

To: Ministry of Foreign Affairs of Romania

EU Department

Directory of General, Financial, Internal and Justice Affairs

Esteemed Officials,

As the European Commission advances the Digital Omnibus proposal and Member States prepare their respective national positions, the American Chamber of Commerce in Romania (AmCham Romania) wishes to engage constructively with the Ministry of Foreign Affairs by sharing observations from the business community. Our contribution aims to support Romania's efforts to promote a balanced, forward-looking approach that safeguards innovation while ensuring regulatory consistency at EU level.

AmCham Romania's proposals focus on key provisions of the Artificial Intelligence Act (AIA), the General Data Protection Regulation (GDPR), and the ePrivacy framework, with the objective of enhancing regulatory coherence and legal certainty within the scope of the European Commission's Digital Omnibus proposal.

I. GDPR & ePrivacy

1. Positive elements welcomed by AmCham

AmCham welcomes several constructive elements included in the Digital Omnibus proposal that contribute to greater legal clarity and regulatory coherence in the EU digital framework.

In particular, we welcome:

- The clarification of the definition of personal data in line with CJEU jurisprudence, moving towards a more operational and realistic, controller-based test of identifiability.
- The explicit recognition of legitimate interest as a lawful ground for AI model development and deployment, notably through the proposed Article 88c, which represents an important step towards legal certainty for AI-driven innovation.
- Targeted improvements strengthening risk-based proportionality under the GDPR, including higher thresholds for breach notification, risk-based transparency obligations, and safeguards against abusive data subject requests.
- Initial steps towards harmonisation, such as EU-level approaches to DPIAs, breach notification templates, and clarification powers for anonymisation and pseudonymisation.

These elements represent meaningful progress toward a more predictable and innovation-friendly data protection framework.

2. Key gaps and areas requiring adjustment

Despite these positive steps, AmCham considers that the Omnibus proposal does not yet fully address structural shortcomings in the GDPR and ePrivacy regimes that affect competitiveness, legal certainty, and innovation.

First, the risk-based approach remains insufficiently embedded as a core principle of the GDPR. While several provisions move in a more proportionate direction, the absence of an explicit horizontal risk-based principle leaves room for absolutist and fragmented interpretations across Member States. AmCham therefore supports explicitly anchoring risk-based proportionality as a core GDPR principle, in line with Article 52 of the Charter of Fundamental Rights.

Second, the current approach to Special Categories of Data (SCD) and health data continues to be overly broad and restrictive. The expansion of Article 9 through jurisprudence and regulatory practice risks classifying vast amounts of ordinary data as “sensitive,” making lawful processing for AI training and data-driven innovation extremely difficult. AmCham supports narrowing SCD and health data definitions to data that directly reveals or is actually used to derive sensitive attributes, and broadening derogations in a technology-neutral and proportionate manner.

Third, the Omnibus does not adequately resolve the long-standing dysfunctions of the cookie consent regime. Partial integration of ePrivacy into the GDPR, while welcome in principle, maintains a fragmented dual system that perpetuates consent fatigue and legal complexity. AmCham supports fully consolidating cookie, traffic data, and direct marketing rules under the GDPR and avoiding parallel consent-centric regimes that undermine simplification.

Finally, the proposal to mandate machine-readable consent signals risks reintroducing complexity, duplicating existing GDPR mechanisms, and imposing disproportionate burdens, particularly on SMEs. AmCham considers that this provision should be removed to preserve coherence and effectiveness.

II. EU AI Act

1. Positive elements welcomed by AmCham

AmCham acknowledges several improvements introduced by the Omnibus proposal in relation to the AI Act.

We particularly welcome:

- The expansion of the legal basis for bias detection and mitigation, including broader possibilities to process Special Categories of Data for this purpose.
- Steps towards more centralized and coherent enforcement, notably by strengthening the role of the AI Office, in line with existing EU digital legislation.
- The replacement of prescriptive AI literacy obligations with a more flexible, encouragement-based approach.
- The recognition of implementation challenges through the introduction of transitional periods for certain obligations.

These elements represent important signals of responsiveness to implementation realities and stakeholder feedback.

2. Key gaps and areas requiring adjustment

However, AmCham remains concerned that the Omnibus proposal does not sufficiently address the structural challenges of the AI Act that affect legal certainty, investment, and innovation.

Most importantly, limiting the “stop-the-clock” approach to the high-risk regime alone does not resolve broader uncertainty across the AI Act. In particular, the rules governing General-Purpose AI Models (GPAIM) continue to blur the distinction between model development and system deployment, departing from the core principle that risk should be addressed at the point of use. AmCham supports extending transitional periods to GPAIM obligations to ensure consistency, legal certainty, and a genuinely risk-based framework.

In addition, the current conditional and staggered timelines for high-risk AI systems create unnecessary complexity and unpredictability. A single, fixed and realistic compliance deadline for all high-risk systems would better support effective implementation and planning for both regulators and industry.

AmCham also notes with concern proposals that introduce asymmetric obligations based on company size rather than risk. The AI Act is founded on a risk-based logic, and deviations from this principle risk undermining both safety and fairness, while creating regulatory blind spots.

Finally, the Omnibus proposal does not establish a clear mandate for EU and national digital regulators to actively support innovation. Without an explicit innovation accountability mandate, there is a risk that fragmented and overly cautious interpretations will persist, undermining Europe’s ability to translate research excellence into globally competitive AI solutions.

III. Concluding remarks

AmCham supports the objectives of the Digital Omnibus to simplify, harmonise, and modernise the EU digital regulatory framework. However, achieving these objectives requires bolder structural adjustments that fully embed risk-based proportionality, strengthen legal certainty, and align regulation with Europe’s competitiveness and innovation goals.

We stand ready to engage constructively with EU institutions and national authorities to support a balanced, future-proof digital framework that protects fundamental rights while enabling sustainable growth and technological leadership.

Yours sincerely,

Nedim Baytorun

Chair of Data Protection and Privacy Task Force