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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 9 January 2026)

Delegations will find enclosed a presentation as prepared by the Commission for the meeting of the Antici Group (Simplification) on 9 January 2026 regarding Q&A on Digital Omnibus on AI (Omnibus VII).

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AI OMNIBUS

Q&A session

Antici Group on Simplification

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I. Processing Special Categories of Data for Bias Detection and Mitigation (Article 4a)

Processing of Special Categories of Personal Data and Bias Mitigation (Article 4a)

For high-risk AI systems, the legal basis specifically refers to Art. 10(2) points (f) and (g). In the new Article 4a, why is this reference limited to high-risk AI systems?

- Reference to Article 10(2)(f) and (g) AI Act in Article 4a applies only in relation to high-risk AI systems because these provisions concern specific requirements for high-risk AI systems; reference remains the same as it is currently in Article 10(5) AI Act
- That does not mean that for other AI systems and AI models there are no conditions to rely on this legal basis – notably, Article 4a(2) specifies that for other (non-high-risk) AI systems and models providers may rely on that legal basis where necessary for the same bias detection and correction purpose and under the same conditions as specified in para 1



Processing of Special Categories of Personal Data and Bias Mitigation (Article 4a)

What is the interaction of Article 4a with the new Article 9(2) GDPR, which was proposed in the Digital Omnibus?

- Article 4a (AI Act) and Article 9(2) (k) (GDPR) are independent and address very specific situations; no overlaps or inconsistencies between the proposed amendments
- Proposed Article 4a provides for a legal basis for processing special categories of personal data for the purpose of bias detection and mitigation in relation to AI systems and models
- Proposed Article 9(2)(k) GDPR in the Digital Omnibus provides for an exemption for the residual processing of special categories of personal data for development and operation of an AI system or an AI model, where the special categories of personal data are not necessary for the purpose of the processing subject to certain conditions; applies in limited situations only



Processing of Special Categories of Personal Data and Bias Mitigation (Article 4a)

What are the different purposes, conditions and safeguards applicable for this legal basis for high-risk AI systems on the one hand and for all AI systems on the other?

- **Purpose:** to allow providers and deployers to exceptionally process special categories of personal data to the extent necessary to detect and correct bias, subject to safeguards already established in the current text of the AI Act
- **Safeguards** foreseen for the high-risk systems also apply for those other AI systems and models, as referred to in para 2 of the new Article 4a
- As an additional measure, the scope of para 2 is limited to cases where the processing is **necessary** and **proportionate**, to justify the exceptional processing



Processing of Special Categories of Personal Data and Bias Mitigation (Article 4a)

Can Article 4a be relied upon by law enforcement authorities?

- Article 4a would create a legal basis to process special categories of personal data otherwise prohibited under data protection law; this includes the prohibitions of such use under the GDPR, EUDPR and Law Enforcement Directive
- Hence, law enforcement authorities that are providers or deployers of AI systems would be able to rely on Article 4a for the purpose of bias detection and correction
- As said in the first paragraph of Article 4a, the applicable safeguards under data protection law continue to apply together with new conditions under the AI Act



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II. AI Literacy (Article 4)

AI Literacy

Will the COM provide further guidance on the definition of AI literacy? How should we measure AI literacy?

- The definition of AI literacy in Article 3(56) and the corresponding obligation in Article 4 are broad and require further guidance
- COM has made significant efforts to provide guidance for the current Article 4 obligation, for example by publishing a Q&A on AI literacy and a repository of AI literacy practices collected through the AI Pact
- AI literacy has different purposes, extends to different actors in the AI value chain and encompasses many forms of competence building; thus it is challenging to lay down specific and generally relevant requirements
- At this stage, COM suggests that the work continues through voluntary guidance and that a common understanding of measures to be taken between the COM and Member States are elaborated in the AI Board
- This work should build on existing initiatives or frameworks, including frameworks such as the Digital Competence Framework for Citizens

AI Literacy

Did COM consider alternative approaches to reduce the burdens for companies, e.g. providing that there cannot be sanctions?

- COM considers the proposal in the AI Omnibus as the appropriate solution to remove uncertainty with maintaining the objective of fostering AI literacy
- Removing Article 4 would have diminished the role of AI literacy in the AI Act
- Further specification of Article 4 to remove uncertainty is challenging, as the implementation work shows that the appropriate AI literacy measures vary strongly between organisations, depending on the size, sector, the specific risks related to the AI system etc.
- An alternative could have been to keep Article 4 unchanged while clarifying that its violation carries no sanctions, which however could have likely undermined its objective

AI Literacy

How does the proposed change improve legal certainty of providers and deployers? Does it affect existing AI literacy programmes? How will a harmonised approach be ensured?

- Amendment will remove the current uncertainty because there would no longer be a binding obligation on deployers and providers of AI systems that is vaguely formulated ('sufficient level of AI literacy'), but at the same time enforceable by means of administrative fines
- This 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; and Article 26(2) continues to apply for high-risk deployers
- Moreover, as is said in recital 5, this change is without prejudice to the broader measures taken by the COM and Member States to promote AI literacy
- Recital 5 also proposes the AI Board as a cooperation mechanism between the COM and Member States, to align approaches and ensure a coherent application



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III. Registration of 'filtered' AI systems (Article 6(4), 49(2))

Registration of 'filtered' AI Systems

Did COM consider alternative approaches to reducing compliance burdens while maintaining traceability?

- COM carried out an assessment of the entire AI Act with the intention to identify requirements which may be simplified without undermining the high level of protection of health, safety and fundamental rights
- Removing the registration obligation for 'filtered' AI system was identified as a proportionate and balanced amendment to facilitate the simplification effort; it reduces compliance burdens, while strong safeguards remain in place (as elaborated in the meeting of December 15)



Registration of 'filtered' AI Systems

Does this amendment undermine legal certainty concerning when the 'filter' applies?

- Amendment only changes the procedural steps that providers are required to take; the conditions of the 'filter' are not changed, thus the amendment does not undermine legal certainty regarding its application
- To enhance legal certainty, the Commission is developing guidelines on classification of high-risk AI systems, including on the scope of the filter, among others on the questions such as what qualifies as a 'preparatory task'
- COM guidelines will also contain guidance on what the provider's documentation should cover when assessing why the filter applies



Registration of 'filtered' AI Systems

What is the impact – how many companies are affected and what is the reduced administrative cost?

- COMs estimate of the cost savings for companies for the proposed measures, including this one, are in the accompanying Staff Working Document (p. 78 onwards)
- Beyond cost savings, the removal of this registration obligations also reduces compliance risk by clarifying that providers whose systems are exempt cannot be held accountable for failing to register.



Registration of 'filtered' AI Systems

Could the forthcoming guidelines on the 'filter' be made mandatory? Could the COM prepare a legally binding template for the documentation made by providers who apply the 'filter'?

- The forthcoming COM guidelines on high-risk classification will contain guidance on what the provider's documentation on the application of the filter should cover
- Guidelines are, by nature, non-binding interpretative tools; converting them into a legally binding instrument such as an Implementing or Delegated Act would require an empowerment of the COM in the AI Act
- Nevertheless, the guidelines will provide guidance for both companies and supervisory authorities on the application of the AI Act; at this stage, we do not see a need for legally binding specification

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IV. Fundamental Rights Protection Authorities (Article 77)

Fundamental Rights Protection Authorities

What happens if the Market Surveillance Authority does not receive the requested information from the provider?

- Article 77(1) gives fundamental rights protection authorities a competence to request information, which is intermediated through the market surveillance authorities (MSAs)
- If the MSA does not receive the requested information, it is empowered to enforce the request for information, for example through sanctions
- Fundamental rights protection authorities can neither launch nor enforce these requests themselves on the basis of Article 77(1)
- In any case, the procedures under Article 77 are without prejudice to the existing mandate and powers of fundamental rights protection authorities: fundamental rights protection authorities maintain the right to request information according to their mandate and to enforce such information requests (if provided under the relevant Union legislation)
- Article 77(1) is intended to fill gaps where fundamental rights protection authorities or bodies do not have such mandate



Fundamental Rights Protection Authorities

Do the cooperation obligations impact the independence of Article 77 authorities?

- The procedures under Article 77 are without prejudice to the competences, tasks, powers and independence of fundamental rights protection authorities (explicitly said in recital 157 AI Act)
- The proposed Article 77(1b) would provide a new legal basis that allows cooperation and mutual assistance, including information sharing
- The limitations of other laws to share certain data may still apply, but now there would be a legal basis that allows information sharing that was not possible before
- It has to be recalled that Article 78 AI Act provides a strong protection of confidentiality of information and data obtained under the AI Act



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V. AI Regulatory Sandboxes (Articles 57, 58)

AI Regulatory Sandboxes (Articles 57, 58)

Can the testing of an AI system in a national AI regulatory sandbox also extend to the underlying GPAI model?

- If an AI system falls under the competences of national authorities, its testing in the sandbox can also cover testing of the model's behaviour and performance as part of the system
- Otherwise, the value of testing systems in the AI sandbox would be incomplete, since key safety, bias and robustness characteristics are often driven by the model upon which the AI system is built
- However, for avoidance of doubt, the national sandbox should not extend to assessing regulatory compliance with the GPAI model rules in the AI Act, which is under the exclusive supervision of the AI Office
- Furthermore, national sandboxes cannot cover situations where the AI systems itself is also under the supervision of the AI Office (when provided by the same model provider (Art. 75(1)))

AI Regulatory Sandboxes (Articles 57, 58)

**Why do you propose to extend the COM implementing act to governance?
Is this not a matter of internal organization of Member States?**

- COM is already preparing the implementing act regarding harmonised conditions for AI regulatory sandboxes, which has been developed with the involvement of the AI Board and is now being discussed in the comitology committee for the AI Act
- In this process, the need to set harmonised conditions for the governance and set-up of sandboxes has been identified; e.g. regarding uniform conditions for evaluations, cross-border cooperation and coordination with the EU-level and the joint AI sandboxes established by authorities from multiple Member States
- The current empowerment does not allow to provide the required common rules on these elements, hence COM proposes the amendment in Article 58(1) point (d)
- Once the AI Omnibus is adopted, the current implementing act could be amended to also cover harmonised conditions for governance aspects



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VI. Real-World Testing of High-Risk AI Systems (Articles 60, 60a)

Real-World Testing of High-Risk AI Systems

How is the supervision of real-world testing under Article 60a foreseen?

- Union harmonisation laws listed in Annex I Section B largely do not rely on the Market Surveillance Regulation and have specific governance frameworks
- Thus, the supervision model for the real-world testing in Article 60 cannot be applied in the same way to real-world testing of high-risk AI systems that fall under Annex I Section B
- The concrete supervision model would be set out in the written voluntary real-world testing agreements, including the criteria for assessing testing plans and the supervision conditions
- This allows for the necessary flexibility to account for the sectoral rules and ensure the participation of the relevant competent authorities for the legislation listed in Annex I Section B



Real-World Testing of High-Risk AI Systems

On which legal basis can voluntary testing agreements between COM and Member States compel those Member States who have not entered into such agreements to ensure e.g. access to physical infrastructure for these tests?

- The testing agreements are voluntary. Member States are not compelled to enter into an agreement, nor can a voluntary agreement have binding effects for other Member States
- The infrastructure developed or made available under the new Article 60a depends on, and is under the control of, the Member State



Real-World Testing of High-Risk AI Systems

By what means does the market surveillance authority responsible for law enforcement authorities supervise real-world testing? At what stage is notification of a potential test required?

- Real-world testing of high-risk AI systems used by law enforcement authorities would mostly fall under the existing framework of Article 60, because these systems are usually covered by Annex III
- The rules for real-world testing of high-risk AI systems have not changed, thus the proposed changes in the Omnibus are not expected to affect law enforcement authorities
- The amendment only extends the scope of Article 60 to high-risk AI systems covered by Annex I Section A and introduces high-risk AI systems covered by Annex I Section B. Where law enforcement authorities are providers of high-risk AI systems that fall under Annex I Section A or Section B, they are provided with additional possibility to test these systems
- According to Article 60(4) points (a) and (b) AI Act, the notification should occur before the testing starts. For the testing under Article 60a, the concrete supervision model would be set out in the voluntary agreement



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VII. Conformity assessments & notified bodies

Single Application Procedure (Articles 28, 29)

Does the single assessment procedure interfere with Member States' internal organisation?

- The main aim is to simplify both administrative and financial burdens for the notifying authorities and the notified bodies by streamlining the process of assessment, designation and monitoring under the AI Act and the applicable Union harmonization legislation
- There is no impact on Member States' discretion on the concrete internal arrangements beyond the functional requirements set in the AI Act



Single Application Procedure (Articles 28, 29)

What criteria and methodology will the COM establish to assess that existing notified bodies possess not only the required sectoral expertise but also the necessary competences to carry out designations under the AI Act?

- Article 30 regulates the notification procedure and Article 31 establishes requirements for notified bodies, among others requiring the necessary technical competence
- A key mechanism to ensure a methodological approach is the establishment of NANDO Codes: as elaborated in previous meetings, these are the codes according to which notified bodies are registered, allowing notifying authorities to check for which type of AI systems these notified bodies are authorised to perform conformity assessments and whether they have the necessary competences and infrastructure
- Further clarifications are made available to notifying authorities in the AI Board

Single Application Procedure (Articles 28, 29)

How does the COM consider the proposals for the single application system to work when the assessment and monitoring is delegated to a national accreditation body under Article 28(2) of the AI Act?

- When a national accreditation body under Regulation (EC) No 765/2008 carries out the assessment and monitoring of conformity assessment bodies, the Member State must still designate at least one notifying authority and ensure that the notification framework is established
- This means that the Member State, via the notifying authority, remains responsible for organising the notification framework so that the single application and assessment procedure is operationalised in practice, even if the assessment and monitoring processes are performed by a national accreditation body



NANDO Codes

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?

- The notification process can be provisionally set up based on these codes
- For example, these Codes could be provisionally adopted as a common understanding of the AI Board, prepared by the AI Board's subgroup of notifying authorities
- While not ideal, this solution would already be a big step towards legal certainty and help the quick designation of notified bodies
- This is also why we included the codes in the AI Omnibus, because this allows a fast adoption
- The alternative would be to adopt NANDO codes on a provisional basis based on country-specific codes or to have no codes, which would leave legal uncertainty

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VIII. Extending Article 63 to SMEs

Extending Article 63 to SMEs

Will the extension of the scope of Article 63 lead to a distortion of competition?

- COM is proposing to extend the simplified compliance pathway in Article 63(1) from microenterprises to SMEs, because compliance is challenging for all SMEs and SMEs require targeted support
- COM also proposes to remove the condition 'provided that they do not have partner enterprises or linked enterprises within the meaning of this Recommendation'
- This clause was initially intended as a safeguard for circumvention, but with the proposed extension of the scope it is no longer necessary
- This is because partner or linked enterprises must be considered in the calculation when assessing whether the threshold for an SME is met. Therefore, the risk of circumvention is no longer so relevant as it was in relation to microenterprises, where a partner or linked enterprise could have been created to benefit from the simplified compliance pathways

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

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

If there is not an implementing act with a template for the post-market monitoring plan, how will legal certainty be ensured?

- As discussed at the meeting on 15 December, the proposal to remove the implementing act setting out a harmonised template for a post-market monitoring follows strong call by stakeholders
- They ask to have flexibility in implementing the post-market monitoring and not a prescriptive plan
- Accordingly, COM proposes to replace the implementing act with non-binding guidance. The intention is to provide guidance on what is expected from providers, but not to impose a mandatory template for the plan

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X. Other Topics

Amendments to AI Act in MDR/IVDR package

How does the AI Omnibus interplay with amendments to the AI Act in the MDR/IVDR simplification package?

- In the Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR) simplification package, the COM proposes to move the MDR and IVDR from Section A to Section B of Annex I of the AI Act
- The objective is to address issues raised by the sector in terms of the specificities of the integration of AI in medical devices and its impact on people's health
- As a consequence, providers and deployers of high-risk AI systems contained in products covered by the MDR and IVDR would follow the rules set in these legislations, including specifically on AI
- However, to ensure the same level of protection as the AI Act, these regulatory frameworks would have to be adapted, where necessary, to take into account the essential requirements of the AI Act
- As this matter is specific to the MDR/IVDR, this change is proposed in that context and not in the AI Omnibus which is more horizontal



Legal basis Article 114 TFEU

Is Article 114 TFEU an appropriate legal basis for all the rules that concern the internal organisation of Member States and their public authorities?

- The AI Omnibus proposal relies on Article 114 TFEU, like the initial AI Act.
- The provisions concerning the cooperation and other elements of MS authorities relate to implementation and supervision mechanisms needed to ensure uniform conditions for AI systems on the EU market and to avoid fragmentation
- There is no impact on Member States' discretion on the concrete internal arrangements beyond the functional requirements set in the AI Act



Requirements in the EU Law to Appoint Authorised Representatives

What legal or other measures could be taken to eliminate the duplication of the requirements to appoint authorised representation in AI Act and other legislation, such as in the WEEE Directive?

- While simplification and reduction of administrative burdens remain COM priority, the objectives of various legislation need to be taken into consideration
- The AI Omnibus is not the appropriate vehicle to harmonise legal representation requirements stemming from other EU legislation, such as the WEEE Directive
- WEEE Directive is not a New Legislative Framework (NLF) instrument, but rather, one of the EU environmental and waste legislation. In contrast, the AI Act is a part of the NLF legislation designed to align product safety and compliance, primarily those requiring CE marking
- Harmonising legal-representation requirements would need to be addressed through a more horizontal initiative under the relevant legal basis and procedure, rather than via a targeted amendment of the AI Act



Research Exemption

Why did the COM not propose legislative amendments to the research exemptions in Article 2(6) and in Article 2(8) of the AI Act?

- COM has taken good note of the many questions raised by stakeholders to clarify the practical application of the research exemptions in Article 2(6) and Article 2(8)
- To answer those questions, guidelines are an appropriate instrument, because the exception as it stands is broad and general enough. The Guidelines will also allow COM to elaborate and take account of sectoral specificities and provide many practical examples.
- For the legislative amendments, COM objective was to propose targeted modifications that facilitate the application of the AI Act, without changing fundamental legislative choices such as the nature, scope or definitions

Reporting of Serious Incidents

What will be covered by the guidelines on the reporting of serious incidents?

- COM has published the draft guidelines for the reporting of serious incidents by providers of high-risk AI systems for [consultation](#) from 26/9/25-7/11/25
- Member States were invited to share feedback separately through the AI Board



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