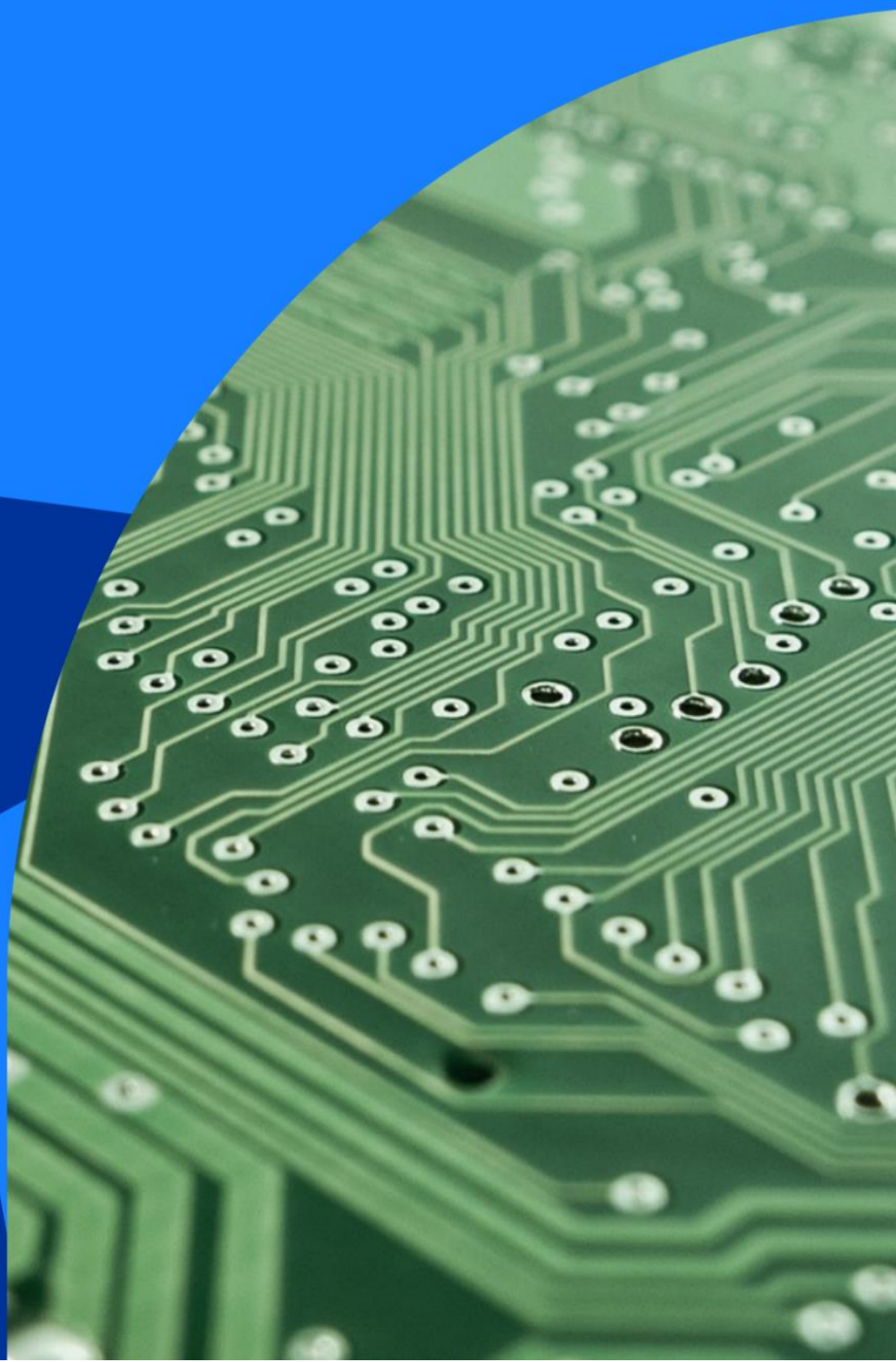


The Digital Omnibus



Context

On the 19th of November, the European Commission published its Digital Omnibus Regulation Proposal. The Digital Omnibus proposal introduces targeted technical amendments to digital laws, designed to offer immediate relief to businesses and citizens. As a first step to optimizing the digital rulebook, the goal is to lower compliance costs while maintaining regulatory objectives, thereby boosting competitiveness for responsible organizations.

The vast majority of Maltese businesses are Small and Medium Sized Enterprises (SMEs). For a small business with limited to no access to compliance and legal staff, having to navigate multiple, complex EU digital regulations represents a disproportionately high administrative and financial cost. Reducing this burden, as the Omnibus aims to do, directly translates into a boost in national competitiveness. This allows local businesses to allocate more resources to innovation and growth rather than bureaucracy.

The Malta Business Bureau presents this policy brief to summarise the Omnibus and ends the brief with the key elements relevant to the Maltese context.

Simplification Proposals – Digital Omnibus on AI & Digital Omnibus on Data, GDPR, cybersecurity reporting etc.)

1. Innovation-friendly AI rules

The European Commission is proposing to amend the new AI Act in order to ensure that it does not hinder innovation. The strict rules for "high-risk" AI systems (like those used in healthcare or critical infrastructure) will not take effect immediately. Instead, their enforcement will be delayed by up to 16 months until the Commission confirms that the necessary practical tools and clear standards are in place. This gives companies the guidance they need before they have to comply.

The Commission is also introducing several key specifications:

- a. Simpler rules and paperwork—originally for just small companies SMEs—will now be extended to slightly larger, small mid-cap companies.
- b. It will create more opportunities for companies to test their AI in a safe environment, called "regulatory sandboxes," before launching them publicly. This includes a new EU-wide sandbox starting in 2028, encouraging real-world testing in major sectors like the car industry.
- c. The newly established AI Office will have stronger powers and will be the main body responsible for watching over powerful, general-purpose AI models. This avoids fragmented supervision and makes governance clearer and more consistent across the EU.

2. Simplifying cybersecurity reporting

The Digital Omnibus proposal introduces a crucial simplification by establishing a single-entry point for companies to report all mandatory cybersecurity incidents. Currently, businesses are burdened with reporting the same incident multiple times under various EU laws, such as the NIS2 Directive, GDPR, and DORA. This new, central interface will eliminate that complexity, allowing companies to meet all their reporting obligations in one place.

3. An innovation-friendly privacy framework

The Commission is introducing focused changes to the GDPR to clarify and streamline certain rules, aiming to boost innovation and make it easier for organisations to comply. These adjustments will be made without weakening the GDPR's core commitment to top-tier personal data protection.

The Digital Omnibus introduces key simplifications and timeline adjustments for the AI Act implementation, aimed at easing compliance and boosting innovation. It postpones the final application deadlines for high-risk AI system rules (specifically Articles 6(2) and 6(1)) until December 2027 and August 2028, respectively, while allowing the European Commission to trigger earlier application if necessary, support tools, such as standards and guidelines, are made available.

To aid compliance, the Commission plans to issue extensive guidance on various aspects, including high-risk classification, transparency requirements, fundamental-rights impact assessments, and clarification on how the AI Act interacts with laws like the GDPR and the Cyber Resilience and Machinery Regulations.

Furthermore, the existing flexibilities for SMEs are extended to Small Mid-Caps (SMCs), granting them benefits like simplified technical documentation and special consideration in penalty application, and a new article is inserted to explicitly permit the processing of special categories of personal data for the purpose of bias detection and mitigation in alignment with GDPR.

4. Modernising cookie rules to improve users' experience online

The amendments will reduce the number of times cookie banners pop up and allow users to indicate their consent with one-click and save their cookie preferences through central settings of preferences in browsers and operating system.

5. Improving data access

The digital package also focuses on leveraging data for innovation by consolidating four existing EU data rules into a single, clearer Data Act. This plan simplifies compliance for businesses, offers targeted exemptions for SMEs and Small Mid-Caps to generate significant savings, and provides guidance via model contractual terms; all of which is designed to boost European AI companies by unlocking access to high-quality datasets.

Data Union Strategy

The Data Union strategy plans actions in three priority areas: scaling up access to data for AI; streamlining data rules; strengthening the EU's global position on international data flows.

The Data Union Strategy is a core component of the EU's Digital Omnibus, designed to transition the focus of data regulation from complex rules to tangible results and improved compliance. To achieve this, the Commission proposes to consolidate four existing legal instruments into a single, cohesive data framework and provide a comprehensive support package, including model contractual terms for data sharing (B2B and B2G), standard cloud clauses, and a dedicated helpdesk to primarily assist SMEs in navigating legal complexity. The strategy will operate across three priority areas: (1) scaling up access to data for AI through initiatives like data labs that pool resources and offer pseudonymisation services; (2) streamlining data rules to simplify data sharing for businesses and researchers, notably by reforming aspects of cookie consent; and (3) strengthening the EU's global position on international data flows by addressing unjustified trade barriers to ensure fair global competition for European companies.

The Recommendation on Data Act's Non-Binding Model Contractual Terms on Data Access and Use, and Standard Contractual Clauses for Cloud Computing Contracts.

The Commission has published non-binding Model Contractual Terms for data access and use and Standard Contractual Clauses for cloud computing contracts. This initiative is part of the Commission's broader work on guidance for implementing the Data Act. It is aimed at helping businesses, especially SMEs, when drafting and negotiating commercial contracts. The goal is to promote the use of contract models that establish fair, reasonable, and non-discriminatory (FRAND) terms concerning rights and obligations.

Specifically, this Recommendation focuses on two key areas: providing non-binding model contractual terms for data sharing and offering non-binding standard contractual clauses for cloud computing contracts. Since the Data Act entered into application on September 12, 2025, the Commission is now called upon to approve the content of this draft. Formal adoption of the final Recommendation will occur later, once it has been translated into all official EU languages.

Proposal for Regulation on the establishment of a European Business Wallets

The European Business Wallet is a core component of the Digital Package, proposed as a harmonised digital solution to significantly simplify administrative procedures for companies and public sector bodies across the EU. Its primary goal is to provide a single, secure, and user-friendly digital identity for businesses of all sizes, including

SMEs. By opting for the European Business Wallet, companies will be able to digitally verify identities, instantly share trusted documents (like licenses and certificates), sign documents, and securely delegate legal actions to others. This initiative will modernise economic activities within the Single Market by digitalising critical paperwork and communications.

This simplification allows for critical actions to be performed remotely, facilitates easy cross-border communication (reducing travel costs, especially important for SMEs which constitute 99% of EU enterprises), and speeds up data validation and submission. Building on the technical architecture of the EU Digital Identity Wallets, these measures are estimated to save up to €5 billion in administrative costs by 2029.

Following its adoption, all public administration bodies across the EU will have two years to implement the capacity to accept the core functions of the Business Wallets. While the public sector is obliged to accept the European Business Wallet, its use remains voluntary for companies, which can decide whether to adopt it for commercial use or interactions with authorities.

A Consultation on the Digital Fitness Check

The Digital Fitness Check is the follow-up to the Digital Omnibus, marking the second stage of the Commission's plan to streamline EU digital rules. This Check will specifically focus on the cumulative impact and complex interplay between different regulations on businesses. Its primary aim is to ensure the digital framework is effective and future-proof, supporting the EU's core objectives regarding competitiveness, values, and fundamental rights.

The call for evidence and a public consultation will run in parallel for sixteen weeks until the 11th March 2026.

The Malta Case

Through the Digital Omnibus, businesses will gain simpler compliance processes and enhanced legal predictability. The measure reduces the administrative burden by introducing efficiencies, such as a single reporting channel for cybersecurity incidents that covers multiple regulations. Simultaneously, the omnibus provides clear rules and safeguards regarding the use of personal and sensitive data for AI development, enabling firms to innovate with confidence and certainty.

The full texts for the simplification proposals can be found [here](#).

The full text on the Data Union Strategy can be accessed [here](#).

The Draft Recommendation on non-binding model contractual terms on data access and use and non-binding standard contractual clauses for cloud computing contracts can be found [here](#).

The full proposal for a Regulation on the establishment of European Business Wallets can be found [here](#).

The Public Consultation on the Digital Fitness Check can be accessed [here](#).

Disclaimer: This is a policy brief to create awareness about the legislative proposal and for information purposes. It is not an official position of the Malta Business Bureau.

For questions or more detailed information please contact Christine Cassar — Senior Projects Executive on infobrussels@mbb.org.mt

The Malta business bureau is the EU advisory organisation of;



and a partner of the Enterprise Europe Network;

