



Council of the European Union
General Secretariat

**Interinstitutional files:
2025/0359 (COD)**

Brussels, 16 December 2025

WK 17396/2025 INIT

LIMITE

**SIMPL
ANTICI
DATAPROTECT
CYBER
TELECOM
CODEC
PROCIV**

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From: General Secretariat of the Council
To: Antici Group (Simplification)

Subject: Omnibus VII: Digital Omnibus on AI – Presentation by the Commission (AGS on 15 December)

Delegations will find enclosed a presentation as prepared by the Commission for the meeting of the Antici Group (Simplification) on 15 December regarding the Digital Omnibus on AI (Omnibus VII).

WK 17396/2025 INIT

LIMITE

EN

PUBLIC



AI OMNIBUS

Q&A session

Antici Group on Simplification

PUBLIC

I. Timeline for high-risk rules (Article 113)

Timeline for high-risk rules (Article 113)

Why the flexible mechanism instead of just moving the initial dates of application?

- Builds on the lessons learnt from the current timeline, which did not match the time required for the implementation processes
- Proposed mechanism allows to link the entry into application of the high-risk rules to the availability of support tools that offer legal certainty
- Nevertheless, the proposed mechanism sets end dates by which the rules apply in any case, which is a safeguard and also provides predictability



Timeline for high-risk rules (Article 113)

Why the choice of Commission decision as legal instrument?

- Under the proposed mechanism, the COM decision confirming the availability of support tools is what triggers the earlier application of the high-risk rules
- If the COM does not take such a decision, the rules apply by a defined date in any case
- Therefore, COM does not receive the mandate to specify the entry into application, its mandate is limited to assessing and confirming that sufficient support tools for the application of the high-risk rules are available
- COM decision neither amends nor supplements (Art. 290 TFEU), nor sets uniform conditions for the implementation (Art. 291 TFEU) of the AI Act, thus alternative instruments were not appropriate for the type of act in question



Timeline for high-risk rules (Article 113)

What are the criteria to trigger the COM decision?

- Proposed Article 113(1)(d) allows COM to assess and confirm the availability of “adequate support measures in support of compliance”
- Relevant measures in support of compliance include harmonised standards, common specifications and COM guidelines (see recital 22)
- COM has requested standards for high-risk requirements with COM decisions C(2023)3215 and C(2025)3871, which cover all aspects for which COM considers that support tools are necessary
- COM will continue to support standardisation process and prepare guidelines for standards with most significant delays a transitional guidance, while standardisation processes to continue



Timeline for high-risk rules (Article 113)

What happens if the standards are not ready by 2 December 2027 or if the support tools become available less than 6 months before?

- COM is preparing guidelines as a transitional instrument to bridge the gap to allow standardisation processes to continue; targeted publication is well ahead of 2 December 2027
- Important to recall that harmonised standards are voluntary and providers can comply with high-risk obligations without relying on them



Timeline for high-risk rules (Article 113)

Practical matters of proposal and ways to ensure clear and predictable timelines?

- If proposal is agreed, COM will actively communicate on the progress of the preparation of support tools (standards and guidelines)
- 2 June 2027 is an important milestone: if COM has not adopted a decision by then, the 'safeguard' dates of 2 December 2027 will apply (6 months in advance a COM decision to trigger the entry into application no longer makes sense)
- Predictability is ensured through the two end dates of 2 December 2027 (Annex III) and 2 August 2028 (Annex I)

Timeline for high-risk rules (Article 113)

What are the consequences of postponing the applicability of the high-risk chapter III on other rules in the AI Act, e.g. Article 86 AI Act?

- As long as Chapter III Section 1 does not apply, Article 6 does not apply, hence no AI systems is considered as high-risk
- Obligations for providers and deployers of high-risk AI systems outside of Chapter III Sections 1, 2 and 3 (which are affected by the postponement) may already apply, e.g. Article 86, but do not yet have practical effect, because there are not yet any entities subject to those rules



PUBLIC

II. Supervision competences of AI systems (Article 75)

AI Act division of supervisory competences

Market surveillance authorities



AI systems built on
'narrow' AI models



AI systems built on GPAI
models

AI systems
in
VLOP/SEs

Same
provider

GPAI models

AI Office

PUBLIC

Supervision competences of AI systems (Article 75)

Will the AI Office be sufficiently independent for the market surveillance responsibilities? Does the AI Office foresee transition into an agency?

- New enforcement powers do not require transition into an agency; AI Office remains part of COM, which also has enforcement role in other areas of the AI Act (GPAI models) and other areas of law (competition law, other digital laws)
- AI Office is not a market surveillance authority, but has the powers of a market surveillance authority, thus is not subject to the same independence requirements
- Article 74(8) specifies how MS should designate MSAs, not provide for an independence requirement for oversight where the designation is made by the AI Act itself

Supervision competences of AI systems (Article 75)

What resources is the AI Office requesting for this role?

- As set out in Legislative and Financial Digital Statement, COM would require additional 53 FTE for the new mandate, 15 FTE of which can be covered by internal redeployment
- Funding for new FTE proposed to come from support expenditure of Digital Europe Programme (see Legislative and Financial Digital Statement)
- COM estimates that maintaining the tasks at national level would require Member States to allocate aggregate amount of 117 FTE to this supervisory task (p. 80 SWD)
- It is important to clarify that no resources already allocated in Member States are void, as national authorities continue to supervise AI systems and GPAI systems based on GPAI models; AI Office takes over those offered by the same provider and AI systems embedded in VLOP/VLOSE, which are already under COM supervision under the DSA

Supervision competences of AI systems (Article 75)

How is the coordination between the AI Office and other competent authorities foreseen?

- AI Act already covers procedures for the cooperation between market surveillance authorities and the AI Office in Article 74(11), 75(2) and (3) and 88(2); both for general oversight as well as in relation to oversight of AI systems based on GPAI models
- When exercising market surveillance powers, AI Office needs to apply all cooperation duties between MSAs and as regards Article 77 authorities and bodies (e.g. notifications of incidents)
- Proposed new element is the cooperation obligation in last paragraph of Article 75(1), which is intended as assistance of national authorities to COM similar to implementation of competition law (e.g. to carry out on-site investigations)
- COM will be responsible for enforcement according to the measures foreseen in the Market Surveillance Regulation, as specified in an implementing act, with assistance from national authorities where need be
- Important to recall that AI Office is part of the Commission, which is also the regulatory authority for the DSA and DMA, thus cooperation is ensured

PUBLIC

III. AI literacy (Article 4)

AI literacy (Article 4)

How does the proposed change improve legal certainty of providers and deployers?

- There is no longer a binding obligation on deployers and providers of AI systems; the previous obligation was vaguely formulated ('sufficient level of AI literacy') and yet subject to possible fines in case of non-compliance
- Change does not affect existing AI literacy programmes, because providers and deployers continue to be encouraged to take measures that ensure AI literacy among their staff members

AI literacy (Article 4)

PUBLIC

What is the obligation of Member States? How is it measured?

- New Article 4 would contain an obligation for both COM and Member States, similar to existing obligations in the AI Act (e.g. Article 95)
- Recital 5 offers examples of measures that COM and Member States would be expected to take to encourage that providers and deployers of AI systems ensure a sufficient level of AI literacy: “offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives”
- Recital 5 proposes the AI Board as a cooperation mechanism between the COM and Member States, which can also serve as a mechanism to monitor the implementation



AI literacy (Article 4)

How can divergent interpretations and fragmentation across Member States be prevented?

- Recital 5 proposes the AI Board as a cooperation mechanism between the COM and Member States, to align approaches and ensure a coherent application

PUBLIC

IV. Processing special categories of data for bias detection and mitigation (Article 4a)

Processing special categories of data for bias detection and mitigation (Article 4a)

What are the conditions to use this legal basis? Which use-cases fall under the new Article 4a?

- While the scope of the legal basis is extended to AI models and systems that are not high-risk, the conditions referred to in Article 4a(1) remain aligned with the current Art 10(5)
- The practical value: bias detection and correction is relevant for all AI systems and models and by extending the legal basis, we are facilitating bias detection and correction in compliance with EU data protection laws for all providers and deployers.
- Examples of non-high-risk AI systems for which the proposed legal basis is relevant: customer-service chatbots, online content-moderation systems and recommender systems



Processing special categories of data for bias detection and mitigation (Article 4a)

Why has the COM changed the requirement "strictly necessary" to "necessary" in the proposed Article 4a(1)(f)?

- This aligns the with threshold under the existing provision in Article 9(2)(g) GDPR for processing special categories of personal data
- Strong safeguards to avoid abuse and hold companies accountable remain in place as already agreed in the AI Act

Processing special categories of data for bias detection and mitigation (Article 4a)

How should the MSAs proactively and reactively monitor the provider or deployer relying on this legal basis?

- Article 4a is primarily an enabling measure for safeguarding fundamental rights and does not imply that MSAs must proactively scan all AI systems/models
- Compliance with the Article 4a conditions will be checked where relevant, using their existing powers to request documentation and evidence
- Data protection authorities will in any case remain competent to supervise the processing of special categories of data under EU data protection law

PUBLIC

V. Registration of 'filtered' AI systems (Articles 6, 49)

Registration of 'filtered' AI systems (Articles 6, 49)

What is the COM's estimate of the administrative burden or cost savings for companies resulting from this change?

- Estimated cost savings for companies for the proposed measures are in the accompanying Staff Working Document (p. 78 onwards)
- Importantly, it also reduces compliance risk by ensuring that providers whose systems are exempt cannot be held accountable for failing to register



Registration of 'filtered' AI systems (Articles 6, 49)

How can the MSAs monitor the decision that a 'filter' applies? How to prevent circumvention?

- There are two safeguards which are strong deterrents from an abusive application of the filter:
 - Providers need to document why they are applying the exemption (Art 6(4)) and that documentation may need to be provided to authorities
 - There is a special procedure in Article 80 that allows authorities to override the exemption from high-risk classification and impose fines if the 'filter' has been used to circumvent the rules
- Anyone suspecting non-compliance or circumvention of the high-risk rules can make complaints under Article 85
- In order to apply the filter, the provider's documentation should explain, at minimum, how each of the required condition in Article 6(3) is met

PUBLIC

VI. AI Regulatory Sandboxes (Article 57)

AI Regulatory Sandboxes (Article 57)

Do the amendments on regulatory sandboxes, particularly in Article 57(13) and (14), expand the obligations and costs for Member States' sandboxes?

- The amendments in Article 57 (13) and (14) are proposed to encourage a cooperation-driven approach to sandboxes. They are not intended to create additional obligations for MS to participate in cross-border or jointly operated sandboxes.



AI Regulatory Sandboxes (Article 57)

Does the amendment in Article 58(1) have an impact on the timeline of the implementing act on AI sandboxes?

- Change to the empowerment in Article 58(1) will allow the implementing act to cover governance questions of AI regulatory sandboxes in the future
- Does not impact the timeline of the current draft implementing regulation, which is already under consideration of the AI comitology committee
- If amendment is approved, the 'current' implementing act could be extended through an amendment

AI Regulatory Sandboxes (Article 57)

What is the expected scope of the EU sandbox? Who are the other authorities involved in the EU sandbox?

- Scope of the EU sandbox is limited to AI systems under exclusive supervision of the AI Office, i.e. referred to in Article 75(1) – that is, AI systems based on general-purpose AI models (offered by the same provider) and AI systems that constitute or that are integrated into VLOPs or VLOSEs
- Thus, scope does not overlap with that of the national AI regulatory sandboxes
- As the EU sandbox is established to support compliance with the AI Act, the intention is not to assess other rules as may be applicable for the providers
- However, considering the intersection between the AI Act and other legislation, then involving other authorities may be relevant – such as the European supervisors for product safety legislation referred to in Annex I of the AI Act



AI Regulatory sandboxes (Article 57)

How will the co-operation framework for facilitating cross-border cooperation between national competent authorities as well as between the EU sandbox and MS sandboxes work?

- This can be discussed and developed between COM and the MS in the AI Board, where there is already a standing cooperation on AI regulatory sandboxes



AI Regulatory sandboxes (Article 57)

Considering the scope of the EU sandbox, does this mean that there is no requirement for MS to have a sandbox for general-purpose AI?

- Member States remain obliged to establish an AI regulatory sandbox by 2 August 2026 according to Article 57(1), which should ensure that prospective providers of AI systems have broad and equal access
- AI regulatory sandboxes should be set up for AI systems under the supervision of the Member States' competent authorities
- However, national sandboxes cannot cover AI systems referred to in Article 75(1), which are under the exclusive supervision of the AI Office
- For avoidance of doubt: there are general-purpose AI systems that do not fall under Article 75(1) and for which Member States can set up AI regulatory sandboxes

PUBLIC

VII. Real-world testing of high-risk AI systems (Articles 60, 60a)

Real-world testing (Articles 60, 60a)

Under the proposed Article 60a, how would the testing plans be evaluated and the testing supervised? What is the role of the existing market surveillance authorities?

- Concrete supervision model would be set out in the written voluntary real-world testing agreements
- Criteria for assessing testing plans and the supervision conditions would therefore be expected to be specified in that agreement
- This allows for the necessary flexibility to account for the sectoral rules and ensure the participation of the relevant competent authorities

PUBLIC

VIII. Conformity assessments & notified bodies

Transitional period for notified bodies (Article 43(3))

How does the transition period work, are sectoral notified bodies automatically considered competent to assess AI and who supervises them?

- Notified bodies could rely on the transitional period proposed in Art 43(3) if they meet the AI Act's requirements for notified bodies in Art 31(4), (5), (10) and (11)
- Sectoral notified bodies need to apply to their sectoral notifying authority to be able to rely on the transitional period; no designation is required under the AI Act and no re-designation under sectoral law, but sectoral notifying authority needs to make an assessment that the additional requirements for AI are fulfilled

Including Article 17 in conformity assessment (Article 43(3))

How can conformity assessments cover the quality management system, in particular as regards high-risk AI systems covered by legislation under Annex I that does not require a quality management?

- Article 17 is one of the AI Act's essential requirements for high-risk AI systems; COM proposal is a clarification of the legal text to confirm that Article 17 must be checked during the conformity assessment
- Conformity assessments of Annex I products covering high-risk AI systems must cover all essential requirements of the AI Act, including Article 17
- References in other parts of the text clearly show that Article 17 AI Act is intended to be covered by the conformity assessment, for example Article 43 Act refers to Annex VII (Conformity assessment based on assessment of quality management systems and assessment of technical documentation)
- COM has requested a standard to be developed for the quality management system (C(2025)3871), which will facilitate conformity assessments



NANDO Codes

What is the scientific basis or internationally standardised approach for the NANDO codes?

- Technical experts were involved in developing the proposed codes
- Key considerations for the approach were:
 - infrastructure necessary to assess conformity (for example, symbolic AI will require standard servers and low compute while GPAI will require high compute and large GPU clusters), and
 - categories of professional skills required to assess conformity

NANDO Codes

What would be the interim arrangements for the notifications? Would it be possible to proceed with notifications in the absence of the codes — potentially on a provisional basis?

- COM proposes to pre-emptively start the notification process based on the new codes (potentially after further discussion in the AI board subgroup on the notifying authorities).
- Adopting the codes on a provisional basis based on country-specific codes or no codes can result in legal uncertainty for conformity assessment bodies and providers

Single application procedure for notified bodies (Article 28, 29)

Is the single application procedure conditional on such a possibility under sectoral law? Can MS still designate a notifying authority other than the existing sectoral one?

- Applies only where such a single application and single assessment procedure is also foreseen in sectoral law (under consideration for the amendment of some sectoral laws)
- Single assessment procedure is optional and applies only in some sectors, thus Member States still need to designate notifying authority/ies for the AI Act

PUBLIC

IX. Extending regulatory privileges to SMEs (Article 63) and SMCs (Articles 11, 17, 70, 95, 96, 99)

Extending regulatory privileges to SMEs (Article 63) and SMCs (Articles 11, 17, 70, 95, 96, 99)

Could Article 63 be extended universally to all enterprises? Is there a risk of distortion of competition?

- Quality management system in Article 17 is an essential high-risk requirement, by default, providers of high-risk AI systems need to ensure compliance of their high-risk AI system with it
- Article 17(2) already allows that the quality management system acknowledges size of the company
- COM proposes to extend simplified compliance pathway in Article 63(1) from microenterprises to SMEs, because compliance is challenging for all SMEs and requires targeted support
- ‘provided that they do not have partner enterprises or linked enterprises within the meaning of this Recommendation’, initially intended as a safeguard for circumvention, is no longer necessary
- If Article 63(1) applies to all SMEs as defined in 2003/361/EC, for the calculation of which partner or linked enterprises must be considered according to Article 3 of that Recommendation, this particular risk of circumvention is no longer relevant

Extending regulatory privileges to SMEs (Article 63) and SMCs (Articles 11, 17, 70, 95, 96, 99)

Simplified compliance pathways depend on COM guidance, will they be available on time? How does COM enable growth of AI-start-ups in Europe?

- Nature of simplified compliance pathways in Article 11, 17 and 63 AI Act has not changed, only the type of company they apply to
- COM will prepare the necessary guidance required by Articles 11 and 63 ahead of the entry into application of those provisions
- COM has launched multiple initiatives to enable innovation and growth of AI-start-ups, relevant recent initiatives are the [AI Continent Action Plan](#) and [Apply AI Strategy](#)
- By way of an example: Apply AI Strategy reinforces the role of the [European Digital Innovation Hubs](#) which are transformed into Experience Centres for AI to become access points to the EU AI innovation ecosystem in particular for SMEs



PUBLIC

X. Transparency (Article 50)

Transparency (Article 50)

What are the Codes of practice referred to in Article 50(7), where are they drawn up and are they relevant for the implementation of the AI Act by market surveillance authorities?

- AI Act already contains the obligation for the AI Office to encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection and labelling of artificially generated or manipulated content
- AI Office has launched the process for the development of this Code of Practice (more information on [dedicated COM webpage](#))
- Relevant for the implementation of the AI Act by market surveillance authorities who oversee the application of Article 50, Member States are therefore closely involved through a dedicated AI Board Subgroup

Transparency (Article 50)

What are the timelines for Article 50? Are there any changes? What is the proposed grace period?

- Application timeline of Article 50 AI Act is not proposed to be changed; under the COM proposal it will continue to apply on 2 August 2026
- COM is delivering on its obligation in Article 50(7) to facilitate the development of a Code of Practice, which is currently under development and foreseen to be available ahead of the entry into application
- COM nevertheless proposes a 6 months grace period for the obligation under Article 50(2) for AI systems which are already on the market (see new para. 4 in Article 111)
- This takes account of the fact that for Article 50(2), which requires to implement technical measures, retroactive application is more challenging and requires more time for adaptation after the Code of practice is completed



PUBLIC

XI. Other topics

Fundamental rights protection authorities (Article 77)

How should the proposed mutual assistance and cooperation work, where there are conflicting rules reducing or blocking information flows?

- Proposed Article 77(1b) provides the legal basis for mutual assistance, including information sharing
- Article 78 AI Act provides strong protection of confidentiality of information and data obtained under the AI Act



Pool of Experts of Scientific Panel (Article 69)

What is the rationale behind the amendments to Article 69(2)? Will the Member States' right to access the expertise change?

- Member States retain the same right to access the pool of experts of the scientific panel under Article 69(1); the conditions for which are also already specified in Article 14 of Commission Implementing Regulation (EU) 2025/454
- Changes affect only the modalities for remuneration fees of the experts for their work, which is proposed to be tied to the costs that are incurred by the COM for employing the experts of the scientific panel



Removal of implementing act for post-market monitoring (Article 72)

Will the COM guidance still cover a template? How will you ensure legal certainty?

- Removal of the implementing act setting out a harmonised template for a post-market monitoring follows strong call by stakeholders to allow more flexibility in implementing the post-market monitoring
- Accordingly, the intention is to provide guidance on what is expected from providers, but not to impose a template for the plan

PUBLIC



© European Union 2025

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

