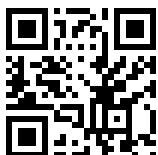


A Digital Omnibus: Identifying Interlinks and Possible Overlaps Between Different Legal Acts in the Field of Digital Legislation to Streamline Tech Rules



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Abstract

This study was prepared at the request of the European Parliament's Committee on the Internal Market and Consumer Protection (IMCO). It analyses the European Commission's Digital Omnibus package proposals published on 19 November 2025, distinguishing administrative simplification from more substantive recalibration of safeguards across data, privacy, cybersecurity and artificial intelligence areas. The study highlights key areas of controversy (legal certainty, enforcement capacity, and impacts on rights) and sets out areas for consideration for parliamentary scrutiny.

This document was requested by the European Parliament's Committee on the Internal Market and Consumer Protection.

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LIST OF ABBREVIATIONS

EU	European Union
AI	Artificial intelligence
B2G	Business-to-government
CER	Critical Entities Resilience Directive
CJEU	Court of Justice of the European Union
DGA	Data Governance Act
DMA	Digital Markets Act
DORA	Digital Operational Resilience Act
DPIA	Data Protection Impact Assessment
DSA	Digital Services Act
DSAR	Data subject access request
EC	European Commission
EDPB	European Data Protection Board
ENISA	European Union Agency for Cybersecurity
EP	European Parliament
EUID	European Digital Identity
FTE	Full-time employee
GDPR	General Data Protection Regulation
GPAI	General purpose artificial intelligence
NIS2	Network and Information Systems 2 Directive
ODD	Open Data Directive
P2B	Platform-to-business
SEP	Single Entry Point

SMC	Small mid-cap
SME	Small and medium-sized enterprise
VLOPSE	Very Large Online Platform and Search Engine

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EXECUTIVE SUMMARY

On 19 November 2025, the European Commission published the Digital Omnibus package¹ (also referred to as the Digital Simplification Package or the Digital Package) that comprises (i) a proposal to amend and consolidate parts of the EU's digital acquis on data, privacy and cybersecurity (the Digital Omnibus Regulation Proposal or General Proposal), and (ii) a separate proposal amending the AI Act (the Digital Omnibus on AI). The package is framed as a competitiveness-oriented simplification agenda: it prioritises clearer timelines and guidance, small business support, streamlined reporting and targeted consolidation, while also recalibrating selected rules to encourage artificial intelligence (AI) industry in Europe. Alongside the Omnibus proposals, the Commission also launched related initiatives to assess cumulative regulatory impacts and signal that simplification may be iterative.

This study, requested by the European Parliament's Committee on the Internal Market and Consumer Protection (IMCO), provides an overview of both Omnibus proposals and a practical assessment of the amendments that have attracted the greatest attention in stakeholder reactions. It draws on desk research, expert interviews, and analysis of the proposal texts.

Key findings

- The package is contested. Some measures are viewed as operational streamlining and generally welcomed by the industry, while others are seen as a more substantive recalibration of existing safeguards;
- Competitiveness is pursued mainly through procedural and definitional loosening, alongside stronger reliance on EU-level guidance;
- General Data Protection Regulation (GDPR) amendments are the most far-reaching and sit at the centre of the debate about simplification vs deregulation;
- The proposal would consolidate large parts of the EU data framework by integrating the Data Governance Act, Open Data Directive, and the Free Flow of Non-Personal Data Regulation into a recalibrated Data Act;
- Platform-to-Business Regulation is proposed to be repealed due to overlaps with Digital Service Act and the Digital Markets Act;
- In cybersecurity, the main proposal encompasses the creation of a Single Entry Point (SEP) operated by European Union Agency for Cybersecurity (ENISA) that would centralise incident notification submissions across several regimes; and
- The Omnibus on AI focuses on timelines, burden reduction and centralisation. It links the start of the high-risk obligations to the availability of standards and guidance, extends simplified pathways to small mid-caps, and increases the AI Office's role for certain advanced systems.

Practical assessment: issues most relevant for legislators

Across both proposals, a recurring question is whether simplification improves usability without weakening uniform protection, enforceability and legal certainty. Several amendments rely on context-dependent clauses, which may reduce over-compliance in some settings but could also generate more legal uncertainty and interpretative disputes.

¹ European Commission (2025, November 19). *Simpler EU digital rules and new digital wallets to save billions for businesses and boost innovation** [press release]. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2718

- Definition of personal data (GDPR): the move towards an entity-specific assessment of identifiability is presented as codifying case law and reducing unnecessary compliance in multi-actor environments. Critics argue it may narrow GDPR protection in practice for pseudonymous and indirectly identifiable data, producing uneven protection and new loopholes where technical capabilities differ between actors;
- Data subject access requests (GDPR): by allowing refusals or fees where requests are considered excessive or pursued for “non-data-protection” purposes, the proposal aims to curb perceived misuse and administrative burden. Stakeholders warn this may weaken a “gateway right” used for accountability (including in employment and research contexts) and may be difficult to apply fairly because controllers would need to infer motive;
- Cookie fatigue and device access: moving core device-access rules from the ePrivacy Directive into GDPR and promoting machine-readable privacy signals could reduce banner fatigue and align consent mechanics. However, effectiveness is likely to depend on the design of standards and interfaces (including by browsers and platforms), and the media service provider exemption may create market distortions and enforcement complexity;
- Data Act consolidation: consolidation may reduce formal fragmentation, but the package also introduces recalibrations, notably narrowing business-to-government access to “public emergency”, moving data intermediation towards a voluntary trust label, and reducing some data altruism obligations. A central question is whether consolidation improves usability while preserving public-interest governance and operational clarity;
- SEP for incidents: a central portal can reduce duplicative submissions, but stakeholders question whether resourcing and the lack of aligned thresholds and definitions across legal regimes will limit its effect;
- AI Act timelines, literacy and sandboxes: a readiness-based “stop–start” approach may better reflect implementation realities, but it can complicate planning if the trigger for “readiness” is not transparent and predictable. Softening AI literacy from a binding obligation to encouragement may reduce formal duties but may weaken practical governance if competence-building is deprioritised. The proposed EU-level sandbox and expanded real-world testing raise design questions about safeguards, transparency and whether sandbox participation delivers a meaningful compliance benefit (for example, stronger regulatory certainty for systems tested under controlled conditions); and
- Sensitive data and fairness testing: broader permission to process special category data for bias detection and the allowance for residual presence of sensitive data in training datasets shift greater discretion to providers and deployers, increasing the importance of clear safeguards, auditability and supervisory capacity.

Recommendations

Parliament may wish to differentiate between: (i) measures that primarily remove duplication without shifting rights balances (for example, reporting streamlining and improved template consistency), and (ii) amendments that recalibrate the substantive operation of core safeguards (notably GDPR scope, access rights, and AI-related lawful bases and sensitive data processing).

The following recommendations are proposed:

1. Require a clearer justification and evidence base for each major amendment, including distributional effects and administrative savings by different actor type.
2. Prioritise legal certainty, implement guidance, standards and templates where feasible and reopen legislative architecture only where necessary and demonstrably proportionate.
3. Investigate further the implementation and enforcement capacity needed to successfully execute the proposed changes (including SEP, expanded AI Office supervision, and EU-level sandbox).
4. Focus on the enforceable safeguards that can be added to proposed changes or protected by refuting some amendments.
5. Take into consideration the broader strategic and geopolitical context to better understand the impact of the proposed changes in the long term and calibrate objectives accordingly.

1. INTRODUCTION

On November 19, 2025, the European Commission (EC) released a regulatory initiative called the Digital Omnibus package² (also referred to as the Digital Package or the Digital Simplification Package). The Package contains two separate proposals:

- **The Digital Omnibus Regulation Proposal** (or the General Proposal) that focuses on digital acquis related to data, privacy, and cybersecurity;
- **The Digital Omnibus on AI** that focuses exclusively on the Artificial Intelligence (AI) Act.

These proposals aim to implement the general goal of the European Commission to pursue “simplification” in order to increase European Union’s (EU) declining competitiveness – the key issue identified in the 2024 Draghi report³. In this context, simplification is understood primarily as providing greater clarity on the application of existing digital rules (for example, through prioritised guidance, clearer sequencing, and improved interpretative consistency) rather than as a substantive modification of the underlying regulatory objectives or standards.

Overall, the EC estimates that, if the Digital Omnibus proposals are adopted by early 2027, they could generate at least EUR 1 billion in annual administrative cost savings and around EUR 5 billion in cumulative savings by 2029⁴.

In addition to the Digital Omnibus proposals, EC also released the **Data Union Strategy**⁵ explaining the long-term goals for the EU data economy, and the **European Business Wallet**⁶, a specific legislative proposal to create a secure, digital ‘identity’ for companies. The three parts comprise a coordinated effort to recalibrate the European economy from being a digital referee (only making rules) to a digital player (building its own tech)⁷. This package of proposed rules and initiatives will now be submitted to the European Parliament and the Council for discussion and adoption. The acts are open for feedback until January 20, 2026 – after which it will be summarised by the EC and presented to the European Parliament (EP) and the Council of the EU with the aim of feeding into the legislative debate.

² European Commission (2025, November 19). *Simpler EU digital rules and new digital wallets to save billions for businesses and boost innovation** [press release]. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2718

³ Torreblanca, J. I. (2025, December 3). Thrown under the omnibus: How the EU’s digital deregulation fuels US coercion, *European Council on Foreign Relations*. Available at: <https://ecfr.eu/article/thrown-under-the-omnibus-how-the-eus-digital-deregulation-fuels-us-coercion/>

⁴ European Commission (2025). COMMISSION STAFF WORKING DOCUMENT Accompanying the documents Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus) Amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI).

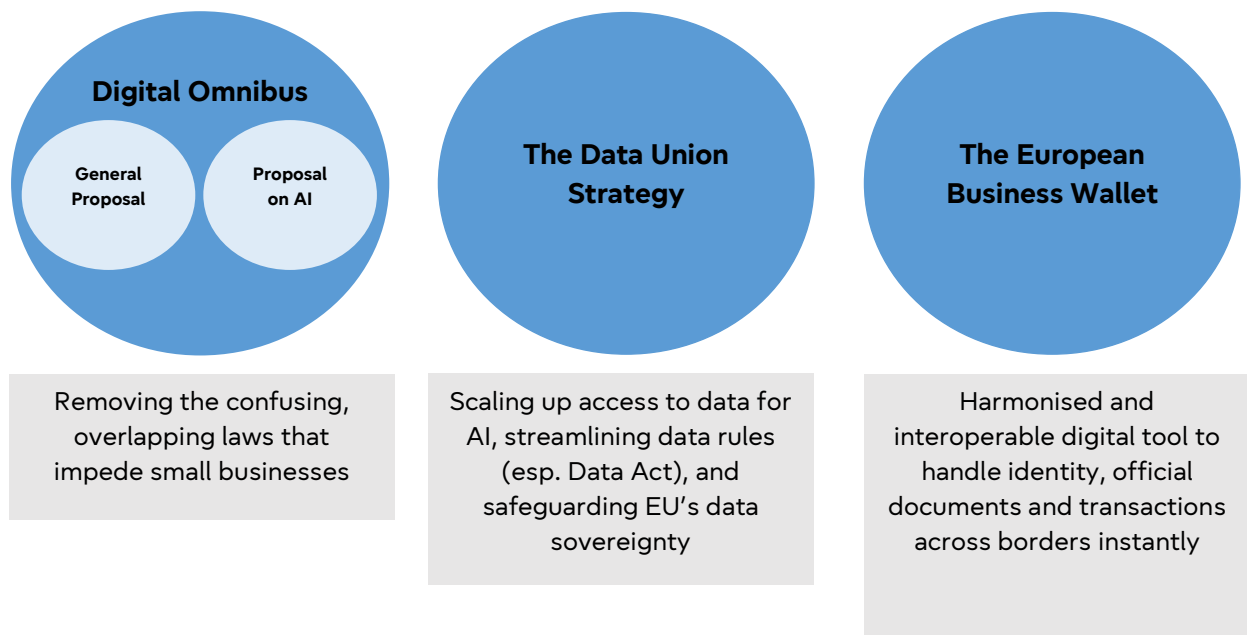
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2025%3A836%3AFIN>

⁵ The Communication was also accompanied by the Recommendation on model contractual terms on data access and use, and standard contractual clauses on cloud computing, available here: European Commission (2025, November 19). *Draft Recommendation on non-binding model contractual terms on data access and use and non-binding standard contractual clauses for cloud computing contracts* [press release]. Available at: <https://digital-strategy.ec.europa.eu/en/library/draft-recommendation-non-binding-model-contractual-terms-data-access-and-use-and-non-binding>

⁶ European Commission (2025, November 19). *Proposal for a Regulation on the establishment of European Business Wallets*. Available at: <https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-establishment-european-business-wallets>

⁷ Mariniello, M. (2025, November 20). Efficiency and distribution in the European Union’s digital deregulation push, *Bruegel*. Available at: <https://www.bruegel.org/policy-brief/efficiency-and-distribution-european-unions-digital-deregulation-push>

Figure 1: EU Digital Omnibus Package and related digital policy initiatives from November 2025



Source: Authors' own elaboration.

Alongside these documents, the EC also launched a **Digital Fitness Check**⁸ – a broad review and public consultation exercise to assess the cumulative impact of the EU's digital legislation. It is framed as a second stage of the plan to simplify digital rules, following the immediate adjustments introduced by the Digital Omnibus proposals. It is open until 11 March 2026. Any insights gained from this fitness check could inform future updates or a next "omnibus" of digital legislation⁹.

⁸ European Commission (2025). *Digital fitness check – testing the cumulative impact of the EU's digital rules*. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15554-Digital-fitness-check-testing-the-cumulative-impact-of-the-EUs-digital-rules_en

⁹ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

Box 1: The “omnibus” method: why it matters for scrutiny

Why the ‘omnibus’ method itself is being debated

Omnibus legislation bundles amendments to several existing EU laws into a single proposal. This law making technique has advantages as it allows to ensure more consistency across different EU law, but legal commentary has also argued that its increasing use as a standard “simplification” vehicle may create risks for transparent and evidence-based lawmaking. The concern is practical as much as legal: when many domains are amended at once, scrutiny can become harder, consultation can be narrower in practice, and it may be more difficult to demonstrate that each change is proportionate to the objective pursued. For the European Parliament, the practical implication is clear: each individual amendment should be justified on its own merits (problem, objective, evidence), and the package should be organised and documented in a way that allows MEPs to scrutinise and amend specific changes without having to accept or reject the whole bundle as a single political take-it-or-leave-it.

Source: Authors’ own elaboration, primarily based on Alemanno, A. (2025)¹⁰.

The aim of the study is to delve deeper into the Digital Omnibus package documents (the General Proposal and the Proposal on AI) and provide a detailed overview with potential recommendations as relevant to the European Parliament. Our data collection and analysis rely on a mixed-method approach and a variety of sources:

- **Desk research and literature review** (with an emphasis on variety and exhaustiveness of sources showcasing reactions to the published Digital Omnibus package);
- **Interviews with legal and policy experts** (covering digital policy areas affected by the proposals) **Analysis of the Digital Omnibus proposals** (aiming to identify the remaining gaps, challenges, and issues as pertinent to the upcoming legislative debate).

The report is structured in the following way: an overview of the Digital Omnibus package (Chapter 2), practical assessment of it (Chapter 3), and recommendations with proposed amendments for the European Parliament (Chapter 4).

¹⁰ Alemanno, A. (2025). The Legality of Omnibus Legislation Under EU Law: A Preliminary Analysis of Omnibus I Simplification Directive of CSRD and CSDD and its Legal Consequences on the EU Legal Order, SSRN. Available at: <https://ssrn.com/abstract=5727822>

2. OVERVIEW OF THE DIGITAL OMNIBUS

KEY FINDINGS

- The Digital Omnibus package lays out the main goals it aims to achieve, including but not limited to reduction of administrative burden, further support to small and medium-sized enterprises (SMEs) and small mid-caps (SMCs), and more legal consistency and predictability.
- “Competitiveness” is pursued mainly through procedural and definitional loosening.
- The General Data Protection Regulation (GDPR) amendments are the most far-reaching.
- There is a clear shift towards facilitating AI development through data-law recalibration and EU-level guidance.
- EU Data Act could become the main data law with the integration of the Data Governance Act (DGA), Open Data Directive (ODD), Free Flow of Non-Personal Data Regulation into the Data Act, and the repeal of P2B Regulation.
- ‘Cookie fatigue’ is addressed by moving device-access rules into GDPR and promoting machine-readable privacy signals
- The proposal also includes the creation of a single EU entry point for incident reporting to be created under the European Union Agency for Cybersecurity (ENISA).
- Digital Omnibus on AI focuses on timelines of high-risk obligations, burden reduction and centralisation.

2.1. Digital Omnibus Regulation Proposal

The Digital Omnibus Regulation Proposal aims to target recurring implementation pain points. The proposal therefore combines (i) amendments to a limited set of core acts and (ii) repeals of instruments that the Commission considers redundant or better absorbed into the remaining framework.

Table 1 provides an overview of the affected acts. In addition, the proposal signals that simplification is intended to be iterative: Figure 2 summarises the evaluation plan for other acts that are not yet amended but will be reviewed separately or as part of a further exercise.

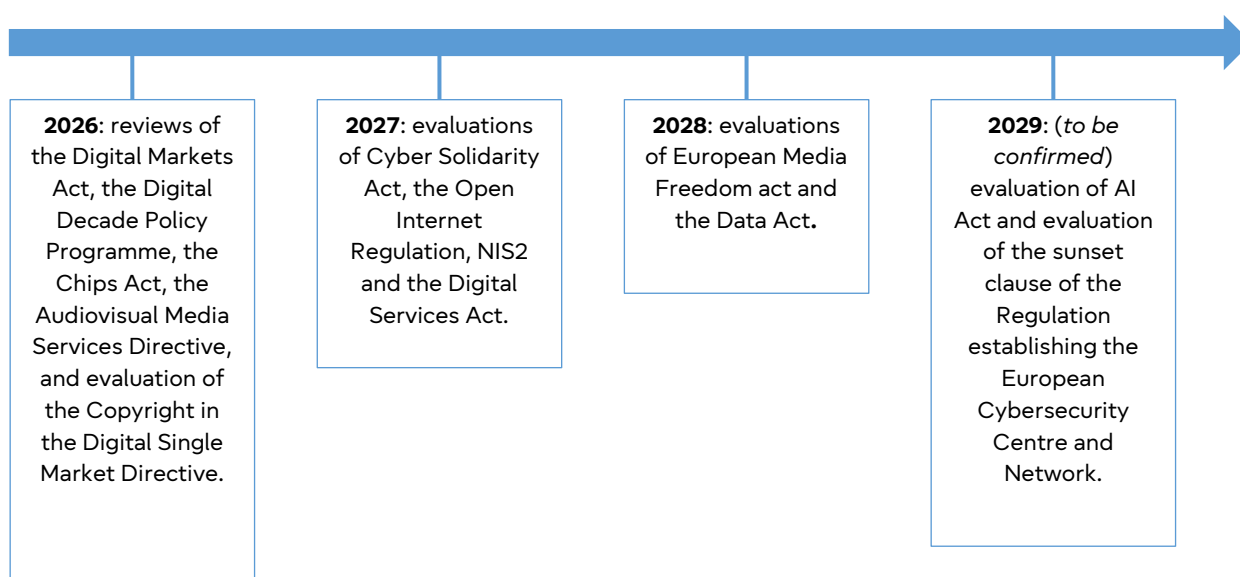
Table 1: Digital Omnibus Regulations Proposals: legal acts affected by amendments and repeals

Affected by proposed amendments	Proposed for repeals
• General Data Protection Regulation (GDPR) — Regulation (EU) 2016/679 • Data Protection Regulation for EU Institutions — Regulation (EU) 2018/1725 • Data Act — Regulation (EU) 2023/2854 • Single Digital Gateway Regulation — Regulation (EU) 2018/1724 <i>Specifically regarding incident reporting:</i>	Data Governance Act (DGA) — Regulation (EU) 2022/868 Open Data Directive (ODD) — Directive (EU) 2019/1024

Affected by proposed amendments	Proposed for repeals
• Network and Information Systems 2 (NIS2) Directive — Directive (EU) 2022/2555 • Critical Entities Resilience (CER) Directive — Directive (EU) 2022/2557 • eIDAS / European Digital Identity (EUID) — Regulation (EU) 910/2014 • Digital Operational Resilience Act (DORA) — Regulation (EU) 2022/2554	Free Flow of Non-Personal Data Regulation — Regulation (EU) 2018/1807 Platform-to-Business (P2B) Regulation — Regulation (EU) 2019/1150 ePrivacy Directive — Directive 2002/58/EC

Source: Authors' own elaboration.

Figure 2: Evaluation plan as outlined in the Digital Omnibus Regulation Proposal



Source: Authors' own elaboration based on the Digital Omnibus Regulation Proposal¹¹.

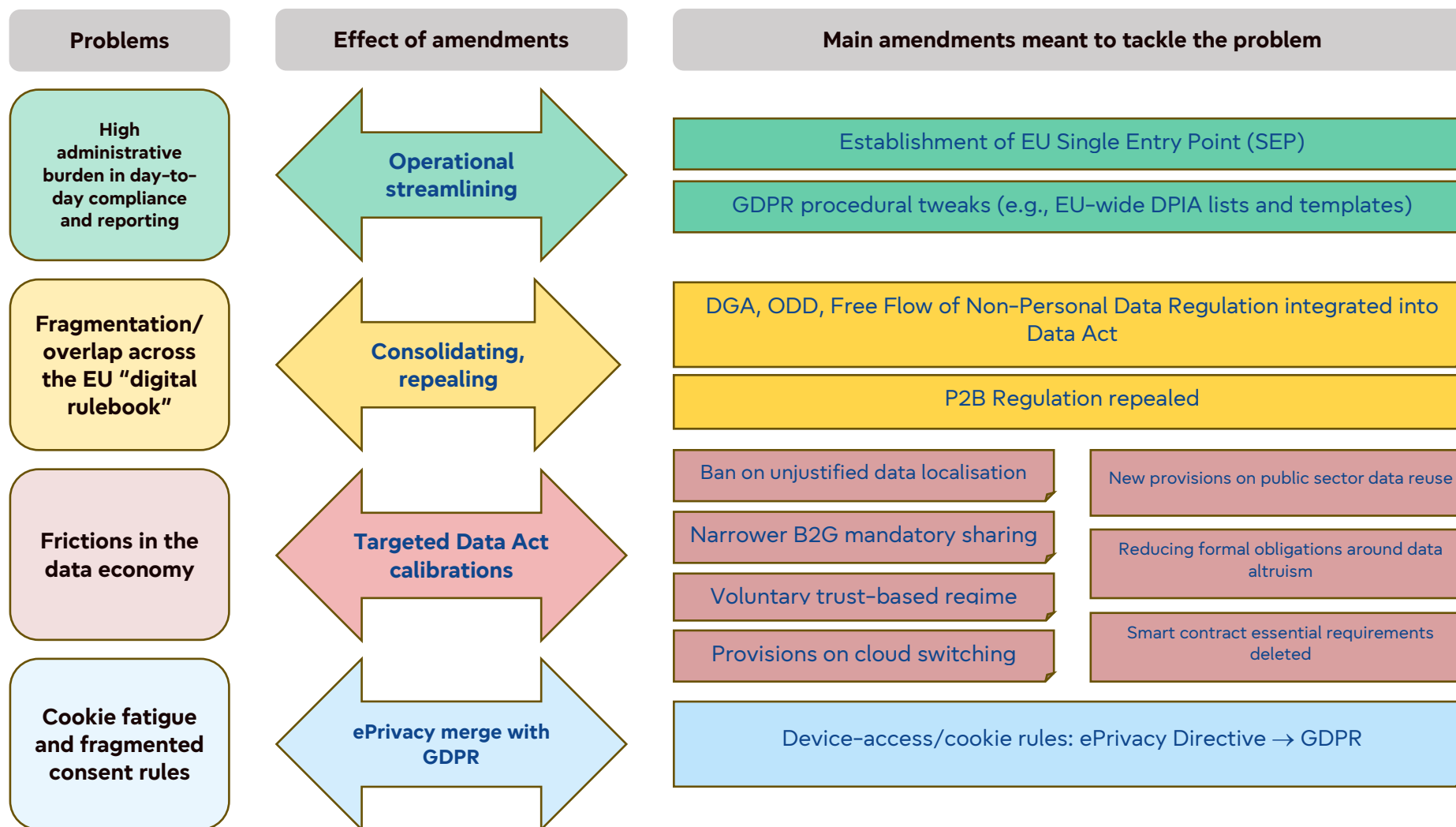
2.1.1. What problems it intends to solve

The proposal is designed to address several challenges that have emerged from a decade of active EU regulation by means of directives and acts instead of national regulations¹². These problems are discussed below in more detail.

¹¹ European Commission (2025). *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus)*. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹² Mezei, K. (2025). *Governing Digital Ecosystems in the EU: A Coordinated Regulatory Approach*, DOT.PL, no. 1/2025. Available at: <https://www.journdot.pl/pdf-215839-133447?filename=Governing-Digital-Ecosyst.pdf>

Figure 3: Summary of main problems and proposed amendments to solve them in the Digital Omnibus Regulation Proposal



Source: Authors' own elaboration.

a. Excessive regulatory burden and "red tape"

The proposal is driven by the concern that excessive digital regulatory complexity has become a persistent burden for EU businesses, particularly small and medium-sized enterprises (SMEs) – a concern voiced by various stakeholders¹³. Multiple parallel laws (for example, separate frameworks for personal data, non-personal data, ePrivacy, cybersecurity, AI, etc.) have led to overlaps and duplicative requirements. Some industry stakeholders and experts claim that the current digital rulebook stifles innovation and compromises the EU's ability to compete with global technopolis like the United States and China. Under the current legal framework, for example, a single cybersecurity incident might trigger multiple, overlapping notification requirements to different authorities under the GDPR, NIS2, DORA, and other acts¹⁴. This creates a lot of confusion for businesses, hurting competitiveness and growth.

b. Frictions in the data economy

A related issue is the fragmentation of the EU data-economy rulebook into multiple instruments (Data Act, DGA, ODD, Free Flow of Non-Personal Data), each with its own concepts, procedures and compliance mechanisms. The Commission frames this accumulation as creating high compliance costs and, in some cases, legal uncertainty, linked to administrative burdens and regulatory inconsistencies¹⁵. Stakeholder commentary has similarly argued that parallel regimes in the EU data rulebook can be costly for firms to navigate in practice, particularly where businesses must assess and comply with overlapping requirements across instruments¹⁶.

c. Consent to data processing: "Cookie fatigue" and fragmented consent rules

Another symptom of this regulatory complexity has been the proliferation of consent pop-ups and "cookie fatigue"¹⁷ – an issue the Commission identified as resulting from overly rigid, overlapping privacy rules that frustrate users and companies alike. Part of it is also due to the industry's approach to implementing the GDPR and ePrivacy Directive, driven by profit incentives to structure consent options for users to increase acceptance rates through, for example, 'dark patterns' – misleading and manipulative website designs and configurations that aim to steer users to disclose more personal data than necessary¹⁸. It has led to increasing user fatigue as they are confronted with multiple consent decisions each time visiting a website and thus tend to opt for frictionless choices that do not necessarily reflect their privacy preferences. This requires further action to consolidate and clarify existing data privacy regulations – the goal that the Digital Omnibus proposals aim to achieve.

¹³ La Maison Élysée (2025, November 18). *Simplification of the EU Digital Rulebook*. [press release]. Available at: <https://www.elysee.fr/en/emmanuel-macron/2025/11/18/simplification-of-the-eu-digital-rulebook>

¹⁴ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

¹⁵ See, for example, p.p. 12–13 in European Commission (2025). *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus)*. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁶ Barysas, M., and Stoilova, S. (2025, July). Simplifying the EU Digital Rulebook: clarity, simplicity, and agility for competitiveness. *BusinessEurope*. Available at: <https://www.bussinesseurope.eu/wp-content/uploads/2025/07/2025-07-17-BusinessEurope-Paper-Simplification-of-the-Digital-Rulebook.pdf>

¹⁷ CookieScript (2024, May 17). *What Is Consent Fatigue and How to Combat It?* Available at: <https://cookie-script.com/blog/consent-fatigue>

¹⁸ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

d. Legal uncertainty and lack of predictability that stem from fragmentation and overlaps

The collection of digital rules has also led to significant legal uncertainty for companies and authorities. Overlapping regulations and unclear interactions between laws (for example, how the AI Act intersects with data protection rules, or how ePrivacy and GDPR align) have made it hard for companies to know exactly what is expected under different legislation. Additionally, because the digital regulatory landscape has been evolving significantly, there is a lack of long-term predictability – businesses find it difficult to plan and make strategic decisions when rules keep changing or may conflict¹⁹.

In practice, legal uncertainty has been particularly visible in debates over the definition of personal data. Regulators, particularly data protection authorities, have historically followed an “absolute” approach: if any person, anywhere, could theoretically identify an individual from a piece of information, that data must be treated as personal data by everyone. This approach has led to significant compliance burdens, especially when entities processing the data could not themselves identify the individual in question. By contrast, the Court of Justice of the European Union (CJEU) has consistently favoured a “relative” approach, focusing on whether the specific entity processing the information can reasonably identify the individual using the means available to it²⁰. As a result, organisations have faced legal risk and practical confusion about how to handle borderline or pseudonymised data – uncertainty the Digital Omnibus aims to reduce.

2.1.2. Key amendments proposed

The Digital Omnibus proposes multiple different amendments, repeals and consolidations – they are explained below as follows.

a. Amendments to GDPR: relative definition of personal data, broader legitimate interest and lighter procedural duties

As argued by experts, industry, and civil society alike, the most consequential amendments proposed target the GDPR. They are presented as clarifications and simplifications that recalibrate how certain core safeguards operate in practice. In substance, amendments related to GDPR have 4 main pillars:

- A re-specification of what counts as ‘personal data’ in multi-actor settings;
- A new, more permissive framework for data use in AI development and operation (in light of the proposed amended definition of ‘scientific research’ and including more exemptions to use some special category data);
- A structural shift of key ‘cookie/device access’ rules from ePrivacy directive into the GDPR;
- Targeted clarification of rules on automated decision-making and information duties; and
- Adjustment to individual rights and compliance processes (access request, breach notifications and Data Protection Impact Assessment (DPIA)).

¹⁹ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

²⁰ The Court of Justice has articulated this “relative” approach in several judgments, including Breyer, Nowak, Scania, and more recently the SRB case, building on the logic set out in Recital 26 of the GDPR. See more: Baumgartner, U. (2025, December 11). EU Digital Omnibus: What the proposed changes to the concept of personal data mean in practice, *IAPP*. Available at: <https://iapp.org/news/a/eu-digital-omnibus-what-the-proposed-changes-to-the-concept-of-personal-data-mean-in-practice>

Starting with the **amended definition of personal data** (Article 4 of GDPR)²¹, the proposal shifts from an objective definition to a subjective/relative approach by making identifiability entity-specific. This means that the information is no longer personal data for an entity if that specific entity cannot reasonably identify the individual with the data and systems it realistically has at its disposal. This aims to codify the approach from most recent decisions of the CJEU, most notably the Single Resolution Board (SRB) case from September 2025²²: two organisations may treat the same dataset differently depending on their technical capacity to identify a person.

Building on this shift, the Omnibus further proposes to introduce a new Article 41a GDPR²³ by empowering the Commission, with the close involvement of the European Data Protection Board (EDPB), to adopt implementing acts setting out technical criteria for when pseudonymised data may be treated as no longer personal data for certain entities. In combination, these changes move the assessment of what qualifies as personal data away from a uniform, abstract standard and towards a more context-dependent and technically grounded determination. As a result, they could significantly narrow the range of situations in which information is treated as personal data under the amended GDPR²⁴.

Another proposal aims to facilitate **GDPR compliance for AI development and operation** by clarifying lawful bases and adding AI-specific exceptions²⁵. If implemented, it would explicitly recognise legitimate interest (Article 6(1)(f)) as a possible legal basis for the development and operation of AI systems and models. It does not, however, take away the usual balancing test for legitimate interests, appropriate safeguards, and any EU or national laws that still require consent for such processing²⁶.

In parallel, the proposal introduced an **amended definition of "scientific research"** to clarify that research may also pursue commercial objectives, while it encompasses "any research which can also support innovation, such as technological development or demonstration"²⁷. While this amendment is not only about AI, it is highly relevant to AI development, training, and experimentation, especially where personal data is used. In practice, it would mean that controllers would no longer need to perform a separate compatibility assessment for data reuse.

The Digital Omnibus also proposes to amend Article 13(5) of the GDPR to clarify the procedural consequences of this reclassification²⁸: where personal data are processed for scientific research under these conditions, controllers would be exempted from directly informing data subjects, on the basis that doing so would involve a disproportionate effort, and would instead be required to make the

²¹ Article 3(1), pp. 54–55 of the General Proposal. Available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

²² De Graeve, L., and Clemens, J. (2025, November 26). One bus, many passengers: How the Digital Omnibus rewrites the EU digital rulebook, *Timelex*. Available at: <https://www.timelex.eu/en/blog/one-bus-many-passengers-how-digital-omnibus-rewrites-eu-digital-rulebook>

²³ Article 3(10), p. 58 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

²⁴ Hickman, T., Gabel, D., Lorenz, S., Hainsdorf, C., and Mair, D. (2025, December 2). GDPR under revision: Key takeaways from the Digital Omnibus Regulation proposal, *White & Case*. Available at: <https://www.whitecase.com/insight-alert/gdpr-under-revision-key-takeaways-from-digital-omnibus-regulation-proposal>

²⁵ New Article 88c as shown in Article 3(15), p. 61 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

²⁶ Hickman, T., Gabel, D., Lorenz, S., Hainsdorf, C., and Mair, D. (2025, December 2). GDPR under revision: Key takeaways from the Digital Omnibus Regulation proposal, *White & Case*. Available at: <https://www.whitecase.com/insight-alert/gdpr-under-revision-key-takeaways-from-digital-omnibus-regulation-proposal>

²⁷ Article 3(1)(b), p. 55; see also: noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

²⁸ Article 3(6), p. 56 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

relevant information publicly available²⁹. Taken together, the amendments seek to provide greater legal certainty for data reuse in research and innovation contexts (including those outside of academia), while shifting greater weight onto the requirement to apply appropriate safeguards. This change is in line with the EDPB's 2019 Study on the secondary use of personal data in the context of scientific research³⁰.

Separately, the proposal introduces two targeted exemptions relating to the processing of special categories of data, which are not limited to scientific research scenarios³¹:

- A narrow exemption for biometric data used to confirm someone's identity, but only under strict conditions. Biometric data (such as a fingerprint or facial scan) may be processed if it is genuinely necessary to verify who the person is and if both the biometric data and the tools used to check it remain entirely under the individual's own control. In practice, this is meant to cover scenarios like on-device authentication on a smartphone and does not constitute a data reuse scenario.
- An exemption for the residual use of sensitive data in AI systems, allowing the residual presence of sensitive data in AI datasets where such data is not intentionally collected but may appear incidentally. This exemption is particularly relevant to AI development and training and may apply both in scientific research contexts and in other AI-related processing. It is subject to strict safeguards, including efforts to avoid collection, remove the data where feasible, or prevent it from influencing system outputs.

While only the second exemption may overlap in practice with the expanded definition of scientific research (Article 3(1)(b) of the proposal), both exemptions (taken together with the changes introduced in the Digital Omnibus on AI; see more in section 2.2.2) reflect a broader shift in the Omnibus towards reducing legal friction for AI-related data processing, while relying more heavily on internal safeguards and accountability mechanisms.

Lastly, the proposal adjusts several **procedural safeguards and day-to-day compliance rules** as related to GDPR, notably in the following areas:

- Data subject access requests (DSARs, Article 12(5)³²): the proposal clarifies how organisations may handle requests by allowing controllers to refuse a request or charge a fee where it is seen as abusive or excessive, including where it pursues aims unrelated to data protection³³. It also specifies that requests should be reasonably specific, and that very broad or undifferentiated requests may be treated as excessive³⁴;
- Data breach notifications³⁵: the threshold for notifying supervisory authorities would be raised, so that notification is required only where a breach is likely to result in a high risk to individuals,

²⁹ noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

³⁰ De Graeve, L., and Clemens, J. (2025, November 26). One bus, many passengers: How the Digital Omnibus rewrites the EU digital rulebook, *Timelex*. Available at: <https://www.timelex.eu/en/blog/one-bus-many-passengers-how-digital-omnibus-rewrites-eu-digital-rulebook>

³¹ Article 3(3)(a), p. 55 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

³² Article 3(4), p. 56 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

³³ Hickman, T., Gabel, D., Lorenz, S., Hainsdorf, C., and Mair, D. (2025, December 2). GDPR under revision: Key takeaways from the Digital Omnibus Regulation proposal, *White & Case*. Available at: <https://www.whitecase.com/insight-alert/gdpr-under-revision-key-takeaways-from-digital-omnibus-regulation-proposal>

³⁴ noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

³⁵ Article 3(8)(a), p. 57 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

aligning more closely with the existing trigger for notifying data subjects (under Articles 33 and 34 of GDPR)³⁶. At the same time, the deadline for notifying authorities would be extended from 72 to 96 hours and required to be submitted via the new Single Entry Point (SEP; see more in sub-section c below);

- Data Protection Impact Assessments (DPIAs)³⁷: to improve EU-wide consistency, the proposal would require the EDPB to draw up single, EU-wide lists of processing activities that do (or do not) require a DPIA, alongside a common methodology and template. These would be reviewed and updated every three years³⁸, replacing the current fragmented system of national lists and approaches that often lead to legal uncertainty³⁹; and
- Lowering the threshold⁴⁰: across several GDPR amendments linked to AI development and research, the proposal replaces the threshold of “strictly necessary” with the less demanding standard of “necessary”. Although this change is subtle, it lowers the bar for controllers when justifying certain forms of processing, particularly in innovation and research contexts. Over time, this may widen the range of processing activities considered permissible under the GDPR.

b. Cookies and consent: integrating device-access rules from ePrivacy Directive and reducing cookie fatigue

When it comes to cookies and consent, the proposal would **integrate core ePrivacy “device access” rules into the GDPR**⁴¹, creating a new GDPR structure governing access to or storage of information on terminal equipment (phones, laptops, smart devices). Consent would remain the default for storing or accessing data on a device with some notable exceptions⁴² that are largely familiar but currently located in the ePrivacy Directive. The Digital Omnibus proposal would instead move, clarify, and only partially adjust them in the process.

Another change (new Article 88b in GDPR) aimed at particularly tackling the cookie fatigue for users would be an **establishment of a framework for automated, machine-readable privacy signals** that browsers and similar user agents would transmit, and websites would be expected to respect (with an explicit exemption for media service providers as defined in the European Media Freedom Act). The proposal also introduces an operational restriction on repeated consent prompting, requiring a minimum interval (e.g. six months) after refusal before requesting consent again for the same purpose⁴³.

³⁶ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

³⁷ Article 3(9), pp. 57–58, also Article 3(14), p. 59 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

³⁸ Hickman, T., Gabel, D., Lorenz, S., Hainsdorf, C., and Mair, D. (2025, December 2). GDPR under revision: Key takeaways from the Digital Omnibus Regulation proposal, *White & Case*. Available at: <https://www.whitecase.com/insight-alert/gdpr-under-revision-key-takeaways-from-digital-omnibus-regulation-proposal>

³⁹ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

⁴⁰ Article 3, pp. 54–61 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁴¹ Article 3(15), pp. 59–60, also see Article 5, p. 65 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁴² De Graeve, L., and Clemens, J. (2025, November 26). One bus, many passengers: How the Digital Omnibus rewrites the EU digital rulebook, *Timelex*. Available at: <https://www.timelex.eu/en/blog/one-bus-many-passengers-how-digital-omnibus-rewrites-eu-digital-rulebook>

⁴³ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

Taken altogether and according to the Commission, 50 per cent of private websites and 80 per cent of public websites would no longer have to rely on consent and the use of cookie banners, alleviating the cookie fatigue for users⁴⁴.

Moreover, the Digital Omnibus introduces a targeted **clarification of the GDPR rules on automated individual decision making**. While Article 22 is not formally removed, it clarifies that automated decisions may be considered lawful where they are deemed necessary for entering into or performing a contract, even where a human decision-making alternative would technically be possible. In practice, this clarification narrows the range of situations in which automated decision-making is treated as exceptional under the GDPR. Controllers may more readily rely on automated systems as part of ordinary contractual arrangements, provided that the general GDPR safeguards continue to apply.

c. Data Act: repeal and integration of Data Governance Act, Open Data and Free Flow rules

Overall, the proposal repeals the DGA, the ODD, and the Free Flow of Non-Personal Data Regulation, merging their key provisions into a “recalibrated” Data Act, turning it into the core of EU data law⁴⁵.

For public-sector data, the proposal creates a **unified regime for the re-use of both protected and non-protected data held by public authorities**, including data that is subject to restrictions⁴⁶. By bringing together rules that were previously spread across DGA and the Open Data Directive, the Omnibus aims to simplify procedures, reduce administrative burden, and make it easier for re-users to understand their rights and obligations. At the same time, public authorities are given greater flexibility to set specific conditions and higher fees for very large enterprises, especially undertakings designated as gatekeepers under the DMA, in order to prevent the misuse of market power and safeguard fair competition and innovation.

In addition, the proposal significantly reshapes the regulatory framework for **data intermediation services**⁴⁷. The mandatory notification and compliance regime previously established under the DGA is replaced with a **voluntary, trust-based regime** embedded in the Data Act. Data intermediation service providers may opt into this framework to signal compliance but are no longer subject to mandatory registration or structural separation requirements.

Within the Data Act itself, several targeted calibrations are introduced. **Business-to-government (B2G) data sharing is narrowed** so that mandatory access is limited to situations of public emergencies, reducing legal uncertainty linked to the broader notion of “exceptional need”⁴⁸. **Safeguards against trade secret leakage to third countries** are strengthened, allowing data holders to refuse access where there is a serious risk of unlawful disclosure and economic harm⁴⁹.

⁴⁴ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

Note from the source about the numbers: these figures represent the proportion of total websites that would not need to use cookie banners with the proposed changes and not the decrease in frequency of cookie banners; some websites already do not require such banners since they do not use cookies nor process personal data.

⁴⁵ Text below is based on European Commission (2025). Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as regards the simplification of the digital legislative framework, and repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868, and Directive (EU) 2019/1024 (Digital Omnibus).

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0837>; Article 10(3) details the repeals.

⁴⁶ See pp. 35–51, Article 1(18) the newly added Chapter VIIc Re-use of data and documents held by public sector bodies, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁴⁷ See pp. 30–34, Article 1(18), the newly added CHAPTER VIIa DATA INTERMEDIATION SERVICES AND DATA ALTRUISM ORGANISATIONS’, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁴⁸ Article 1(7), p. 25 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁴⁹ Article 1(3), p. 24 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

Relatedly, safeguards concerning unlawful third-country governmental access to non-personal data are broadened in scope, so that these ‘cloud sovereignty’-style protections apply beyond cloud service providers to other relevant stakeholders covered by the Data Act framework⁵⁰. The proposal also removes the essential requirements for smart contracts, easing compliance for developers but at the same time leaving issues such as intervention, reversibility and interoperability to be addressed through private arrangements or non-binding guidance rather than binding EU rules⁵¹.

The Omnibus also **relaxes the framework for data altruism**⁵². Several reporting and governance obligations are removed, including the requirement to develop an EU-level data altruism rulebook and to maintain national coordination arrangements⁵³. While data altruism remains possible, it is subject to fewer formal obligations, reflecting a broader move toward simplification and voluntary participation. Although the Free Flow of Non-Personal Data Regulation is formally repealed, its core principle — the prohibition of unjustified data localisation requirements within the EU — is preserved and incorporated directly into the Data Act⁵⁴. This ensures continuity of internal market protections despite legislative consolidation.

For **cloud and data services**, the proposal keeps the main goal of the Data Act: making it easier for users to switch providers and avoid being locked in. However, it introduces an important **exception for custom-made services**⁵⁵. The switching rules will not apply to contracts signed on or before 12 September 2025 where the service was specially tailored to a customer’s needs and would not work without that prior adaptation. In practice, this means providers of such customised services will not have to change or renegotiate existing contracts just to meet the new switching requirements. The aim is to avoid retroactive obligations, while still applying the switching rules to standard, off-the-shelf services going forward.

Finally, the proposal extends existing **SME facilitation measures under the Data Act to SMCs**⁵⁶, recognising that these firms often face similar compliance constraints but play an important role in innovation and market development. Overall, the Commission presents these changes as a consolidation and fine-tuning exercise: the ambition and core achievements of the Data Act are maintained, but the framework is streamlined, aligned with the Data Union Strategy, and intended to offer greater legal clarity, lower compliance costs, and stronger support for a competitive European data economy.

⁵⁰ Article 1(16), p. 29 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵¹ Recital 16, also Article 1(17), p. 5 and 30 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵² See pp. 30–34, Article 1(18), the newly added CHAPTER VIIa DATA INTERMEDIATION SERVICES AND DATA ALTRUISM ORGANISATIONS’. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵³ See, for example, Articles 32e or 32g of the new CHAPTER VIIa DATA INTERMEDIATION SERVICES AND DATA ALTRUISM ORGANISATIONS’. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵⁴ See p. 34, Article 1(18), the newly added ‘CHAPTER VIIb Free flow of non-personal data in the Union’. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵⁵ Article 1(15), pp. 28–29 of the General Proposal. Available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁵⁶ See, for example, Article 1(15), p. 28 of the General Proposal. Available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

d. EU-level single entry point for cybersecurity and data-breach reporting

The Digital Omnibus proposes that **incident notifications** under NIS2, GDPR, DORA, CER be **submitted via an EU single entry-point platform**, established and maintained by the ENISA, and routed to national competent authorities under each regime⁵⁷.

However, it remains uncertain whether incidents under eIDAS2 would fall within the scope of this platform, and AI Act incident reporting is not currently included. The European Commission estimates that “maintaining the single-entry point would require 8 FTEs [full time employees] within ENISA”⁵⁸. Until the system is functional and in cases of technical issue in the new SEP, existing reporting channels remain available.

ENISA will have to work together with the Member States and the private sector to determine the types and formats of information that would need to be notified – this will be formalised through implementing acts. A pilot should be run 18 months after the Digital Omnibus Regulation would come into force⁵⁹.

Beyond centralising the submission of incident notifications, the proposal also empowers the Commission to harmonise the content and templates of reports across different legal regimes (including earlier-mentioned DPIA templates)⁶⁰. In doing so, it must take account of experience gained under existing frameworks, notably the reporting templates developed under DORA. This may further standardise how incidents are described and assessed across sectors.

e. Repealing Platform-to-Business (P2B) regulation

Lastly, in addition to all amendments explained above, the Digital Omnibus Proposal **repeals the Platform-to-Business (P2B) regulation**⁶¹ arguing that its functions are now covered by the Digital Services Act (DSA) and the Digital Markets Act (DMA). However, references to the P2B Regulation that appear in other EU laws would continue to apply for a transitional period. These references would remain in force until the relevant legislation is formally amended and, in any event, no later than 31 December 2032. This includes, for example, provisions on the restriction or suspension of online intermediation services, complaint-handling mechanisms for business users, and related enforcement rules⁶².

⁵⁷ See Articles 6, 7, 8, 9, pp. 65–68. Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

⁵⁸ Staff Working Document accompanying the Proposal, p. 62. Available at: <https://digital-strategy.ec.europa.eu/en/library/digital-omnibus-regulation-proposal>

⁵⁹ Talayero, N. (2025, November 24). Regulatory Simplification: the digital omnibus package as a first step? *Telefónica*. Available at: <https://www.telefonica.com/en/communication-room/blog/regulatory-simplification-digital-omnibus-package-step/>

⁶⁰ Article 3(8)(c), Article 3(9), Article 3(14), Article 4(8) of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁶¹ Recital 59, p. 19, Article 10, pp. 68–69 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁶² Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

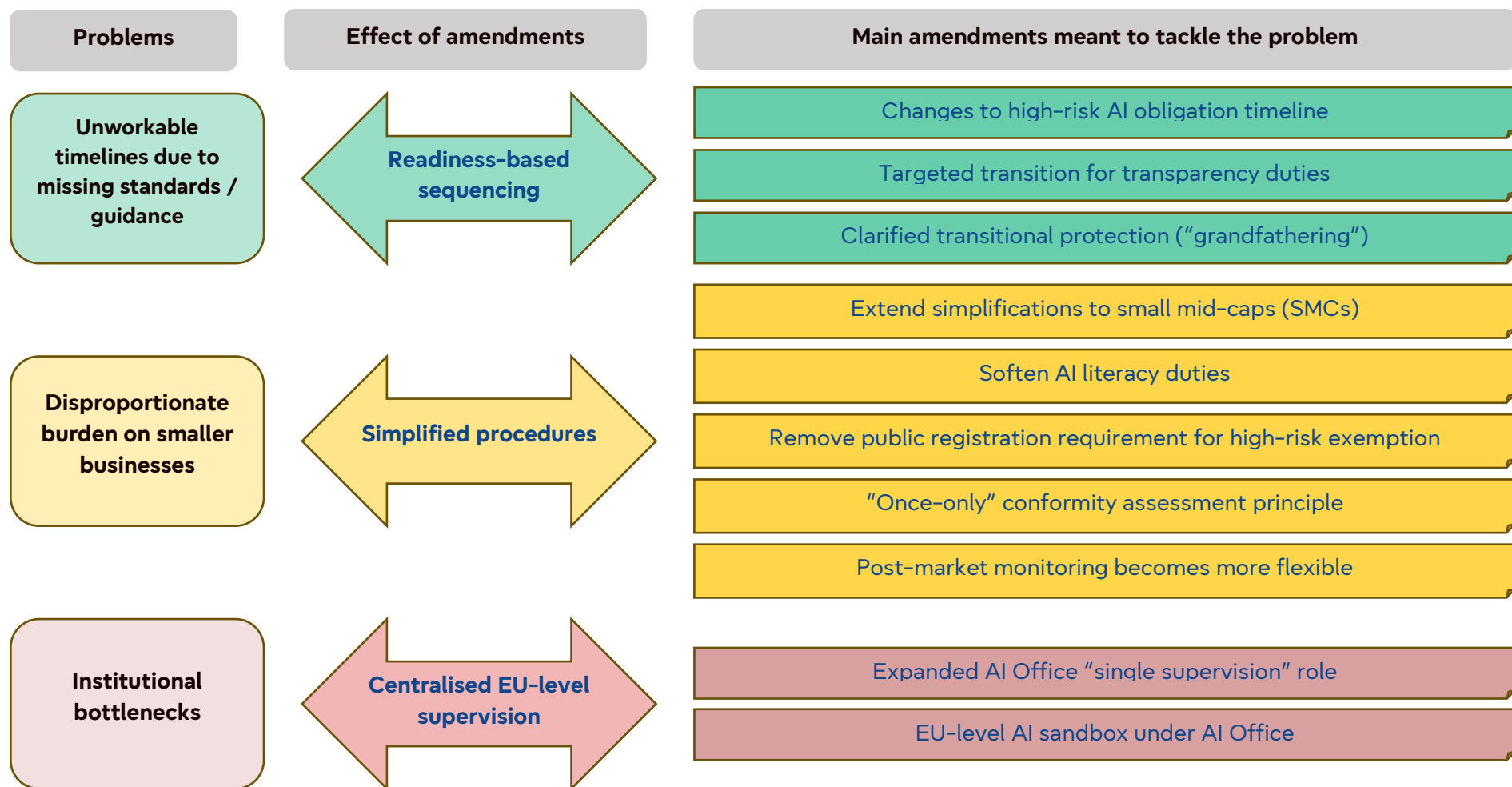
2.2. Digital Omnibus on AI Regulation

2.2.1. What problems it intends to solve

A prevailing sense among experts and industry has been that the Act is quite complex and difficult to implement, so some things had to change⁶³. The overall goal of the Omnibus is not to review the act but make targeted technical adjustments to solve practical implementation challenges and issues – discussed in more detail below.

⁶³ Interview with Andrej Savin.

Figure 4: Summary of problems and main amendments targeted at solving them in the Digital Omnibus on AI



Source: Authors' own elaboration.

a. Unworkable timelines due to missing standards

The EU's AI Act set fixed dates by which high-risk AI systems must comply (initially August 2026 for most high-risk uses, and 2027 for some products). However, these original enforcement deadlines for high-risk AI systems especially (August 2026) are no longer realistic given the lack of support tools (e.g., technical standards, guidelines, and certification bodies) necessary for proper implementation⁶⁴. This created a 'regulatory timing mismatch': companies were expected to meet detailed requirements before standards or official guidance existed to show them how. This mismatch is especially problematic for Europe's nascent AI industry. In mid-2025, dozens of European tech executives publicly called for a pause on the AI Act's timeline, arguing it was unfair to force compliance when American competitors could deploy AI freely and standards were unfinished. They warned that charging ahead without adjustments would put European firms at a disadvantage against Silicon Valley companies who do not face such immediate constraints⁶⁵. The timing issue has also become a political one: EU Member States like France and Germany pushed for a delay once they realised the original timeline might hurt industry readiness⁶⁶.

b. Disproportionate burden on smaller businesses

Some stakeholders have expressed concern that the AI Act's largely "one-size-fits-all" compliance requirements may impose disproportionate costs on small European businesses, potentially affecting their competitiveness⁶⁷. The AI Act (in addition to other digital regulations) contains extensive obligations – from detailed technical documentation and risk assessments to registration and monitoring duties – which can be costly and labour-intensive. While global tech giants have extensive legal and engineering teams at their disposal to handle compliance, SMEs, start-ups and small mid-cap firms have limited resources and thus compliance pathways for them were especially uncertain⁶⁸. Reducing compliance burdens is thus critical not only economically but also to maintain public support for the AI regulatory framework.

c. Institutional bottlenecks and fragmented oversight

Under the AI Act, enforcement and oversight of AI compliance is largely left to national authorities in each Member State, coordinated by a European AI Board. While this works for many local or sector-specific AI applications, it posed a problem for large-scale, cross-border AI systems – particularly general-purpose AI (GPAI) models and AI deployed by Very Large Online Platforms and Search Engines (VLOPSEs). These systems do not fit neatly into one country's jurisdiction; a foundation model might be developed by one company and then integrated into services across Europe, and a platform's AI can affect millions of users EU-wide.

⁶⁴ Somers, G. and Torfs, W. (2025, November 21). The European Commission Proposes a One-Year Delay for High-Risk AI Obligations and Softens AI Literacy to Encouragement, *Timelex*. Available at: <https://www.timelex.eu/en/blog/european-commission-proposes-one-year-delay-high-risk-ai-obligations-and-softens-ai-literacy-0>; See also the interview with Andrej Savin [conducted on 5 January 2026].

⁶⁵ Obedman, Y. M. (2025, November 19). EU's bet on looser AI rules risks backfiring, *Courthouse News Service*. Available at: <https://www.courthousenews.com/eus-bet-on-looser-ai-rules-risks-backfiring/>

⁶⁶ Obedman, Y. M. (2025, November 19). EU's bet on looser AI rules risks backfiring, *Courthouse News Service*. Available at: <https://www.courthousenews.com/eus-bet-on-looser-ai-rules-risks-backfiring/>

⁶⁷ Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

⁶⁸ Savin, A. (2025, November 19). The EU's Digital Omnibus on AI: A New Phase of Simplification for the AI Act, *EU Internet Law & Policy Blog*. Available at: <https://euinternetpolicy.wordpress.com/2025/11/19/the-eus-digital-omnibus-on-ai-a-new-phase-of-simplification-for-the-ai-act/>

The initial framework risked a patchwork of oversight: a company offering a GPAI service in multiple countries might have to answer to numerous national regulators, possibly facing inconsistent directives. Similarly, enforcement of AI rules on Big Tech platforms could clash or overlap with the EU's DSA, which already gives the European Commission direct supervisory powers over VLOPSEs. In practice, these structural risks are compounded by implementation realities: the designation of national competent authorities is already slow or uneven across Member States⁶⁹, so capacity gaps can emerge, coordination becomes harder, and the likelihood of inconsistent enforcement increases. In short, there was a gap in supervision for the most impactful AI: no single authority had a complete picture or clear responsibility, leading to fragmented governance and potential "forum-shopping" (companies exploiting uneven enforcement).

2.2.2. Key amendments proposed

The Digital Omnibus on AI introduces targeted amendments to the AI Act that are presented as implementation-focused simplifications. The overall intended effect is to delay and smooth the application of particularly obligations for high-risk systems, reduce burden for smaller actors, and centralise oversight of certain powerful AI systems at the EU level.

Before delving into proposed changes, it is crucial to note that the Digital Omnibus on AI does not reopen or weaken the AI Act's bans. The overall risk-based structure also remains unchanged.

a. High-risk AI: revised timelines and other changes

The most consequential change proposed concerns high-risk AI systems, which are at the core of the AI Act's regulatory model. Instead of following fixed calendar dates, the Digital Omnibus **links the start of high-risk obligations to the availability of implementation tools**, such as harmonised standards and Commission guidance⁷⁰. Once these tools are formally confirmed as ready, obligations will apply after a defined transition period, with different timelines for stand-alone high-risk systems (that fall under Annex III of the AI Act) and high-risk AI embedded in regulated products (Annex I). This approach aims to replace the current regime with a readiness-based mode, while still preserving absolute backstop dates to ensure the rules apply albeit later. For concrete changes, see *Figure 6* below. Overall, this change delays enforcement by 16 or 24 months⁷¹.

In the proposal, the Commission lists various documents and guidelines that it is in the process of producing to support overall compliance with the AI Act (see the list in *Table 2* below). None of these are directly related to the "stop-the-clock" restart for high-risk AI obligations – it is up to the Commission to confirm the availability of necessary measures.

The proposal further adjusts how ongoing compliance after market entry is organised for high-risk systems. It **removes Commission's power to impose a single, mandatory template for post-market monitoring plans for high-risk AI systems**⁷².

⁶⁹ Bashir, E. (2025, September 30). EU AI Act implementation: Only a few countries have designated AI Act enforcement authorities, *Cullen International*. Available at: <https://www.cullen-international.com/news/2025/09/EU-AI-Act-implementation--Only-a-few-countries-have-designated-AI-Act-enforcement-authorities.html>

⁷⁰ Article 1(2), p. 20, also Article 1(31), pp. 30–31 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁷¹ MacCarthy, M., and Propp, K. (2025, December 15). The European Union Changes Course on Digital Legislation, *Lawfare*. Available at: <https://www.lawfaremedia.org/article/the-european-union-changes-course-on-digital-legislation>

⁷² Article 1(24), p. 27. Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

Instead, the Commission promises to issue high-level guidance (included in *Table 2* below), leaving providers greater flexibility to design monitoring systems tailored to their technology and risk profile.

Alongside timeline and monitoring changes, the Digital Omnibus on AI proposes to **remove a public registration requirement for providers claiming an exception from high-risk requirements** under Article 6(3) of the AI Act (on the basis that the system performs only narrow or procedural tasks)⁷³. The amended clause would state that providers need to document their self-assessment and provide it to authorities upon request, but they would no longer need to face the reputational and administrative burden of public disclosure⁷⁴. In simple words, companies could internally decide that their AI is not high-risk, without telling the public – as long as they could justify it to regulators upon request.

Finally, the Omnibus **clarifies the scope of transitional protection for existing high-risk systems** (falling both under Annex I and III)⁷⁵. In simple words, one early sale could keep an entire AI model under old rules – even after the new rules (after 2027 or 2028) are supposed to apply. The protection would disappear if the company changed how the AI works, updates the model in a meaningful way, adds new functions, or adapts it to a new use⁷⁶.

⁷³ Article 1(6), (14), and (32) of the Digital Omnibus on AI.

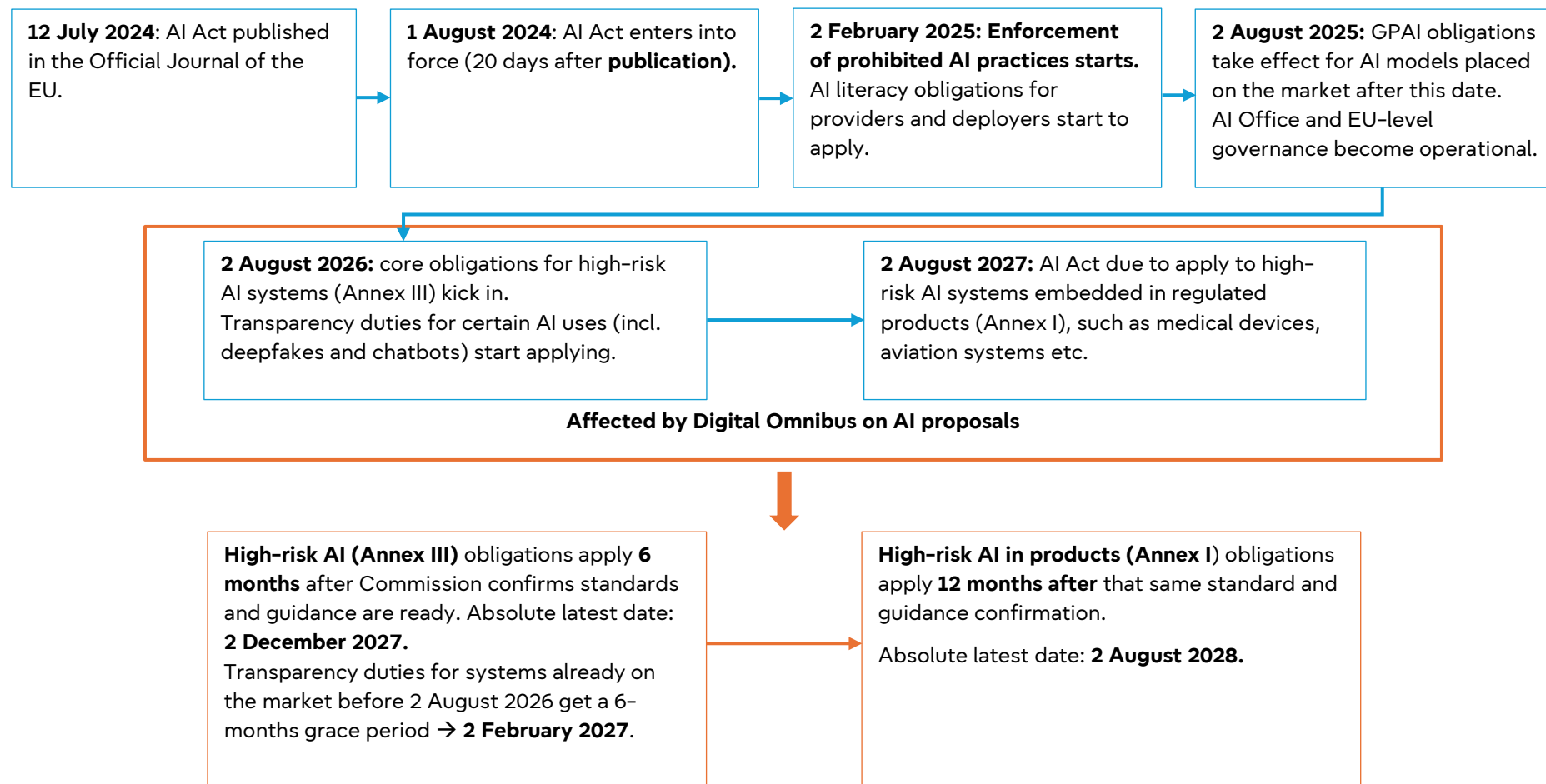
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁷⁴ Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>, see also: Somers, G., and Torfs, W. (2025, November 21). The European Commission proposes a one-year delay for high-risk AI obligations and softens AI literacy to encouragement, *Timelex*. Available at: <https://www.timelex.eu/en/blog/european-commission-proposes-one-year-delay-high-risk-ai-obligations-and-softens-ai-literacy-0>

⁷⁵ Article 1(30)(a), p. 30, also Recital 21, pp. 17-18 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁷⁶ Rubio, R. (2025). Proposal for a Regulation as regards the simplification of the implementation of harmonised rules of artificial intelligence (Digital Omnibus on AI), *Pérez-Llorca*. Available at: <https://www.perezllorca.com/wp-content/uploads/2025/12/Legal-Briefing-Proposal-for-a-Regulation-as-regards-the-simplification-of-the-implementation-of-rules-on-AI.pdf>

Figure 5: AI Act timeline and proposed changes in the Digital Omnibus



Source: Authors' own elaboration.

Table 2: Mapping of Commission guidelines announced in the Digital Omnibus

Guidelines announced in the Digital Omnibus on AI	Why it matters for legislators
Guidelines mainly related to high-risk AI obligations	
Guidelines on the practical application of the high-risk classification	Determine whether systems fall under Annex III or Annex I and therefore face the most burdensome obligations. Central to the delayed timeline logic.
Guidance on the reporting of serious incidents by providers of high-risk AI systems	This obligation exists only for high-risk systems and is part of post-market control.
Guidelines on obligations for providers and deployers of high-risk AI systems	Clarify who is responsible for what in high-risk deployments (providers vs deployers), a key enforcement issue.
Guidelines on the practical application of the high-risk requirements	Cover risk management, data governance, robustness and human oversight for Annex I and III systems.
Guidelines on post-market monitoring of high-risk AI systems	Clarify who must do what along the deployment chain for high-risk systems.
Guidelines on the competences and designation procedure for conformity assessment bodies	Functionally tied to high-risk AI, because conformity assessment is required only for high-risk systems, especially Annex I product-embedded systems.
Guidelines that go beyond high-risk AI (horizontal AI Act rules)	
Guidelines with a template for the fundamental rights impact assessment	While required mainly for certain high-risk uses, the methodology interacts with GDPR and public-sector use more broadly.
Guidelines on transparency requirements under Article 50 of the AI Act	Article 50 applies to a wide range of AI systems, including non-high-risk ones. This guidance affects content moderation, media, platforms and consumer-facing AI.
Guidelines on responsibilities along the AI value chain	Applies across the AI Act, including GPAI, integrators and deployers outside high-risk contexts.
Guidelines on the practical application of the provisions related to substantial modification	Determines when any AI system becomes "new" and must reassess compliance, regardless of risk category.

Guidelines announced in the Digital Omnibus on AI	Why it matters for legislators
Guidelines that directly support Digital Omnibus changes (outside deadline extensions)	
Guidelines on the elements of the quality management system which SMEs and SMCs may comply with in a simplified manner	Reflects a core Digital Omnibus change extending simplified regimes to small mid-caps, not a feature of the original AI Act.
Guidelines on the AI Act's interplay with other Union legislation	Explicitly omnibus-driven. It covers the following interplays: - AI Act ↔ GDPR (including new data-use rules), - AI Act ↔ Cyber Resilience Act, - AI Act ↔ Machinery Regulation.
Guidance on the research exemptions under Article 2(6) and (8)	Applies horizontally across the AI Act and is prioritised for sectors like life sciences and medical R&D.

Source: Authors' own elaboration based on European Commission (2025)⁷⁷.

b. Streamlining conformity assessment and certification procedures for high-risk AI

Other high-risk-AI related changes aim at simplifying how they are certified, particularly when those systems are already subject to other EU product-safety laws. Under the original AI Act, high-risk AI systems must undergo conformity assessment before being placed on the market. In practice, this often meant that a product already assessment under sectoral EU law (for example, medical devices or machinery rules) could face additional or parallel assessment procedures for the AI Act, raising concerns about duplication, longer time-to-market, certification bottlenecks and other issues.

The Digital Omnibus instead introduces a **"once-only" assessment principle for high-risk AI systems** to cover both AI Act requirements and sectoral product rules⁷⁸. The proposal would enable notified bodies already designated under sectoral legislation to assess AI-related requirements as well, without having to undergo a full re-designation process specifically for the AI Act. To make this workable, the Omnibus introduces a transition period until 2 February 2028, during which existing notified sectoral bodies can continue to operate for AI Act purposes even if they have not yet completed a formal AI-specific designation.

The Commission justified these amendments by pointing to limited capacity of notified bodies, risks of delays once high-risk AI obligations start applying and the need to keep highly regulated sectors functioning without disruption.

⁷⁷ European Commission (2025). *Supporting the implementation of the AI Act with clear guidelines*. Available at: <https://digital-strategy.ec.europa.eu/en/news/supporting-implementation-ai-act-clear-guidelines>

⁷⁸ Article 1(10), (11), and (13), pp. 22–24; Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

c. Targeted transition for AI-generated content transparency

As seen in *Figure 6* earlier, the Digital Omnibus on AI changes the deadlines concerning how quickly transparency obligations apply to AI-generated content, such as synthetic images, videos, audio or text (often referred to as 'deepfakes' or generative AI outputs). Under the original obligations, providers of AI systems generating or manipulating content were required to ensure that such content is clearly labelled or identifiable as AI-generated once the relevant transparency rules applied. These requirements were designed to apply uniformly, regardless of when a system was first placed on the market. Instead, Digital Omnibus **introduces a targeted transition period**⁷⁹; specifically:

- AI systems that were placed on the market before August 2026 benefit from an additional 6-month grace period (obligations kick in from 2 February 2027);
- AI systems placed on the market after August 2026 must comply immediately without a grace period.

The grace period is intended to avoid disruption because technical solutions as well as concrete guidance for consistent watermarking and detection are still evolving⁸⁰. A Code of Practice on AI-generated content is also expected to be finalised by May–June in 2026 with the first draft published in December 2025⁸¹.

d. Easier compliance pathways for small mid-caps

The Digital Omnibus on AI **extends several existing simplifications beyond micro and small enterprises to include SMCs**, reflecting that compliance costs could otherwise disproportionately affect growing European firms. In practice, this means:

- Simplified technical documentation requirements (see Article 1(8) of the Digital Omnibus on AI);
- Lighter quality-management obligations (Article 1(9) and (21));
- More favourable treatment when calculating administrative fines (Article 1(29)); and
- Priority access to regulatory sandboxes and support channels (Article 1(23), Article 1(17)(a) and (c)).

These changes do not exempt smaller actors from the AI Act, but they lower the cost and complexity of compliance, especially during early deployment and scaling phases⁸².

⁷⁹ Article 1(30)(b), p. 30; Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

⁸⁰ Gallo, V. (2025, November 19). The EU's Digital Omnibus Package is out, and it carries significant implications for AI, *LinkedIn*. Available at: <https://www.linkedin.com/pulse/eus-digital-omnibus-package-out-carries-significant-ai-valeria-gallo-bu2je/?trackingId=ObFe9btzR1uuXvCCqExh3g%3D%3D>

⁸¹ European Commission (2025). *Code of Practice on marking and labelling of AI-generated content*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/code-practice-ai-generated-content>

⁸² Caroli, L. (2025, November 19). First thoughts on the Digital Omnibus, *Substack*. Available at: <https://lauracaroli.substack.com/p/first-thoughts-on-the-digital-omnibus>

e. Centralised supervision and regulatory sandboxing under the AI Office

The Digital Omnibus on AI would expand the AI Office's responsibilities in a way that is meant to reduce fragmentation and provide **clearer "single supervisor" for certain large-scale and complex AI deployments**⁸³. At the same time, it introduces a **new EU-level regulatory sandbox under the AI Office**, alongside (not instead of) the national sandboxes that Member States must establish by August 2026⁸⁴. In practice, the AI Office would have exclusive or central competence for:

- AI systems built of general-purpose AI models where the same provider controls both the model and the downstream system;
- AI systems embedded in VLOPSEs.

The proposal envisages more hands-on supervisory powers for the AI Office in these areas, including the ability to run checks and, in some cases, conduct conformity-type assessments and tests for systems within its remit (rather than relying entirely on national bodies).

This centralisation responds to delays and uneven enforcement capacity at national level and is intended to ensure more consistent enforcement across the EU. At the same time, it shifts oversight away from Member States in some of the most economically and politically sensitive AI deployments.

In line with the expanded role, the AI Office would also be tasked with creating an EU-level AI regulatory sandbox, designed for a narrow category of systems (advanced, GPAI-based systems, especially where the same provider develops both the model and the system – the same category that is being brought under AI Office supervision).

The purpose is to provide a single controlled testing environment for systems likely to affect multiple Member States at once, and to avoid "forum shopping" or inconsistent sandbox conditions across borders. Importantly, the EU-level sandbox is not presented as a general sandbox for all AI innovation. It is more like a specialised route for a limited group of high-impact systems that the AI Office is expected to supervise anyway.

The Omnibus emphasises that sandboxing and support tools should be more accessible for smaller players and extends certain simplifications to small mid-caps alongside SMEs as explained earlier. In addition to sandbox changes, the proposal broadens the ability to test high-risk systems in real-world conditions outside a sandbox framework. The aim is to make controlled testing more practical, particularly for systems already on the high-risk lists, while maintaining safeguards.

f. Softening AI literacy obligations

Another change introduced by the Digital Omnibus on AI concerns AI literacy. Under the original AI Act, providers and deployers of AI systems had a direct legal obligation to ensure that their staff and other persons, involved in operating or using AI systems on their behalf, had a sufficient level of AI literacy. This did not mean that every employee needed to be an AI expert. Rather, it meant that people working with AI systems should understand their basic functioning, be aware of the system's limitation and risks as well as when and how human oversight is required. In practice, this obligation creates a clear legal expectation that organisations should invest in training, internal guidance, and awareness-raising measures tailored to how AI was actually used in their activities.

⁸³ Article 1(25), pp. 27-28 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁸⁴ Article 1(17), p. 25 of the Digital Omnibus on AI, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

The Digital Omnibus on AI suggests **removing this binding obligation and shift it instead to the European Commission and the Member States**⁸⁵. These institutions would be required to encourage AI literacy only through non-binding measures, such as informational resources, voluntary training initiatives, and exchanges of best practices. In practice, it should mean that compliance may focus more on paperwork and procedures, while the actual internal understanding of AI systems would vary more widely, especially in sectors where resources for training are limited or incentives are weak.

g. Broader use of data for bias detection and fairness

Lastly, the Digital Omnibus on AI **expands the conditions under which providers and deployers may use sensitive personal data (like race, religion, or health-related data) to detect, measure, and correct bias in AI systems**⁸⁶. Previously, this possibility was largely restricted to providers of high-risk systems and framed narrowly. The amended approach (primarily by replacing the existing Article 10(5) of the AI Act with a new, broader Article 4a) allows providers and deployer of all AI systems and models to process such data for fairness purposes, provided safeguards are in place and the data is not used to produce discriminatory outputs or disclosed improperly. In other words, this allows developers of even low-risk systems, such as chatbots or image generators, to use sensitive data to test for and correct biased outputs.

Together with changes in the GDPR (especially changing the threshold from 'strictly necessary' use of personal data to 'necessary use' and allowing for residual processing of sensitive data), it could significantly expand the scope of what is acceptable use of personal data for training of AI systems⁸⁷.

To mitigate risks, the proposal explains that the use of sensitive data for bias detection is subject to a specific framework of safeguards⁸⁸:

- No alternatives: it must be demonstrated that providers cannot achieve the same goal with synthetic, anonymised or non-personal data;
- Technical and organisational controls: measures include pseudonymisation, strict access controls and timely deletion once bias has been addressed or the retention period ends;
- Proper documentation: all processing activity must be meticulously recorded in records of processing activities to remain accessible to competent authorities.

2.3. Overlaps between different digital legislation addressed by the Digital Omnibus package

Beyond the individual amendments described above, the Digital Omnibus package also serves to address how different EU digital laws intersect and interact in practice. In doing so, the proposal addresses several areas where overlapping obligations, parallel supervisory structures or partially inconsistent concepts have created legal and operational friction.

⁸⁵ Article 1(4), pp. 20–21 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁸⁶ Article 1(5), p. 21 of the Digital Omnibus on AI, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

⁸⁷ Casovan, A. (2025, December 17). Notes from the AI Governance Center: What the EU's proposed Digital Omnibus means for AI governance professionals, *IAPP*. Available at: <https://iapp.org/news/a/notes-from-the-ai-governance-center-what-the-eu-s-proposed-digital-omnibus-means-for-ai-governance-professionals>

⁸⁸ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

A first set of overlaps concerns **privacy, AI, and data governance rules**. Regarding privacy, the integration of device-access rules from the ePrivacy Directive into the GDPR (see sub-section 2.1.2.b above for more details on the amendments) aims to reduce fragmentation between two partially overlapping consent regimes.

At the same time, the amendments to the GDPR on scientific research, lawful bases and special-category data (see sub-section 2.1.2.a above) interact directly with the AI Act's data governance and bias-mitigation provisions. In parallel, the Digital Omnibus on AI introduces a new legal basis for the use of sensitive data for bias detection (see sub-section 2.2.2.g above), explicitly situating this within the broader EU data protection framework. Taken together, these changes attempt to reduce tension between GDPR compliance and AI development obligations, bridging the two regimes.

The proposal also aligns amendments to the GDPR with parallel changes to Regulation (EU) 2018/1725 (the data protection framework applicable to EU institutions), thereby avoiding divergence between private-sector and EU-level data protection standards⁸⁹.

A second cluster of overlaps tackled by the Digital Omnibus relates to **platform governance and enforcement architecture**. The repeal of the P2B Regulation (see sub-section 2.1.2.e above) reflects the Commission's view that its transparency and fairness objectives are now largely absorbed by the DSA and the DMA, thereby removing a parallel platform rulebook. In addition, the Data Act amendments link public-sector data re-use conditions to the DMA framework⁹⁰ by allowing differentiated pricing and stricter conditions for very large enterprises, including companies designated as gatekeepers.

In addition, the Omnibus strengthens the role of the AI Office for systems embedded in VLOPSEs (see sub-section 2.2.2.e above), reinforcing synergies between enforcement structures of the DSA and the AI Act. This is complemented by the "once-only" conformity assessment logic for high-risk AI systems (see sub-section 2.2.2.b above) already subject to sectoral product legislation, addressing duplication between the AI Act and existing product-safety regimes.

A third area concerns **incident reporting and supervisory coordination**, where the overlap problem is particularly visible. Under the current legal framework, a single cybersecurity or data incident may trigger parallel notification obligations under the GDPR, NIS2, DORA, and the CER Directive, often to different national authorities and in different formats. The introduction of an EU-level Single Entry Point addresses this structural duplication. Instead of eliminating reporting duties under the respective acts, the proposal centralises their submission through a common digital interface operated by ENISA. Reports submitted via the SEP would then be routed to the competent authorities under each applicable regime. In addition, the Commission would be empowered to harmonise reporting templates and content requirements across the different instruments. The SEP therefore tackles not only administrative duplication, but also fragmentation in supervisory workflows and information flows between authorities. While it does not merge the legal bases of the various reporting obligations, it creates an operational layer intended to reduce overlap in practice.

⁸⁹ Article 4, pp. 61-65 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

⁹⁰ Article 1(18), the newly added Articles 32q(6) and 32r(4) under Chapter VIIc, p. 4 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

Finally, overlaps are addressed in the field of **data mobility, sovereignty and access safeguards**. The consolidation of the Data Governance Act, the Open Data Directive and the Free Flow of Non-Personal Data Regulation into a recalibrated Data Act (see sub-section 2.1.2.c above) aims to eliminate parallel re-use and intermediation frameworks.

Within that consolidation, the narrowing of B2G data access to public emergencies reshapes the boundary between public-interest access and private data-holder discretion.

At the same time, strengthened safeguards against unlawful third-country access to non-personal data (extended beyond cloud providers to other actors within the Data Act framework) address an overlap between internal market data mobility rules and digital sovereignty concerns. The result is not only a consolidation of instruments, but a rebalancing of how access, portability and protection rules interact across the EU's broader digital rulebook.

Overall, the Omnibus package seeks to transform a layered and sometimes duplicative digital acquis into a more coherent architecture. Whether this exercise ultimately reduces regulatory friction without weakening substantive safeguards will depend less on the formal consolidation itself and more on how these newly aligned interfaces are interpreted and enforced in practice – see more discussion on this in Chapter 3 below.

3. PRACTICAL ASSESSMENT OF THE DIGITAL OMNIBUS REGULATION PROPOSAL AND DIGITAL OMNIBUS ON AI

KEY FINDINGS

- While some parts of the Digital Omnibus package are contested, others are generally supported.
- Contested parts: stakeholders are divided over whether it meaningfully reduces red tape or represents a substantive rollback of digital rights and safeguards.
- Weak evidence base: while the EC maintains the changes are minor and not require a full impact assessment, some stakeholders note that the absence of it and limited consultation undermine transparency, democratic accountability, and legislators' ability to assess who benefits or loses from the reforms.
- Risk of legal uncertainty: several changes introduce conditional, context-dependent rules that may complicate compliance planning and enforcement further.
- GDPR amendments may weaken uniform protection: narrower scope of the personal data definition and changes to access rights are seen as the most high-stakes recalibrations, not just operational tweaks.
- Several changes appear poorly targeted to SMEs: critics argue many changes may disproportionately advantage large, often non-EU firms that can operationalise flexibility at scale.
- Implementation capacity is a key bottleneck and requires sufficient resources and expertise: the SEP, Data Act consolidation, AI literacy changes, and EU-level sandbox all raise concerns about under-resourcing the enforcement, uneven implementation, and diluted safeguards that could limit their effectiveness.
- Normalisation of intrusive processing (residual sensitive data, broader fairness testing): several changes shift discretion to controllers and raises risks for vulnerable groups in workplaces and education.

Before delving into the details on the Digital Omnibus proposals, it is crucial to mention the geopolitical context of this initiative. The package is being launched at a geopolitically relevant moment for EU tech regulation: the Commission seems to be signalling "simplification" and pro-business pragmatism to support EU companies, while it is simultaneously facing transatlantic pressures and an increasingly confrontational trade-tech linkage. Commentators note that EU representatives presented the Omnibus to US counterparts in late November 2025, but US officials reportedly dismissed it and explicitly tied any tariff relief to the EU weakening its flagship platform laws (DMA/DSA) — a demand Commission leaders have characterised as coercive⁹¹.

⁹¹ Torreblanca, J. I. (2025, December 3). Thrown under the omnibus: How the EU's digital deregulation fuels US coercion, *European Council on Foreign Relations*. Available at: <https://ecfr.eu/article/thrown-under-the-omnibus-how-the-eus-digital-deregulation-fuels-us-coercion/>

At the same time, the Omnibus conspicuously does not amend the DMA or DSA, and the Commission has continued active enforcement and competition action against major US tech firms⁹². Against this backdrop, the package can be read as an attempt to address internal EU concerns that cumulative digital regulation may impede innovation and investment, while maintaining (and visibly enforcing) the EU's most political sensitive rule in the face of external pressure.

On a general note, some experts are warning that there is a thin line between simplification and deregulation, which should always be considered, as smart simplification can boost innovation, investment and ensure better compliance with the rules, all the while decreasing compliance costs, but improper deregulation would have the precisely opposite effect⁹³.

Reactions to the Digital Omnibus proposals reflect this debate: while the European Commission and industry groups frame the package as "simplification" to reduce red tape⁹⁴, civil society organisations, trade unions, and some legal experts characterise it as "sweeping deregulation" and the largest rollback of digital rights in the EU history⁹⁵.

Overall, the Digital Omnibus Package is criticised for the following shortcomings⁹⁶:

- Weak evidence base: The Omnibus proposals were not supported by full impact assessments, limiting understanding of their economic, social and environmental effects and weakening the basis for informed policy choices⁹⁷;
- Limited transparency and accountability reduced democratic scrutiny: The lack of robust evidence and proper public consultation makes it difficult to assess who benefits or loses from the proposed changes, reducing transparency and shifting responsibility for distributive trade-offs onto legislators. Other related concerns include weakened parliamentary oversight, blurred accountability for policy choices, and setting a precedent of using omnibus legislation to introduce substantive changes while circumventing democratic processes and the rule of law⁹⁸;
- Over-reliance on a single competitiveness narrative: The strategy is largely framed around "catching up" with the US, which risks oversimplifying structural differences between markets and narrowing the range of policy options for strengthening Europe's digital economy⁹⁹;
- Administrative reduction and SME support goals not achieved: some experts also raise concerns about the amendments actually benefitting the large non-EU firms more than the

⁹² MacCarthy, M., and Propp, K. (2025, December 15). The European Union Changes Course on Digital Legislation, *Lawfare*. Available at: <https://www.lawfaremedia.org/article/the-european-union-changes-course-on-digital-legislation>

⁹³ Thomakadis, A. (2025, October 13). The EU is walking a fine line between simplification and deregulation, *Centre for European Policy Studies*. Available at: <https://www.ceps.eu/the-eu-is-walking-the-fine-line-between-simplification-and-deregulation/>

⁹⁴ See, for example, BusinessEurope (2025, November 19). *Digital Omnibus proposals: An important milestone for EU competitiveness* [press release]. Available at: <https://www.buinessurope.eu/publications/digital-omnibus-proposal-an-important-milestone-for-eu-competitiveness/>

⁹⁵ See, for example, EDRI (2025, November 15). *Press Release: Commission's Digital Omnibus is a major rollback of EU digital protections*. Available at: <https://edri.org/our-work/commissions-digital-omnibus-is-a-major-rollback-of-eu-digital-protections/>

⁹⁶ Maranello, M. (2025, November 20). Efficiency and distribution in the European Union's digital deregulation push, *Bruegel*. Available at: <https://www.bruegel.org/policy-brief/efficiency-and-distribution-european-unions-digital-deregulation-push>

⁹⁷ Also corroborated by interview respondents (Oskar Gstrein, Andrej Savin, Paul Timmers, anonymous expert, Natali Helberger).

⁹⁸ Interviews with Paul Timmers and Natali Helberger.

⁹⁹ Also corroborated by interview respondents (Oskar Gstrein, Mark MacCarthy).

European small businesses¹⁰⁰, given the extent of the Big Tech's influence on the Digital Omnibus proposals¹⁰¹; and

- Erosion of legal certainty¹⁰²: the package introduces an additional level of regulatory flexibility that increases complexity and uncertainty for regulators and industry alike. This also creates an expectation that core digital rules may be repeatedly reopened and revised, undermining their stability and credibility over time.

Despite overall criticism, on one hand, stakeholder feedback suggests that part of the Digital Omnibus proposal is most broadly supported. These measures would likely remove duplication without weakening underlying protections (listed in Table 3 below).

Table 3: Broadly supported elements of the Digital Omnibus package

Broad topic	Specific amendments
Administrative simplification that could reduce duplication	Single entry point for incident reporting ¹⁰³
	Harmonised DPIA lists and templates (properly done in order not to become a tick-box exercise ¹⁰⁴)
	The repeal of P2B Regulation ¹⁰⁵
	Streamlining conformity assessment and certification procedures for high-risk AI and some other procedural changes (e.g., making post-market monitoring more flexible) ¹⁰⁶
	Centralised supervision of some large-scale and complex AI under the AI Office ¹⁰⁷

¹⁰⁰ Interview with Gianclaudio Maltieri. See also: Ruschemeier, H. (2025, November 17). The Omnibus Package of the EU Commission of How to Kill Data Protection Fast, *Verfassungsblog*. Available at: <https://verfassungsblog.de/the-omnibus-package-of-the-eu-commission/>; Digiday Editors (2025, November 21). The EU's Digital Omnibus offers relief for ad tech, but hands more power to Big Tech and AI agents, *Digiday*. Available at: <https://digiday.com/marketing/the-eus-digital-omnibus-offers-relief-for-ad-tech-but-hands-more-power-to-big-tech-and-ai-agents/>

¹⁰¹ Corporate Europe Observatory and LobbyControl (2026, January 14). *Article by article, how Big Tech shaped the EU's roll-back of digital rights*. Available at: <https://corporateeurope.org/en/2026/01/article-article-how-big-tech-shaped-eus-roll-back-digital-rights>

¹⁰² Interviews with Andrej Savin, Oskar Gstrein; see also: Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>

¹⁰³ See Articles 6, 7, 8, 9, pp. 65–68 of the General Proposal.
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁰⁴ Interview with Gianclaudio Maltieri; see Article 3(9), pp. 57–58, also Article 3(14), p. 59 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁰⁵ Recital 59, p. 19, Article 10, pp. 68–69 of the General Proposal.
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁰⁶ Article 1(10), (11), and (13), pp. 22–24 of the Digital Omnibus on AI.
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹⁰⁷ Article 1(25), pp. 27–28 of the Digital Omnibus on AI.
Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>. Some experts are concerned about the further concentration of power at the EU level and how it would affect the protection of fundamental rights and democratic citizen access to the AI Office; based on the interview with Natali Helberger.

Broad topic	Specific amendments
Targeted SME/SMC measures	Simplified documentation, reduced fines ¹⁰⁸
	Easier access to sandboxes and real-world testing ¹⁰⁹
Coherence improvements in the data framework and security	Streamlining the rules for public sector-held data reuse (resolving overlaps and inconsistencies between the Open Data Directive and the DGA) ¹¹⁰
	Allowing public sector bodies to apply differential pricing and stricter conditions to very large enterprises and designated gatekeepers under the DMA when they seek to re-use public sector data ¹¹¹
	Exceptions for pre-existing and genuinely custom-made cloud and data services under the switching rules ¹¹²
	Strengthening protections against unlawful access to non-personal data by third-country authorities, and extending these safeguards beyond cloud providers to other relevant data holders and service providers ¹¹³
	Lowering thresholds for refusing data access to protecting the disclosure of trade secrets (if there is a high risk of disclosure to third countries) ¹¹⁴
	Removal of smart contract requirements (Data Act Article 36) ¹¹⁵

Source: Authors' own elaboration.

On another hand, different aspects of both the General Proposal and the Digital Omnibus on AI have received diverging responses from the industry, civil society, and experts. Most discussed elements are summarised in Table 4 below and elaborated in the following sub-sections to cover the practical implications as well as how they are likely to operate in practice.

¹⁰⁸ Article 1(8) and (29) of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹⁰⁹ Article 1(23), Article 1(17)(a) and (c) of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹¹⁰ Newly added SECTION 2 RE-USE OF OPEN GOVERNMENT DATA in Article 1(18), pp. 39-43 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹¹ See Article 32q(6) and 32r(4) in newly added SECTION 2 RE-USE OF OPEN GOVERNMENT DATA in Article 1(18), pp. 41-42 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>. Although, some researchers are warning that it might be incompatible with standard open licenses, such as Creative Commons, which generally do not permit different terms of use to be applied to the same material for different users; see more: Wyber, S. (2025, December 1). What the EU's Digital Omnibus Means for Researchers, *Tech Policy Press*. Available at: <https://www.techpolicy.press/what-the-eus-digital-omnibus-means-for-researchers/>

¹¹² Article 1(15), pp. 28-29 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹³ Article 1(16), pp. 29-30 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹⁴ Article 1(3) and (4), pp. 24-25 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>. Some experts claim that they may generate trade frictions with international partners; see more here: Rubio, R. (2025). Proposal for a "Digital Omnibus" Regulation for the simplification of the EU digital acquis, *Pérez-Llorca*. Available at: <https://www.perezllorca.com/wp-content/uploads/2025/12/Legal-Briefing-Proposal-for-a-Digital-Omnibus-Regulation-for-the-simplification-of-the-EU-digital-acquis.pdf>

¹¹⁵ Article 1(17), p. 30 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

Rather than revisiting the legal text in detail, these sub-sections examine how the changes may alter incentives, enforcement dynamics and the balance between innovation, rights protection and regulatory certainty.

Table 4: Summary of the most discussed amendments in the Digital Package

Most discussed amendments in the General Proposal	Most discussed amendments in the Digital Omnibus for AI
• Amended definition of personal data¹¹⁶ • Data subject access requests (Article 12(5))¹¹⁷ • Establishment of the SEP for cybersecurity incident reporting¹¹⁸ • Legitimate interest for AI data processing¹¹⁹ • An exemption for the residual use of sensitive data in AI systems¹²⁰ • An establishment of a framework for automated, machine-readable privacy signals on browser-level and the media service provider exemption¹²¹ • Aspects of Data Act consolidation (as explained in more detail below)	• Timeline changes to high-risk AI obligations¹²² • Broader use of personal data for bias detection and fairness¹²³ • Changing AI literacy requirements¹²⁴ • The establishment of EU-level AI sandbox and the expansion of real-world testing to all AI systems¹²⁵

Source: Authors' own elaboration.

3.1. Debate over the definition of personal data in the GDPR

While framed as clarifications and streamlining, several proposed changes in GDPR rely on context-dependent assessments (such as identifiability, necessity, or abuse of rights), which may increase interpretative uncertainty rather than reduce it¹²⁶. Specifically, **a lot of discussion has focused on the amended definition of personal data in the GDPR**. On the one hand, it seems that this approach merely codifies existing practice and case law, notably the CJEU decisions, which have emphasised that identifiability depends on “means reasonably likely to be used” rather than on purely theoretical

¹¹⁶ Article 3(1), pp. 54–55 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹⁷ Article 3(4), p. 56 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹⁸ Articles 6, 7, 8, 9, pp. 65–68 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹¹⁹ New Article 88c as shown in Article 3(15), p. 61 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹²⁰ Article 3(3)(a), p. 55 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹²¹ Article 3(15), pp. 59–60, also see Article 5, p. 65 of the General Proposal.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹²² Article 1(2), p. 20, also Article 1(31), pp. 30–31 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹²³ Article 1(5), p. 21 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹²⁴ Article 1(4), pp. 20–21 of the Digital Omnibus on AI.

Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹²⁵ Article 1(17), p. 25 of the Digital Omnibus on AI. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0836>

¹²⁶ Schmon, C., and Gullo, K. (2025, December 4). EU's New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>

possibilities¹²⁷. From this perspective, the change is presented as a clarification that would reduce over-compliance and legal uncertainty (especially in relation to the Data Act¹²⁸).

On the other hand, some experts and civil society have expressed strong concerns over this amendment. Critics warn that this undermines the GDPR's core objective of providing a stable and uniform level of protection across the EU¹²⁹. Notably, some experts claim that this goes *against* these cases, reversing CJEU jurisprudence and creating regulatory uncertainty and compliance loopholes by risking the exclusion of pseudonymous and indirectly identifiable data from GDPR protections¹³⁰. While the Court has accepted a relative assessment of identifiability, it has also consistently stressed that indirect identifiability and realistic third-party access must be taken seriously. Critics¹³¹ warns that the amendment could push pseudonymous and indirectly identifiable data outside the GDPR's scope in practice, creating compliance loopholes, regulatory fragmentation, and increased legal uncertainty, while reopening long-settled debates rather than providing genuine clarification. Other concerns include a loss of transparency, erosion of data subject rights¹³², as well as undermining cybersecurity given the risk of powerful modern re-identification techniques and post-quantum cryptography making the "reasonableness" of identification a moving and dangerous target¹³³. Overall, it is unclear how this change would support the goals of competitiveness, efficiency and simplification¹³⁴.

3.2. Concerns about restricting access rights

Another highly contested amendment concerns change to Article 12(5) GDPR, which would allow controllers to refuse or charge for the DSARs where they are considered to pursue purposes other than data protection. **This would represent a substantive change to how the right of access operates in practice.**

A central concern raised by legal scholars and civil society is that the proposal would depart from established case law of the CJEU¹³⁵ as well as contradict Article 8 of the EU Charter, which enshrines

¹²⁷ MacCarthy, M., and Propp, K. (2025, December 15). The European Union Changes Course on Digital Legislation, *Lawfare*. Available at: <https://www.lawfaremedia.org/article/the-european-union-changes-course-on-digital-legislation>

¹²⁸ Baumgartner, U. (2025, December 11). EU Digital Omnibus: What the proposed changes to the concept of personal data mean in practice, *IAPP*. Available at: <https://iapp.org/news/a/eu-digital-omnibus-what-the-proposed-changes-to-the-concept-of-personal-data-mean-in-practice>

¹²⁹ Interviews with Andrej Savin and anonymous expert.

¹³⁰ Savin, A. (2025, November 10). EU's Digital Omnibus: Major Data Protection Changes Explained, *EU Internet Law & Policy Blog*. Available at: <https://euinternetpolicy.wordpress.com/2025/11/10/the-eus-digital-omnibus-draft-changes-to-gdpr-and-eprivacy-raise-alarm-bells/>

¹³¹ See, for example: Stalla-Bourdillon, S. (2025). Déjà vu in data protection law: the risks of rewriting what counts as personal data, *Privacy and Data Protection*, 26(2), 9–13. Available at: https://cris.vub.be/ws/portalfiles/portal/142369597/Deja_vu_in_data_protection_the_risks_of_rewriting_what_counts_as_personal_data_by_Sophie_Stalla-Bourdillon_Privacy_Data_Protection_Volume_26_Issue_2.pdf

Savin, A. (2025, November 10). EU's Digital Omnibus: Major Data Protection Changes Explained, *EU Internet Law & Policy Blog*. Available at: <https://euinternetpolicy.wordpress.com/2025/11/10/the-eus-digital-omnibus-draft-changes-to-gdpr-and-eprivacy-raise-alarm-bells/>; nyob (2025, November 19). *Digital Omnibus: EU Commission wants to wreck core GDPR principles*. Available at: <https://noyb.eu/en/digital-omnibus-eu-commission-wants-wreck-core-gdpr-principles>

¹³² Ruschemeier, H. (2025, November 17). The Omnibus Package of the EU Commission of How to Kill Data Protection Fast, *Verfassungsblog*. Available at: <https://verfassungsblog.de/the-omnibus-package-of-the-eu-commission/>; see also interviews with anonymous expert and Andrej Savin.

¹³³ Malgieri, G. (2025, November 26). The Digital Omnibus is a risk for our digital rights, *Universiteit Leiden*. Available at: <https://www.universiteitleiden.nl/en/in-the-media/2025/11/the-digital-omnibus-is-a-risk-for-our-digital-rights>

¹³⁴ Ruschemeier, H. (2025, November 17). The Omnibus Package of the EU Commission of How to Kill Data Protection Fast, *Verfassungsblog*. Available at: <https://verfassungsblog.de/the-omnibus-package-of-the-eu-commission/>

¹³⁵ Mahieu, R. (2025, December 3). The Ominous Omnibus: Dismantling the Right of Access to Personal Data, *Verfassungsblog*. Available at: <https://verfassungsblog.de/digital-omnibus-right-of-access-to-personal-data/>; see also: noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

the right of access as a fundamental right¹³⁶. Recent rulings have consistently treated the right of access as “motive-blind”, meaning that controllers must comply regardless of why the individual seeks their data. EDRi and other civil society groups also warn that access rights are “gateway rights” that allow journalists, researchers, and activists to uncover systemic unlawful practices, such as the abuse of personal data by data brokers – they would be thus severely undermined by the proposed amendments¹³⁷. In an open letter, academic researchers also warn that the proposal could obstruct forms of independent research that rely on voluntary data access and donation by individuals¹³⁸. Studies on digital well-being, political polarisation or platform-driven behavioural harms often depend on individuals exercising their Article 15 rights and sharing the resulting data with researchers. As such research typically serves broader public-interest or scientific purposes rather than narrow data-protection objectives, controllers could use the amended language to refuse access and charge extra (something that researchers cannot afford in most cases), limiting external scrutiny of large digital platforms¹³⁹.

Moreover, the right of access is widely used in employment contexts to support claims in labour or medical disputes. Under the proposal, controllers could classify such requests as “abusive” on the grounds that they serve litigation or employment purposes rather than data protection¹⁴⁰. In this case, the effectiveness of the GDPR as an individual and collective transparency tool for workers would be reduced¹⁴¹.

Industry groups and several Member State authorities argue that the reform is necessary to curb what they describe as the “misuse” of DSARs¹⁴². They contend that access rights are increasingly used as tactical tools to gather evidence for unrelated civil claims, such as employment disputes or rent reductions, imposing disproportionate administrative burdens on controllers. Some media organisations also argue that the current rules apply uniformly regardless of risk or scale, placing small publishers under the same procedural obligations as large technology firms¹⁴³. However, there is a lack of evidence showcasing this issue and the extent to which it causes problems to businesses¹⁴⁴.

Beyond the normative debate, some commentators question whether the proposal is workable in practice.

¹³⁶ Savin, A. (2025, November 10). EU’s Digital Omnibus: Major Data Protection Changes Explained, *EU Internet Law & Policy Blog*. Available at: <https://euinternetpolicy.wordpress.com/2025/11/10/the-eus-digital-omnibus-draft-changes-to-gdpr-and-eprivacy-raise-alarm-bells/>

¹³⁷ Domínguez de Olazábal, I. (2025, December 3). The EU’s Digital Omnibus Must Be Rejected by Lawmakers. Here is Why. *Tech Policy Press*. Available at: <https://www.techpolicy.press/the-eus-digital-omnibus-must-be-rejected-by-lawmakers-here-is-why/>; see also: noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

¹³⁸ DSA40 Data Access Collaboratory (2025). *Open Letter: The Amendment to Article 15, paragraph 5 GDPR in the Omnibus Proposal Undermines Evidence-Based Policymaking*. Available at: <https://dsa40collaboratory.eu/open-letter-omnibus/>

¹³⁹ Interview with Natali Helberger.

¹⁴⁰ Celeste, E. (2025, December 9). Digital Omnibus: quo vadis? *Dublin City University*. Available at: <https://www.dcu.ie/blog/2151/digital-omnibus-quo-vadis>; see also: Mahieu, R. (2025, December 3). The Ominous Omnibus: Dismantling the Right of Access to Personal Data, *Verfassungsblog*. Available at: <https://verfassungsblog.de/digital-omnibus-right-of-access-to-personal-data/>

¹⁴¹ Mariniello, M. (2025, November 13). The European Commission’s Digital Omnibus could increase risks, not growth, *Bruegel*. Available at: <https://www.bruegel.org/first-glance/european-commissions-digital-omnibus-could-increase-risks-not-growth>; see also: Ponce Del Castillo, A. (2025, December 3). The Digital Omnibus: Deregulation Dressed as Innovation, *Social Europe*. Available at: <https://www.socialeurope.eu/the-digital-omnibus-deregulation-dressed-as-innovation>

¹⁴² Mahieu, R. (2025, December 3). The Ominous Omnibus: Dismantling the Right of Access to Personal Data, *Verfassungsblog*. Available at: <https://verfassungsblog.de/digital-omnibus-right-of-access-to-personal-data/>

¹⁴³ News Media Europe (2025, November 19). *Digital Omnibus: A Foundation for Modern Rules, Publishers Urge EU to Maintain Simplification Drive* [press release]. Available at: <https://www.newsmediaeurope.eu/news/digital-omnibus-a-foundation-for-modern-rules-publishers-urge-eu-to-maintain-simplification-drive/>

¹⁴⁴ Interviews with Andrej Savin, anonymous expert.

Conditioning access on motive requires controllers to infer a data subject's "true intention", which is inherently subjective. This is expected to generate disputes, litigation and divergent national interpretations. At the end, however, individuals could also simply state their purpose is data protection, rendering the clause ineffective while encouraging protracted litigation and inconsistent interpretation¹⁴⁵.

3.3. Complications with tackling cookie fatigue for users (integrating ePrivacy into GDPR)

In an effort to curb 'cookie fatigue', the proposal introduces automated, machine-readable consent signals instead of website-level consent banners. This is generally seen as a positive step, especially by the civil society groups, privacy activists, and other experts¹⁴⁶. Yet, some stakeholders identify **several tension points that go to the heart of whether this new proposed change would strengthen meaningful user control or simply repackage consent in a new technical format that would not solve the underlying issues:**

- The commercial conflict of interest in delegating practical implementation to browser providers. Many browsers and related actors benefit financially from data sharing and advertising that rely on collecting data (or after amendment – browser-level consent). From a technical point of view, this should be rather easy to implement¹⁴⁷. Nevertheless, critics argue that, unless minimum usability requirements are set, interfaces could be made confusing, fragmented, or intentionally difficult to navigate, undermining the reform's purpose even while formally complying with it¹⁴⁸;
- The effectiveness depends on standards that may be strongly influenced by the dominant market players. There are concerns that, without legally binding minimum protections in the legislative text itself, the "devil in the details" may be decided through technical specifications where large firms have strong influence, potentially weakening privacy outcomes¹⁴⁹;
- "Low-risk" consent exemptions introduced in the proposal may be stretched in ways that reduce protection. While this could reduce unnecessary banner prompts (and consequently lower compliance costs and annoyance for users)¹⁵⁰, critics argue that the categories may be interpreted broadly in practice, leading to a gradual expansion of non-consensual tracking or analytics and a corresponding reduction in meaningful user control¹⁵¹;

¹⁴⁵ Mahieu, R. (2025, December 3). The Ominous Omnibus: Dismantling the Right of Access to Personal Data, *Verfassungsblog*. Available at: <https://verfassungsblog.de/digital-omnibus-right-of-access-to-personal-data/>

¹⁴⁶ noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>; EDRI (2025, November 15). *Press Release: Commission's Digital Omnibus is a major rollback of EU digital protections*. Available at: <https://edri.org/our-work/commissions-digital-omnibus-is-a-major-rollback-of-eu-digital-protections/>; see also Interview with Andrej Savin.

¹⁴⁷ Interview with Andrej Savin.

¹⁴⁸ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

¹⁴⁹ Schmon, C., and Gullo, K. (2025, December 4). EU's New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>; Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

¹⁵⁰ noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

¹⁵¹ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>; Mariniello, M.

- The exemption for media service providers risks creating a structural loophole and distort the online advertising market. Critics argue undermines the aim of reducing banner fatigue on some of the most visited sites and creates an arbitrary carve-out compared with other data-reliant sectors. Stakeholders also warn it could distort digital advertising competition by allowing media sites continued access to banner-based behavioural advertising data while others must rely on automated signals, potentially favouring certain business models and encouraging boundary-pushing attempts to qualify as “media” to retain tracking-based revenue¹⁵². Industry is also noting technical and legal issues with implementation of this exception – ad tech intermediaries would have to distinguish which sites qualify as “media service providers”, a determination they are reluctant to risk and that will create more problems for publishers¹⁵³; and
- The exclusion of mobile operating systems is viewed as a significant oversight, as users deserve the same privacy rights and “fatigue” relief on mobile apps as they do on websites¹⁵⁴. This could create a two-tier system: streamlined consent on the web, but continued friction and opaque practices in apps.

Overall, experts pointed out that this step might not be effective at curbing dark patterns (such as one-click refusal and restriction on repeated prompts) and is inherently reactive¹⁵⁵. They may reduce the most visible abuses, but do not fully address the underlying incentive problem: firms that profit from extensive tracking will continue to experiment with interface design strategies that increase acceptance rates unless enforcement is credible and dissuasive – an issue in reality where most national data protection authorities are chronically under-resourced to investigate such violations¹⁵⁶.

In general, it is crucial to keep in mind that the issue of tracking and tracing cannot be solved by only removing cookie obligations and empowering certain technologies as solutions—they might be soon outdated as well, so a more general, tech-neutral, future-oriented approach could be more effective¹⁵⁷.

3.4. Implementation and governance concerns with Data Act consolidation

While consolidation can reduce formal fragmentation, a number of stakeholders argue that the package leaves **important governance and implementation gaps, and, in some areas, risks shifting the balanced towards a more data-holder-driven model**, with consequences for public sector capacity, user rights and the EU’s stated public-interest objectives.

(2025, November 20). Efficiency and distribution in the European Union’s digital deregulation push, *Bruegel*. Available at: <https://www.bruegel.org/policy-brief/efficiency-and-distribution-european-unions-digital-deregulation-push>

¹⁵² Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>; Martens, B. (2025, December 8). The European Union needs more than the digital omnibus to make digital services competitive, *Bruegel*. Available at: <https://www.bruegel.org/analysis/european-union-needs-more-digital-omnibus-make-digital-services-competitive>

¹⁵³ Davies, J. (2025, December 5). European publishers say the Digital Omnibus ‘cookie fix’ leaves them worse off, *Digiday*. Available at: <https://digiday.com/media/european-publishers-say-the-digital-omnibus-cookie-fix-leaves-them-worse-off/>

¹⁵⁴ Schmon, C., and Gullo, K. (2025, December 4). EU’s New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>

¹⁵⁵ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

¹⁵⁶ Richter, P., and Schenk, T. (2025, December 11). EU data processing consent reform must account for market incentives, *Bruegel*. Available at: <https://www.bruegel.org/analysis/eu-data-processing-consent-reform-must-account-market-incentives>

¹⁵⁷ Interview with Paul Timmers.

A central concern is that, while the reform is presented as technical streamlining, it also introduces substantive recalibrations¹⁵⁸: it narrows the circumstances in which public authorities can access privately held data¹⁵⁹, lowers the threshold for data holders to refuse disclosure¹⁶⁰, and dilutes institutional mechanisms intended to build trust-based data sharing (such as structured intermediation and data altruism). These changes could risk weakening the EU's ability to treat data as a governed resource in support of public policy, not only as an economic asset.

Other more detailed concerns include the following¹⁶¹:

- Weaker "trust and oversight" safeguards leaving data altruism under-supported and shifting the system towards a more market-driven approach¹⁶²;
- Persistent legal uncertainty (notably around "product data" scope and mixed-data environments)¹⁶³.

Overall, the core question for legislators is whether the consolidation improves usability while preserving public-interest governance, or whether it risks consolidating market power and discretion without adequate safeguards and operational clarity.

3.5. Resource and efficiency questions about the Single Entry Point

While welcoming the underlying logic of the proposal to eliminate duplication and empower ENISA to create the SEP, stakeholders note that the European Commission's estimate of 8 FTEs to maintain the platform is likely insufficient¹⁶⁴. The scope (covering 27 countries, 24 languages, and 18 critical sectors) would **likely require a "substantial increase" in ENISA's already limited resources to be effective – more than the proposal currently foresees**. In addition, industry groups like the Computer & Communications Industry Association warn that without aligned definitions and reporting thresholds across different laws, a single portal will merely "centralise fragmentation" rather than fixing it¹⁶⁵.

¹⁵⁸ Lazarotto, B. (2025, December 19). The Data Omnibus: The Good, the Bad, and The Ugly Behind the DGA and Data Act Rewrite, *MediaLaws*. Available at: <https://www.medialaws.eu/the-data-omnibus-the-good-the-bad-and-the-ugly-behind-the-dga-and-data-act-rewrite/>

¹⁵⁹ Article 1(5), (6), and (7), pp. 25-27 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁶⁰ Article 1(3) and (4), pp. 24-25 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁶¹ Based on the following sources: Lazarotto, B. (2025, December 19). The Data Omnibus: The Good, the Bad, and The Ugly Behind the DGA and Data Act Rewrite, *MediaLaws*. Available at: <https://www.medialaws.eu/the-data-omnibus-the-good-the-bad-and-the-ugly-behind-the-dga-and-data-act-rewrite/>; Matteo, O. (2025, November 19). The European Commission released its Digital Package today, *LinkedIn*. Available at: <https://www.linkedin.com/pulse/european-commission-released-its-digital-package-today-matteo-orta-1cyme/?trackingId=Ri9b9WEdRgWSSJzHERhhBg%3D%3D>; Martens, B. (2025, December 8). The European Union needs more than the digital omnibus to make digital services competitive, *Bruegel*. Available at: <https://www.bruegel.org/analysis/european-union-needs-more-digital-omnibus-make-digital-services-competitive>; Wyber, S. (2025, December 1). What the EU's Digital Omnibus Means for Researchers, *Tech Policy Press*. Available at: <https://www.techpolicy.press/what-the-eus-digital-omnibus-means-for-researchers/>

¹⁶² Article 1(1)(a), Article 1(2)(d), pp. 20-21 of the General Proposal. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁶³ Article 1(2)(b), p. 21 of the General Proposal, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC0837>

¹⁶⁴ Talayero, N. (2025, November 24). Regulatory Simplification: the digital omnibus package as a first step? *Telefónica*. Available at: <https://www.telefonica.com/en/communication-room/blog/regulatory-simplification-digital-omnibus-package-step/>. See also: interview with Paul Timmers.

¹⁶⁵ Computer & Communications Industry Association (CCIA Europe) (2025, November 19). *Digital Omnibus: Simplification of EU Tech Rules Requires Bolder Action* [press release]. Available at: <https://ccianet.org/news/2025/11/digital-omnibus-simplification-of-eu-tech-rules-requires-bolder-action/>; see also: Connect Europe (2025, November 19). *Telecoms industry backs the Digital Omnibus as a first step towards simpler, smarter EU digital rules, but calls for bolder ambition in further simplification* [press release]. Available at: <https://connecteurope.org/news/telecoms-industry-backs-digital-omnibus-first-step-toward-simpler-smarter-eu-digital-rules>

Because the SEP routes notifications to various different national authorities, businesses may still face parallel investigations and duplicative requests for information from multiple regulators¹⁶⁶.

Other concerns include the technical and operational aspects, for example, the security of such system against hacking, proper consultation and collaboration with the industry, Member States and other stakeholders about how this system would work properly, as well as the broader mechanism around it¹⁶⁷. Especially for Member States, the SEP could be seen as controversial due to national security concerns—thus, more communication and attention in the debate is key to ensure buy-in¹⁶⁸.

3.6. Legitimate interest for AI data processing vs individuals' rights

While the stated goal of the new Article 88c of the GDPR was to give AI developers a clearer legal basis to use personal data for AI training (that has been an issue for some actors¹⁶⁹), some civil rights groups raised concerns that **it would privilege AI firms at the expense of individuals' rights**¹⁷⁰. According to the proposal, individuals would need to officially opt out if they did not want their personal data to be used in AI training. A primary worry is that this shift is practically unworkable for individuals as users would then need to opt out thousands of times per year to prevent every company that scrapes the internet from using their data¹⁷¹. There are also concerns over the fact that individuals often do not know when or by whom their data is being used in a training pipeline, making it very hard to exercise this right to object in time to stop the processing¹⁷².

Furthermore, under the current GDPR, the legitimate interest basis requires a rigorous, case-by-case balancing test to ensure that a company's interests do not override the fundamental rights of individuals. Critics¹⁷³ contend that the proposal short-circuits this test by treating AI development as a presumptively legitimate interest, which grants companies broad discretion to justify large-scale processing without sufficient oversight and safeguards that are part of traditional balancing tests. In simpler words, companies might be able to simply say that all of their activities fall under legitimate interest and use this clause as a workaround instead.

¹⁶⁶ Savova, D., Kennedy, A., Flakoll, R., Balducci, A., Barbier, B., Cannon, K., Cohen, E., Davis, S., Gondos, O., Kaidouchi, W., Manasterski, A., and Sroussi, G. (2025, November 25). All aboard the Digital Omnibus? An overview of the EU's Digital Simplification Package, *Clifford Chance*. Available at: <https://www.cliffordchance.com/briefings/2025/11/overview-of-the-eu-digital-simplification-package.html>; see also: Connect Europe (2025, November 19). *Telecoms industry backs the Digital Omnibus as a first step towards simpler, smarter EU digital rules, but calls for bolder ambition in further simplification* [press release]. Available at: <https://connecteurope.org/news/telecoms-industry-backs-digital-omnibus-first-step-toward-simpler-smarter-eu-digital-rules>

¹⁶⁷ Interviews with Andrej Savin and Paul Timmers.

¹⁶⁸ Interview with Paul Timmers.

¹⁶⁹ Interviews with Andrej Savin and an anonymous expert.

¹⁷⁰ Ada Lovelace Institute (2025, November 19). *Our response to the official text of the EU Digital Omnibus Regulation Proposal*. Available at: <https://www.adalovelaceinstitute.org/news/our-response-to-the-eu-digital-omnibus-regulation-proposal/>

¹⁷¹ nyob (2025, November 19). *Digital Omnibus: EU Commission wants to wreck core GDPR principles* [press release]. Available at: <https://noyb.eu/en/digital-omnibus-eu-commission-wants-wreck-core-gdpr-principles>

¹⁷² Domínguez de Olazábal, I. (2025, November 27). Europe is dismantling its digital rights from within, *EDRI*. Available at: <https://edri.org/our-work/europe-is-dismantling-its-digital-rights-from-within/>; see also: De Graeve, L., and Clemens, J. (2025, November 26). One bus, many passengers: How the Digital Omnibus rewrites the EU digital rulebook, *Timelex*. Available at: <https://www.timelex.eu/en/blog/one-bus-many-passengers-how-digital-omnibus-rewrites-eu-digital-rulebook>

¹⁷³ Interview with Andrej Savin. See also: Domínguez de Olazábal, I. (2025, December 3). The EU's Digital Omnibus Must Be Rejected by Lawmakers. Here is Why. *Tech Policy Press*. Available at: <https://www.techpolicy.press/the-eus-digital-omnibus-must-be-rejected-by-lawmakers-here-is-why/>; Malgieri, G. (2025, November 26). The Digital Omnibus is a risk for our digital rights, *Universiteit Leiden*. Available at: <https://www.universiteitleiden.nl/en/in-the-media/2025/11/the-digital-omnibus-is-a-risk-for-our-digital-rights>; Schmon, C., and Gullo, K. (2025, December 4). EU's New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>

3.7. Issues that stem from AI training and de-biasing with sensitive data

Three related amendments matter in practice: (1) broader permission to process sensitive data for bias testing and fairness purposes across a wider set of AI systems (rather than only high-risk systems) in the AI Act; (ii) a new allowance for residual presence of sensitive data in datasets where its removal would require “disproportionate effort”, and (iii) a stronger reliance on legitimate interest under GDPR rather than consent as a legal basis for AI-related processing (discussed earlier). **Together, these changes might blur the line between “bias testing” and “training”, creating uncertainty about which legal basis and safeguards apply when sensitive data is involved**¹⁷⁴.

Other critics argue that these changes could normalise intrusive processing by framing it as routine for AI, creating an AI-specific leniency not available for other technologies and, in practice, weakening the GDPR’s strict limits on processing sensitive data¹⁷⁵. Supporters respond that real-world fairness testing is difficult without representative data and that the change provides a workable route to detect and correct discriminatory outcomes¹⁷⁶. The tension is therefore not about whether bias correction is desirable, but whether the proposed pathway shifts too much discretion to controllers and weakens the “exceptional” status of sensitive data under EU law.

A particular point of concern is the “disproportionate effort” threshold for removing sensitive data. In principle, it is framed as a narrow safeguard for messy, large-scale datasets where sensitive attributes may appear incidentally. In practice, critics warn that it risks making retention the default¹⁷⁷: organisations can credibly claim that purging specific traits from large, unstructured datasets is technically complex or costly, especially when training pipelines involve repeated copying, transformation and re-use. The proposal requires organisational and technical measures to avoid collecting such data and to remove it when identified, but it leaves open what counts as “appropriate” measures and how they should be demonstrated to regulators. This ambiguity could make enforcement difficult¹⁷⁸ and, together with other changes, might increase the possibility of AI systems reinforcing discrimination rather than reducing it¹⁷⁹.

Therefore, stakeholders warn of uneven impacts on vulnerable groups and in high-power environments. In workplaces, the expanded space for AI-related processing may make it easier for employers or service providers to justify the use of extensive human resources records, communications data or performance signals to build systems for scheduling, productivity scoring or algorithmic management¹⁸⁰.

¹⁷⁴ Interview with Gianclaudio Malgieri.

¹⁷⁵ Schmon, C., and Gullo, K. (2025, December 4). EU’s New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>

¹⁷⁶ Interview with Mark MacCarthy. See also: Hacker, P., Kilian, R. and Costas, J. (2025) Simplifying European AI Regulation – An Evidence-based Study, *Bertelsmann Stiftung*. Available at: https://www.bertelsmann-stiftung.de/fileadmin/files/BSt/Publikationen/GrauePublikationen/Simplifying_European_AI_Regulation_An_Evidence-based_Study.pdf

¹⁷⁷ Ruschemeier, H. (2025, November 17). The Omnibus Package of the EU Commission of How to Kill Data Protection Fast, *Verfassungsblog*. Available at: <https://verfassungsblog.de/the-omnibus-package-of-the-eu-commission/>

¹⁷⁸ noyb.eu (2025). *Digital Omnibus: First Analysis of Selected GDPR and ePrivacy Proposals by the Commission*. Version 1.0. Available at: <https://noyb.eu/en/digital-omnibus-first-analysis-select-gdpr-and-eprivacy-proposals-commission>

¹⁷⁹ Domínguez de Olazábal, I. (2025, November 27). Europe is dismantling its digital rights from within, *EDRI*. Available at: <https://edri.org/our-work/europe-is-dismantling-its-digital-rights-from-within/>

¹⁸⁰ Ponce Del Castillo, A. (2025, December 3). The Digital Omnibus: Deregulation Dressed as Innovation, *Social Europe*. Available at: <https://www.socialeurope.eu/the-digital-omnibus-deregulation-dressed-as-innovation>

In education, similar concerns arise about intensive tracking and profiling, especially where procurement decisions and oversight are weak. Even if the reforms are not targeted at these settings, they may lower barriers in contexts where individuals have limited bargaining power¹⁸¹.

3.8. Effects on legal (un)certainty: AI Act timeline changes

The concerns about increasing legal uncertainty rather than decreasing it have been particularly visible in the reactions to the revised application of the AI Act's high-risk obligations, which move from fixed calendar dates to a conditional, readiness-based system dependent on future standards and guidance. While from the empirical perspective, this is a rather welcome move (companies are worried about the approaching deadline and more time is necessary to produce the materials¹⁸²), **this approach introduces a "stop–start" dynamic: obligations may formally exist, be temporarily deferred, and later be revived under new timelines.** For businesses, this complicates product planning and investment decisions; for regulators, it creates uncertainty about when and how enforcement should intensify¹⁸³. Some are also worried about the timing – even with postponed deadlines, guidelines and standards might not be ready in time¹⁸⁴. At the end, however, these standards should be voluntary, and other ways exist to showcase compliance rather than EU's guidance¹⁸⁵.

3.9. Criticism and concerns with changing AI literacy requirements from mandatory to encouraged

Some stakeholders argue that changing AI literacy from a mandatory company-level obligation to an encouragement-based model led by the Member States and the EU represents **a substantive weakening of the AI Act's governance architecture that could turn out costlier in the future**¹⁸⁶. A central concern raised about the amended rules is the loss of enforceability. For example, the removal of a binding obligation deprives workers and their representatives of a clear legal basis to demand training and capacity-building from employers¹⁸⁷. Experts warn that by downgrading literacy to a matter of "encouragement", general requirements for human oversight and meaningful explanation risk becoming merely aspirational as AI developers may no longer be legally required to understand the systems they create and manage¹⁸⁸.

While some commentators noted that the original Article 4 is poorly framed and lacks operational clarity, leading to significant uncertainty about what the "sufficient" literacy actually entailed¹⁸⁹,

¹⁸¹ European Trade Union Committee for Education (2025, November 19). *Stop the Rollback: EU Digital Omnibus endangers children's and teachers' rights*. Available at: <https://www.csee-etu.org/en/item/4125:stop-the-rollback-eu-digital-omnibus-endangers-childrens-and-teachers-rights>

¹⁸² Interviews with Andrej Savin, Mark MacCarthy, and anonymous expert.

¹⁸³ Interviews with Oskar Gstrein and Natali Helberger; see also: Schmon, C., and Gullo, K. (2025, December 4). EU's New Digital Package Proposal Promises Red Tape Cuts but Guts GDPR Privacy Rights, *Electronic Frontier Foundation*. Available at: <https://www.eff.org/deeplinks/2025/12/eus-new-digital-package-proposal-promises-red-tape-cuts-guts-gdpr-privacy-rights>

¹⁸⁴ Interview with Andrej Savin.

¹⁸⁵ Casovan, A. (2025, December 17). Notes from the AI Governance Center: What the EU's proposed Digital Omnibus means for AI governance professionals, *IAPP*. Available at: <https://iapp.org/news/a/notes-from-the-ai-governance-center-what-the-eu-s-proposed-digital-omnibus-means-for-ai-governance-professionals>

¹⁸⁶ LinkedIn post by Natali Helberger (2025). Available at: https://www.linkedin.com/posts/natali-helberger-2473901_ai-omnibus-applyaistrategy-activity-7400100287744733186-yog9/

¹⁸⁷ Ponce Del Castillo, A. (2025, December 3). The Digital Omnibus: Deregulation Dressed as Innovation, *Social Europe*. Available at: <https://www.socialeurope.eu/the-digital-omnibus-deregulation-dressed-as-innovation>

¹⁸⁸ Malgieri, G. (2025, November 26). The Digital Omnibus is a risk for our digital rights, *Universiteit Leiden*. Available at: <https://www.universiteitleiden.nl/en/in-the-media/2025/11/the-digital-omnibus-is-a-risk-for-our-digital-rights>

¹⁸⁹ Gallo, V. (2025, November 19). The EU's Digital Omnibus Package is out, and it carries significant implications for AI, *LinkedIn*. Available at: <https://www.linkedin.com/pulse/eus-digital-omnibus-package-out-carries-significant-ai-valeria-gallo-bu2je/?trackingId=ObFe9btzR1uuXvCCqExh3g%3D%3D>

questions remain whether the amendment genuinely resolves the problem it seeks to address. Firms will still need AI-literate staff—from technical teams to senior management—to meet their remaining obligations under the AI Act, including risk management and liability. At the same time, assigning the literacy agenda to Member States raises concerns about uneven implementation and resource constraints, given that several governments have historically resisted mandated training and awareness campaigns¹⁹⁰. As a result, critics characterise the change as trading a definitional challenge for a broader risk of fragmentation and weaker practical uptake of AI competence across the Union.

3.10. AI sandbox and real-world testing considerations

While the general idea of EU-level AI sandbox has been welcomed by various stakeholders, **a primary criticism is that the current sandbox model lacks a definitive “exit” benefit**. Analysts note that the “true benefit” of regulatory sandbox will only materialise if authorities have the power to certify that a system tested within the sandbox complies with the AI Act¹⁹¹. This means that the EU-level AI sandbox should come with a genuine presumption of conformity for systems that successfully complete the sandbox process, which would consequently provide companies with the legal certainty needed to move from testing to commercialisation.

Other experts also note the need for further design considerations¹⁹², including but not limited to: (i) defining which systems are suitable for the sandbox; (ii) outlining how large does the sandbox need to be to properly assess risks; (iii) institutionalised transparency obligations to ensure proper awareness to data subjects whether they are in the sandbox or whether they can opt out. In addition, given the fact that the sandbox managed by the AI Office is not expected to be operational before 2028, experts recommend that innovative companies already begin identifying pilot projects, despite the lack of immediate infrastructure (or even a confirmation of it yet)¹⁹³. Overall, it is crucial to ensure that a sandbox managed by the AI Office would fulfil the commitment made in the recital 142 of the AI Act to achieve socially and environmentally beneficial outcomes, while guaranteeing researchers’ right of access to sandbox data – something that is currently missing from the draft implementing act for regulatory sandboxes at the national level.

When it comes to the expanded use real-world testing, experts are questioning how it relates to the sandbox provision as well as are concerned about the safeguards and surrounding mechanism. The current proposal would allow real-world testing for high-risk AI systems without binding conditions, as long as there is a voluntary agreement; yet, it is not clarified what should be included in such agreements, what entails real-world testing and what concrete safeguards should apply (especially on fundamental rights and protection). It would be recommended that the agreements would be mandatory rather than voluntary and that testing would not be allowed on vulnerable groups¹⁹⁴.

¹⁹⁰ Caroli, L. (2025, November 19). First thoughts on the Digital Omnibus, *Substack*. Available at: <https://lauracaroli.substack.com/p/first-thoughts-on-the-digital-omnibus>.

¹⁹¹ Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

¹⁹² Interview with Oskar Gstrein. For further suggestions, see: Zarra, A. (2026). Experimentalism beyond ex ante regulation: A law and economics perspective on AI regulatory sandboxes, *Cambridge Forum on AI: Law and Governance*, 2:e58. doi:10.1017/cfl.2025.10039.

¹⁹³ Rubio, R. (2025). Proposal for a Regulation as regards the simplification of the implementation of harmonised rules of artificial intelligence (Digital Omnibus on AI), *Pérez-Llorca*. Available at: <https://www.perezllorca.com/wp-content/uploads/2025/12/Legal-Briefing-Proposal-for-a-Regulation-as-regards-the-simplification-of-the-implementation-of-rules-on-AI.pdf>

¹⁹⁴ Interview with Natali Helberger.

4. RECOMMENDATIONS AND CONCLUSIONS

KEY FINDINGS

- While a big part of the Digital Omnibus package is contested (as discussed in Chapter 3), some proposals are generally supported. The most discussed elements could also be improved during the legislative process.
- As the Digital Omnibus represents only the first step in a more ambitious reform of the EU digital rulebook, the Parliament may wish to insist on a stronger evidentiary basis, clearer justification per amendment, and a staged approach that prioritises implementation tools before reopening core legislative architecture where not strictly necessary.
- To improve regulatory consistency, the EP could also use the Omnibus process as an opportunity to further harmonise legal definitions across the EU digital rulebook as well as strengthen mechanisms for cooperation among EU and national regulatory authorities.
- Parliament could consider going beyond the Commission's proposals and prioritise legal certainty through targeted fixes as well as address missing social and workplace dimensions.
- Parliament may consider the broader strategic context and available tools, especially when it comes to materially shifting Europe's position in AI industry.

This chapter aims to highlight the areas where Parliament may wish to clarify or complement the package. It also outlines some strategic and next step considerations. In general, these recommendations and conclusions are based on preliminary reactions and first experts' analysis and thus should be treated as a starting point of discussion. A general point is that **there is a need for a stronger evidentiary basis** (that applies both to the Digital Omnibus package and the next steps going forward) **to ensure proper evidence-based policymaking**.

The overall recommendation for these amendments is to **strongly scrutinise their evidence base, estimate potential impact onto different types of actors and weigh the amendments against the expressed goals by the Commission**. In line with the Draghi Report, a particular attention should be given to the reduction of the costs to SMEs and SMCs. While the Digital Omnibus contains some cost savings estimations, wider costs are not considered. For example, as one expert pointed out, the browser-level privacy signals would potentially affect ad intermediaries and the broader online advertising industry. Even the media service provider exemptions might not be as effective given the broader shift in underlying mechanisms for online advertising¹⁹⁵.

Missed opportunities. Besides the amendments discussed in Chapter 3, stakeholders and policy analysts have highlighted several critical areas that remain unaddressed or have been "missed opportunities" for deeper simplification to be considered going into the legislative debate.

¹⁹⁵ Interview with Marco Botta.

One series of reforms that could be considered as mere simplification measures to ensure more consistency within the EU digital rulebook could contain:

- **Refinement of definitions:** for example, the definition of an AI provider and the criteria for systemic risk in GPAI models remain insufficiently clear¹⁹⁶; other experts point to streamlining legal lexicon further when it comes to Data Act, DGA, and other legislation¹⁹⁷;
- **Harmonisation of incident reporting thresholds and definitions:** critics note that SEP only centralises the *location* of reporting rather than the *rules* themselves. It does not align the divergent definitions of key concepts like "significant incidents" or "vulnerability", timelines, and reporting thresholds found in different legislation – further assessment is necessary¹⁹⁸;
- **Further investigation of interactions between various legal frameworks:** for example, EDPB and AI Office could issue unified templates and coordinated enforcement protocols to resolve any overlaps in compliance between the DPIAs (required by GDPR) and Fundamental Rights Impact Assessments (mandated by the AI Act) among other aspects¹⁹⁹.

Another series of changes that would go a bit beyond mere simplification could include:

- **Increasing the legal ability and incentive of the different EU and national regulatory or supervision authorities to cooperate more** on technology understanding and horizon scanning, on developing joint policy papers or guidelines, or even working jointly on cases as recommended by the Court of Justice under the sincere cooperation obligations of the Treaties²⁰⁰. In particular, this would imply more possibilities to exchange confidential information among regulators;
- **Allowing sandboxes to grant presumption of conformity:** the Omnibus could better leverage AI regulatory sandboxes as compliance tools. Allowing conformity assessment via controller sandbox trials could encourage innovation while ensuring new AI systems meet safety requirements before full market release²⁰¹;
- **Full repeal of the ePrivacy Directive**²⁰²: telecommunications sector expressed a complaint that moving cookie rules into the GDPR leaves the rest of the ePrivacy Directive intact, maintaining unfair and complex dual-regime for telecom providers.

¹⁹⁶ Computer & Communications Industry Association (CCIA Europe) (2025, November 19). *Digital Omnibus: Simplification of EU Tech Rules Requires Bolder Action* [press release]. Available at: <https://ccianet.org/news/2025/11/digital-omnibus-simplification-of-eu-tech-rules-requires-bolder-action/>; Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

¹⁹⁷ Interview with anonymous expert.

¹⁹⁸ Computer & Communications Industry Association (CCIA Europe) (2025, November 19). *Digital Omnibus: Simplification of EU Tech Rules Requires Bolder Action* [press release]. Available at: <https://ccianet.org/news/2025/11/digital-omnibus-simplification-of-eu-tech-rules-requires-bolder-action/>; see also: European Cyber Security Organisation (2025, November 25). *ECSC Statement on the Digital Omnibus Proposal* [press release]. Available at: <https://ecs-org.eu/ecso-statement-on-the-digital-omnibus-proposal/>; Interviews with Oskar Gstrein and Paul Timmers.

¹⁹⁹ Graux, H., Garstka, K., Murali, N., Cave, J., and Botterman, M. (2025). *Interplay between the AI Act and the EU digital legislative framework*, publication for the Parliament's Committee on Industry, Research and Energy (ITRE), Policy Department for Transformation, Innovation and Health, European Parliament. Available at: [https://www.europarl.europa.eu/RegData/etudes/STUD/2025/778575/ECTI_STU\(2025\)778575_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2025/778575/ECTI_STU(2025)778575_EN.pdf)

²⁰⁰ See, for example, the policy proposals made by the EDPS: European Data Protection Supervisor (2026, January 27). *Towards a Digital Clearinghouse 2.0*. Available at: https://www.edps.europa.eu/data-protection/our-work/publications/events/2026-01-27-towards-digital-clearinghouse-20_en

²⁰¹ Wagner, C., Moerel, L., Storm, M., and Tüzün, Y. (2025, December 1). EU Digital Omnibus on AI: What Is in It and What Is Not? *Morrison & Foerster LLP*. Available at: <https://www.mofo.com/resources/insights/251201-eu-digital-omnibus>

²⁰² Talayero, N. (2025, November 24). Regulatory Simplification: the digital omnibus package as a first step? *Telefónica*. Available at: <https://www.telefonica.com/en/communication-room/blog/regulatory-simplification-digital-omnibus-package-step/>

The proposal also does not mandate the repeal of national laws linked to these directives, which could leave inconsistencies in national rules; and

- **Labour and social safeguards:** trade unions point out that the Omnibus proposals will have a direct impact on workplaces that use AI-assisted monitoring and algorithmic management; yet it adds no specific safeguards for workers²⁰³.

Strategic reality check. Several stakeholders caution against overestimating the macroeconomic impact of regulatory relief alone: while simplification may reduce friction, it is unlikely, by itself, to shift Europe's structural position in global AI value chains. This shift to simplification risks sidelining the real barriers to competitive European AI industry that include fragmented internal markets, a lack of mechanisms to keep savings and skills in Europe, underdeveloped capital markets, and punitive bankruptcy laws²⁰⁴. Nevertheless, experts and stakeholders agree that **in order to kick-start AI industry in Europe, a genuine industrial policy and investments** combined with other initiatives like European preference in public procurement are the way forward²⁰⁵.

Under current market conditions, changes that weaken regulatory protections are also likely to disproportionately benefit already dominant digital players, which, according to recent evidence on Europe's cyber and software dependencies, are overwhelmingly non-European²⁰⁶. In the short term, this could further entrench external dependencies and narrow Europe's digital sovereignty options rather than expand them – a crucial aspect to consider the Digital Omnibus package in.

More broadly, Europe is simultaneously facing substantial military, economic and technological investment needs, alongside an evolving landscape of strategic partnerships in which EU regulatory capacity has functioned not only as a governance tool but also as a source of leverage and an international reference model. Against this backdrop, simplification that is not clearly embedded within a coherent industrial and investment strategy risks diluting that leverage.

Next step considerations. For changes that shift rights balances (especially GDPR), Parliament may want (i) stronger evidence requirements, (ii) clearer delineation of what should be done via legislative amendment versus guidance/standards, and (iii) a staged approach (secondary legislation and implementation measures first; deeper legislative reopening only where necessary).

To expand, some experts highlighted the fact that for genuine simplification a more productive way would be to choose a different method or pathway, for example, proper procedures re-doing the different laws separately, especially when it comes to GDPR reform²⁰⁷.

²⁰³ Ponce Del Castillo, A. (2025, December 3). The Digital Omnibus: Deregulation Dressed as Innovation, *Social Europe*. Available at: <https://www.socialeurope.eu/the-digital-omnibus-deregulation-dressed-as-innovation>

²⁰⁴ Torreblanca, J. I. (2025, December 3). Thrown under the omnibus: How the EU's digital deregulation fuels US coercion, *European Council on Foreign Relations*. Available at: <https://ecfr.eu/article/thrown-under-the-omnibus-how-the-eus-digital-deregulation-fuels-us-coercion/>; see also: MacCarthy, M., and Propp, K. (2025, December 15). The European Union Changes Course on Digital Legislation, *Lawfare*. Available at: <https://www.lawfaremedia.org/article/the-european-union-changes-course-on-digital-legislation>; Mariniello, M. (2025, November 13). The European Commission's Digital Omnibus could increase risks, not growth, *Bruegel*. Available at: <https://www.bruegel.org/first-glance/european-commissions-digital-omnibus-could-increase-risks-not-growth>

²⁰⁵ Interviews with Mark MacCarthy, Oskar Gstrein, and Gianclaudio Malgieri. See also: Toffaletti, S. (2025, November 19). *Digital Omnibus: A step forward, but Europe still needs its own tech stack* [press release], European Digital SME Alliance. Available at: <https://www.digitalsme.eu/digital-omnibus-a-step-forward-but-europe-still-needs-its-own-tech-stack/>; Ruschemeier, H. (2025, November 17). The Omnibus Package of the EU Commission of How to Kill Data Protection Fast, *Verfassungsblog*. Available at: <https://verfassungsblog.de/the-omnibus-package-of-the-eu-commission/>

²⁰⁶ Gineikyte-Kanclere, V., Eggert, M., and Skiotyte, G. (2025, December). *European Software and Cyber Dependencies*. Publication for the Committee on Industry, Research and Energy, Policy Department for Transformation, Innovation and Health, European Parliament. Available at: [https://www.europarl.europa.eu/RegData/etudes/STUD/2025/778576/ECTI_STU\(2025\)778576_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2025/778576/ECTI_STU(2025)778576_EN.pdf)

²⁰⁷ Interview with Andrej Savin.

The issue experts point to is the way that the reform has been kickstarted—the Omnibus package—may introduce new uncertainties and contestation. Overall, the suggestion could be to **clearly decide what issues can be addressed through secondary legislation changes and what – through policy and implementation measures**²⁰⁸.

Lastly, as explained at the beginning of the study, the Digital Omnibus is only the first step of the reforms of the EU digital rulebook, which would be followed by comprehensive revisions of some legal acts, currently excluded in the proposals as well as then by the outcome of the ongoing Digital Fitness Check. Depending on its findings, the Digital Fitness Check may either validate the direction of the Omnibus or point to areas where simplification has limited impact, unintended effects, or distributional consequences that warrant adjustment through targeted amendments, changes in implementation or enforcement, or, where justified, more substantive legislative revision. Those subsequent steps should be based on robust, independent, and evidence-based evaluation of the current rulebook, in particular in terms of effectiveness and consistency. Too often in the past, the EU has failed to evaluate the effects of its laws appropriately and enforce the Better Regulation Guidelines in practice²⁰⁹.

The Digital Omnibus could be an opportunity to reverse this shift and ensure that long-term objectives are clarified with short-term aspects (time horizon and scope conditions for temporary measures) clearly defined. The European Parliament is uniquely positioned to use the synthesis of consultation evidence and the Digital Fitness Check results to align regulatory ambitions, including by seeking clarity on the operational convergence required and on the shared objectives and pathways for delivery.

²⁰⁸ Interviews with Oskar Gstrein and Natali Helberger.

²⁰⁹ Bassini, M., Maggolino, M., and de Streel, A. (2025, January). Better law-making and evaluation for the EU digital rulebook, *CERRE*. Available at: <https://cerre.eu/publications/better-law-making-and-evaluation-for-the-eu-digital-rulebook/>

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ANNEX 1. LIST OF INTERVIEWEES

- Prof. Dr. Paul Timmers [2 January 2026]
- Prof. Andrej Savin [5 January 2026]
- Dr. Oskar Josef Gstrein [6 January 2026]
- Prof. Mark MacCarthy [9 January 2026]
- Anonymous expert [12 January 2026]
- Anonymous expert [13 January 2026]
- Prof. Dr. Natali Helberger [13 January 2026]
- Dr. Gianclaudio Malgieri [16 January 2026]
- Dr. Marco Botta [22 January 2026]

This study was prepared at the request of the European Parliament's Committee on the Internal Market and Consumer Protection (IMCO). It analyses the European Commission's Digital Omnibus package proposals, distinguishing administrative simplification from more substantive recalibration of safeguards across data, privacy, cybersecurity and artificial intelligence laws. The study highlights key areas of controversy (legal certainty, enforcement capacity, and impacts on rights) and sets out areas for consideration for parliamentary scrutiny.
