



# Power to the standards

Expert consultation on the role of norms  
and standards in the European regulation of  
artificial intelligence

## Executive Summary

AI systems such as chatbots and image-generators are playing an increasing role in Europe's everyday life. To address the risks and opportunities posed by this new technology, the European Union is seeking to establish a comprehensive set of rules through its AI Act.

Standards and norms will be central to the practical implementation of these legal requirements. It is their purpose to translate regulatory requirements into technical specifications and development and management processes. However, many observers have doubts whether the experts gathered at the *European Committee for Standardization (CEN)* and the *European Committee for Electrotechnical Standardization (CENELEC)* will be able to meet the European Union's ambitious goals of developing a total of ten standards covering different requirements such as transparency, safety, or fairness. Based on expert interviews, this study documents the existing barriers to AI-standardisation. In addition to the practical and technological challenges, the study also raises questions of democratic legitimacy. This is because requirements such as fairness or transparency are often seen as criteria to be set by the legislator, not by the standardisation bodies.

The conclusion of this study therefore is that a targeted and comprehensive participation of civil society actors is required above all to compensate for existing shortcomings in participation in the standardization process. In order to allow for adequate civil society participation and to ensure the high quality of the standards to be developed, the *CEN* and *CENELEC* should promote participation even if this means that some requirements won't be standardised in time. Since at least some standards will be finalized according to the original time schedule, the *European Commission* should prepare for the remaining requirements by providing its own specifications through implementing acts, at least on an interim basis.

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## 1 Why do we need to talk about AI standards?

Interactive chatbots, AI-generated images, driver assistance systems and online store recommendations: AI systems have arrived in the everyday lives of consumers. They provide practical support in a wide range of situations and may provide increasingly complex assistance in the future. In order to identify and address the risks that may be associated with this technological development, the European institutions are currently negotiating a new regulation on artificial intelligence – referred to as the AI Act.<sup>1</sup> It sets binding requirements for the transparency, safety, robustness, and fairness of AI systems. The greater the risk of an AI system, the greater the responsibilities of its provider and deployers.

Standards and norms will play a crucial role in the implementation of the AI Act.<sup>2</sup> Under the heading of “product safety”, they are to translate the legal requirements in the area of high-risk AI systems into technical requirements that are as precise as possible in order to make them more tangible for developers and companies. They aim to improve the quality and reliability of AI systems, better protect the safety and fundamental rights of European citizens and stimulate research and business innovation in the field of AI systems.<sup>3</sup> In particular, the needs and interests of consumers should be taken into account.<sup>4</sup> Tellingly, the *European Commission* mandated the European standardisation organisations to develop such standards in May 2023, before the *European Parliament* could even vote on its proposal to regulate AI systems.<sup>5</sup> A preliminary draft mandate with the same wording was published even earlier.<sup>6</sup>

With this working paper, the Center for Trustworthy Artificial Intelligence (CTAI, German: ZVKI) seeks to answer the question of how the standardisation of AI systems should be designed in order to meet the high expectations of the AI Act. As

a national and neutral interface between science, industry, politics, and civil society, we examine the process of AI standardisation in Europe to determine whether the interests of consumers are sufficiently considered and protected. The goal is to identify potential challenges and derive recommendations for overcoming them.

### How does product safety work in the European Union?

Technical products traded within the *European Union* must not pose a risk to human health and safety: this is the basic idea and goal of product safety law. It is also the logic by which AI systems should be subject to regulation.<sup>7</sup>

### Legal and Technical Requirements of Product Quality and Development

Contextual requirements for products are defined by laws. For example, if product quality is required to be “state of the art,” this means an advanced level of development that has been accepted in practice by leading experts.<sup>8</sup>

Implementing such open-ended requirements is a challenge for manufacturers.<sup>9</sup> To avoid legal risks, they work with experts and other stakeholders in standardisation bodies to develop guidance on how to produce legally compliant products. The compromise established is then referred to as a norm or standard.<sup>10</sup> Standardisation bodies are not governmental institutions. They are organised under private law and financed primarily by business.

European product safety legislation provides for the *European Commission* the option to mandate the European standardisation organisations to develop specific standards.<sup>11</sup> These organisations are the *European Committee for Stan-*

<sup>1</sup> European Commission 2021; Council of the European Union 2022; European Parliament 2023.

<sup>2</sup> Ibid, Art. 40, and Baeva 2023, p. 5f.

<sup>3</sup> European Commission 2023, p. 1f.

<sup>4</sup> Ibid, p. 3.

<sup>5</sup> Ibid.

<sup>6</sup> European Commission 2022a.

<sup>7</sup> Cf., for example, Reusch 2023, p. 152ff. on the currently unfinished reform of product safety law.

<sup>8</sup> For the exact definition, cf. BMJ 2008.

<sup>9</sup> Nativi/ De Nigris 2021, p. 9.

<sup>10</sup> Ada Lovelace Institute 2023, p. 10.

<sup>11</sup> On the aspect of the New Legislative Framework, cf. ibid, p. 14f.

standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). If the standards developed meet the requirements of the European Commission, they are published in the *Official Journal of the European Union* as what are referred to as Harmonised Standards.<sup>12</sup>

### Monitoring and Enforcing Product Safety

Member states are responsible for monitoring and enforcing product safety obligations.<sup>13</sup> In Germany, market surveillance is the responsibility of the federal states.<sup>14</sup> Additionally, a conformity assessment is also required for certain products before they are placed on the market. If the products pass this test, they are allowed to carry the CE mark.<sup>15</sup> Because European product safety law assumes that manufacturers have the best knowledge of the product and how it works,<sup>16</sup> it often relies on them to test their own products through self-assessment.<sup>17</sup> In other cases, the product needs to be certified by an accredited certification body such as TÜV or DEKRA.

Regulatory agencies, certification bodies, and manufacturers verify that the product meets regulatory requirements. However, if manufacturers can demonstrate that the product has been developed in accordance with a harmonised standard, there is a rebuttable presumption in favor of the manufacturer that its product is compliant with the law as well.<sup>18</sup>

Even if legal product requirements derive from the legislation only, products are in reality primarily manufactured according to standards and harmonised norms.

### Developing AI Standards: A Particular Challenge

Several challenges are emerging in creating effective and consumer-friendly AI standards. In particular, current analyses and position papers point out that:<sup>19</sup>

- (1) Ethical, fundamental rights and socio-political issues are generally considered difficult to standardise. Various ongoing projects that seek to standardise ethical criteria in the development and use of AI systems face hurdles that are difficult to overcome.<sup>20</sup> However, as AI systems will also be used in sensitive areas, AI standards should not be limited to purely technical requirements: They must also operationalise the requirements of fundamental rights (especially non-discrimination) and socio-technical aspects (e.g., transparency and human oversight).<sup>21</sup>
- (2) To legitimise AI standards, broad stakeholder participation is needed.<sup>22</sup> In practice, however, civil society actors in particular are underrepresented in standardisation organisations.<sup>23</sup> This is mainly due to a lack of financial and human resources.<sup>24</sup>
- (3) If the European standardisation bodies fail to develop their own standards, existing international standards could fill the standardisation gaps. However, such international standards are usually insufficiently aligned with European requirements.<sup>25</sup>
- (4) It is unlikely that the *European Commission's* tight time schedule for producing harmonised standards in less than two years will be met: Many AI-specific standardisation issues remain to be resolved.<sup>26</sup>

<sup>12</sup> European Commission 2021; Council of the European Union 2022; European Parliament 2023, Art. 10.

<sup>13</sup> Lenz 2022, p. 532ff.

<sup>14</sup> Federal Institute for Occupational Safety and Health (BAuA) n.d.

<sup>15</sup> Chamber of Industry and Commerce Munich and Upper Bavaria n. d.

<sup>16</sup> On the New Legislative Approach, cf. for example Schucht 2021, p. 32ff.

<sup>17</sup> Veale/ Zuiderveen Borgesius 2021, p. 102.

<sup>18</sup> Lenz 2022, p. 528ff.

<sup>19</sup> See also the ZVKI paper on the role of standards in testing and certifying AI systems (Baeva 2023).

<sup>20</sup> Ada Lovelace Institute 2023, S. 18; DIN/ DKE 2020, p. 28f.

<sup>21</sup> Nonnecke/ Dawson 2022, p. 17.

<sup>22</sup> Kettemann et al. 2022, p. 13.

<sup>23</sup> Ada Lovelace Institute 2023, p. 29.

<sup>24</sup> Ibid, p. 35.

<sup>25</sup> Ebd., p. 24; Nativi/ De Nigris 2021, p. 54; Soler Garrido et al. 2023, p. 34.

<sup>26</sup> European Commission 2023; Perarnaud 2023.

## Expert Interviews as an Empirical Approach

Since the *European Commission's* mandate to the standardisation organisations in May 2023 marks the formal start of the development of harmonised standards for AI systems, this paper has not been able to compare the above criticisms with the current state of work. Nevertheless, the question of what challenges exist in the current standardization process was already raised during the preparation of this study. We therefore chose expert consultation as our empirical approach. We derived questions from existing research and discussed them with experts in the field of standardisation. Conclusions were then drawn based on the knowledge and experience of these experts.<sup>27</sup>

We used the following criteria to select the experts consulted: If possible, they should have first-hand experience in the field of AI standardisation and cover different perspectives, such as industry, small and medium-sized enterprises, research, civil society, and certification and accreditation bodies.<sup>28</sup> Although the focus was on experts from Germany, it was also possible to consult interview partners with experience at the European level. A total of twelve interviews were conducted between January and May 2023. The interviews were conducted using a partially standardised questionnaire<sup>29</sup>, which was used by the interview partners to assess the above assumptions and criticisms in a structured manner.

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<sup>27</sup> For the methodology, cf. Hildebrandt 2015, p. 241.

<sup>28</sup> A list of the experts surveyed can be found in the Annex.

<sup>29</sup> von dem Berge 2020, p. 286ff.



## 2 What are the pitfalls of standardising AI systems?

### 2.1 How is the process of AI standardisation organised?

European institutions have been quick to focus on the technical application of any legal requirement when regulating AI systems. Back in 2018, the *European Commission* had already emphasized that European standardisation organisations should help develop reliable regulations and specifications for the safety, interoperability, and ethical functioning of AI systems.<sup>30</sup> This is because the effective regulation of AI systems depends on its actual application in the real world, which should be guided by harmonised standards.<sup>31</sup> Here, the *European Commission* took a special approach and coordinated a draft standardisation mandate with the European standardisation bodies, *CEN* and *CENELEC*, at an early stage so that they could prepare to perform their tasks.<sup>32</sup>

#### The Standardisation Process at the *CEN* and *CENELEC*

Every standardisation process begins with a standardisation request. When the general assembly of a European standardisation organisation adopts a mandate to develop a standard, the task is referred to an appropriate working group. The technical details are discussed within this working group. The experts involved are delegated and supported by what are known as mirror committees at the national level.<sup>33</sup>

When the working group agrees on a draft, it is put out for public consultation. The national standardisation bodies play a decisive role here, too: They collect statements and opinions (also from civil society), bundle them, and forward them to the European standardisation organisations. In Germany, this task is performed by the *DIN* and the *DIN Consumer Council*, among others. Based on the statements submitted by the national standardisation organisations, a final draft is prepared and voted on by the general assembly.

*CEN* and *CENELEC* had reported their technical competence to the *European Commission* and established a joint technical committee (*JTC 21*) in spring 2021. The joint technical committee is to provide leadership, with pooled resources, to the many working groups and subgroups established to address the standardisation mandate.<sup>34</sup> Together with its national partner organisations, *JTC 21* has performed some preliminary work.<sup>35</sup>

#### A European Path in AI Standardisation

All the experts interviewed emphasize the importance of AI standards for the regulation of AI systems as envisaged in Europe. Since standards are based on technical expertise, they will play a crucial role in translating the legal requirements into practice. In doing so, they might play a more significant role in shaping the implementation of the AI Act than the actual legislative text.

*This is why standards are important, because while the AI Act sets the goals, it does not say how to achieve them. A standard defines how best to use the tools of technology to secure the goals.*

Susanne Kuch, Deutsche Akkreditierungsstelle (DAKKS)

The concrete approach taken by the *European Commission* is viewed as being expressly positive. Normally, requests for standardisation would be received after the actual legislative process has been formally completed, and technical standards would therefore begin to be developed at a much later stage. The fact that the Commission sought to take a different approach in this case, with the early release of the draft mandate, underscores the importance of both AI regulation per se and the specific role of AI standards.

*AI is the greatest transformative technology of our age. This is such a fundamental issue that you have to start early enough – with standards and laws. (...) I think that the European way of shedding a lot of blood, sweat and tears early on and putting a lot of effort into this complex issue*

<sup>30</sup> European Commission 2018a, 2018b and 2019.

<sup>31</sup> European Commission 2021, p. 7.

<sup>32</sup> European Commission 2022a, Art. 2.

<sup>33</sup> Koch 2016, p. 93.

<sup>34</sup> McFadden et al. 2021, p. 11; DIN/ DKE 2022, p. 46 ff.; CEN/ CENELEC 2020. For the CEN/ CENELEC focus group, cf. also Ebers 2021a, p. 8.

<sup>35</sup> McFadden et al. 2021, p. 10f.; DIN/ DKE 2022, p. 55 ff.; CEN/ CENELEC 2023.

*to find the best solution is preferable to doing everything that's possible technically in AI development.*

*Jörg Firnkorn, DEKRA Digital*

At the same time, several interview partners emphasized that European standardisation processes are still in their infancy. One expert criticised the fact that the time since the standardisation mandate was drafted has not been used to develop an authoritative plan of work. Instead, they have waited for the final standardisation request for most of the work steps. According to individual interview partners, the relevant discussions on content are not expected until the summer of 2023. Thus, the European standardisation processes do not seem to be flexible enough to fully benefit from the approach taken so far by the *European Commission*.

### **The Daily Routine of Standardisation Projects**

The experts consulted described the actual standardisation process as follows: Following an analysis of the (final) standardisation request, this would be divided into thematic sections. Working groups that meet monthly would then work on these sections. The progress and work status for all the working groups would then be discussed and voted on at the biannual general meeting.

Some experts describe the first steps in particular as extremely dynamic and intensive. Unexpected overlaps and coordination needs often arise between working groups or subject areas.

*It is incredible how many working groups and sub-working groups deal with the individual items.*

*Camille Dornier, ANEC-BEUC*

Intensive and complex discussions and often new sub-groups and working groups would become necessary, especially when the same problem was to be tackled against the background of different expert opinions. One respondent gives examples of technological and sociological solutions. Several experts describe how the painstaking search for the best solution often runs the risk of getting bogged down in complexity.

Furthermore, there are extensive discussions involving a great amount of effort which take place in the individual working groups and on individual topics and sub-aspects. It is precise-

ly in the compromises found in this way that the hoped-for benefits of standards and standardisation procedures lie:

*Standardisation is an open and transparent process in which everyone can participate and make a contribution.*

*Filiz Elmas, DIN*

*Working in a truly international context with different perspectives, including political ones from around the world, is exciting but also challenging. In the past, the different levels, which look at AI systems not only from a technological perspective but also from a legal one, have not always worked together ideally. It's an attempt to bring these different worlds together more effectively.*

*Susanne Kuch, Deutsche Akkreditierungsstelle (DAKKS),*

However, several interview partners emphasized that reaching the desired compromises often requires ongoing collaboration across multiple working groups. Individual proposals and contributions would have to be repeated, explained, and defended in the next, but also in later working sessions. Otherwise, they risked being set aside without consideration. Among other things, standardisation committees, which have historically been staffed primarily by representatives of industry and certification organisations, continue to be dominated by the latter because of the resources required.

*You have mostly private companies and big corporations in the working groups of CEN/CENELEC. There tends to also be a big proportion of international companies, such as US and Chinese companies. So it's as if we are talking about implementing European values on the one side but asking Amazon and Microsoft to draft the standards on the other.*

*Camille Dornier, ANEC-BEUC*



*Designing a good standard takes a great deal of time. You need some heavy horses to do the job: individuals or companies who put in massive amounts of unpaid time.*

Jörg Firnkorn, DEKRA Digital

In summary, standardisation takes place in committees that, for historical and economic reasons, continue to be dominated by representatives of industry and certification and testing organisations. The processes that lead to the creation of standards are time-consuming and require both technical and process knowledge. This makes it difficult for new actors to join the process and results in the experts already involved having to perform multiple tasks. In brief: the procedures do not encourage broad participation. Despite this, AI standardisation is described as a mainstay of the entire regulatory project.<sup>36</sup>

The literature confirms the huge amount of effort and money typically required for active participation in standardisation processes.<sup>37</sup> Studies have also documented the disproportionate involvement by industry.<sup>38</sup> However, while several publications describe at least the broad outlines of the standardisation process, the exact workings of the

individual working groups remain opaque.<sup>39</sup> A transparent description of the negotiation processes is lacking, especially within the standardisation bodies themselves.

A special role is attributed to the *European Commission's* standardisation request and its concrete formulation: The request formally initiates the standardisation process and determines how it will proceed.<sup>40</sup> Moreover, the literature often emphasizes its importance from the perspective of legitimacy and the rule of law: only a sufficiently precise standardisation request with clear requirements for the standardisation organizations could provide a legitimate basis for entrusting privately organised committees with the de facto regulation of existential areas of life.<sup>41</sup> Furthermore, democratic control of the standardisation process depends entirely on the standardisation request itself.<sup>42</sup> The *European Commission* would only be able to refuse to publish a standard it had commissioned if it failed to comply with the standardisation request itself or its requirements.<sup>43</sup> It is bound by the specifications of the standardisation organizations in all other respects.<sup>44</sup> It is therefore very important that *CEN* and *CENELEC* be given a sufficiently well-defined mandate.

<sup>36</sup> Ebers 2021a, p. 18f.; Ebers 2021b, p. 591ff.

<sup>37</sup> Veale/ Zuiderveen Borgesius 2021, p. 105.

<sup>38</sup> Ada Lovelace Institute 2023, p. 32f.

<sup>39</sup> DIN o. J.; Koch 2016, p. 53 ff., p. 84 ff.

<sup>40</sup> Cf., for example, DIN o. J. and KAN 2020.

<sup>41</sup> Veale/ Zuiderveen Borgesius 2021, p. 105.

<sup>42</sup> Ebers 2021b, p. 594. The supervisory power of the Commission and therefore also of the ECJ is controversial, cf. in relation ECJ 2016 and Veale/ Zuiderveen Borgesius 2021, pp. 105f.

<sup>43</sup> Ebers 2021b, p. 594f.

<sup>44</sup> Veale/ Zuiderveen Borgesius 2021, p. 105. The constitutional issues behind these positions have largely been debated since the ECJ ruling C-613/14 (“James Elliot Construction”) and have not yet been finally clarified, see e.g., Dingemans/ Kottmann 2020, p. 15 ff, or Cuccuru/ Eliantonio, p. 478 ff.

## 2.2 What topics do AI standards need to cover?

The standardisation request provides an initial point of reference for assessing the scope and content of the planned AI standards. The *European Commission* notified *CEN* and *CENELEC* in May 2023 of the standards to be established under this mandate.<sup>45</sup> In detail, however, many of the requirements remain superficial. Although the request establishes a link between the mandated standards and the specific legal requirements, it barely goes beyond the abstract formulations of the AI Act. Only in a few places the *European Commission* explicitly calls for substantiations concerning individual sectors (referred to as vertical standards).<sup>46</sup>

### Standardisation Request with Wide Latitude

The interviewed experts agree that the planned AI standards are highly relevant mainly because of the lack of precise specifications in the standardisation request. These leave room for interpretation of the sometimes vague legal requirements.

*It is important that experts are aware of the importance of standardisation. This is because, ultimately, standardisation can be used to shape AI regulation. For example, the European Commission's AI Act assigns a central role to standardisation. Harmonised European standards will be used in the future to specify the technical requirements for AI systems, especially in the area of high-risk AI applications. Virtually anyone can help shape the AI Act by participating in the standardisation committees.*

Filiz Elmas, DIN

Some of the interview partners see this as an opportunity to achieve even more ambitious goals than those set out in the AI Act itself. At the same time, they raise the risk that the course of standardisation may weaken legal requirements to the detriment of consumers. Representatives from business often have an interest in specifying the requirements for products, especially in a form that is easy to implement.

The *European Commission's* standardisation request covers all areas necessary for assessing high-risk AI systems. However, the experts consulted highlighted a number of issues as particularly important for the effective implementation of the goals of the AI Act:

- Since the AI Act is aimed at product safety in AI systems, requirements for functional safety and cybersecurity are central. Requirements such as transparency would also ultimately serve product safety by facilitating safety measures throughout the life-cycle of an AI system. At the same time, the AI Act expands the concept of safety to include fundamental rights and ethical aspects, which makes standardisation challenging.
- Standards relating to non-technical aspects such as transparency, fairness, or privacy would be of particular importance, especially with regard to civil rights and consumer protection.
- The regulation of technical aspects such as the robustness and accuracy of AI systems is fundamental to the implementation of the AI Act. Procedures that make such aspects measurable indirectly help in deciding on the use of AI systems. In addition, issues around the representativeness of data sets could have a direct impact on the everyday lives of people who may be adversely affected by AI decisions.
- The way in which risk management processes are organized is an overarching issue that helps determine the implementation of all other requirements.

In many places, however, the standardisation request is formulated in such an abstract manner that it fails to provide a sufficiently binding framework for the standardisation processes on these issues. Considering that the AI Act raises issues not only related to technology but also to fundamental rights, this form for manoeuvre in shaping the regulation seems problematic.

<sup>45</sup> European Commission 2023.

<sup>46</sup> Ibid, Annex II.

## Missing Foundations for AI Standards

In dealing with imprecisely formulated mandates, standardisation bodies can help themselves by taking existing national and international standards and making them the basis for their work.<sup>47</sup> Although national and international standardisation organisations have been working on issues around AI systems for years, aspects remain for which absolutely no standards exist at any level. In addition, the experts interviewed do not consider all existing standards to be suitable for effectively implementing the goals of the AI Act. For example, IEEE standards are cited as not well fitted to cover the challenges with regard to transparency requirements.

With a view to potential gaps and contextual challenges in AI standards, the experts identify different groups of standards:

- **A good basis:** Many international standards have already covered issues related to risk management, data quality and data management, and the management of product quality, and these could be transferred to harmonised standards with minor adaptations. Work in recent years has also largely clarified definitions around AI systems.<sup>48</sup>
- **Currently in progress:** Requirements for AI systems would need to be better integrated with existing standards for other topics, such as functional safety. This also requires the implementation of applied pilot projects to clarify open questions. The procedures for conformity assessment are also generally well developed and largely governed by existing harmonised standards. Although the addition of AI-specific aspects raises many operational issues for certification bodies, many international projects already exist that could be taken into account in European standardisation. The first standards for transparency are now in place at the international level. However, some experts emphasize that these would need to be significantly adapted to effectively meet the requirements of European legislation.
- The experts identified the **largest gaps** in standardisation topics that are AI-specific, such as robustness

and explainability. Since there is no equivalent in existing technical standards, the problems need to be solved from scratch. Robustness and explainability are related because complex AI systems hardly allow for full transparency and traceability.<sup>49</sup> This makes it difficult to determine their accuracy and robustness. It would therefore be difficult to interpret different test results on the reliability of AI systems in any meaningful way. How to measure robustness and how to interpret the results of these measurements remain unanswered questions.

Other unresolved issues include the design of human oversight and dealing with AI-specific issues of cybersecurity. There are no standards specific enough to address consequential bias and move toward fairer AI systems. The many unanswered questions, including those at the international level, lead some experts to doubt that the comprehensive safety of AI systems is even possible.

*It's incredibly complex, and I don't know if we can ever achieve the legislative goal that way. One has to abandon the idea of absolute safety and define it in relative terms. Take autonomous driving for example: do I say that my system has to be so safe that it doesn't cause any accidents, or do I say how high the source of error is allowed to be in relation to the latest accident statistics? After all, we face risks and things that are not one hundred percent safe every day.*

Susanne Kuch, Deutsche Akkreditierungsstelle (DAKKS)

## Horizontal and Vertical Standards Go Hand-In-Hand

Universally formulated standards are not very well fitted to model aspects where contexts of use differ greatly and where different requirements are placed in the foreground. For example, issues of fairness and equal treatment are much more important in the management of people than in industrial production.<sup>50</sup> Some applications, such as in the medical context, have dif-

<sup>47</sup> DIN/ DKE 2022, p. 23.

<sup>48</sup> The ISO/IEC 22989:2022 standard "Artificial intelligence concepts and terminology" already outlines key terms and concepts related to AI systems.

<sup>49</sup> Schmid 2022, p. 291.

<sup>50</sup> Adler et al. 2021, p. 13.

ferent requirements for accuracy and robustness of AI systems than online shopping or service chatbots. For this reason, in addition to general horizontal standards, vertical specifications for individual sectors and deployment contexts are also required. The importance of vertical standards is also highlighted in the *European Commission's* standardisation request, particularly with regard to requirements for human supervision and accuracy.<sup>51</sup>

European standardisation is currently focused primarily on horizontal standards since these were mandated to come first by the *European Commission*. Most experts agreed that this represents a reasonable first step toward AI standardisation:

Topics exist where it doesn't matter if I'm talking about a car, a medical component, an industrial component, or IT software. This includes issues such as access authorization, authentication, or ensuring trustworthiness. These always have to be guaranteed and the procedures for doing so are similar.

*Annegrit Seyerlein-Klug, Brandenburg University of Applied Sciences (THB)*

Some experts also note that vertical differentiation is not always the best solution to technical complexity. In many cases, it is not the differences between industrial sectors that are important, but rather the technical characteristics and specific applications within a sector. Horizontal standards are also particularly relevant as a technical framework for testing bodies, although subsequent sector-specific guidance is necessary as well. Individual experts therefore call for standards to be written with existing testing infrastructures in mind.

All of the experts consulted assume that vertical standards should be implemented quickly and in parallel with ongoing standardisation projects. Such standards would be needed in particular for high-risk AI applications in medicine, transportation, critical infrastructure, and other highly regulated areas. The precise determination of test procedures and thresholds is particularly pressing in these areas. Without vertical specifications, general standards often remain vague and of little use.

Within horizontal standards the technical requirements remain a little bit vague because they have to apply to all kinds of AI systems. We are missing precise numbers and thresholds.

*Camille Dornier, ANEC-BEUC*

For accuracy for example we will need metrics and a bar. But in setting that bar, I don't think it makes sense to say in some generic way that your systems must be 90 percent effective or accurate. Standards should be established in the light of the intended purpose.

*Hadrien Pouget, Carnegie Endowment for International Peace*

Horizontal and vertical standards should therefore be reconciled:

It's not about them being against each other, but rather with one another. In an ideal case, one standard should fit all. This is then specified in the domains and applied to domain-specific problems because different domains have different acceptable risks.

*Andreas Hauschke, German Association for Electrical, Electronic & Information Technologies (VDE)*

Existing works also point out the lack of AI-specific standards. Citing the examples of people management and industrial production, the *ExamAI* report notes a lack of technical standards for operationalising relevant requirements for AI systems.<sup>52</sup> The recommendations made in the second edition of the *German Standardisation Roadmap* identify a particular need for standards that facilitate AI certification, data quality standards, human oversight and transparency requirements, requirements for medical devices and mobility-related applications, and guidelines for determining energy efficiency and environmental impact.<sup>53</sup>

Two analyses commissioned by the *European Commission* investigate the general applicability of international standards to fill the gaps. They conclude that the standards created or being created by the *ISO* and *IEC* concretize many relevant requirements for

<sup>51</sup> European Commission 2023, Annex II, p. 3f.

<sup>52</sup> Adler et al. 2021, p. 43.

<sup>53</sup> DIN/ DNE 2022, p. 34ff.



AI systems, but also contain gaps.<sup>54</sup> Standards being developed by the organisation *Institute of Electrical and Electronics Engineers (IEEE)* complement these significantly and have the potential to be translated into AI standards relevant for regulatory purposes. However, these standards also lack important aspects, particularly in the areas of transparency and human oversight. In addition, most of these standards have yet to be finalized.<sup>55</sup> A recent analysis of the *JTC 21* committee work program shows that substantial work needs to be done on almost all of the criteria related to AI standards: International standards that are intended to serve as a starting point are in many respects too broad, do not provide precise details for implementing the new legal requirements, or do not provide guidance on specific issues of European regulation.<sup>56</sup>

International standards also suffer from legitimacy problems because they are negotiated in committees without democratic control.<sup>57</sup> Nevertheless, under current agreements, they still take precedence over European or national standards. In many cases, international standards are also adopted directly as European standards.<sup>58</sup>

The required AI standards therefore have to be developed from scratch in some cases and face many unresolved technical issues. In particular, technical hurdles specific to AI, such as capturing the accuracy and robustness of systems, but also requirements related to transparency, explainability, and human oversight, complicate the work of standardisation. Vertical specifications are also needed in parallel to basic standards.

### 2.3 To what extent can the ethical and fundamental rights aspects of AI use be standardised?

AI applications raise many societal issues due to their myriad potential applications in sensitive areas. Issues of this nature are therefore included in the proposed standard as well. It is widely agreed that the trustworthiness of AI systems ought to be an essential criterion of their use.<sup>59</sup> This includes requirements related to ethics and fundamental rights, i.e., requirements that cannot be

covered by purely technical specifications. They can have a significant impact on the exercise of fundamental rights.

#### What Can Harmonised Standards Cover?

Disagreement already exists on the basic question of whether harmonised standards should address fundamental rights issues at all. On the one hand, standards committees are not seen as the right place to discuss such issues because they lack sufficient legitimacy. On the other hand, standardisation processes are seen as appropriate formats for discussion because they are results-oriented and can contribute to consensus building on requirements related to ethics and fundamental rights.

Regardless of this, all experts agree that there are limits to harmonised standards in this area. Requirements such as fairness, equity, or accountability cannot be completely translated into quantitative metrics. Rather, these issues need to be addressed substantively through social debate or through other institutions, such as the legislature itself. Problematic aspects include, for instance, decisions about which requirements are relevant and how to resolve conflicts between different requirements.

*I would like to separate moral issues of 'good/evil' from more technical issues. Standards provide recommendations for technical and organisational issues that are neutral and measurable in technical and organisational terms: The value measured is either met or not. Whether this value corresponds to the specifications of "right/wrong" or "good/bad" is not being evaluated, neither is it the task.*

*Annegrit Seyerlein-Klug, Brandenburg University of Applied Sciences (THB)*

#### Process Criteria as a Possible Solution?

The question is which aspects of such requirements can be represented in standards and norms. Many experts refer to procedural steps that can describe *how* requirements are implemented. For example, there is opposition to fixed benchmarks for fairness

<sup>54</sup> Nativi/ De Nigris 2021, p. 54.

<sup>55</sup> Soler Garrido et al. 2023a, p. 29.

<sup>56</sup> Soler Garrido et al. 2023b, p. 2ff.

<sup>57</sup> Ebers 2021a, p. 13.

<sup>58</sup> Pelkmans 2023, p. 18.

<sup>59</sup> European Commission 2019; European Commission 2020, p. 3.

metrics on the grounds that these cannot be set in standards. However, the process of defining and capturing a fairness metric could very well be reflected in a harmonised standard. This also means that ethically relevant properties of AI systems can be described with the help of norms and standards. How to evaluate a particular property in a given context, i.e., whether a deviation from a fairness target by a particular metric is still appropriate or too much, would then be a matter for the market surveillance regulator or the industry producing the product to decide. At this point, context is crucial.

At the same time, some experts warn that purely procedural standards and audits could contribute to tokenism and thus to an unjustified presumption of trustworthiness: Finally, even the fairest of processes can only approximate meeting the requirement of fairness.

*We cannot write into a standard what is good and what is bad. What we can write into it, however, is a description of the ethically relevant properties of the system, i.e., the degree of transparency, the degree of fairness, the degree of privacy, the degree of robustness, and the methods for measuring them. That I can standardise, I can also obtain a European or even global consensus for it.*

*Sebastian Hallenleben, VDE*

Other experts are of the opinion that the ethics and fundamental rights requirements mandated by the *European Commission* could be met by additional certification bodies and experts. These would be equipped with the necessary skills and could, for example, ensure that the right (standardised) questions are asked in (standardised) processes.

But is it really possible to separate such issues from purely technical ones, to represent one in terms of process criteria and the other in terms of product criteria? Both individual experts and academic research doubt this.<sup>60</sup> For them, the transition between seemingly technical issues and those affecting funda-

mental rights is fluid. Nor could this challenge be solved by completely excluding fairness,: Depending on the context, technical requirements such as robustness also require ethical considerations.

*What level of accuracy is acceptable for a high-risk AI system to be deployed? Who decides and based on what criteria? Can the system do what it is intended to do in a variety of different settings? Who decides which areas the system should be tested in before deployment for robustness? These questions have very strong human rights and fundamental rights implications.*

*Connor Dunlop, Ada Lovelace Institute*

### Standards alone are not enough

The experts surveyed agreed that harmonised standards alone cannot solve all the contextual issues around the use of AI. This challenge is particularly pronounced when it comes to implementing requirements related to ethics or fundamental rights. The academic literature also agrees that standards are no substitute for the interpretation of fundamental rights.<sup>61</sup> Such requirements should instead be covered by process criteria such as transparency and documentation requirements, which then allow for independent verification by third parties.<sup>62</sup>

*Standards on most topics are good and the best we can do, but you can't, I don't think, expect us to be able to reduce all the risks associated with AI to zero with that.*

*Jörg Firnkorn, DEKRA Digital*

Harmonised standards will not and should not replace existing safeguards such as jurisprudence. However, other institutions can help to define ethical requirements in addition to standards committees. One expert mentioned the idea of a benchmarking institute that could develop thresholds for different application contexts through a participatory process.<sup>63</sup>

<sup>60</sup> Veale/ Zuiderveen Borgesius 2021, p. 105.

<sup>61</sup> Wachter/ Mittelstadt/ Russell 2021; EDRI 2022; Veale/ Zuiderveen Borgesius 2021, p. 105.

<sup>62</sup> Laux/ Wachter/ Mittelstadt 2023.

<sup>63</sup> Ada Lovelace Institute 2023, p. 53.



## 2.4 Do we need more civil society in standardization?

Some experts believe that it is difficult to address societal issues in the standardisation of AI systems, primarily because standardisation organisations do not have access to all the necessary expertise. This gap could be filled in particular by civil society organisations. However, these have little or no representation on standardisation bodies.<sup>64</sup>

### Inadequate Participation by Civil Society

Almost all experts describe the participation by actors from civil society as inadequate to date.

The few organisations that are present would mainly be observers and could only selectively contribute to the development of harmonised standards. There is no real dialogue. One expert describes why this is considered a deficit: While civil society generally plays a minor role in standardisation processes, the development of harmonised standards for the AI Act is a special case. These standards are not only developed from within the standardisation bodies themselves but are ascribed a special role by the *European Commission's* standardisation request described above.

Why has civil society been less involved in standardisation bodies to-date than is desired or required? Some experts believe that all the conditions for participation have been met: the committees and forums are basically open and there is no known case of an organisation being excluded simply because it is from civil society.

However, a large number of interview partners agree that there are structural barriers to the participation of civil society organisations. Two specific examples are mentioned: First, some committees would impose conditions on the organisational form of the participants. For example, not all civil society organisations are structured as legal entities, and sometimes this may be a condition for participation. A second barrier is the division into national standardisation bodies, which then appoint people to functions and mandate members to participate in European standardisation committees. Only these actors then have the right to vote. However, civ-

il society organisations are not always organised at national level; it would often be much easier for them to participate directly at the European level.

### Reasons for the Limited Involvement of Civil Society

The experts describe three main challenges that have contributed to the limited participation of civil society organisations to date.

The first challenge is the technical and procedural expertise required for participation. The topic of regulating artificial intelligence is complex, and translating policy requirements into harmonised standards is challenging. A lack of knowledge about how standardisation bodies work also exists on the process level. This is not a trivial matter; after all, the working forms and processes may be as unfamiliar to civil society organisations as the language that has to be used in standards and norms, or the existing standards that have to be taken into account in the development of new ones. In some cases, there is also a lack of awareness of the relevance of harmonised standards in the context of the AI Act. The necessary intersection between expertise in standardisation processes, technical knowledge and knowledge of fundamental rights or ethical issues is generally rare and, as a result, hardly exists in civil society organisations. Acquiring this expertise for the first time can represent a significant hurdle.

The second challenge is that participation in standards bodies is usually unpaid. For the companies involved, the time spent contributing represents an investment from which they derive a direct benefit. In some cases, companies have established “standards professionals” who have been working with standards and norms for years and know their way around. Civil society organisations are often unable to make this investment with their own resources. When you factor in the amount of effort required to secure significant participation, the problem is exacerbated. One expert estimates that about ten full-time positions would be needed to cover all the working groups and sub-working groups of the *JTC 21* committee responsible for European AI standards. Some experts also warn that contributions made by civil society organisations may be forfeited if continuous cooperation cannot be ensured. An issue raised at one work-

<sup>64</sup> Pernarnaud 2023; EDRI 2022; European Commission 2022b; Ada Lovelace Institute 2023; Veale/ Zuiderveen Borgesius 2021, p. 105.

ing session may not be revisited at the next. Thus, if civil society organisations are only able to invest a limited number of resources, their contributions run the risk of not making it into the final document.

*Experts in AI or Human Rights might not know how to contribute to standardisation. That for example if you voice a contribution but you are not there at the next meeting and nobody will support your contribution, that contribution is gone. There are operational processes that they are not aware of.*

*Emilia Tantar, Black Swan LUX*

The aforementioned timeframe for developing harmonised standards represents the third challenge. Substantial participation by new civil society actors would require a period of familiarisation and possibly also a rehashing of previously concluded discussions. This stands in contrast to the ambitious time schedules pursued by the standardisation bodies. Nevertheless, individual experts emphasize that broader participation could ultimately lead to a better outcome, despite the additional difficulties.

### How More Participation Can Work

These three hurdles – required expertise, resources, and time – are also described to some extent in the academic papers, which attest to the exclusionary or non-transparent culture and practices of standardisation organisations.<sup>65</sup>

For this reason, some experts are in favor of political intervention. Such intervention should, for example, provide resources

that facilitate the participation of civil society. However, existing programs in this area are still too bureaucratic, underutilized, or in need of expansion. The *European Commission* has also called on standardisation bodies to make their governance structures more inclusive.<sup>66</sup> This call can also be found in the research community, and there are complementary proposals, for example, to establish hubs that could act as focal points for civil society participation.<sup>67</sup> Positive mention can be made of the working group at *CEN/ CENELEC* which champions inclusivity. In addition, some experts suggest that new, low-threshold opportunities for participation be developed, such as consultations, comments and reviews of published norms and standards.

*In other words, a technology will only be adopted and used if it is accepted and trusted by the society. This is where civil society plays an important role, because it raises issues that may not be raised or seen from a purely technological perspective.*

*Filiz Elmas, DIN*

Many experts agree that more participation is needed, especially to facilitate discussion about the social and ethical requirements for trustworthy AI systems. Civil society organisations in particular have the necessary expertise for this. Some experts go so far as to call for a guarantee of civil society participation to ensure real participation and not just selective or token involvement.

<sup>65</sup> Cath 2021, p. 206ff.; Pernarnaud 2023; EDRI 2022; Ada Lovelace Institute 2023; Ebers 2021a, p. 21.

<sup>66</sup> European Commission 2022b, p. 4f.

<sup>67</sup> Ada Lovelace Institute 2023, p. 45ff.

## 2.5 Can dynamic AI systems be standardised at all?

But even assuming a more active participation by civil society, the highly dynamic development of AI systems poses other major challenges. Typically, relatively new technologies such as artificial intelligence are not yet sufficiently integrated into market-ready test guidelines and test procedures.<sup>68</sup> With AI systems, the situation is complicated by the fact that new AI methods are being developed and brought to market at a very rapid pace. In addition, many AI systems are capable in principle of adapting to modes of use and input during operation, and thus of changing after they have been approved for the market.<sup>69</sup> Dynamic changes of this nature would need to be reflected in standards from the very beginning. As a result, the usually required update after five years may not be sufficient to take into account new developments.

### How Flexible are Standards?

The experts interviewed observed a high level of dynamism, especially at the interface between research and the use of AI systems in industry. For this reason, standards should be developed with a view to current technical developments and be derived from the examination of best practice examples and concrete application scenarios.

At the same time, most experts agree that established standardisation processes and cycles are sufficient to capture innovations in AI. Standards should in themselves be formulated in a technology-neutral manner:

*Technological neutrality is the ultimate goal of standardization. Standards are solution agnostic. They contain safety goals and suggestions on how to achieve them but do not specify the path for their implementation. This typically makes them fit for the future.*

*Andreas Hauschke, German Association for Electrical, Electronic & Information Technologies (VDE)*

In practice, there are differences between the various topics of standardisation. Standards for terminology, taxonomies, and process management are relatively stable. Specific standards for individual types of AI procedures, which are changing rapidly, may need to be updated more quickly. However, by deferring to the state of the

art and allowing the barriers to be tested in order to be adapted in implementation, most standards remain current for years.

However, there is disagreement among experts about the extent to which new classes of applications, such as the currently much-discussed foundational models like *GPT-3*, *BERT*, or *BLOOM*, might complicate standardisation. While some anticipate an increased amount of effort and need for action, there are voices that consider the current processes to be sufficient in the long term:

*There is this misconception that new disruptive techniques appear in AI every one or two years. But since I started my research career in AI more than 20 years ago, I haven't seen that much of disruption than bringing to scale and bringing AI to business.*

*Emilia Tantar, Black Swan LUX*

The frequency with which AI standards need to be updated is evaluated very differently. It is suggested that AI development and AI standardisation should be more closely intertwined to better reflect new technological developments.

*We need new approaches to identify application-specific needs at an early stage and ultimately develop AI standards that are ready for the market. The practical implementation of norms and standards needs to be verified by actual use cases in practice, and the experience gained from this needs to be fed back into the standardization process. This will require new, iterative, and agile processes that incorporate reciprocal input from research, industry, society, and regulators in shaping standards.*

*Filiz Elmas, DIN*

### Challenges Associated with AI Systems that Learn during Operation?

The experts consulted describe the ability to change autonomously once the system is up and running as one of the greatest challenges associated with AI systems. Although the possibility to autonomously learn concerns the testing, certifi-

<sup>68</sup> Koch 2019, p. 18.

<sup>69</sup> Ebers 2021a, p. 12.

cation, and possible recertification of an AI system, it also has implications for the development of AI standards.

On the one hand, test periods and requirements for recertification need to be specified: At what point should changes to the AI system trigger the need for a new conformity assessment? On the other, self-learning systems require regular testing. Most experts consider automated tests to be a possible solution. In this connection, machine-readable standards are discussed that could be automatically evaluated and verified. Such “smart standards” could then make quality requirements measurable and assessable throughout the whole AI lifecycle with significantly less effort.

The second edition of the German Standardisation Roadmap has already noted that the rapid development of AI – especially with respect to reinforcement learning during operation – pose new challenges.<sup>70</sup> For the standardisation of AI systems, this means an additional hurdle, which the standards bodies are trying to overcome by making technical and structural adjustments to their processes and introducing new tools for collaborative work.<sup>71</sup>

## 2.6 When are the AI standards expected to be finalized?

The original time schedule envisaged by the *European Commission* was to complete the standards and publish the harmonised standards in the *Official Journal of the European Union* by autumn 2024.<sup>72</sup> In its standardisation request, the Commission now sets a target date of April 30, 2025.<sup>73</sup> In view of the considerable challenges and the need expressed by many actors for greater involvement of civil society in AI standardisation, this date appears very ambitious. Thus, necessary standards might not be ready in time for when the AI Act comes into force.

### Ambitious Time Schedule with Unclear Outcome

The experts interviewed have different opinions on how realistic the schedule is. One group of interview partners is optimistic, given that they have been working on AI standards at European level since 2018. In addition, appropriate international standards could be adopted and adapted. This could significantly limit the actual need for standardisation. A clearly defined time schedule also provides an opportunity to reduce complex discussions to the essentials and bring them to a conclusion that is focused on solutions. The fact that the AI Act provides for the *European Commission* to draw up its own specifications adds to the pressure on involved actors.

*The AI Act has a plan B built in: if the standards are not ready in time, the Commission can look around at what already exists somewhere in the world, be it a standard or a framework, and decide to use it for now. This is putting a certain amount of pressure on people to agree and get things done.*

Sebastian Hallensleben,  
VDE & Chair JTC21

Moreover, even if the standardisation process were to continue for several years, it would not solve all problems or address every issue. The proposed time schedule is considered therefore expedient and realistic.

<sup>70</sup> DIN/ DKE 2022, p. 286.

<sup>71</sup> Ibid, p. 288.

<sup>72</sup> Veale/ Zuiderveen Borgesius, p. 105.

<sup>73</sup> European Commission 2023, p. 4.



We have worked on these standards since 2018. If we don't make it now, we won't make it later.

*Emilia Tantar, Black Swan LUX*

Another group, in contrast, expresses clear doubts about the time schedule envisaged. Despite the early announcement of the preliminary standardisation request, the standardisation process at European level is “still in the midst of being born,” as one expert put it. The lengthy discussions at the beginning of the process showed that actors were used to longer standardisation processes. Discussions taking place outside the standardisation bodies are also intense and still completely open in terms of content. This is also reflected in the development of standards at international level.

ISO/ IEC have been working on AI standards since 2017 and they have done a lot of work on definitions but have done less work on more normative questions.

*Hadrien Pouget, Carnegie Endowment for International Peace*

Another complicating factor is the low involvement of civil society. If this were to change as demanded, further delays are likely.

### **Prioritise Key AI Standards**

One group of experts also points out that the completion of the standardisation process depends on the final wording of the AI Act. Until the AI Act is passed, there will be no agreement on AI standards even within the European standardisation bodies. Given the lengthy dialogue, it can be assumed that not all the standards will be completed within the time schedule.

On the technical side, the two years are almost immaterial because it is not only about how much time you have to resolve these issues. The problem is that it is not clear the extent to which some issues, like explainability, can be technically resolved. Maybe we will make huge research leaps in two years and have a great set of metrics, but there's a good chance we won't. At the same time, the state of the field is constantly evolving.

*Hadrien Pouget, Carnegie Endowment for International Peace*

In this context, one expert points out that it would be useful to limit the standardisation request to the most important regulatory issues. Well-developed solutions to these should be available within the time schedule.

The gap between dynamic technological development and the sluggish progress in European and international standardisation is sweepingly emphasized in the academic literature.<sup>74</sup> The timeframe envisaged by the *European Commission* seems extremely ambitious compared to the three or five years that would normally be required to develop a standard.<sup>75</sup> The second edition of the *German Standardisation Roadmap* also documents that standardisation work on AI systems is generally not completed within a few months: For example, the finalisation and publication of many of the *ISO* standards, many of which began in 2018, cannot even be foreseen.<sup>76</sup> In addition, time delays might also occur due to effort to effectively involve civil society or small to mid-sized businesses.<sup>77</sup>

<sup>74</sup> McFadden et al. 2021, p. 18.

<sup>75</sup> KAN 2005; Ada Lovelace Institute 2023, p. 30.

<sup>76</sup> DIN/ DKE 2022, p. 58ff.

<sup>77</sup> McFadden et al. 2021, p. 18; Ada Lovelace Institute 2023, p. 38 and p. 44.

### 3 How Do We Arrive at AI Standards that Deliver Safety and Fundamental Rights Protections?

Technical standards are developed in traditional, complex, labor-intensive processes dominated by representatives of large corporations. Even though the participation in the relevant committees is open to everyone in principle, the practical processes and time schedules are difficult for outsiders to understand. Often, barely anyone knows about the opportunities that exist for participation. These characteristics of standardisation take on a new political significance with the *European Commission's* request to develop standards under the AI Act. For this reason, we asked experts for their assessment of standardisation processes in the context of regulating AI systems.

European standardisation bodies are developing standards which, in addition to technical safety and product quality, also include guidance on the implementation of ethical and fundamental rights requirements. Requirements for fairness, transparency, or human oversight are considered difficult to standardise: there is a lack of appropriate metrics. Furthermore, contradictory goals often have to be weighed up against each other. At the same time, the necessary expertise and awareness of fundamental rights issues are not traditional elements of the standardisation process. The resource-intensive and opaque processes within standards bodies make participation even more difficult for new actors from civil society. Thus, when it comes to AI standards, new ethical questions are encountering structures that are not equipped to deal with them.

AI systems in themselves pose multiple challenges for standardisation. On the one hand, many AI-specific issues such as robustness, accuracy, explainability, and cybersecurity are under-researched and therefore difficult to translate into metrics. On the other, the potential for self-learning AI systems to change significantly after deployment, together with the dynamic development of new components and models, further adds to the complexity of AI standardisation. Policymakers and the industry are exerting pressure to finalize the new AI standards before the AI Act comes into force. Under these unfavorable conditions, how can AI standards be achieved that adequately implement the ambitious goals of the AI Act?

The targeted and broad participation of civil society actors can help to successfully respond to the new questions surrounding standardisation. Existing barriers have to be systematically addressed, such as a lack of knowledge about processes, structures and access, a lack of financial and human resources, as well as a lack of incentives on the part of standardisation bodies to effectively involve such actors. These include formats for orientation and knowledge transfer, individual and organisational support programs, and new obligations for standardisation bodies to include more and diverse civil society interests. The currently listed social groups with access to *CEN* and *CENELEC* leave out many stakeholder groups and, with their limited capacity, can often only play an observer role.

Such necessary but resource-intensive actions are at odds with the tight timeframe that the Commission's request set for the standardisation. There needs to be more room for participation, a strong focus on the quality of the standards to be produced, and an awareness that the AI Act may enter into force without a final set of standards – as is quite common in product safety. Standardisation bodies need to prioritize content to ensure that missing pieces of the puzzle do not impact the implementation of key regulatory requirements. This also includes the clarification of sector-specific issues when these are particularly pressing in terms of fundamental rights protection. Adopting international standards without the necessary adaptation to the goals of the AI Act would be fatal.

Finally, both the AI Act and the Harmonised Standards Acceptance Procedures provide some ways to ensure the quality and suitability of AI standards. On one side, the *European Commission* has the power to establish common specifications through implementing acts that may replace missing or inappropriate AI standards (Art. 41 (1) AI Act). On the other side, the contents of draft European standards is reviewed before they become harmonised standards. Given the goals of the AI Act and the challenges identified in this paper, the *European Commission* should use its powers to ensure the quality of European AI standards. Most importantly, this includes positioning itself on time for adequate ex-post reviews of AI standards to compensate for the lack of perspective and inadequate participation of civil society. The *European Commission* should not be content with passing on all the issues related to content to the standardisation bodies. Instead, there is an urgent need for the Commission's own preparatory work,



especially on issues related to the protection of fundamental rights. Such work could form the basis for common specifications.

An effective participation of civil society, an adapted time schedule and the active involvement of European institutions can address the challenges of standardising AI systems. This would also ensure that the AI Act actually addresses the socio-technical risks of AI deployment and provides for greater safety and the protection of fundamental rights.

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This study is the result of several interviews conducted between January and May 2023. We would like to thank all the experts for their participation and support, as well as for approving each of their quotes:

**Annegrit Seyerlein-Klug,**  
Brandenburg  
University of Applied Sciences (THB)

**Andreas Hauschke,**  
VDE Verband der Elektrotechnik  
Elektronik Informationstechnik e.V.

**Camille Dornier,**  
ANEC-BEUC

**Connor Dunlop,**  
Ada Lovelace Institute

**Dirk Schlesinger,**  
TÜV Süd (until April 2023)

**Emilia Tantar,**  
Black Swan LUX

**Filiz Elmas, DIN**  
Hadrien Pouget, Carnegie Endowment  
for International Peace

**Hadrien Pouget,**  
Carnegie Endowment for International Peace

**Jörg Firnkorn,**  
DEKRA Digital

**Sebastian Hallensleben,**  
VDE & Chair JTC21

**Susanne Kuch,**  
Deutsche Akkreditierungsstelle (DAKKS)



## Edition Notice

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**Copy-Editing:** Hannah Willing (text | structure)

**Translation:** Übersetzungsbüro Perfekt

**Typesetting:** Christoph Löffler

**Publication:** November 2023

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As a central place for debate in Germany, CTAI makes developments tangible around societal issues of artificial intelligence and algorithmic systems. As a national and impartial interface between science, industry, politics, and civil society, CTAI provides information on many aspects relevant to consumers, facilitates public debate and develops tools for evaluating and certifying trustworthy AI. This study provides interested parties from civil society, academia, and politics with insights into a rarely discussed area of AI regulation in Europe.

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Network partners: Fraunhofer AISEC, Fraunhofer IAIS, Free University of Berlin

Sponsored by: German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV)



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für Umwelt, Naturschutz, nukleare Sicherheit  
und Verbraucherschutz