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Targeted stakeholder consultation on classification of AI systems as high-risk

Fields marked with * are mandatory.

Targeted stakeholder consultation on the implementation of the AI Act's rules for high-risk AI systems

Disclaimer: This document is a working document of the AI Office for the purpose of consultation and does not prejudge the final decision that the Commission may take on the final guidelines. The responses to this consultation paper will provide important input to the Commission when preparing the guidelines.

This consultation is targeted to stakeholders of different categories. These categories include, but are not limited to, providers and deployers of (high-risk) AI systems, other industry organisations, as well as academia, other independent experts, civil society organisations, and public authorities.

The Artificial Intelligence Act (the 'AI Act')[1], which entered into force on 1 August 2024, creates a single market and harmonised rules for trustworthy and human-centric Artificial Intelligence (AI) in the EU.[2] It aims to promote innovation and uptake of AI, while ensuring a high level of protection of health, safety and fundamental rights, including democracy and the rule of law. The AI Act follows a risk-based approach classifying AI systems into different risk categories, one of which is the high-risk AI systems (Chapter III of the AI Act). The relevant obligations for those systems will be applicable two years after the entry into force of the AI Act, as from 2 August 2026.

The AI Act distinguishes between two categories of AI systems that are considered as 'high-risk' set out in Article 6(1) and 6(2) AI Act. Article 6(1) AI Act covers AI systems that are embedded as safety components in products or that themselves are products covered by Union legislation in Annex I, which could have an adverse impact on health and safety of persons. Article 6(2) AI Act covers AI systems that in view of their intended purpose are considered to pose a significant risk to health, safety or fundamental rights. The AI Act lists eight areas in which AI systems could pose such significant risk to health, safety or fundamental rights in Annex III and, within each area, lists specific use-cases that are to be classified as high-risk. Article 6(3) AI Act provides for exemptions for AI systems that are intended to be used for one of the cases listed in Annex III, but which do not pose significant risk since they fall under one of the exceptions listed in Article 6(3).

AI systems that classify as high-risk must be developed and designed to meet the requirements set out in Chapter III Section 2, in relation to data and data governance, documentation and recording keeping, transparency and provision of information to users, human oversight, robustness, accuracy and security. Providers of high-risk AI systems must ensure that their high-risk AI system is compliant with these requirements and must themselves comply with a number of obligations set out in Chapter III Section 3, notably the obligation to put in place a quality management system and ensure that the high-risk AI system undergoes a conformity assessment prior to its being placed on the market or put into service. The AI Act also sets out obligations for deployers of high-risk AI systems, related to the correct use, human oversight, monitoring the operation of the high-risk AI system and, in certain cases, to transparency vis-à-vis affected persons.

Pursuant to Article 6(5) AI Act, the Commission is required to provide guidelines specifying the practical implementation of Article 6, which sets out the rules for high-risk classification, by 2 February 2026. It is further required that these guidelines should be accompanied with a comprehensive list of practical examples of use cases of AI systems that are high-risk and not high-risk. Moreover, pursuant to Article 96(1)(a) AI Act, the Commission is required to develop guidelines on the practical application of the requirements for high-risk AI systems and obligation for operators, including the responsibilities along the AI value chain set out in Article 25.

The purpose of the present targeted stakeholder consultation is to collect input from stakeholders on practical examples of AI systems and issues to be clarified in the Commission's **guidelines** on the classification of high-risk AI systems and future guidelines on high-risk requirements and obligations, as well as responsibilities along the AI value chain.

As not all questions may be relevant for all stakeholders, respondents may reply only to the section(s) and the questions they would like. Respondents are encouraged to provide **explanations and practical cases** as a part of their responses to support the practical usefulness of the guidelines.

The targeted consultation is available in English only and will be open for **6 weeks starting on 6 June until 18 July 2025.**

The questionnaire for this consultation is structured along 5 sections with several questions.

Regarding section 1 and 2, respondents will be asked to provide answers pursuant to the parts of the survey they expressed interest for in Question 13, whereas all participants are kindly asked to provide input for section 3, 4 and 5.
Section 1. Questions in relation to the classification rules of high-risk AI systems in Article 6(1) and the Annex I to the AI Act

- This section includes questions on the concept of a safety component and on each product category listed in Annex I of the AI Act.

Section 2. Questions in relation to the classification of high-risk AI systems in Article 6(2) and the Annex III of the AI Act. This category includes questions related to:

- AI systems in each use case under the 8 areas referred to in Annex III.
- The filter mechanism of Article 6(3) AI Act allowing to exempt certain AI systems from being classified as high-risk under certain conditions.
- If pertinent: Need for clarification of the distinction between the classification as a high-risk AI system and AI practices that are prohibited under Article 5 AI Act (and further specified in the Commission's guidelines on prohibited AI practices[3] from 3 February 2025) and interplay of the classification with other Union legislation.

Section 3. General questions for high-risk classification. This category includes questions related to:

- The notion of intended purpose, including its interplay with general purpose AI systems.
- Cases of potential overlaps within the AI Act classification system under Annex I and III.

Section 4. Questions in relation to requirements and obligations for high-risk AI systems and value chain obligations. This category includes questions related to:

- the requirements for high-risk AI systems and obligations of providers.
- the obligations of deployers of high-risk AI systems.
- the concept of substantial modification and the value chain obligations in Article 25 AI Act.

Section 5. Questions in relation to the need for amendment of the list of high-risk use cases in Annex III and of prohibited AI practices laid down in Article 5.

- Input for the mandatory annual assessment of the need for amendment of the list of high-risk use-cases set out in Annex III
- Input for the mandatory annual assessment of the list of prohibited AI practices laid down in Article 5

All contributions to this consultation may be made publicly available. Therefore, please do not share any confidential information in your contribution. Individuals can request to have their contribution anonymised. Personal data will be anonymised.

The AI Office will publish a summary of the results of the consultation. Results will be based on aggregated data and respondents will not be directly quoted.

[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689).

[2] Article 1(1) AI Act.

[3]https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-prohibited-artificial-intelligence-ai-practices-defined-ai-act.

Information about the respondent

* First name

Sarada

* Surname

Das

* Email address

sarada.das@cpme.eu

* Do you represent an organisation (e.g., think tank or civil society/consumer organisation) or act in your personal capacity (e.g., independent expert or from a downstream provider)?

- (●) Organisation
- ( ) In a personal capacity

* Name of the organisation

Standing Committee of European Doctors (CPME)

* Type of organisation

Civil society organisation/association

* Is a representation of the organisation located in the EU?

- (●) The organisation's headquarter is located in the EU
- ( ) A branch office, or any representation of the organisation is located in the EU
- ( ) None of the representations of the organisation is located in the EU

* Select the EU member state where the organisation's headquarter, or representation is located

BE - Belgium

* Select the size of the organisation

Micro (0-9 employees)

* Sector(s) of activity

- [ ] Information technology
- [ ] Employment
- [ ] Transport

- [ ] Public administration
- [ ] Education and training
- [ ] Telecommunications
- [ ] Law enforcement
- [ ] Consumer services
- [ ] Retail
- [ ] Justice sector
- [ ] Business services
- [ ] E-commerce
- [ ] Legal services sector
- [ ] Banking and finances
- [ ] Advertising
- [ ] Cultural and creative sector, including media
- [ ] Manufacturing
- [ ] Consumer protection
- [x] Healthcare
- [ ] Energy
- [ ] Others

* Describe the activities of your organisation or yourself

1300 character(s) maximum

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe, covering more than 1.7 million doctors in 37 countries. We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

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* All contributions to this consultation may be made publicly available. Therefore, please do not share any confidential information in your contribution. Your e-mail address will never be published. Should your contribution be anonymised in the instance that all contributions are made publicly available?

If you act in your personal capacity: *All contributions to this consultation may be made publicly available. You can choose whether you would like your details to be made public or to remain anonymous. The type of respondent that you responded to this consultation as, your answer regarding residence, and your contribution may be published as received. Your name will not be published. Please do not include any personal data in the contribution itself.*

If you represent one or more organisations: *All contributions to this consultation may be made publicly available. You can choose whether you would like respondent details to be made public or to remain anonymous. Only organisation details may be published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its size, its presence in or outside the EU and your contribution may be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.*

- ( ) Yes, please anonymise my contribution.
- (•) No

* Do you agree that we may contact you in the event of follow-up questions or if we want to learn more about your responses?

- (•) Yes
- ( ) No

- [x] I acknowledge the attached privacy statement.

Privacy_statement_high_risks.pdf

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* **On which part(s) of the public consultation are you interested to contribute to?** *Multiple answers are possible. Please note that selecting a particular answer will direct you to a set of questions specifically related to subject specified.*

- [ ] Questions in relation to **Annex I of the AI Act.** (Section 1)
- [ ] Questions in relation to **Annex III of the AI Act.** (Section 2)
- [ ] Questions on **horizontal aspects** of the high-risk classification. (Section 3)
- [x] Questions in relation to **requirements and obligations for high-risk AI systems and value chain obligations**. (Section 4)
- [x] Questions in relation to the **need for possible amendments of high-risk use cases in Annex III and of prohibited practices in Article 5**. (Section 5)

Section 4 – Questions in relation to requirements and obligations for high-risk AI systems and value chain obligations

A. Requirements for high-risk AI systems

The AI Act sets mandatory requirements for high-risk AI systems as regards risk management (Article 9), data and data governance (Article 10), technical documentation (Article 11) and record-keeping (Article 12), transparency and the provision of information to deployers (Article 13), human oversight (Article 14), and robustness, accuracy and cybersecurity (Article 15).

Providers are obliged to ensure that their high-risk AI system is compliant with those requirements before it is placed on the market. Harmonised standards will play a key role to provide technical solutions to providers that can voluntarily rely on them to ensure compliance and rely on a presumption of conformity. The Commission has requested the European standardisation organisations CEN and CENELEC to develop standards in support of the AI Act. This work is currently under preparation.

Question 35. Beyond the technical standards under preparation by the European Standardisation Organisations, are there further aspects related to the AI Act's requirements for high-risk AI systems in Articles 9-15 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

Question 36. Are there aspects related to the requirements for high-risk AI systems in Articles 9-15 which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

B. Obligations for providers of high-risk AI systems

Beyond ensuring that a high-risk AI system is compliant with the requirements in Articles 9-15, providers of high-risk AI systems have several other obligations as listed in Article 16 and further specified in other corresponding provisions of the AI Act. These include:

- *Indicate on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable, their name, registered trade name or registered trademark, the address at which they can be contacted;*
- *Have a quality management system in place which complies with Article 17;*
- *Keep the documentation referred to in Article 18;*
- *When under their control, keep the logs automatically generated by their high-risk AI systems as referred to in Article 19;*
- *Ensure that the high-risk AI system undergoes the relevant conformity assessment procedure as referred to in Article 43;*
- *Draw up an EU declaration of conformity in accordance with Article 47;*
- *Affix the CE marking to the high-risk AI system, in accordance with Article 48;*
- *Comply with the registration obligations referred to in Article 49(1);*
- *Take the necessary corrective actions and provide information as required in Article 20;*
- *Cooperate with national competent authorities as required in Article 21;*
- *Ensure that the high-risk AI system complies with accessibility requirements in accordance with Directives (EU) 2016/2102 and (EU) 2019/882.*

Question 37. Are there aspects related to the AI Act's obligations for providers of high-risk AI systems for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

Question 38. Are there aspects related to the obligations for providers of high-risk AI systems which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

C. Obligations for deployers of high-risk AI systems

Article 3(4) defines a deployer as a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity.

Deployers of high-risk AI systems have specific responsibilities under the AI Act. Transversally, Article 26 obliges all deployers of high-risk AI systems to:

- *Take appropriate technical and organisational measures to ensure that AI systems are used in accordance with the instructions accompanying the AI systems;*
- *Assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support;*
- *Ensure that input data is relevant and sufficiently representative in view of the intended purpose of the high-risk AI system;*
- *Monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72;*
- *Keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system of at least six months.*

Additionally, Article 26 foresees the following obligations in specific cases:

- *For high-risk AI system at the workplace, deployers who are employers shall inform workers' representatives and the affected workers that they will be subject to the use of the high-risk AI system;*
- *Specific authorization requirements and restrictions apply to the deployer of a high-risk AI system for post-remote biometric identification for law enforcement purposes;*
- *Deployers of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to natural persons shall inform the natural persons that they are subject to the use of the high-risk AI system.*

Question 39. Are there aspects related to the AI Act's obligations for deployers of high-risk AI systems listed in Article 26 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

If no legislative measure on liability is taken, the market will growth with legal uncertainty creating risks to patients and doctors using medical devices with AI systems. There needs to be trust and clear definition of roles and responsibilities in relation to the products with self-learning capabilities. A doctor that uses an AI system according to the training provided and in adherence with the instructions and guidelines, he/she should be fully indemnified against adverse outcomes. He/she cannot be held liable for the default of the machine, otherwise

the incentive for using new and innovative systems will perish. New rules are needed to address liability for self-learning algorithms and to clearly identify who is responsible for what.

Question 40. Are there aspects related to the obligations for deployers of high-risk AI systems listed in Article 26 which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

Moreover, according to Article 27, deployers of high-risk AI systems that are bodies governed by public law, or are private entities providing public services, and deployers of high-risk AI systems referred to in points 5 (b) and (c) of Annex III, shall perform an ***assessment of the impact on fundamental rights*** *that the use of such system may produce. The AI Office is currently preparing a template that should facilitate compliance with this obligation.*

Article 27 specifies that where any of its obligations are already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

Question 41. Are there aspects related to the AI Act's obligations for deployers of high-risk AI systems for the fundamental rights impact assessment for which you would seek clarification in the template?

3000 character(s) maximum

AI systems used for determining insurance premium can pose a risk of harm to health and safety or a risk of adverse impact on fundamental rights of patients. The proliferation of data about patients/citizens allows insurers to consider a wider array of personal and behavioural data, including genetic data where citizens have no control, making it easier to identify high-risk characteristics in individuals, resulting in refusing insurance cover or increasing prices of insurance policies (ex. premiums for home insurance policies in the Netherlands increasing considerably). 3 It also facilitates 'cherry-picking' of low-risk citizens and is thus discriminatory. AI systems used for assessing medical treatments can pose a risk of harm to health and safety or a risk of adverse impact on fundamental rights of users. There are cases of misdiagnosis or underdiagnosis.

Question 42. In your view, how can complementarity of the fundamental rights impact assessment and the data protection impact assessment be ensured, while avoiding overlaps?

3000 character(s) maximum

In case of complaints, medical regulators need to have access to the algorithm, while respecting trade secrets. This provision needs to be reinstated.

Finally, deployers of high-risk AI systems may have to provide an explanation to an affected person upon their request. This right is granted by Article 86 AI Act to affected persons which are subject to a decision,

which is taken on the basis of the output from a high-risk AI system listed in Annex III and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights.

Question 43. Are there aspects related to the AI Act's right to request an explanation in Article 86 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

D. Substantial modification (Article 25 (1) AI Act)

Article 3 (23) defines a substantial modification as a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider. As a result of such a change, the compliance of the AI system with the requirements for high-risk AI systems is either affected or results in a modification to the intended purpose for which the AI system has been assessed.

The concept of 'substantial modification' is central to the understanding of the requirement for the system to undergo a new conformity assessment. Pursuant to Article 43(4), the high-risk AI system should be considered a new AI system which should undergo a new conformity assessment in the event of a substantial modification.

This concept is also central for the understanding of the scope of obligations between a provider of a high-risk AI system and other actors operating in the value chain (distributor, importer or deployer of a high-risk AI system). Pursuant to Article 25, any distributor, importer, deployer or other third-party shall be considered to be a provider of a high-risk AI system and shall be subject to the obligations of the provider, in any of the following circumstances:

(a), they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are otherwise allocated;

(b), they make a substantial modification to a high-risk AI system that has already been placed on the market or has already been put into service in such a way that it remains a high-risk AI system;

(c), they modify the intended purpose of an AI system, including a general-purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system.

Question 44. Do you have any feedback on issues that need clarification as well as practical examples on the application of the concept of 'substantial modification' to a high-risk AI system.

3000 character(s) maximum

Article 43(4) second sentence describes the circumstances under which the change does not qualify as a substantial modification: 'For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.'

Question 45. Do you have any feedback on issues that need clarification as well as practical example of pre-determined changes which should not be considered as a substantial modification within the meaning the Article 43(4) of the AI Act.

3000 character(s) maximum

E. Questions related to the value chain roles and obligations

Throughout the AI value chain, multiple parties contribute to the development of AI systems by supplying tools, services, components, or processes. These parties play a crucial role in ensuring the provider of the high-risk AI system can comply with regulatory obligations. To facilitate compliance with regulatory obligations, Article 25(4) require these parties to provide the high-risk AI system provider with necessary information, capabilities, technical access and other assistance through written agreements, enabling them to fully meet the requirements outlined in the AI Act.

However, third parties making tools, services, or AI components available under free and open-source licenses are exempt from complying with value chain obligations. Instead, providers of free and open-source AI solutions are encouraged to adopt widely accepted documentation practices, such as model cards and datasheets, to facilitate information sharing and promote trustworthy AI.

To support cooperation along the value chain, the Commission may develop and recommend voluntary model contractual terms between providers of high-risk AI systems and third-party suppliers.

Question 46. From your organisation's perspective, can you describe the current distribution of roles in the AI value chain, including the relationships between providers, suppliers, developers, and other stakeholders that your organisation interacts with?

3000 character(s) maximum

Question 47 Do you have any feedback on potential dependencies and relationships throughout the AI value chain that should be taken into consideration when implementing the AI Act's obligations, including any upstream or downstream dependencies between providers, suppliers, developers, and other stakeholders, which might impact the allocation of obligations and responsibilities between various actors under the AI Act? In particular, indicate how these dependencies affect SMEs, including start-ups.

3000 character(s) maximum

Question 48. What information, capabilities, technical access and other assistance do you think are necessary for providers of high-risk AI systems to comply with the obligations under the AI Act, and how should these be further specified through written agreements?

3000 character(s) maximum

Benchmarking guidelines on the content of the agreements between providers and users are needed as there could be enormous imbalances in terms of knowledge between parties leading to unfair practices in the market. Guidance on which obligations and how each party should comply with, in particular on offering adequate training on AI techniques and approaches to users of AI systems prior to their use in the healthcare environment, should be provided. These guidelines would support the development of digital skills and capacity building of users in relation to new technologies.

Question 49. Please specify the challenges in the application of the value chain obligations in your organisation for compliance with the AI Act's obligations for high-risk AI systems and the issues for which you need further clarification; please provide practical examples.

1500 character(s) maximum

Section 5. Questions in relation to the need for possible amendments of high-risk use cases in Annex III and of prohibited practices in Article 5

Pursuant to Article 112(1) AI Act, the Commission shall assess the need to amend the list of use cases set out in Annex III and of the list of prohibited AI practices laid down in Article 5 by 2 August 2025 and once a year from then onwards.

The Commission is empowered to adopt delegated acts to amend Annex III by adding or modifying use-cases of high-risk AI systems pursuant to Article 7(1) AI Act. The findings of the assessment carried out under Article 112(1) AI Act are relevant in this context. The empowerment to amend Annex III requires that both of the following conditions are fulfilled:

- *the AI systems are intended to be used in any of the areas listed in Annex III and*

- *the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.*

Article 7(2) AI Act further specifies the criteria that the Commission shall take into account in order to evaluate the latter condition, including:

(a) the intended purpose of the AI system;

(b) the extent to which an AI system has been used or is likely to be used;

(c) the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;

(d) the extent to which the AI system acts autonomously and the possibility for a human to override a decision or recommendations that may lead to potential harm;

(e) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect multiple persons or to disproportionately affect a particular group of persons;

(f) the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports or documented allegations submitted to national competent authorities or by other reports, as appropriate;

(g) the extent to which persons who are potentially harmed or suffer an adverse impact are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

(h) the extent to which there is an imbalance of power, or the persons who are potentially harmed or suffer an adverse impact are in a vulnerable position in relation to the deployer of an AI system, in particular due to status, authority, knowledge, economic or social circumstances, or age;

(i) the extent to which the outcome produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;

(j) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;

(k) the extent to which existing Union law provides for:

- effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;

- effective measures to prevent or substantially minimise those risks.

Question 50. Do you have or know concrete examples of AI systems that in your opinion need **to be added to the list of use cases in Annex III, among the existing 8 areas, in the light of the criteria and the conditions in Article 7(1) and (2)** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

If so, please specify the concrete AI system that fulfils those criteria as well as evidence and justify why you consider that this system should be classified as high-risk.

3000 character(s) maximum

Certain AI systems used for emotion recognition and behaviour cannot be deployed without clear validation as there can be misuse leading to discrimination and harm (e.g. AI systems on emotion recognition for alcohol addiction, violent behaviour, potential misbehaviour which can be used in health research).

Question 51. Do you consider that some of the use cases listed in Annex III require adaptation in order to fulfil the conditions laid down pursuant to Article 7(3) AI Act and should therefore **be amended** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

- Yes
- No

Question 52. Do you consider that some of the use cases listed in Annex III no longer *fulfil* the conditions laid down pursuant to Article 7(3) AI Act and should therefore **be removed from the list of use cases in Annex III** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

- Yes
- No

Pursuant to Article 112(1) AI Act, the European Commission shall assess the need for amendment of the list of prohibited AI practices laid down in Article 5 once a year. In order to gather evidence of potential needs for amendments, respondents are invited to answer the following questions.

Question 53. Do you have or know concrete examples of AI practices that in your opinion contradict Union values of respect for human dignity, freedom, equality and no discrimination, democracy and the rule of law and fundamental rights enshrined in the Charter and for which there **is a regulatory gap because they are not addressed by other Union legislation**?

If so, please specify the concrete AI system that fulfils those criteria and justify why you consider that this system should be prohibited and why other Union legislation does not address this problem.

3000 character(s) maximum

Question 54. Do you consider that some of the prohibitions listed in Article 5 AI Act are already sufficiently addressed by other Union legislation and should therefore **be removed from the list of prohibited practices in Article 5 AI Act**?

- Yes
- No

Contact

Contact Form