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From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus VII (Digital Omnibus on AI) - compiled comments (ddl 18/12)

Following the meeting of the AGS on 15 December on the Omnibus VII (part on Digital Omnibus on AI), delegations will find a compilation of additional questions and comments as received from: BE, CZ, DE, IE, EL, IT, HU, AT, PT and FI.

Omnibus VII - Digital Omnibus on AI
MS comments (ddl 18/12/25)

AGS meeting on 15/12/25

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BELGIUM

AI

Exceptional processing of special categories of personal data for bias detection:

- For high-risk AI systems a specific reference to Art. 10.2 (f) and (g) is mentioned and is crucial to delimitate the objective of bias detection : "when bias are likely to **affect the health and safety of persons**, have a **negative impact on fundamental rights** or lead to **discrimination prohibited under Union law**, especially where data outputs influence inputs for future operations". This specific reference is still referred to in the new Art. 4a but limited to high-risk AI systems. Why such a condition is, in the COM proposal, only limited to high-risk AI systems?
- Could COM explain more specifically the regime (purpose, conditions and safeguards) applicable for this exceptional processing of special categories of personal data, on the one hand for high risk AI systems and, on the other hand, for all AI systems? What are the differences and why such differences are provided?

Consistency of the above, and interaction with new art. 9.2 GDPR :

- Art. 4a provides for an exceptional processing of special categories of personal data, as an exception to Article 9.1 GDPR and applies in addition to the safeguards set out in the GDPR.
- The digital omnibus also includes a new exception to the prohibited processing of such categories of personal data for any processing in the context of the development and operation of an AI system. Could this 'broader' exception include the cases referred to in Art. 4a AI omnibus? In such a case, this article 4a shall also respect the conditions referred to in Art. 9.5 (new) that are, on the contrary, much restricter than the conditions provided for in Art. 4a AI omnibus?

AI literacy obligations,

- Other than a complete shift towards national governments and the Commission, do you see any alternative measures to reduce the burdens for European companies that use AI systems?
- Does the Commission intend to provide a clearer definition of "AI literacy"?

Registration requirements (article 6.3 and 6.4 4 AI act)

- How many European companies are concretely affected by this exemption?
- What is the actual reduction in administrative burden for a company, resulting from the removal of the registration requirement?
- Did the Commission consider alternative approaches to reducing compliance burdens while maintaining traceability?

Regarding article 77, authorities protecting fundamental rights would henceforth need to request and get access to documentation from AI providers through the Member State Authority (MSA). However, what happens if the MSA does not receive the requested information from the provider? Would it then fall to the MSA to impose sanctions, even though the documentation was requested under the mandate of the Fundamental Rights Authority? Or would the Fundamental Rights Authority itself be empowered to take enforcement action?

CZECHIA

CZ Questions regarding the Omnibus VII (deadline 18. 12.)

AI OMNIBUS

- We would like to thank for the clarification and examples of possible measures in relation to the obligation for both COM and Member states in encouraging providers and deployers of AI systems to ensure sufficient level of AI literacy. We consider it crucial that it is also **clarified how we intend to measure AI literacy as such.** Is the European Commission planning/considering integration of AI literacy within the Digital Competence Framework for Citizens (DigComp)? Currently, **there is no unified framework at the European level for a closer description of AI literacy**. From our point of view, it **would be appropriate to use DigComp to ensure a uniform approach and methodological basis** for the development of digital competences in the context of using AI systems across Member States.
- In view of that, is the European Commission planning/considering additional wording adjustment of the article No.4 to make it clear that the development of AI literacy could be based on DigComp?

PUBLIC

GERMANY

Questionary on the Omnibus VII Proposal

PUBLIC

Preliminary note: The questions already submitted by GER have not been fully answered yet. We assume that the Commission will answer them. Therefore, we have refrained from resubmitting the same questions. Thus, the following questions should be understood as additional questions.

I. AI

1. Why does the Omnibus contain the required and urgently needed clarifications of the research exemptions in Article 2(6) and in Article 2(8) of the AI Act not as legislative measure, but only as a "further measure to facilitate compliance" through guidance on the practical application of these exemptions? In its position paper, DE called for an expanded research exemption. What is the reason for not having introduced this idea in the AI Omnibus?

IRELAND

IE Comments Digital Omnibus – AI

Following the presentation of Omnibus VII (Digital Omnibus) in the AGS on 12 December, Ireland is submitting the following two points for consideration:

1. IE is still reviewing and considering the proposed amendment to Article 75 of the AI Act, contained in para 25 of the proposal. We are looking at how the roles and responsibilities might be allocated within the proposed new arrangements set out in this proposed amendment and would welcome more detail on this.

2. Could the Commission provide further detail on the proposal of 16 December for a regulation to simplify rules on medical and in vitro diagnostic devices which proposes to amend the AI Act (Article 4 – see supplemental document) and how this might work with the amendments to the AI Act proposed in the digital omnibus?

PUBLIC

GREECE

Subject: The Hellenic Ministry of Digital Governance responses on Omnibus VII (part on AI) - Presidency discussion note for the AGS on 15 December

Question 1: Do Member States agree that there is a need to extend the implementation timelines in the AI Act?

Response: Yes, with the exception of Article 50, which should enter into force as soon as possible.

Question 2: Regarding the mechanism for extension of timelines for high-risk AI-systems as proposed by the Commission in article 1, paragraph 31, litra a, first part, in the Digital Omnibus on AI, Members States are invited to express their preference between the following options setting the direction going forward:

a. Support the mechanism for extending the timelines as put forward by the Commission.
b. Support the mechanism but prefer a stronger role for the Member States/AI Board in assessing whether the support measures are adequate.
c. Prefer a timeline not dependent on the availability of support measures.
d. Prefer another solution. Please elaborate.

Response*: b.*

Question 3: Regarding the length of the extensions of the timelines for high-risk AI-systems as

proposed by the Commission in article 1, paragraph 31, litra a, second part, in the Digital Omnibus on AI to 2 December 2027 for Annex III AI systems and to 2 August 2028 for Annex I AI systems, Members States are invited to express their preference between the following options setting the direction going forward:

a. Support the length of the extensions of the timelines as proposed by the Commission.
b. Prefer longer extensions – if so, how long?
c. Prefer shorter extensions – if so, how short?
d. Prefer another solution. Please elaborate.

Response*: a.*

However, any delay exceeding one year risks rendering the obligations obsolete before they enter into force.

Question 4: In relation to this, do you agree to distinguish in the timelines for Annex I high-risk AI systems and Annex III high-risk AI systems?

Response*: Probably yes. However, in this case, the implementation deadlines for Annex III systems should be shorter, as these systems do not depend to the same extent as Annex I systems on standards and third-party assessment.*

The Special Secretariat for Artificial Intelligence and Data Governance of the MDG personnel remains at your disposal for any further information or clarification.

ITALY

Following the discussion on AI Act, please find hereafter an Italian comment.

*Italy expresses **concern about the amendment to Section 75 of the AI Act, as provided for in Section 1(25) of the proposed Digital Omnibus AI**.*

By granting exclusive supervisory powers over AI systems that integrate general-purpose models (GPAIs) developed by the same provider (e.g. the Copilot service provided by Microsoft) and over AI systems integrated into the so-called Very Large Online Platforms defined in the Digital Services Act (Regulation (EU) 2022/2065), the ability of Member States to exercise oversight of the national market over entities producing systemic impact would be significantly reduced.

This is particularly true in light of current market trends, which see both GPAI model providers and AI system providers engaged in the development of "vertical" AI systems, characterised by the integration of GPAI models into systems applied in specific contexts (e.g. cybersecurity, energy, medicine, finance). This means that in the coming years, such systems will be widely used in sectors that are key to the economy and society, including for the uses described in Annex III of the AI Act.

*

Other comments:

- We do not support the proposed removal of the obligation for providers to register AI systems in the EU database for high-risk systems listed under Annex III, where such systems have been exempted from classification as high-risk pursuant to Article 6(3) of the AI Act. While we acknowledge the objective of reducing administrative burdens for providers of "filtered" AI systems, eliminating this requirement would significantly impair the ability of competent authorities to monitor the actual deployment of these systems and to verify the accuracy of providers' risk assessments, including the possibility of reclassifying them as high-risk under Article 80 where necessary.
  Conversely, the benefit for providers appears negligible, as they would remain subject to the obligation to conduct and document the risk assessment. Should the deletion of the registration requirement be maintained, we recommend replacing it with an obligation for providers of "filtered" AI systems to notify the competent MSA, thereby ensuring that the information required to exercise the powers under Article 80 remains available.

- With reference to the scope of the EU sandbox, in order to avoid overlap with the national AI regulatory sandboxes, when AI systems are built on GPAI models by different providers, is it correct to assume that only the AI systems — and not also the GPAI models on which the systems are based — can be tested within the national sandbox? If an AI system tested in the sandbox relies on a GPAI model, does the testing apply exclusively to the system component, excluding the GPAI model?

HUNGARY

Question on Artifical Intelligence:

Paragraphs 10 (new paragraph 8 of Article 28 AI Act) and 11 (new paragraph 4 of Article 29 AI Act)
How does the Commission consider these proposals for amendments to the single application and assessment system to be enforceable when the national accreditation body under Regulation (EC) No 765/2008 is the designating authority under section 28(2) of the AI Act?

PUBLIC

AUSTRIA

PUBLIC

Austrian questions and comments regarding the Omnibus VII
18 December 2025

Please note that the following comments are of preliminary nature. AT is still analysing the Digital Omnibus and the Digital Omnibus on AI and therefore raises a scrutiny reservation.

ad Digital Omnibus on AI – COM(2025)836 final

Art 1 (AI Act)

Art 1 (4)

- Could Cion explain, how it envisages the improved legal certainty for providers and deployers in terms of AI literacy of the proposed changes and it affects existing AI literacy programmes?
  - Is a harmonised approach to AI literacy envisaged, including a centralised (Union-level) mechanism for knowledge-building?

Art 1 (5)

- Under which concrete conditions would the proposal to allow the processing of personal data for the detection and correction of bias for all providers and operators of AI systems apply, as the phrasing in the proposal ('may apply', 'where necessary and proportionate') is very vague?
- In addition, as this provision would also have to be monitored by one or more market surveillance authorities, how should these market surveillance authorities proactively and reactively monitor all AI systems and even AI models which are not classified as general-purpose AI models? Has the impact of this proposal on the regulatory burden of providers and deployers as well as the administrative burden for competent authorities been assessed?
  - Without standards, bias cannot be effectively addressed or mitigated. In the context of law enforcement authorities (LEAs), who is responsible for detecting and mitigating potential bias, and to what extent is such mitigation required?
- It should be noted that it is not clear if or when LEAs can make use of this provision.

Art 1 (6, 14, 32)

- How can legal certainty for providers and deployers of AI systems be ensured if the registration of high-risk AI systems which are not deemed to be high-risk by providers of these AI systems is eliminated, as the powers of market surveillance authorities remain in place? Furthermore, it remains unclear what exactly a "preparatory task" is. Could Cion provide clarification?
  - Is there a possibility to convert the forthcoming Guidelines on high-risk AI systems into a legally binding instrument, assuming they define "preparatory task" clearly and in a manner recognised as legally authoritative? And if so, will Cion proceed this way?

Art 1 (10)

- Which legal basis provides Cion with a mandate to propose an integration of the assessment of the requirements for conformity assessment bodies seeking notification for the AI Act into the assessment of requirements for other legislation set out in Annex I Section A? This would result in existing notifying bodies having to assess competence requirements for the AI Act and is therefore a matter of the internal organisation of Member States.

Art 1 (10, 18, 20 and 26)

- On which legal basis has Cion based its proposed provisions affecting the internal organisation of Member States, their public authorities and infrastructures?

Art 1 (12 and 33)

- How can negative effects on market actors, in particular the public sector, be prevented in case the dates of entry into application do not change as a result of the Omnibus negotiations?
  - It must be stressed in this context that **notifying authorities cannot notify conformity assessment bodies until NANDO codes are made available to allow registration at EU level**. This means that if

the Omnibus negotiations take longer than August 2026, **market actors will not be able to make use of notified bodies for conformity assessment**, whether as part of their regular conformity assessment procedures in the case of Annex I, as required for law enforcement and other sensitive areas in the case of Annex III point 1, or voluntarily in the absence of harmonised standards in the case of other points of Annex III. **It is strongly encouraged to continue developing the implementing act for the NANDO codes as planned while negotiations for the Omnibus are ongoing in order to ensure a modicum of legal certainty for market actors, including law enforcement**.

- On which scientific basis or using which internationally standardised definitions has Cion developed the technology-specific codes for the notification of conformity assessment bodies (known as NANDO codes)?

Art 1 (13)

- How will the actual assessment of the quality management system be ensured, as the proposed wording of the requirements for integrating the assessment of quality management systems into existing conformity assessment procedures for Annex I does not take into account that some Annex I products do not contain requirements related to quality management?

Art 1 (17)

- How will the involvement of national authorities responsible for the AI Act in the regulatory sandbox for general-purpose AI models and systems be ensured in light of other provisions of the AI Act which call for close cooperation between regulatory sandboxes for the AI Act?

Art 1 (18)

- Which legal basis provides the Cion with a mandate to propose in para 1 (d) to determine the cooperation between national competent authorities involved in the regulatory sandbox via a delegated act (which precludes Member State involvement), which is a matter of the internal organisation of Member States?

Art 1 (19) and (20)

- With the proposed extension of the possibilities for testing under real-world conditions to all sectors listed in Annex I Section B, it appears a competence gap has emerged where existing market surveillance authorities for these sectors would not be able to approve testing plans for testing under real-world conditions (due to a lack of mandate provided by the AI Act). How, in this case, would tests be supervised? According to which criteria should testing plans evaluated and how can the protection objectives set out in Art 1 AI Act be met if these products do not need to comply with any other requirements of the AI Act?
  - By what means does the market surveillance authority responsible for market surveillance authority responsible for law enforcement authorities (LEAs) supervise real-world testing, and at what stage is notification of a potential test required?
- It should be noted that it is not clear how these changes affect LEAs.

Art 1 (20)

- On which legal basis can voluntary testing agreements between Cion and certain Member States compel even those Member States who have not entered into this agreement to ensure e.g. access to physical infrastructure for these tests?
  - E.g. if FR, DE and Cion sign a testing agreement for testing AI systems used within civil aviation, AT would need to ensure that airports will participate in these tests by providing access to their infrastructure; this proposal therefore infringes against the sovereignty of Member States.

Art 1 (21 and 29)

- How will a distortion of competition due to the proposal to not only extend the possibility of applying simplified quality management from micro-enterprises to SMEs and SMCs, but also removing the condition that these companies must not have any partner companies or affiliated companies be prevented?

Art 1 (22)

- How will the right of Member States to access members of the scientific panel, as enshrined in Art 69(1) AI Act be ensured if Cion's obligation to ensure this access is removed?

Art 1 (24)

- How will the proposed guidance improve legal certainty (instead of an implementing act to specify the post-market monitoring plan)?

Art 1 (26)

- Which legal basis provides Cion with a mandate to propose that Art 77 authorities with very strict independence requirements (such as the "Volksanwaltschaft" in AT) would be obliged to inform other authorities about the details of their investigations?

Art 1 (25)

- How will the proposed strengthening of the AI Office's responsibilities be matched in terms of the requirements applied to the AI Office as market surveillance authority, in particular regarding independence?
- Does the AI Office foresee an imminent evolution into an independent agency?
- On which legal basis does the AI Office plan to oversee providers and deployers of high-risk AI systems in the areas of law enforcement, border control, immigration or asylum?

Art 1 (31)

- Has the proposal to determine the entry into application of requirements for high-risk AI systems on the basis of a Commission Decision been assessed in terms of its validity as a legal instrument for such a purpose?
  - If so, which legal basis provides Cion with a mandate to unilaterally specify the entry into application of a broad range of requirements?
- Based on which objective criteria does Cion plan to determine that standards are available for an entry into application to be justified?
- What effect does the focus on the availability of harmonised standards offering a presumption of conformity have on other valid means of compliance, including conformity assessment by notified bodies?
- What are the consequences of postponing the applicability of high-risk AI rules for Art 86 of the AI Act, which is stated in Section 4 (remedies), but which is only applicable for high-risk AI systems as per Annex III?
  - AT sees no need to postpone the applicability of the AI Act. However, there are concerns regarding the effects on innovation-promoting measures (such as real-life testing and regulatory sandboxes) as well as on safeguards for citizens.

Concerning further (non-legislative) measures to facilitate compliance with the AI Act

Reporting

- Cion will draft guidelines on the reporting of serious incidents by providers of high-risk AI systems:
  - Which matters must be reported without undue delay to the AI Office or the market surveillance authority, and what information is reported solely if specifically requested?
  - What are the timelines and recipients for reporting, how will the database with restricted access be established and operated, and what impact will the planned postponement of the applicability of high-risk systems have on this database?

PUBLIC

PORTUGAL

PT questions on Omnibus VII
18.12.2025

I. DIGITAL OMNIBUS ON AI

Incoherence in the Digital Omnibus on AI regarding the legal representation and compliance burdens for non-EU producers subject to the AI Act and EPR obligations (e.g., Waste Framework, EEE Directive, Batteries Regulation)

The Digital Omnibus on AI introduces targeted simplifications to the AI Act to enhance legal certainty and ease administrative burden for operators. However, it fails to address a critical dimension of compliance for producers established outside the Union: the fragmentation of mandatory legal representation across distinct policy domains.

The current legislative framework requires two legally separate representatives for the same product:

- An Authorized Representative (AI Act) (for software safety);
- A Legal Representative for EPR/WEEE (for the "ecovalor" and environmental obligations, as mandated by WEEE Directive Art. 17).

This omission imposes an unnecessary duplication of administrative burdens and fixed costs exclusively on third-country operators, which are not required for competitors established within the EU, thereby creating an unwarranted administrative barrier to market access.

The act of placing a physical product (like Electrical and Electronic Equipment – EEE) incorporating high-risk AI on the EU market triggers concurrent but separate obligations:

Obligation	Legal Basis	Legal Focus	Specific Mandate
I. Safety and AI Conformity	AI Act (Reg. 2024/1689)	Validation of CE Marking, Technical Documentation, Cooperation with the AI Office.	Authorized Representative (AI Act)
II. Environmental/EPR Obligations	WEEE Directive (Art. 17) / National EPR Legislation	Registration, Annual Quantity Declaration, Payment of the Ecovalor.	Legal Representative (EPR/WEEE)

The Digital Omnibus simplifies Column I (AI Act – in blue) but ignores Column II (EPR/WEEE – in green). The Authorized Representative under the AI Act, while mandatory for the non-EU supplier, lacks the legal mandate and powers to fulfill the essential EPR obligations (Ecovalor and declarations), which are of a financial and environmental statistical nature. This perpetuates the dual representation, which is inefficient.

Reinforced operational inefficiency and asymmetry

The WEEE Directive, through Article 17, confirms that the EPR Representative is the legal point of compliance for environmental obligations (including annual market placement declarations and "ecovalor" payment).

This creates administrative burden, as this structural separation forces the non-EU producer to manage two different legal contracts and reporting streams for the same physical product: one to the Market Surveillance Authorities (AI/Safety) and one to the Environmental/EPR Authorities (Waste/Finance).
It also creates competitive asymmetry, as this regulatory fragmentation imposes an unnecessary and exclusive fixed cost on the third-country operator, violating the principle of proportional treatment for accessing the single market, as EU-established competitors handle both responsibilities internally.

Critical incoherence regarding documentation and annual declarations

EPR legislation requires the annual submission of product quantities placed on the market, a task belonging to the EPR Representative. The Digital Omnibus does not integrate this obligation.

The AI Act Authorized Representative is not legally empowered to handle these quantity declarations or the financial settlement of the Visible Fee. Furthermore, while the Omnibus simplifies the AI Act by eliminating the public registration requirement for exempted high-risk systems, the risk of fragmentation remains. The lack of a harmonized template for the internal non-high-risk assessment documentation (Art. 6(4)) exposes the Authorized Representative to inconsistent substantive interpretations across different National Market Surveillance Authorities (MSAs).

Questions:

1) Coordination between AI Act and Extended Producer Responsibility

Acknowledging the mandatory nature of the Legal Representative for EPR (WEEE Directive Art. 17), what binding procedural or implementing acts will the Commission propose to establish an administrative mechanism for institutional coordination between the National Competent Authorities for the AI Act and the National Environmental Authorities (EPR Bodies)? The objective is to create a single-window entry point for non-EU producers, allowing the AI Act Authorized Representative to absorb the declarative (quantities) and administrative obligations of the EPR Representative, thereby eliminating the mandatory duplication of legal representation and the resulting fixed cost for third-country operators.

2) Simplification and legal certainty regarding documents

Following the deletion of the public registration requirement for exempted high-risk systems (Art. 6(3)), will the Commission commit to issuing a harmonized, mandatory template or common specification for the technical documentation of the non-high-risk assessment (Art. 6(4))? This measure is essential to provide legal certainty to the Authorized Representative and ensure uniform application of the law across MSAs.

3) Resources and competences of Notified Bodies

Regarding the proposed single application and single assessment procedure for Notified Bodies (NBs) designated under both the AI Act and sectoral legislation (Art. 28(8)), what specific criteria and resource verification methodology will the Commission establish in the forthcoming implementing acts to rigorously assess that existing NBs possess not only the

required sectoral expertise (e.g., in EEE) but also the requisite high-level technical competence in data science, algorithmic risk management, and cybersecurity (AI-specific) before granting dual designation?

PUBLIC

FINLAND

Updated FI written comments and questions on Digital Omnibus (updated on 18.12.2025)

Artificial Intelligence Act

The article 4 on AI literacy article has brought about and inspired several actions by companies, public sector and NGOs. In the preparation of our national legislation to implement the AI Act, however, we view that the provision on AI literacy does not in itself create obligations, and the AI Act does not include regulation on sanctioning for neglect or violation of Article 4. Has the Commission considered keeping the AI literacy article 4 as it is, except clarifying that no sanctions are related to it?

The COM is introducing a new Article 4a, replacing Article 10(5) AI Act, which provides a legal basis for providers and deployers of high risk AI systems and AI models to exceptionally process special categories of personal data for the purpose of ensuring bias detection and correction under certain conditions. **We would like to inquire why the COM has changed the requirement "strictly necessary" to "necessary". There is no assessment concerning this, but taking account that this Article concerns high risk AI systems, it seems that this would also lower the current level of protection and should have been evaluated properly – especially when the derogation would now apply to more entities.**

Concerning Article 3 and definitions, why hasn't the COM proposed to streamline some of the definitions with the GDPR/LED. Different definitions cause unnecessary administrative burden and unclarities to entities. It could also jeopardize the level of personal data protection. For instance, **biometric data (see Article 3, points 34 to 36) should be streamlined with GDPR/LED. It is also unclear whether law enforcement authorities in Article 3, point 45 is in line with the LED** and how the definition should be interpreted with the LED.
