



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction & machinery  
Standards Policy

Brussels, 5.12.2022

### A Notification under Article 12 of Regulation (EU) No 1025/2012<sup>1</sup>

#### Subject matter related to

<input type="checkbox"/>	Annual Union Work Programme for European standardisation (Art. 12, point a)
<input checked="" type="checkbox"/>	Possible future standardisation requests to the European standardisation organisations (Art. 12, point b)
<input type="checkbox"/>	Formal objections to harmonised standards (Art. 12, point c)
<input type="checkbox"/>	Identifications of ICT technical specifications (Art. 12, point d)
<input type="checkbox"/>	Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12, point e)

#### Title of the initiative

Draft standardisation request to the European Standardisation Organisations in support of safe and trustworthy artificial intelligence

#### Additional information

<b>Legislative/Policy reference(s)</b>	COM(2021) 206 final of 21.4.2021 Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts
<b>EN reference(s)</b>	-
<b>Status</b>	Draft
<b>Other information</b>	This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
<b>Deadline for feedback</b>	3.1.2023

#### Commission contact point for this notification

CNECT-A2@ec.europa.eu

<sup>1</sup> OJ L 316, 14.11.2012, p. 12

Brussels, XXX  
[...] (2022) XXX draft

## COMMISSION IMPLEMENTING DECISION

of XXX

on a standardisation request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in support of safe and trustworthy artificial intelligence

(Only the English, French and German texts are authentic)

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# COMMISSION IMPLEMENTING DECISION

of **XXX**

**on a standardisation request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in support of safe and trustworthy artificial intelligence**

(Only the English, French and German texts are authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council<sup>1</sup>, and in particular Article 10(1) thereof,

Whereas:

- (1) Artificial intelligence (AI) should be a tool for people and be a force for good in society with the ultimate aim of increasing human well-being. The European approach to artificial intelligence centres on excellence and trust; it aims to boost research and industrial capacity, while ensuring safety and the protection of fundamental rights, as enshrined in the Charter of fundamental rights. To concretise this approach, the Commission published its AI package<sup>2</sup> in April 2021, proposing new rules and actions to turn Europe into the global hub for trustworthy AI. This package consisted of a Communication on Fostering a European Approach to Artificial Intelligence, the updated 2021 Coordinated Plan with Member States and the proposal for a Regulation on Artificial Intelligence laying down harmonised rules for AI systems placed on the market or put into service and used in the EU (Artificial Intelligence Act).
- (2) Standards are important to support the implementation of EU policies and regulations to ensure a high level of protection of safety and fundamental rights for EU citizens throughout the Union. Standards can also support the establishment of equal conditions of competition and a level playing field for the design and development of AI systems, in particular for SMEs that develop AI solutions.
- (3) Building on the work of a High Level Expert Group set by the Commission in June 2018<sup>3</sup> to support the implementation of the 2018 European Strategy on Artificial Intelligence, the proposed AI Act introduces inter alia requirements for the placing

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<sup>1</sup> OJ L 316, 14.11.2012, p. 12.

<sup>2</sup> [A European approach to artificial intelligence | Shaping Europe's digital future \(europa.eu\)](#)

<sup>3</sup> [High-level expert group on artificial intelligence | Shaping Europe's digital future \(europa.eu\)](#)

on the market and putting into service of high-risk AI systems. These requirements cover areas related to risk management, data quality and governance, technical documentation, record keeping, transparency and provision of information to users, human oversight, accuracy, robustness and cybersecurity. The proposed Act also sets certain obligations for providers of high-risk AI systems, notably the obligation to establish a quality management system, a conformity assessment procedure to demonstrate the compliance of the system and the provider's organisation with the requirements and a post-market monitoring system.

- (4) To advance the technical harmonisation in the field of trustworthy artificial intelligence and prepare the necessary technical ground for the implementation of the future AI Act, once applicable, it is necessary to draft European standards or European standardisation deliverables in order to support the key technical areas covered by the proposed AI Act. These include the requirements for design and development of AI systems defined as high-risk in the proposed AI Act, the AI providers' quality management system, conformity assessment and auditing of AI systems.
- (5) The intention to request drafting of European standards or European standardisation deliverables in support of safe and trustworthy Artificial Intelligence systems is stated in point 63 of the table entitled 'Standardisation urgencies set by the Commission on the Standardisation strategy' within the Annex of the Commission Notice C(2022) 546 on 'The 2022 annual Union work programme for European standardisation'<sup>4</sup>.
- (6) The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) have indicated that the work covered by the request falls within their area of competence.
- (7) International standardisation can, on the one hand, help to consolidate a common vision of trustworthy AI across the globe and, on the other hand, facilitate trade and removing possible technical barriers in relation to products and services which are powered by artificial intelligence. Certain standards developed at international level by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) in relevant areas may be adopted as European standards by CEN and CENELEC on the basis of the Vienna<sup>5</sup> agreement and the Frankfurt<sup>6</sup> agreement under the condition of adapting them to the requirements of the Union legal framework. CEN and CENELEC, in line with those agreements, and without prejudice to their role and obligations arising from this request and their organisational and planning prerogatives, are expected to cooperate with ISO/IEC in relation to relevant standardisation areas for which international work does not exist or is deemed not be sufficient or adequate for the fulfilment of this request.
- (8) It is therefore appropriate to request CEN and CENELEC to draft new European standards or European standardisation deliverables in support of the European

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<sup>4</sup> COM(2022) 546 final of 2 February 2022.

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[https://isotc.iso.org/livelink/livelink/fetch/2000/2122/3146825/4229629/4230450/4230458/01\\_Agreement\\_on\\_Technical\\_Cooperation\\_between\\_ISO\\_and\\_CEN\\_\(Vienna\\_Agreement\).pdf?nodeid=4230688&vernum=-2](https://isotc.iso.org/livelink/livelink/fetch/2000/2122/3146825/4229629/4230450/4230458/01_Agreement_on_Technical_Cooperation_between_ISO_and_CEN_(Vienna_Agreement).pdf?nodeid=4230688&vernum=-2).

<sup>6</sup> [https://www.iec.ch/about/globalreach/partners/pdf/IEC-CENELEC\\_Frankfurt\\_Agreement%7B2016%7D.pdf](https://www.iec.ch/about/globalreach/partners/pdf/IEC-CENELEC_Frankfurt_Agreement%7B2016%7D.pdf).

approach to artificial intelligence. Those standards should be adopted by CEN and CENELEC by the deadlines set out in this Decision.

- (9) Recalling that all relevant interested parties, including the Member States and the European stakeholder organisations receiving Union financing in accordance with Regulation (EU) No 1025/2012, may identify a need to develop additional standards or to complement existing ones, it may be necessary to consider adding new elements to the list of standards set out in Annex I to this Decision. The scope of this request may need to be adjusted accordingly.
- (10) CEN and CENELEC have agreed to follow the Guidelines for the execution of standardisation requests<sup>7</sup>.
- (11) In order to ensure transparency and facilitate the execution of the requested standardisation activities, CEN and CENELEC should prepare a work programme and submit it to the Commission. Given that the European Telecommunications Standards Institute (ETSI) has already done work and possesses specific expertise on certain matters, such as security, it is appropriate that during the preparation of the programme, CEN and CENELEC consult ETSI in order to possibly identify modalities for allowing ETSI's contribution on those matters.
- (12) In order to enable the Commission to better monitor the requested standardisation work, CEN and CENELEC should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardisation request and should report regularly on the execution of that request.
- (13) In line with Article 10(1) of Regulation (EU) No 1025/2012, the policy objectives of the Commission in the field of artificial intelligence should be taken into account when drafting European standards and European standardisation deliverables in reply to this request. Such policy objectives include ensuring that AI systems placed on the market or put into service in the Union are safe, are used in compliance with fundamental rights and in full respect Union values, strengthen the Union's digital sovereignty, promote investment and innovation in AI as well as competitiveness and growth of the Union market, while strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests. The public interest should take a prominent role when executing this standardisation request, given its importance for the development and the deployment of AI. The United Nations Convention on the Rights of Persons with Disabilities shall be also taken into account when drafting the relevant standards. CEN and CENELEC shall carefully monitor the adherence to the above principles during the standardisation process, and shall report to the Commission any undue interference aiming at jeopardising the Commission policy objectives, the public interest, and the rights of persons with disabilities.
- (14) The European Standardisation Organisations are expected to take all steps to ensure the involvement of EU small and medium enterprises and civil society organisations, including consumer organisations, in the standardisation processes and in the consensus-building exercise, both at the national and European level. Moreover, given the fundamental rights implications of the European standards and European standardisation deliverables requested, relevant expertise in the area

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<sup>7</sup> SWD(2015) 205 final of 27 October 2015.

of fundamental rights should be also guaranteed. CEN and CENELEC should thus include in the work programme the actions to be undertaken to ensure appropriate involvement of EU small and medium enterprises, civil society organisations and experts in the areas of fundamental rights, and shall provide the necessary evidence in the context of interim and final reports provided on the execution of the standardisation request.

- (15) The proposed AI Act is currently subject to negotiations with the Council and the European Parliament in the context of the ordinary legislative procedure. This request may thus be amended by the Commission when the AI Act is finally adopted in order to request CEN and CENELEC to develop harmonised standards to support that Act. Any future harmonised standards should build on the work done on the basis of this request.
- (16) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, each standardisation request is subject to acceptance by the relevant European standardisation organisation. It is therefore necessary to provide for rules on the validity of this request if it is not accepted by CEN and CENELEC.
- (17) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision.
- (18) The European standardisation organisations, the European stakeholder organisations receiving Union financing and the experts of the Member States who are part of the Multi-stakeholder Platform on ICT standardisation have been consulted.
- (19) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Regulation (EU) No 1025/2012.

HAS ADOPTED THIS DECISION:

#### *Article 1*

##### *Requested standardisation activities*

The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are requested to draft the new European standards or European standardisation deliverables listed in Table 1 of Annex I in support of safe and trustworthy artificial intelligence.

The European standards or European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.

#### *Article 2*

##### *Work programme*

1. CEN and CENELEC shall prepare a work programme indicating all the standards listed in Annex I, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadlines set out in that

Annex, including the actions to be undertaken to ensure effective participation of EU small and medium enterprises and civil society organisations, and to gather relevant expertise in the area of fundamental rights.

During the preparation of the work programme referred to in paragraph 1, CEN and CENELEC shall consult the European Telecommunications Standards Institute (ETSI) so as to explore and possibly agree on modalities to ensure ETSI's contribution to the following elements:

- (a) the preparation of the European standards and European standardisation deliverables referred to in point 8 of Table 1 of Annex I;
- (b) the evaluation and integration of security aspects in the European standards and European standardisation deliverables listed in Table 1 of Annex I other than those referred to in point 8 of that Table;
- (c) the preparation and elaboration of possible vertical specifications as referred to in Annex II, Section 1.

The description of the modalities and extent of possible ETSI's contribution shall be included under the work programme referred to in paragraph 1. Where CEN, CENELEC and ETSI are unable to agree on possible ETSI's contribution as referred to in previous subparagraph, the work programme shall provide the related reasons.

Possible ETSI's contributions remain without prejudice to the responsibility of CEN and CENELEC for the execution of the request pursuant to Article 1 and to the requirements for European standards and European standardisation deliverables set out in Annex II.

3. CEN and CENELEC shall submit the work programme to the Commission by 4 months after adoption by the Commission of the standardisation request referred to in Article 1. CEN and CENELEC shall inform the Commission of any amendments to the joint work programme.
4. CEN and CENELEC shall provide the Commission with access to an overall project plan.

### *Article 3*

#### *Reporting*

1. CEN and CENELEC shall report every six months to the Commission on the execution of the standardisation request referred to in Article 1, indicating the progress made in the implementation of the work programme referred to in Article 2.
2. CEN and CENELEC shall submit the first joint semestrial report to the Commission by 10 months after adoption of the standardisation request referred to in Article 1.
3. CEN and CENELEC shall provide the Commission with the joint final report by 31 January 2025
4. CEN and CENELEC shall promptly report to the Commission any major concerns relating to the execution of the request and to the deadlines set in Annex I.
5. The reports referred to in paragraphs 1 to 3 shall include evidence of how CEN and CENELEC have planned for and ensured the appropriate involvement of EU small and medium enterprises, civil society organisations, and the gathering of relevant

expertise in the area of fundamental rights, as well as a description of ETSI's contribution.

#### *Article 4*

##### *Validity of the standardisation request*

Where, in accordance with Article 10(3) of Regulation (EU) No 1025/2012, CEN and CENELEC indicate that they do not accept the request referred to in Article 1 of this Decision, that request may not constitute a basis for the standardisation activities referred to in Article 1 of this Decision.

This Decision shall expire on 30 November 2025.

#### *Article 5*

##### *Addressees*

This Decision is addressed to CEN and CENELEC .

Done at Brussels,

*For the Commission*



## ANNEX I

### **List of new European Standards and/or European standardisation deliverables to be drafted**

**Table 1: List of European standards and/or European standardisation deliverables to be drafted and deadlines for their adoption**

<b>Reference information</b>		<b>Deadline for the adoption by CEN and CENELEC</b>
1.	European standard(s) and/or European standardisation deliverable(s) on risk management system for AI systems	31/01/2025
2.	European standard(s) and/or European standardisation deliverable(s) on governance and quality of datasets used to build AI systems	31/01/2025
3.	European standard(s) and/or European standardisation deliverable(s) on record keeping through logging capabilities by AI systems	31/01/2025
4.	European standard(s) and/or European standardisation deliverable(s) on transparency and information provisions to the users of AI systems	31/01/2025
5.	European standard(s) and/or European standardisation deliverable(s) on human oversight of AI systems	31/01/2025
6.	European standard(s) and/or European standardisation deliverable(s) on accuracy specifications for AI systems	31/01/2025
7.	European standard(s) and/or European standardisation deliverable(s) on robustness specifications for AI systems	31/01/2025
8.	European standard(s) and/or European standardisation deliverable(s) on cybersecurity specifications for AI systems	31/01/2025
9.	European standard(s) and/or European standardisation deliverable(s) on quality management system for providers of AI systems, including post-market monitoring process	31/01/2025
10.	European standard(s) and/or European standardisation deliverable(s) on conformity assessment for AI systems	31/01/2025

## **ANNEX II**

### **Requirements for the European standards and European standardisation deliverables referred to in Article 1**

#### **1. Requirements for all European standards and European standardisation deliverables**

European standards and European standardisation deliverables shall reflect the generally acknowledged state of the art<sup>1</sup> in order to minimise the risks to health and safety and fundamental rights of persons as guaranteed in the Charter of Fundamental Rights of the EU which arise from the design and development of AI systems in view of their intended purpose<sup>2</sup>. In this respect, CEN and CENELEC shall ensure the appropriate involvement in the standardisation work of EU small and medium enterprises, civil society organisations, and gather relevant expertise in the area of fundamental rights.

The European Standards and European standardisation deliverables shall provide, to the necessary extent and taking into account the state of the art, technology-, process- or methodology-based technical specifications in relation to the design and development of AI systems, including verification, validation and testing procedures, objectively verifiable criteria and implementable methods to assess compliance with such specifications. Supporting specifications (e.g. on terminology<sup>3</sup>) should also be identified and provided when necessary to ensure the consistency and ability to implement the European standards and European standardisation deliverables. When drafting the European standards and European standardisation deliverables, specific account shall be taken of the risks which are common (horizontal<sup>4</sup>) to the AI systems that the Commission has defined as posing high-risk in the context of the proposal for a Regulation on Artificial Intelligence (AI Act) adopted on 21 April 2021<sup>5</sup>.

Notwithstanding their general horizontal nature, European standards or European standardisation deliverables may provide vertical specifications, when deemed necessary in the light of the specific risks posed by certain AI systems.

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<sup>1</sup> State-of-art should be understood as a developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience and which is accepted as good practice in technology. The state of the art does not necessarily imply the latest scientific research still in an experimental stage or with insufficient technological maturity.

<sup>2</sup> While it is indeed not always possible to develop standards that consider each specific intended purpose, technical specifications should cover a range of technical solutions and options, which the manufacturer can assess and implement, taking into consideration the intended purpose of their specific system. Standards should also possibly include guidance on how such assessment and implementation of standards should be executed.

<sup>3</sup> All the European Standards and European standardisation deliverables elaborated on the basis of this request shall rely on a common set of terms. Moreover, supporting specifications on terminology shall build as much as possible on terminology adopted at international level and notably in international standards.

<sup>4</sup> The term “horizontal” shall be meant as the faculty of the European standards and European standardisation deliverables to lay down technical specifications, which are applicable to all AI applications that the Commission has defined as posing high-risk in the context of the proposal for a Regulation on Artificial Intelligence adopted on 21 April 2021. On the other hand, the term “vertical” shall be meant as the faculty of European standards and European standardisation deliverables to lay down technical specifications which are intended for certain specific AI systems (use cases) or sectors, in consideration of their intended purpose and/or context of use.

<sup>5</sup> COM(2021) 206 final.

In the fields of human oversight and accuracy, specific requirements for vertical specifications are laid down in Sections 2.5 and 2.6.

The European Standards and European standardisation deliverables produced should take into account the interdependencies between the different requirements listed in Section 2 of this Annex, and to the extent possible, reflect them explicitly in the corresponding specifications.

CEN and CENELEC should ensure that the European Standards and European standardisation deliverables produced are, when applicable, consistent with existing and future European and harmonised standards developed in the various relevant sectors, notably those related to products covered by existing EU safety legislation, including the general product safety legislation.

CEN and CENELEC should take into due account that the areas covered by the European Standards and European standardisation deliverables may be the object of a future standardisation request for harmonised standards to support the rules of the future AI Act, when finally adopted.

CEN and CENELEC shall ensure that the European Standards and European standardisation deliverables are drafted in such a way so as to reflect an adequate consideration of the specificities and costs of small and medium enterprises, notably in relation to quality management system and conformity assessment (Sections 2.9 and 2.10 of this Annex).

## **2. Requirements for specific European Standards and European standardisation deliverables**

### **2.1 Risk management system for AI systems**

This (these) European standard(s) or European standardisation deliverable(s) shall set up specifications for a risk management system for AI systems. Risk management should be intended as a continuous iterative process run throughout the entire lifecycle of the AI system, which is aimed at preventing or minimising the relevant risks to health, safety or fundamental rights.

Specifications shall be drafted in such a way that, for AI systems which are safety components of products, the risk management system aspects related to the AI system should, when applicable, be integrated into the risk management system for the overall product.

Specifications shall be drafted in such a way so as to enable usability by relevant operators and market surveillance authorities.

### **2.2 Data and data governance.**

This (these) European standard(s) or European standardisation deliverable(s) shall include:

- (a) specifications for adequate data governance and data management procedures to be implemented by providers of AI systems (with specific focus on data generation and collection, data preparation operations, design choices, procedures for detecting and addressing biases or any other relevant shortcomings in data);

- (b) specifications on quality aspects of datasets used to train, validate and test AI systems (including representativeness, relevance, completeness and correctness).

### 2.3 Record keeping through logging capabilities

This European standard shall include specifications for automatic logging of events for AI systems. Those specifications shall enable the traceability of those systems throughout their lifecycle as well as the monitoring of their operations and shall facilitate the post-market monitoring of the AI systems by the providers.

### 2.4 Transparency and information to the users

This (these) European standard(s) or European standardisation deliverable(s) shall provide specifications related to:

- (a) design and development solutions which ensure transparency of the operation of the AI system to enable users to understand the system's output and use it appropriately;
- (b) instructions for use accompanying AI systems, including instructions on the system's capabilities and limitations as well as on maintenance and care measures, taking into particular account:
  - (i) the need to identify and appropriately distinguish information, which is relevant and comprehensible for different professional user profiles and lay users;
  - (ii) without prejudice to point (i), the need to ensure that identified information is sufficient to enable users to interpret the system's output and use it appropriately.

### 2.5 Human oversight

This (these) European standard(s) or European standardisation deliverable(s) shall specify measures and procedures for human oversight of AI systems which are:

- (a) identified and built, when technically feasible, into the AI system by the provider before it is placed on the market or put into service;
- (b) identified by the provider before placing the AI system on the market or putting it into service and that are appropriate to be implemented by the user.

These shall include measures enabling users to understand, monitor, interpret, assess and intervene in relevant aspects of the operation of the AI system.

This (these) European standard(s) or European standardisation deliverable(s) shall also define, where justified, appropriate oversight measures which are specific to certain AI systems in consideration of their intended purpose. With respect to AI systems intended for remote biometric identification of persons, human oversight measures shall, inter alia, foresee the possibility that no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been separately verified and confirmed by at least two natural persons.

## 2.6 Accuracy specifications for AI systems

This (these) European standard(s) or European standardisation deliverable(s) shall lay down specifications for ensuring an appropriate level of accuracy of AI systems<sup>6</sup> and for allowing providers to declare the relevant accuracy metrics and levels.

This (these) European standard(s) or European standardisation deliverable(s) shall also define, where justified, a set of appropriate and relevant tools and metrics to measure accuracy against suitably defined levels, which are specific to certain AI systems in consideration of their intended purpose.

## 2.7 Robustness specifications for AI systems

This (these) European standard(s) or European standardisation deliverable(s) shall lay down specifications for the robustness of AI systems, taking into consideration relevant sources of errors, faults and inconsistencies, as well as the interactions of the AI system with the environment, including those AI systems, which continue to learn after being placed on the market or put into service, notably in respect to feedback loops.

## 2.8 Cybersecurity specifications for AI systems

This (these) European standard(s) or European standardisation deliverable(s) shall provide suitable organisational and technical solutions, to ensure that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the AI systems' vulnerabilities. Organisational and technical solutions shall thus include, where appropriate, measures to prevent and control cyberattacks trying to manipulate AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploiting vulnerabilities in an AI system's digital assets or the underlying ICT infrastructure. Those technical solutions shall be appropriate to the relevant circumstances and risks.

This (these) European standard(s) or European standardisation deliverable(s) shall take due account of the essential requirements for products with digital elements as listed in sections 1 and 2 of Annex I to the proposal for a Regulation on horizontal cybersecurity requirements for products with digital elements adopted by the Commission in September 2022<sup>7</sup>.

## 2.9 Quality management system for providers of AI systems, including post-market monitoring process

This (these) European standard(s) or European standardisation deliverable(s) shall lay down specifications for a quality management system to be implemented by providers of AI

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<sup>6</sup> "Accuracy" should be understood as referring to the capability of the AI system to perform the task for which it has been designed. This should not be confused with the narrower definition of statistical accuracy, which is one of several possible metrics for evaluating the performance of AI systems.

<sup>7</sup> COM(2022) 454 final

systems within their organisations. Such quality management systems shall ensure inter alia continuous compliance of an AI system with the aspects described under points 2.2, 2.3, 2.4, 2.5, 2.6, 2.7 and 2.8. Appropriate consideration shall be given to the implementation of quality management system measures by medium and small size organisations.

Specifications shall be drafted such that the quality management system aspects related to the AI system may be integrated in the overall management system of the provider.

#### 2.10 Conformity assessment for AI systems

This (these) European standard(s) or European standardisation deliverable(s) shall provide procedures and processes for conformity assessment activities related to AI systems and quality management system of AI providers.

This (these) European standard(s) or European standardisation deliverable(s) shall also provide criteria for assessing the competence of persons tasked with those conformity assessment activities.

This (these) European standard(s) or European standardisation deliverable(s) shall consider both the scenarios whereby the conformity assessment is carried out by the provider itself or with the involvement of a professional external third-party organisation.