Digital Omnibus on AI

The Confederation of Swedish Enterprise believes that the EU's Digital Omnibus on AI is a first step towards a more predictable and less bureaucratic regulation that can strengthen competitiveness. For Swedish companies, it is crucial that the EU now takes the opportunity to correct key problems in the AI Regulation and ensure that it is proportionate, technology-neutral with clear risk-based requirements and deadlines that make compliance possible in practice.

Omnibus is a step in the right direction – but extensive obstacles and problems remain to ensure innovation and competitive AI use.

Summary

1. The application date for high-risk AI is very time-critical and should be handled separately.

A single application date of 2 August 2028 should apply to all high-risk AI (Annexes I and III) at the earliest.

2. Risk assessment, registration and documentation, Articles 5 & 6

Unclear delimitation of high-risk AI creates great uncertainty. Regulation must be based on risks, not technology or entire areas.

The removal of registration requirements for non-high risk in Annex III is positive but should also include documentation requirements as it does not contribute to higher protection or effective supervision.

3. Article 4 should be deleted

• There is no market failure that justifies regulation.

• The wording "encourage..." creates a risk of fragmentation between Member States.

4. Sensitive personal data (Article 4a): the adjustment is necessary and practicable (bias mitigation) but not sufficient to have a real effect.

5. Transparency requirements, Articles 50 & 53: application two months after the Code of Practice is available is unrealistic. Businesses need more time.

6. Real-world testing, Articles 2.8, 60 and 60a: the opportunity is essential for innovation, risk management and adaptation and should therefore cover all AI systems, not only those tested in regulatory sandbox by amendment to Article 2.8.

7. Relief for startups, SMEs and SMEs

Administrative easing is welcome, but exceptions based on size are problematic. Rules should be designed so that all companies, regardless of size, can comply with the law. This is important for a level playing field, to avoid growth-inhibiting thresholds and for supply chain issues when subcontractors have simplified documentation.

8. Overlapping rules

Documentation requirements in the Medical Device regulation, MDR, and the AI Act, collaboration between notified bodies under the MDR and questions how the AI Act links to GDPR, Data Act, NIS2, CRA need to be addressed.

• Move NLF legislation from List A to B in Annex I.

• Consider exemptions for B2B solutions from high-risk requirements.

9. Governance structures and market surveillance

• A central role for the AI Office is positive as it counteracts fragmentation between Member States.

• Mutual recognition of national decisions is recommended.

10. Notified bodies: risk of bottlenecks arising in the area of the AI Act due to capacity and skills shortages.

11. Liability in the value chain (Article 28b): substantial modification needs to be more clearly defined. For example, integration, configuration, or limited customization should not turn users into vendors.

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Comments

1. Extension of the application date for high-risk AI

The Confederation of Swedish Enterprise believes that the issue of the date of application needs to be dealt with separately as it is significantly more time-critical than the other parts of the omnibus proposal.

It is very welcome that the high-risk requirements are postponed until the relevant standards are in place. However, the omnibus proposal's parallel triggers for the application of the regulations create uncertainty and complicate planning.

A coherent application date, no earlier than 2 August 2028, for all high-risk (Annexes I and III) is essential for legal certainty and for companies to be able to plan their investments, adapt their quality systems, internal procedures and documentation.

Postponement of application is a fundamental prerequisite for legal certainty and predictability, but above all for companies to know how to achieve regulatory compliance. In practice, companies cannot change their operations in six months or less. It usually takes at least 24 months to adjust to new standards.

The omnibus proposal for a gradual and conditional transition period should be replaced by a single, coherent postponement. For regulatory compliance, it is crucial that the regulations are predictable and practicable. All provisions related to high-risk AI should therefore start to apply from a common fixed date, regardless of whether the systems are covered by Annex I or Annex III.

2. Risk assessment, registration and documentation requirements, Article 5 or 6

There is still a lack of a clear, practically applicable delimitation for what constitutes high-risk AI. This creates great uncertainty about which requirements actually apply.

Regulation must be based on risks – not technology

• Article 5 prohibits certain uses without including a case-by-case risk assessment.

• Article 6(3) contains a risk assessment, but it is unclear and too narrow and lacks sufficient "filters" to exclude AI systems in Annex III that do not involve actual high risk.

The Confederation of Swedish Enterprise supports the removal of the registration requirement for AI systems in Annex III areas that are not high-risk. The proposal is a step in the right direction but should go even further.

Registering AI systems that do not pose high risk would:

• create administrative burden without a clear safety or risk mitigation effect.

• allocate resources to low-priority areas

• risk undermining the focus on truly risky systems.

In addition, we believe that the requirement to document the classification of whether an AI system is not subject to the rules on high-risk (filtering mechanism) should be removed. It is disproportionate that companies should be required ex ante to document how they interpret a particular piece of legislation. They are usually responsible for being able to account for their assessments and what has been the basis for them in a possible supervisory case. Moreover, the documentation requirement does not contribute to a higher level of protection for individuals or to more effective supervision.

3. Article 4 should be deleted

Companies have strong interests in training staff, and the article is not based on a market failure.

New Article 4 wording "encourage..." risks being interpreted differently between Member States and creates legal uncertainty and fragmentation in the internal market.

The Confederation of Swedish Enterprise believes that Article 4 should be deleted because AI knowledge and internal skills development are already handled effectively by the companies. In addition, skills development should not be included in legislation, either at EU level or nationally, as needs and skills profiles are constantly changing.

How AI literacy is best ensured varies depending on the size of the organization, the nature of the business, and the distribution of roles. This should therefore be left to the businesses to decide and not regulated in the AI Act.

4. Sensitive personal data insufficient amendment, Article 4a

Article 4a provides the possibility to process sensitive personal data to some extent (bias mitigation) and clarifies that there is a need for bias detection also for AI systems other than high-risk AI. This is a practically justified adjustment. The provision does not change the balance of data protection law and should be seen as a limited, but necessary correction. However, the proposal will not be enough to be a game-changer for AI development and competitiveness.

5. Transparency requirements under Articles 50 and 53

The same type of measure should apply to the proposed pause of the transparency requirements in Article 50 regarding generative AI systems and other AI systems (Art. 50)

A two-month period after the upcoming Code of Practice is unreasonable. Companies will probably need 12 months after the publication of the Code of Practice and the pause should cover the entire Article 50 with a common and realistic date of application. Not least the Deep fake requirements (Article 50.4) are technically impossible until definitions and tools are in place.

The current regulation of GPAI lacks impact assessment and risks becoming disproportionate and inhibiting innovation. It is clearly produced in haste and very problematic in most sectors.

6. Real-world testing, Article 2.8, 60 and 60a

The ability to test AI solutions in a real-world environment outside of the regulatory sandbox is very important for innovation, risk management and competitiveness. (Arts 60 and 60a). In addition, real-world testing is often necessary for the adaptation of AI systems to European requirements.

Today's requirements in the AI regulation risk making such testing unreasonably difficult or in practice impossible. Exemptions should therefore cover all AI systems, not just those tested in regulatory sandboxes. This could be done by deleting the last sentence in Article 2(8) of the AI Regulation: "testing in real world conditions shall not be covered by that exclusion".

7. Relief for start-ups SMEs and SMEs

Administrative relief is in itself welcome but could become problematic in terms of simplified documentation for those who are subcontractors.

In general, we are hesitant to ask for exceptions based on company size. Instead, legislation should be designed so that companies of all sizes can live up to their obligations. This is central to ensuring regulatory compliance throughout the value chain. And also important for competition on equal terms and growth-inhibiting regulatory thresholds.

8. Overlapping rules creating duplication of regulation

Companies describe a growing frustration with overlapping and sometimes conflicting rules, such as:

• MDR (Medical Device Regulation) that creates requirements for double documentation.

• Uncertainty about how notified bodies, e.g. under MDR, should interact with the notified bodies that will approve AI systems.

• Unclear links between the AI Act, GDPR, Data Act, NIS2 and the Cyber Resilience Act.

It is positive that there has recently been a legislative proposal to move the MDR and IVR from List A to List B in Annex III. More sectors should be relocated accordingly to reduce overlapping application of regulations. Therefore, exempt sectors that are already covered by NLF legislation by moving list A in Annex I, to list B.

Also consider exempting B2B AI solutions from the high-risk requirements.

9. Governance structures/market surveillance

A more central and coordinating role for AI Office is positive for uniform application and reduces the risk of national fragmentation.

With fragmentation, similar to that which has arisen in GDPR enforcement, there is a risk of uneven compliance, distortion of competition and increased costs for companies.

We therefore believe that a centralised model is justified, but also mutual recognition of national supervisory decisions, in order to avoid parallel or contradictory assessments in the Member States.

10. Notified Bodies

There are already large queues for, and lack of competence at, other notifying bodies, for example during MDR. The current model risks creating bottlenecks in the AI regulation as well.

11. Liability in the value chain, Article 28b

The concept of substantial modification in Article 3(23) and Recital 128 needs to be clarified and harmonised in order not to unduly affect the roles in the value chain.

Clearer criteria are needed for what counts as a significant modification. Integration, configuration, or limited customization of AI systems should not reclassify users as vendors. The rules must be objective and practicable.

The concept of substantial modification therefore needs:

• be harmonised with equivalent concepts in other legislation (e.g. MDR significant change)

• be clarified so that integration and configuration do not mistakenly turn companies into "providers".