

Stakeholder consultation on the Draft Guidelines on the classification of high-risk AI systems under Article 6 of the AI Act

Fields marked with * are mandatory.

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Disclaimer: This document is a working document of the AI Office for the purpose of consultation and does not prejudice the final decision that the Commission may take on the final guidelines. The responses to this consultation paper aim to provide relevant stakeholder input to the Commission when finalising 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 and the citizens.

The Artificial Intelligence Act (the 'AI Act'), 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. 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 AI Act distinguishes between two categories of AI systems that are considered as 'high-risk', as 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 use-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 Act.

With the [AI Omnibus](#) the entry into application of the requirements and obligations for high-risk AI systems under Article 6(2) and Annex III will be postponed to 2 December 2027. As regards the AI systems under Article 6(1) and Annex I the rules will apply from 2 August 2028. Other changes introduced to the classification rules under Article 6(1) and the definition of a 'safety component' are considered in the draft guidelines.

The draft Guidelines relate exclusively to the classification of high-risk AI systems. Further guidance from the Commission will follow, as indicated in the list of forthcoming guidelines published under: [Supporting the implementation of the AI Act with clear guidelines | Shaping Europe's digital future](#).

The draft Guidelines are prepared pursuant to Article 6(5) AI Act and focus on the rules for the high-risk classification. It is further required that these draft 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.

These draft Guidelines take into account the outcome of a stakeholder consultation organised by the Commission in June-July 2025 and input provided by the Member States in the context of the European Artificial Intelligence Board ('AI Board').

In addition to the written consultation process, the AI Office organised a series of targeted stakeholder workshops in December 2025 in order to gather further practical and sector-specific feedback on the draft Guidelines.

To complement these discussions and ensure the inclusion of a broad range of stakeholders, including representatives from industry, academia, civil society, public authorities and other relevant organisations, the AI Office also circulated a follow-up questionnaire aimed at collecting additional written input on specific aspects of the high-risk classification framework and its practical application.

On the basis of this input, the Commission prepared the draft guidelines which are now open for stakeholder feedback.

This second consultation accompanies the draft Guidelines on the classification of high-risk AI systems under Article 6 AI Act that aim to support consistent interpretation and effective implementation of the AI Act classification rules for high-risk AI systems across the EU.

This consultation seeks to collect targeted feedback on the clarity, completeness and practical usability of the draft Guidelines prepared by the Commission based on broad stakeholder input.

In particular, the Commission seeks feedback on whether the explanations, methodologies and examples provided sufficiently support stakeholders in determining whether an AI system qualifies as high-risk under the AI Act.

The draft Guidelines address the classification of high-risk AI systems in accordance with Article 6 AI Act and are structured as follows:

- **Section I** presents an introduction outlining the purpose, scope and legal context of the draft Guidelines. It recalls the objectives and risk-based structure of the AI Act, situates the concept of high-risk AI systems within that framework, and explains the legal basis and role of the draft Guidelines pursuant to Article 6(5) AI Act.
- **Section II** sets out general principles for the classification of high-risk AI systems, including the requirement that the system qualifies as an AI system and the role of the intended purpose for its classification.
- **Section III** explains the classification of high-risk AI systems under Article 6(1) AI Act and Annex I, including the key elements (such as the notion of a safety component and third-party conformity assessment).
- **Section IV** addresses the classification of high-risk AI systems under Article 6(2) AI Act and Annex III, including:

horizontal issues applicable across Annex III use cases (such as human involvement, the “intended to be used” criterion, and the interaction with national and EU law);

the application of the filter mechanism under Article 6(3) AI Act, including its conditions, exceptions, and safeguards;

detailed guidance on each high-risk use case listed under the eight areas in Annex III (biometrics; critical infrastructure; education and vocational training; employment; access to essential private and public services; law enforcement; migration, asylum and border control management; and administration of justice and democratic processes).

- **Section V** explains the transitional and grandfathering provisions of the AI Act, clarifying the entry into application of the high-risk AI system requirements and the conditions under which AI systems placed on the market or put into service before the relevant application dates remain subject to the new obligations.

All participants are invited to provide feedback on the particular sections of the draft Guidelines they are

interested in. In particular, respondents are encouraged to focus on:

- whether specific sections or subsections require further clarification or refinement to ensure effective implementation and compliance; and
- whether additional or current examples or use-cases should be included or excluded, taking into account the legal provisions of the AI Act.

The feedback collected through this consultation will support the Commission in refining and finalising the draft Guidelines, with the objective of ensuring they are clear, comprehensive, and practically useful for all stakeholders involved in the development, deployment and supervision of AI systems under the AI Act.

As not all sections may be relevant for all stakeholders, respondents may reply only to the section(s) they would like. Respondents are encouraged to provide **explanations and practical cases** as part of their responses to support the practical usefulness of the draft Guidelines. We kindly ask that the respondents to specify the exact section and paragraph of the draft Guidelines to which their comments refer.

The consultation also aims to collect input for the annual review of the list of prohibitions (Article 5 AI Act) and the high-risk use cases in Annex III AI Act to inform the Commission review pursuant to Article 112(1) AI Act.

The targeted consultation is available in **English only** and will be **open for 5 weeks starting on 19 May until 23 July 2026 (22:00 CET)**.

All contributions to this consultation may be made publicly available. Therefore, please do not share any personal or confidential information in your contribution (your written feedback). It is your responsibility to avoid personal data and any reference in your written feedback itself that would reveal your identity.

For information on how the Commission processes your personal data please read our Privacy Statement

[20250122_Public_Consultation_classification_of_high-risk_AI_systems_PrivacyStatement.pdf](#)

Information about the respondent

* First name

Kwinten

* Surname

Van Hoecke

* Email address

kwinten@esmond.be

* Do you agree that we may publish your identity together with your contribution 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 respondent category that you selected for this consultation, your answer regarding residence, and your contribution may be published as received. Should you choose to remain anonymous, 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 the following organisation details may be published: The respondent category that you selected for this consultation, 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 as received. Should you choose to remain anonymous, your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- ☒ Yes
☐ 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

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

- ☒ Organisation
☐ In a personal capacity

* If you are representing an organisation, please specify the name of the organisation:

Ramirez BV

* Type of organisation

Company

* 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 |
| ☐ Healthcare | ☐ Energy | ☐ Others |

* Describe the activities of your organisation or yourself

1300 character(s) maximum

Ramirez BV is a Belgian company providing AI-generated formative feedback on academic writing to students in Belgium, the Netherlands and Italy. Our system ('Esmond'; <https://esmond.be>) is evaluative, never generative: it reads a draft the student has already written and returns critical feedback on argumentation, use of sources and methodology. It does not write, rewrite or produce text on the student's behalf.

Three design choices define our intended purpose. The system is used by students on their own initiative and at their own expense, not provided or required by their educational institution. It produces no grade, score, score band or predicted mark; this is enforced in the system itself, not merely in our terms. And the assessors' judgement remains entirely independent: they neither see nor rely on our output.

We are a provider of an AI system built on general-purpose models accessed via API.

Our interest in these Guidelines is the boundary drawn in Section IV between summative and formative evaluation of learning outcomes, which determines the classification of our category of tools.

* **On which part(s) of the draft Guidelines would like comment?** *Multiple answers are possible. Please note that selecting a particular answer will direct you to a set of questions specifically related to subject specified.*

- ☐ **General principles for classification of high-risk AI systems under Article 6.** (Section II)
- ☐ **High-risk classification according to Article 6(1) – Annex I.** (Section III)
- ☒ **High-risk classification according to Article 6(2) – Annex III.** (Section IV)
- ☐ **Questions in relation to Article 112 paragraph 1 (Evaluation and Review)**

High-risk classification according to Article 6(2) – Annex III (Section IV of the draft Guidelines)

Select the relevant subsection(s):

- ☐ IV.1 Rationale and approach
- ☐ IV.2 Horizontal issues applicable to Annex III use cases
- ☒ IV.3 High-risk AI systems in the areas of Annex III

IV.3 High-risk AI systems in the areas of Annex III

Please select the sector(s) you wish to comment on. *Multiple answers are possible*

- ☐ 3.1 Biometrics
- ☐ 3.2 Critical infrastructure
- ☒ 3.3 Education and vocational training
- ☐ 3.4 Employment, workers' management and access to self-employment
- ☐ 3.5 Access to and enjoyment of essential private services and essential public services and benefits
- ☐ 3.6 Law enforcement
- ☐ 3.7 Migration, asylum and border control management
- ☐ 3.8 Administration of justice and democratic processes

3.3 Education and vocational training

Question A. Are there any aspects / sections / paragraphs of this Section of the draft Guidelines that you believe require further clarification, and if so, how would you suggest they be improved to ensure effective implementation and compliance?

- ☒ Yes
- ☐ No
- ☐ N/A

Relevant paragraph number

Only values of at most 1000 are allowed

223

Please specify

500 character(s) maximum

Para 223 limits point 3(b) to evaluation "towards a final decision based on a summative assessment". Unclear: does this catch formative feedback a student voluntarily seeks on a draft that is LATER assessed by the institution (e.g. a thesis draft)? Suggested: "The fact that work on which formative feedback is given may subsequently be subject to a summative assessment does not, in itself, bring the system within point 3(b), provided the output is not used by the institution in that assessment."

Do you have more suggestions?

- ☒ Yes
☐ No

Question A. Are there any aspects / sections / paragraphs of this Section of the draft Guidelines that you believe require further clarification, and if so, how would you suggest they be improved to ensure effective implementation and compliance?

- ☒ Yes
☐ No
☐ N/A

Relevant paragraph number

Only values of at most 1000 are allowed

223

Please specify

500 character(s) maximum

We suggest para 223 name the decisive criteria: WHO INITIATES the use (the student, or the institution) and WHO DECIDES the outcome (the examiner independently, or the system). Where the student initiates and the assessors neither see nor rely on the output, the system is outside the summative chain. Any other reading would make a spellchecker or a writing tutor high-risk merely because the text is eventually graded, which cannot be the intention and would be disproportionate.

Do you have more suggestions?

- ☒ Yes
☐ No

Question A. Are there any aspects / sections / paragraphs of this Section of the draft Guidelines that you believe require further clarification, and if so, how would you suggest they be improved to ensure effective implementation and compliance?

- ☒ Yes
☐ No
☐ N/A

Relevant paragraph number

Only values of at most 1000 are allowed

215

Please specify

500 character(s) maximum

Para 215 states that systems within point 3 should always be classified as high-risk where they perform profiling, even if Article 6(3) applies. Please clarify that para 215 operates only AFTER a system is found to fall within point 3. A system that remains outside 3(b) under paras 224–225 is not brought back within scope by para 215.

Do you have more suggestions?

- ☐ Yes
- ☒ No

Question B. Do you think there are additional examples or use-cases , relevant for this Section of the draft Guidelines, that you find important that the Guidelines include or exclude from the scope of high-risk classification, taking into account the legal provisions in the AI Act? If so, please explain why you think they should be treated as such, in order to help the Commission refine the draft Guidelines and ensure they are comprehensive.

- ☒ Yes
- ☐ No
- ☐ N/A

If so:

- a) please explain why do you think they should be treated as such and
- b) if your suggested example(s) or use case(s) are to be considered as in or out of scope.

2500 character(s) maximum

We suggest one addition. We consider the example OUT of scope of point 3(b):

"An AI system that a student chooses to use, at their own initiative and expense, to obtain critical feedback on a draft of their own written work before submitting it. The system does not produce a grade, score or predicted mark, is not required or provided by the educational institution, is not visible to the assessors, and does not lead to any credential or recognised validation. The examiner's assessment remains entirely independent. Such a system supports the learning process and falls outside point 3(b)."

Why it should be out of scope:

1. It meets every condition para 225 already states: the student's own volition, no institutional requirement, no recognised credential. The reasoning is the Commission's own. We only ask that it be made visible for a category beyond language learning.
2. It does not engage the rationale in Recital 56. The concern there is systems that "may determine the educational and professional course of a person's life". A system that produces no grade, that the institution never sees, and that precedes an independent human judgement does not determine that course. It strengthens the student's own capacity before the assessment takes place.
3. The existing example is a language tool, which some readers may treat as a narrow case about mechanical correction. The broader and growing category is student-initiated evaluative feedback on substantive written work: systems that read what the student has already written and return critical commentary, without writing anything on the student's behalf. Where genAI produces work for the student, these systems evaluate work the student produced. Leaving this implicit creates avoidable uncertainty for European providers in precisely the segment that reinforces, rather than substitutes, student learning.

One observation relevant to para 12. That paragraph rightly warns that a limitation asserted only in terms of service is insufficient where the provider's overall presentation permits or promotes high-risk use. We support that strict line. It would help if the final text also recognised the converse: a limitation enforced in the system's own design, for example a system architecturally incapable of producing a grade or score band, is a stronger

and more verifiable signal than a contractual clause. Recognising that distinction rewards providers who anchor the limitation technically rather than write it away.

Contact

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