeholders and decided at ISO level raises questions of sovereignty, because if a European standard is contradictory, it should be withdrawn.

Yet, different terms may be understood differently in international standards and in European regulation such as the AI Act. For instance, the notions of quality management, risk, representativeness, transparency, intended use, accuracy, etc., have a specific meaning in the AI Act. But they are also defined in standards that may not be aligned with the definition given in the regulation (Soler Garrido et al., 2024). For instance, in the AI Act, the risk are considered to the safety, health and fundamental rights of individuals. On the contrary, in international standards, risks are understood as business risk for companies. In addition, quality management in ISO is a well established notion since ISO 9001 and refers, like risk, mostly to business expectations. Yet, under the NLF in European law, it is considered as one of the elements to check for conformity assessments and has its own characteristics defined in the corresponding European regulation, such as in Article 9 of the AI Act.

Similarly, for Europe, if the AI Act does not give a definition of trustworthiness, the High-Level Expert Group on Artificial Intelligence set up by the European Commission (HLEG) gives one in their guidelines: a trustworthy AI system is a system that is ethical, lawful and robust both from a technical and social perspective (HLEG, 2019). If this definition could still be overridden in further works, notably by European standards, it nevertheless reflects Europe’s desire to be open to more dimensions than just a technical one. On the contrary, trustworthiness is defined in international standards as “*the ability to meet stakeholders expectations in a verifiable way*” (ISO/IEC, 2020).

But this lack of alignment is even more worrying when it comes to technical terms such as data representativeness, transparency or accuracy, which are both used in the AI Act and in international standards with different meanings. Nevertheless, if the ESOs want the references of their harmonised standards to be published in the OJEU, these standards will need to respect the vocabulary and meaning of the law, which is not always aligned with the definitions of international standards. European standards find themselves in a place where they cannot align at the same time with international standards and European regulation and where both the international experts also present at JTC 21 and the European Commission are pushing for alignment with their respective frameworks. They will therefore have to find a compromise that promises to be difficult to work out.

6 The strong participation from the industry can create conflict of interests

6.1 The industry is over-represented in standardisation

Standardisation organisations have a large history of being dominated mainly by the private sector (Brunsson and Jacobsson, 2002), particularly large companies and certification organisations (Baeva et al., 2023). In ISO for instance, the largest stakeholder group is the industry, and

¹⁹Between the AI Act (European Parliament and Council, 2024) and the revision of the OECD Principles on AI (OECD, 2024).

²⁰In the Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (Council of Europe, 2024).

the private sector as a whole accounts for around two-thirds of all participants (Morikawa and Morrison, 2004)²¹. Indeed, private actors have always had more incentive to participate in standardisation, which explains why this activity first developed outside government spheres (Hesser and Czaya, 2010). Standardisation activities enable companies to increase their market share and influence, avoid costs by being informed of future compliance requirements at an early stage, and save time and money on product testing (de Vries et al., 2009). This dominance of the private sector is also explained by the resources required to participate (Baeva et al., 2023), whether in terms of the cost of full-time employees working on these subjects, the fees sometimes required by the NSBs or the cost of travelling all over the world to attend meetings.

Due to their capacity to deploy large resources, private organisations have emerged as a driving force in standardisation, and have ultimately proven to be better at producing effective standards than public entities (Yates and Murphy, 2019). This composition also gives standardisation organisations access to beneficial industrial expertise (McFadden et al., 2021), an essential competence for the development of technical requirements related to product safety. McFadden et al. (2021) even believe that more industrial expertise, such as that of international SDOs, would be beneficial to ESOs, whose stakeholder group is more diverse.

However, not everyone is happy with the important role of the industry in standardisation, with some feeling that key stakeholders are not sufficiently represented (Werle and Iversen, 2006). With regard to AI standardisation in particular, Edwards (2022) deplores the fact that those affected by AI have no role to play in standardisation or certification processes. This has prompted some scholars to call for greater participation of civil society in standardisation, to counterbalance the weight of the industry and bring more legitimacy to standardisation organisations (Baeva et al., 2023).

6.2 Standards can lead to economic war between companies

This industry-led composition can lead to competition between companies to impose their standards, which is sometimes to the detriment of standardisation and the legitimacy of the standards bodies. The most well-known example is perhaps the competition, in the early 2000s, between the Office Open Extensible Markup Language (OOXML) standard and the Open Document Format for Office Applications (ODF) standard.

In 2008, the American BigTech company Microsoft proposed to translate an ECMA (the former European Computer Manufacturer’s Association) standard – the ECMA-376-1 OOXML standard – into a new ISO standard: ISO/IEC 29500:2008. However, a few years earlier, in 2006, international organisations ISO and IEC already adopted a standard for document format: ISO/IEC 26300:2006, also called the ODF standard, supported among others by IBM, another American tech giant. Several ISO members, except Microsoft and ECMA, expressed serious reservations as regard the adoption of a new standard that would contradict the ODF one (Blind, 2011). After initially failing to pass, the draft standard was proposed in a fast-tracking standardisation process and managed to obtain the 75% approval criterion of the votes cast by participating members of JTC 1 on Information Technology, and was subsequently published in addition to the existing ODF standard (ISO, 2008).

The standardisation processes in the OOXML case have been widely criticised, with strong accusations of procedural flaws and irregularities, including vote manipulation and vote buying,

²¹The study was conducted in TC 207 on Environmental management. “Industry” represented 32%, “Consulting” 18%, and “Standards Organization”, which are also private bodies, represented 21%. Note however, that the study dates from the late 90s.

committee stuffing and intervention of public authorities²². The debate became so heated that IBM reportedly threatened to leave the standards body (Kirk, 2008).

The case of the ODF and OOXML standards is therefore often presented as an example of economic competition between opposing companies, IBM and Microsoft (Blind, 2011). But this further shows that international standardisation organisations, such as ISO, allow dominant companies, such as Microsoft, to exert undue influence on the standardisation processes (Kirk, 2008). This influence could threaten the legitimacy of standardisation organisations.

6.3 Standards capture political and social aspects

Standards are strongly associated with power (Busch, 2011). Since their early days, European standardisation has been very political, as differences on the political level were reproduced on the standard one (Hesser and Czaya, 2010). As pointed out by Solow-Niederman (2024), “*standards have politics*”, they are neither objective nor neutral. They are the result of political steering by both public and private powers. Since standards have a strong regulatory power, specifically in Europe, they attract many different stakeholders who all have an interest in influencing AI rule-making.

However, in technical fields, the industry has all the power, due to the economic dominance of BigTech companies (Almada and Petit, 2023). In AI in particular, as people become increasingly dependent on these technologies, the corporate resources that BigTech can deploy give them considerable power (Whittaker, 2021). This economic power is reflected in standardisation, where the industry is over-represented, which, according to Werle and Iversen (2006) give them the power to steer the choices of standard organisations towards their preferences. This industry-led composition therefore raises risks of regulatory capture and conflicts of interest, since industrial stakeholders are drafting the very same laws by which they will be governed (Bryson, 2022). Regulatory capture is defined by Dal Bó (2006) as “*the process through which special interests affect state intervention*”. According to Mitnick (2011), the industry “captures” decision making “*so that what regulators decide [...] is what industry prefers they decide*”. This risk of regulatory capture is accentuated by the strong lobbying activities of these private actors (Büthe and Mattli, 2011).

The risk of capture is particularly high in standardisation, where decisions are taken by “consensus”, i.e. everyone has to agree for a decision to be adopted, which confers considerable power on all the stakeholders and risks steering technological development towards those who are most represented (Yates and Murphy, 2019). This work of operating has led (Schmidt and Werle, 1998) to assert that, although standards are called “technical”, they are often constructed in processes that are not technical.

But beyond their processes, the question of what they should address is also strongly debated. Some believe that standardisation is wrongly moving away from scientific and technical issues to embrace social issues that require political consensus (European Council of Engineers Chambers, 2021). Similarly, according to EDRi (2022), standards should not try to take decisions that require democratic scrutiny or legal interpretation. Some go so far as to accuse the European standards organisations of playing politics with standards (McFadden et al., 2021). Standardisation is therefore often seen as a way to bypass traditional law making (Abbott and Snidal, 2009). The standardisation of AI is no exception as, according to Ebers et al. (2021) it is “*not a matter of purely technical decisions. Rather, a series of legal and ethical decisions must be made, [...] which require a political debate involving society as a whole*”.

²²A list of irregularities are compiled in a Wiki held by the association iNOiOOXML: <http://nooxml.wikidot.com/irregularities>.

7 The ESOs face a legitimacy problem

7.1 The ESOs lack transparency and democratic accountability

From the inside, standardisation organisations generally think that their processes resemble deliberative democracy, as they work on the basis of “consensus”. From the outside, however, they look more like a technocracy, since expert knowledge is usually a condition for being included in the discussion (Yates and Murphy, 2019). For instance, the ESOs, as numerous SDOs, have agreed to the follow the WTO principles (WTO, 2000), which are meant to guide international standard-setting organisations, including the principles of “transparency” and “openness”²³. Even if these principles can simply be considered as good governance, the WTO has been called out for not respecting its own principles, given that its meetings are closed to the public (Charnovitz, 2005). The same applies to standardisation organisations, as working group meetings, and subsequently ongoing work on AI standards, are reserved for expert members who have registered with a national body, or who are part of a partner organisation. Transparency is therefore understood in the standardisation world as transparency within organisations, not transparency of the organisation itself.

In addition to their lack of transparency, the ESOs also lack democratic accountability. Even if responsibility for issuing the hENs is shouldered in large part by the Commission, ESOs that develop the standards are governed by private law, lacking the democratic legitimacy of the Commission and the other EU institutions. As private law bodies, the transparency and accountability of the ESOs are necessarily different from those of public authorities (Elia Antonio and Cauffman, 2020). The delegation of power that operates under the Meroni doctrine, from the Commission to the ESOs, is therefore “excessive” according to some (Ebers et al., 2021). With AI, the lack of legitimacy of the ESOs is even more worrying, because of the consequences that the deployment of AI systems could have on society (Wachter, 2024).

7.2 ESOs do not have the competency to deal with fundamental rights

The legitimacy of ESOs is further challenged by the AI Act, as standards will encompass fundamental rights issues and ESOs lack the expertise to assess them (Veale and Borgesius, 2021). Indeed, ethics and fundamental rights are at the heart of the AI Act discourse, and standardisation initiatives are multiplying in an attempt to address these normative questions (Gornet and Maxwell, 2024). However, it is extremely difficult to standardise ethics and fundamental rights, and some academics believe that it could be almost impossible to translate concepts such as “risks to fundamental rights” into technical criteria without the help of lawyers (Smuha and Yeung, 2024).

Fundamental rights might therefore be outside of the scope of expertise of the ESOs (EDRi, 2022). The engineering experts who sit in standardisation organisations are unlikely to be familiar with human rights jurisprudence, what constitutes interference with fundamental rights and what may be considered necessary in a democratic society (Smuha and Yeung, 2024). There is therefore a need, either to recruit new experts from a wider range of backgrounds, or to train staff working in these SDOs in legal issues (Almada and Petit, 2023). In a previous version of the standardisation request, the European Commission stated that CEN-CENELEC should ensure to “gather relevant expertise in the area of fundamental rights” (European Commission, 2022c, art. 2.1). This is necessary to ensure the relevance of technical standards with judicial norms, yet it might not be sufficient to guarantee the legitimacy of the ESOs in the establishment of EU legal acts dealing with the protection of fundamental rights.

²³The other principles are “Impartiality and Consensus”, “Effectiveness and Relevance”, “Coherence” and “Development Dimension”.

This lack of legitimacy can be extended to the notified bodies who are in charge of the conformity assessment procedure in certain cases. To have the right to conduct conformity assessments, notify bodies must be accredited in accordance with the ISO/IEC 17011 (2017) standard, demonstrating notably their impartiality and the competence of their staff. While this accreditation justifies their technical knowledge of a specific field, it does not account for their expertise in fundamental rights issues. For the AI Act specifically, many systems will not be audited by a third party and the conformity assessment will be carried out internally. This calls into question the legitimacy of a provider of an AI system to assess the risk of their product to fundamental rights, particularly when this assessment is carried out without external oversight.

7.3 The different types of legitimacy undermined in the standardisation processes

Legitimacy is often simply defined as to be “*allowed by law*” or “*acceptable*” (Cambridge Dictionary, n.d.). But to Senden (2020), legitimacy is also about the validity and the justification of authority. Scholars often separate legitimacy into three types: “input”, “output” and “throughput” legitimacy (Schmidt, 2013). Input legitimacy is judged from the effective participation of citizens into policy making and the responsiveness of institutions to their concerns; output legitimacy from the effectiveness of the policy outcomes; and throughput legitimacy from the efficacy, accountability, transparency, inclusiveness and openness to interest consultation of the governance processes. Some warn that these types of legitimacy could be in tension with each other, for example the inclusion of more diverse interests in policy making, and therefore greater input legitimacy, could reduce the efficiency of this policy and therefore its output legitimacy (Eliantonio and Cauffman, 2020). However, a good balance between input, output and throughput legitimacy is necessary for an authority to be considered legitimate.

These three types of legitimacy, input, output and throughput, could all be compromised in standardisation processes (Senden, 2020), and in particular for AI standards. First, standardisation bodies lack some diversity in the interests that are represented, with the industry being over-represented; they therefore lack input legitimacy. This is reinforced by their lack of competence in fundamental rights matter, a crucial aspect of AI standards. This explains why the EU has always strive to include civil society actors in regulation processes: to make them more legitimate (Dunkerley and Fudge, 2004). However, historically, standardisation has been more concerned with its output legitimacy, i.e. having standards that work well (Werle and Iversen, 2006). Output legitimacy is a hard dimension to evaluate as it strongly depends on the content of the standards and the sector in which they are deployed. For instance, in the telecoms sector, where interoperability is necessary for systems to function, output legitimacy is very high (Cantero Gamito, 2018). On the contrary, food safety standards are not the most effective (Bevilacqua, 2020). To assess the output legitimacy of AI standards, we will therefore have to wait until they are published. Nevertheless, scholars worry that the shift towards open-ended quality management frameworks might undermine the effectiveness of AI standards (Choi, 2024). Finally, standardisation bodies might lack throughput legitimacy because of their design and development processes which lack transparency (Volpato and Eliantonio, 2020).

The overall picture shows a standardisation system that is striving to improve its input and throughput legitimacy by seeking to include more interests in the standardisation process and by adhering to principles that advocate transparency. But despite these efforts, the current standardisation system remains biased and opaque.

8 The Commission is forced to find solutions

8.1 Including more SMEs and societal stakeholders: and EU priority

CEN-CENELEC states that *“it is a principle of standards activity that all interests affected by the work are taken into account”* (CEN-CENELEC, 2001). Similarly, the EU has always strive to include civil society actors in regulation processes (Dunkerley and Fudge, 2004). However, in practice, large companies still dominates discussions on standardisation, despite smaller companies also having interests in participating (de Vries et al., 2009). The effective participation of European SMEs and societal stakeholders is therefore recognised by European institutions as a major challenge (European Commission, 2011a; European Parliament, 2023b). In particular, the European Parliament (2023b) has called on the European Commission to find better ways to accommodate for SME participation in standardisation.

SMEs are most often excluded because they do not have the necessary financial resources (Cauffman and Gérardy, 2020). Indeed, the main barriers to access to the ESOs are the time required by standardisation work, travel costs and entry fees (European Commission, 2011a). Similarly, some societal organisations such as ANEC or BEUC seek to get more involved (Smuha and Yeung, 2024). However, apart from bigger NGOs, most organisations do not have experience in standardisation (Smuha and Yeung, 2024).

The Commission is therefore making great efforts to diversify participation in standardisation. With the standardisation regulation, it has pushed for the inclusion of societal stakeholders in the ESOs by negotiating a special place for them as associates of CEN and CENELEC, granting them voting rights and a seat at the table (European Commission, 2011a). The Commission also provides funding, in the form of “action grants” and “operating grants”²⁴, to enable these organisations to send experts. This funding is provided through the means of different programmes, directed to SMEs, consumer organisations, NGOs and trade unions (European Commission, 2011a).

In the context of AI, this already existing desire to strengthen the participation of the various stakeholders is reaffirmed. Recital 121 of the AI Act notably states that *“a balanced representation of interests involving all relevant stakeholders in the development of standards, in particular SMEs, consumer organisations and environmental and social stakeholders [...] should therefore be encouraged”*, and Article 40(3) further calls on standards setting bodies to *“enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders”*.

8.2 The dual discourse of European institutions regarding international standards

In general, the ESOs strongly encourage the development of relationships between themselves and international organisations. They recognise, for instance, that *“any interested party from any part of the world can participate in the technical work of CEN and/or CENELEC through different channels”* (CEN et al., 2021). According to Hesser and Czaya (2010), the ESOs are therefore “regional” standards bodies that aspire to become “global players”. For some scholars, the expanding boundaries of the ESOs to the rest of the world is a good development and can be seen as a gain in autonomy from the power the European Commission exercises over them (Hudson et al., 2013).

On the other hand, the European Commission and the other European institutions have more mixed opinions when it comes to international standards. Depending on which documents we consider, European institutions convey a dual discourse, sometimes pushing for the adoption of

²⁴See the conditions to receive these special grants at (European Commission, n.d.b).

international standards, and sometimes calling European bodies to develop their own standards for the sake of European sovereignty. In 2011, the Commission notably stated that “*European standards should [...], wherever possible, be based upon the internationally accepted standards of ISO, IEC and ITU*”. In the same document, it called for greater cooperation on standardisation with a number of countries, including the US, China, Russia, Japan, India and Brazil (European Commission, 2011b). More recently, the European Parliament has also recognised that adopting international standards “*would allow for easier understanding and implementation*” (European Parliament, 2023b).

However, recent communications from the Commission show that the discourse on the role of international stakeholders in European standardisation may be shifting. In particular, in the 2022 EU strategy on standardisation, the Commission recognises that “*in sensitive areas [...] other world regions are taking the lead in international technical committees promoting their technological solutions, which are often incompatible with the EU’s values, policies and regulatory framework*”. The strategy therefore sets a clear objective of “*technological sovereignty*” (European Commission, 2022b). This determination to remain sovereign in the field of standardisation is best described by the sentence: “*European standards [...] must be decided by European players*” (European Commission, 2022d). To ensure this goal, the 2022 standardisation strategy notably proposes to tighten the rules for the drafting of harmonised standards. As a result, Regulation 1025/2012 has been amended (European Parliament and Council, 2022b) so that, in order to be eligible for Commission standardisation requests, delegates of the EU NSBs must be those with decision-making power at each stage of the development of the standard. For the Commission, this is a way of avoiding “*any undue influence of actors from outside the EU and EEA²⁵ in the decision-making processes during the development of standards*” (European Commission, 2022d).

8.3 A lack of trust in standardisation? The case of ETSI

In the 2022 standardisation strategy, the European Commission states its concerns regarding the decision-making processes of the ESOs which gives an “*uneven voting power to certain corporate interests*” (European Commission, 2022b). It therefore calls on the ESOs to “*modernise their governance structures*”. The Commission, although referring to the three ESOs, calls out ETSI in particular as “*multinationals have acquired more votes than the bodies that represent the entire stakeholder community*”.

ETSI is usually less studied in the literature (Volpato and Eliantonio, 2024), but recent works have raised ongoing concerns regarding its governance (Volpato and Eliantonio, 2024; Cantero Gamito and Marsden, 2024; Kanevskaia, 2024; Stanojevic, 2024; Wiegmann, 2024). This interest in ETSI’s governance was triggered in particular by the fact that the European Commission left it out of the standardisation request for the AI Act (European Commission, 2023), which was only addressed to CEN and CENELEC. This exclusion was seen as a sign of the Commission’s desire to limit foreign influence on AI standards (Bertuzzi, 2022; Perarnaud, 2023).

ETSI was created specifically to give Europe a voice in ICT standardisation and to ensure that these standards could be support EU legislation (Cantero Gamito, 2018). However, ETSI differ from CEN and CENELEC in its membership structure. While CEN and CENELEC are based on NSBs, ETSI allow for direct representation of industry and national governments. It also has a “one table approach” where representatives from different sectors sit at the same table, while CEN and CENELEC are separated into different sectoral groups. This approach is seen as one of the reasons for the success of ETSI, whose standards are broadly accepted by market players (Cantero Gamito, 2018). Another difference lies in the business model of the three ESOs. While ETSI includes funding from international stakeholders, CEN and CENELEC still rely on EU funding (Bertuzzi, 2022).

²⁵European Free Trade Association.

Although ETSI has undertaken a number of reforms in response to criticisms (Volpato and Eliantonio, 2024), some concerns remain about its legitimacy and procedural safeguards. If this mistrust were to last, it could be detrimental to the European standardisation system as a whole (Kanevskaia, 2024).

The case of ETSI therefore shows that the European institutions are cautious regarding the ESOs and their governance model. Like ETSI, CEN-CENELEC could be under scrutiny if it does not properly address its ongoing problems regarding international and industrial influences, the transparency of its processes or its lack of competence in fundamental rights.

8.4 More power to the Commission: the role of common specifications

The AI Act, although strongly based on compliance with harmonised standards, notably for high-risk AI systems, also provides for an emergency mechanism in case standards fail: common specifications. Common specifications do not date back to the AI Act, but they remain a fairly recent mechanism. They are, for instance, present in other recent European legislation, such as in Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices, or more recently in Regulation 2019/881, also known as the Cybersecurity Act, or in Regulation 2023/1230 on machinery products²⁶.

Common specifications are “technical specifications” within the meaning of Regulation 1025/2012, Article 2(4), i.e. technical standards that are not adopted by “recognised” entities such as the ESOs, but are adopted by the Commission by means of implementing acts (art. 41.1 AI Act). The Commission can adopt common specifications in four situations: (i) when the standardisation request has not been accepted by the ESOs; (ii) when hENs are not delivered within the deadline; (iii) when the proposed hENs “insufficiently address fundamental rights concerns”; and (iv) when the hENs do not comply with the request. According to the Commission, the purpose of common specifications is to “ensure that the public interest is served where harmonised standards are absent and insufficient” (European Commission, 2022b). Common specifications provide for the same presumption of conformity as harmonised standards (art. 41.3 AI Act), however, they should be repealed once harmonised standards are published on the same topics (art. 41.4 AI Act).

It seems clear by Article 41 that the Commission could decide to adopt common specifications for AI if standards are late. However, it is still debated in which circumstances the Commission could decide that the proposed harmonised standards are not fit for purpose. Gonzalez Torres and Ali-Vehmas (2024) suggests that a harmonised standards consultant (HAS consultant), responsible for assessing the standards to be harmonised on behalf of the Commission before they are published in the OJEU, could for instance refuse a hEN when they consider that it does not respect EU values.

The Commission strongly insist on the fact that common specifications should be “an exceptional fall back solution”²⁷ (rec. 121 AI Act) and should not become the norm. Similarly, for the Parliament, “this mechanism should only be used in exceptional cases” (European Parliament, 2023b). The gradual integration of common specifications into European legislation could signal the risk of capture from the ESOs (Cantero Gamito and Marsden, 2024), and could be seen as a way for the Commission to put pressure on the ESOs to deliver standards on time and without too much industrial and international influence.

However, common specifications are not a miracle solution. First, they would be drafted only

²⁶Other examples include Directive 2016/2102 on the accessibility of the websites of public sector bodies, Regulation 2019/1009 on fertilising products, Regulation 2023/1542 on batteries, Regulation 2024/1789 on the hydrogen and gas market and Regulation 2024/1781 on ecodesign requirements for sustainable products.

²⁷The 2022 strategy on standardisation (European Commission, 2022b) also uses the term “fallback solution” to refer to common specifications.

after hENs have failed. Indeed, for the Commission to have the right to invoke Article 41, the standards must be late, so the common specifications process will have to wait until the end of the official deadline. This means that common specifications will probably be developed in a hurry. This is why the Commission recognises that this solution is not recommended in the event of a delay due to the “*technical complexity*” of the standard (rec. 121 AI Act).

Furthermore, common specifications may not solve the problem of the influence of private entities, since the Commission is encouraged to “*cooperate with international partners and international standardisation bodies*” in drafting common specifications (rec. 121 AI Act). Since this solution has never been tested, it is not clear who exactly would draft these common specifications. While the AI Office is expected to support the Commission in developing these frameworks (European Commission, 2024, art. 3.2(d)), it is not clear whether it should do so alone or with the help of external stakeholder groups. Indeed, the origin of common specifications is not specified. According to Baeva et al. (2023), the Commission could therefore choose to adopt a framework from anywhere in the world. But it could also choose to take the same stakeholders as in the ESOs, simply bypassing traditional standardisation processes. As such, common specifications are not to everyone’s taste. The German standardisation bodies have even recommended their elimination during negotiations on the AI Act (DIN and DKE, 2021).

The question also remains as to whether common specifications could have more legitimacy than standards. Their legitimacy is supported in particular by Mazzini and Scalzo (2023), two former EU Commission officials who explain that, since they are adopted by implementing acts, common specifications will have to respect the examination procedure whereby member states have to provide a positive opinion for it to pass. On the contrary, the EU Parliament is worried that “*recourse to implementing acts affects the co-legislators’ powers of scrutiny*” (European Parliament, 2023b). In its amendments to the AI Act, the Parliament therefore proposed that the Commission should provide justifications before resorting to common specifications (European Parliament, 2023a, amendment 445). However, this element will not be retained in the final version of the text. Furthermore, for Cantero Gamito and Marsden (2024), common specifications would be “*equally flawed as standardisation in terms of input legitimacy*”, for two reasons. Firstly, it is likely that the discussions over common specifications will remain “largely technocratic and behind closed doors”. Secondly, the Commission does not have more legitimacy in terms of fundamental rights as it is an executive actor, not a parliamentary one.

Following the 2022 standardisation strategy, the Commission has decided to re-evaluate Regulation 1025/2012 to “*assess whether it is still fit for purpose*” (European Commission, 2022b). A public consultation has been launched and a Commission decision is expected in the fourth quarter of 2024 (European Commission, n.d.a). According to EU officials, the revision of Regulation 1025/2012 could be an opportunity to include common specifications in the list of possible technical specifications to facilitate their use in future European legislation (Mazzini and Scalzo, 2023).

9 Conclusion

This work has examined the European standardisation system as a whole and the various criticisms it faces. With this work, we provide insights into how these issues might translate into AI standardisation and we show that the problems already raised by the academic literature are likely to accelerate with AI. Despite this prominent role of hENs in European law, they are not untouchable. The consultant sent by the Commission to review hENs before they are published could decide that they do not match European goals, and even when published, they can be challenged by Member States. However, these mechanisms are insufficient to challenge standards on fundamental

rights questions that they will nonetheless have to address with AI.

In addition to its business model, the standardisation system is also heavily criticised for its governance process. Standards are influenced by international stakeholders even when they are intended to support European law, and industry is still over-represented despite the Commission's efforts to diversify the profiles of participants. With AI, the world of standardisation has embarked on a gold rush to develop standards as quickly as possible. Indeed, the rapid development of AI technology and regulation has created a new demand that organisations are struggling to meet. As international stakeholders are calling for more convergence on standards, pressure is increasing to adopt existing frameworks for AI. Furthermore, the field of expertise of ESOs, made up mainly of industrial experts, is not that of fundamental rights, and they could face a legitimacy problem if they tried to take on this role reserved for legislators and judges. However, if the ESOs fail to develop standards for AI that provide a sufficient level of protection against the dangers of these technologies, the AI Act risks becoming virtually unenforceable.

To counter this, the Commission has planned for a fallback solution: common specifications that could replace hENs for the AI Act in case standards are late or insufficiently address fundamental rights. However, the anticipation of such an emergency exit could also reveal a lack of confidence in the proper functioning of the European standardisation system, as the Commission might not trust the ESOs to deliver standards in line with its vision.

If AI standards are to deliver on their promise to safeguard fundamental rights in accordance with the AI Act, they will need to withstand international and industry pressure, while meeting deadlines. Time is of the essence, as the Commission closely scrutinises their progress.

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