Contribution to the Call for evidence on the Digital Omnibus Package

Luxembourg, 8 October 2025

I. Introduction

FEDIL welcomes the European Commission's forthcoming Digital Omnibus package as a critical opportunity to streamline and harmonize the EU's digital regulatory framework. In recent years, companies have faced a tsunami of new digital regulations (AI Act, Data Act, NIS2, DSA/DMA, Cyber Resilience Act, etc.), which, despite their individual merits, have created overlaps, inconsistencies, and heavy administrative burdens. This regulatory complexity undermines legal clarity, disproportionately strains SMEs and cross-border businesses, and even risks slowing innovation in Europe. FEDIL urge the Commission to make the Digital Omnibus a landmark in "*better regulation*" by **streamlining existing obligations, ensuring consistent terminology and requirements across laws, and maintaining enforcement proportionate and predictable for all companies.**

This position paper outlines the key challenges identified by our members and presents clear recommendations to ensure the Digital Omnibus delivers tangible simplification, significantly reduces compliance costs and uncertainty and mostly improves Europe's competitiveness. We call on the Commission to integrate these priorities so that businesses can focus on innovation rather than paperwork.

II. Context – Why the Digital Omnibus?

Over the last five years, the EU has enacted an ambitious suite of digital regulations to address issues from cybersecurity to AI and data governance. While each law has a valid objective, their cumulative effect has led to complex patchwork that is increasingly difficult for companies to navigate. Major businesses report assembling large interdisciplinary teams just to interpret the interplay of various rules, and SMEs often struggle to comply at all due to limited resources. Recognizing this challenge, the European Commission plans to launch the Digital Omnibus package by the end of 2025, a set of legislative adjustments aimed not at adding new rules, but at "tidying up" and aligning existing ones. The intent is to simplify and reduce bureaucracy, harmonize terms and requirements across the digital acquis, and enhance legal certainty for businesses, particularly SMEs and mid-caps.

FEDIL fully supports this initiative. We see it as timely and necessary to ensure that Europe's high regulatory standards do not inadvertently stifle innovation or competitiveness. A well-executed Digital Omnibus can turn the EU's digital rulebook from a source of frustration into a competitive advantage, benefitting companies of all sizes and the Single Market as a whole and demonstrating that smart, streamlined regulation can protect societal interests while fostering a dynamic digital economy.

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III. Key Challenges

FEDIL pinpoints here several **systemic challenges** identified in the current digital regulatory landscape that the Digital Omnibus should address.

1. Complex and overlapping obligations

Many digital laws cover similar or intersecting areas, causing **duplicate or conflicting obligations**, leading to duplicate work. One company may be simultaneously subject to the AI Act, the GDPR, and sector-specific rules when deploying an AI-driven product, each law imposing separate documentation, assessments or notifications for what is essentially a single system. We qualify this as a "compliance maze" where different rules speak different languages and require parallel processes. This not only increases workload but also causes confusion over which requirements take precedence.

2. Heavy administrative and reporting burdens

Companies face an onslaught of reporting obligations, often with tight deadlines. A single cybersecurity incident might trigger up to four separate notifications and reports under NIS2, GDPR, the Cyber Resilience Act, and the Critical Entities Directive; each with its own format and timeline. Preparing these multiple reports is resource-intensive and can distract from actually resolving the issue. Multiple members noted that during incident response, they spend nearly as much time on paperwork as on technical remediation.

More broadly, routine compliance (e.g. maintaining overlapping logs, audit trails, annual assessments) has grown significantly with each new regulation. This burden hits SMEs especially hard, as they lack dedicated compliance departments, but even large firms feel the pinch, diverting legal and engineering hours that could be better spent on improving products and services.

Multiplying reporting obligations not only doubles or triples the work, but also leads to disjointed oversight. Companies are confused by multiple channels and fear penalties if they miss one. This clearly illustrates a case where "once-only" simplification is urgently needed.

3. Inconsistent terminology and definitions

A fundamental source of complexity is that different regulations define key terms differently, leading to legal ambiguity. The concept of what constitutes a "product" can vary between the Product Safety Regulation, the Data Act ("connected product"), and the CRA ("product with digital elements"). Terms like "incident", "risk", or "AI system" are likewise defined in varying ways across legislation.

Additionally, terminology triggers obligations. A company might not even be sure if it falls under a law's scope because of how a term is defined. It also means companies must double-check compliance for each definition variant, effectively erring on the side of the strictest interpretation, which adds cost.

Our members stress that terms need to refer to the same things to avoid misinterpretation. The current inconsistent terminology breeds uncertainty leading to compliance mistakes and inconsistent enforcement.

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4. Fragmented enforcement and divergent national implementations

Where EU rules allow national discretion (or where directives must be transposed), businesses experience uneven enforcement across Member States, thus navigating varying interpretations and implementation speeds. For example, the NIS2 Directive, which EU countries implement individually, may be enforced more strictly in one country than another, or with additional national requirements. This is especially challenging for companies operating across the EU. An IMF study[1] suggests that internal single-market regulatory divergences impose an additional cost equivalent to a ~40% tariff barrier on companies.

This fragmentation undercuts the idea of a Digital Single Market and undermines the level playing field. Furthermore, when laws are enforced differently, it creates uncertainty and risk; a practice acceptable in one jurisdiction might incur penalties in another.

While the Omnibus itself cannot change past directives into regulations, it should strive to minimize divergence in any adjusted provisions and encourage uniform application. While harmonization in law is the goal, harmonization in practice is equally crucial.

5. Disproportionate impact on SMEs, cross-border businesses & value chains

Smaller firms, as well as companies active in multiple EU countries, bear the brunt of these issues. SMEs often lack in-house legal expertise and economies of scale to handle the complex compliance puzzle. Many FEDIL members have observed an uneven compliance readiness across the value chain: larger companies have generally implemented required measures (albeit at high cost), whereas many smaller partners or suppliers are struggling to keep up with the current framework at all. This means the intended benefits of regulations (e.g. increased security or data portability) might not be fully realized in practice, because significant portions of the ecosystem find the rules too complex to implement properly.

Crucially, FEDIL is concerned about a regulatory "two-speed" Europe: the solution is ***not*** to pile more obligations on large companies while exempting all others, but simplification must be broad-based. It should not result in a scenario where only small players get relief and bigger ones are asked to carry even more weight. Europe's digital competitiveness depends on all enterprises, large and small, operating under a manageable, efficient set of rules. Simplification across-the-board is seen as beneficial for everyone, making Europe more competitive, and a counterbalance to the lighter regulatory environment of some global competitors (e.g. the United States).

6. Risk of innovation slowdown due to uncertainty

The cumulative legal uncertainty and burden have tangible effects on innovation. Several companies indicated that they have delayed or canceled digital innovation projects because of legal uncertainty or fear of non-compliance in this complex regulatory context. This is especially problematic in fast-moving fields like AI and data analytics, where Europe needs to foster agile development. For example, introducing a new AI-driven feature might be put on hold until it's clear how the AI Act requirements interplay with existing data protection and consumer protection laws.

When regulatory uncertainty forces risk-avoidance to this degree, it is a clear sign that the framework needs clarification and streamlining. Europe cannot afford to have its innovators "on pause" due to convoluted rules. We risk falling behind in emerging technologies if compliance becomes an all-consuming concern. Ensuring legal clarity and proportional rules is thus key to keeping Europe an attractive place to innovate.

[1] https://www.imf.org/en/News/Articles/2024/12/15/sp121624-europes-choice-policies-for-growth-and-resilience

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IV. Key recommendations for the Digital Omnibus

In light of these challenges, FEDIL puts forward the following priority recommendations, reflecting the consensus of our member companies. We ask the European Commission to incorporate these points into the Digital Omnibus package:

1. Adopt the "Once-Only" principle for incident and information reporting

"*One incident, one report*": this should be the guiding rule.

The Omnibus should enshrine the *once-only principle* for regulatory reporting. Wherever multiple laws demand notifications or reports that cover similar ground, the Omnibus should enable a company to fulfill all obligations with a single submission. In practice, this means creating a one-stop reporting mechanism whereby a company can notify a single authority/portal for a given incident and fulfill all legal reporting obligations at once; EU and national authorities can then share the information amongst themselves "behind the scenes."

For example, a cybersecurity breach that today requires separate notices under NIS2, GDPR, and the CRA should, in the future, be reportable through one unified portal, counting for all three. We recommend establishing one-stop reporting interfaces at national level, and legally mandating that notification to one competent authority is deemed notification to all relevant authorities. This change would eliminate redundant reports and ensure a more efficient crisis response. Luxembourg's SERIMA platform[2] is a practical model: it allows companies to report incidents in one place to satisfy various regulatory regimes (GDPR, NIS1/2, EECC and CER), greatly simplifying the process. The Omnibus should encourage or require the rollout of such integrated platforms across the EU.

In addition, reporting timelines should be aligned. Conflicting deadlines (24h vs 72h, etc.) only add confusion in crisis moments. Setting a single harmonized timeframe will ensure clarity. No time should be wasted on redundant paperwork when rapid incident response is needed.

In short: **report once, to one place, within one clear timeframe**. This will dramatically reduce administrative workload and improve compliance, as companies are far less likely to miss an obligation. Adopting "once-only" reporting will free up valuable resources and improve the quality and timeliness of information regulators receive.

2. Ensure consistent definitions and avoid ambiguity (Cross-Reference, Don't Redefine)

The Omnibus should make a priority of eliminating inconsistent terminology across the digital acquis to avoid ambiguity. FEDIL suggests a practical approach: require cross-referencing of definitions in related legislation and use internationally agreed terminology wherever possible. For instance, if the AI Act defines what constitutes an "AI system" or a "high-risk" scenario, then any future law touching on algorithmic systems should reference those definitions rather than inventing new ones.

Where available, adopt internationally agreed terminology (e.g. ISO standards for information security, or internationally recognized terms for data categories) to maximize clarity, common understanding and global interoperability.

Crucially, any definitional harmonization exercise must *not* unintentionally expand the scope of regulation or create new obligations for actors currently out-of-scope. Importantly, FEDIL stresses that whoever is not covered by a rule today should remain unaffected after definitional alignment. The Omnibus should maintain the *status quo* of application.: i.e. no company currently outside the

[2] https://www.ilr.lu/en/sectors/niss/serima/

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scope of a law should be pulled in just because of a definitional change, otherwise simplification efforts could paradoxically result in new compliance obligations for entities previously exempted. The goal is to streamline interpretation, *not* to rope in new targets inadvertently. We insist that companies or activities currently outside the ambit of certain laws remain outside, unless a deliberate policy decision (with full impact assessment) is made to include them. Simplification is about making compliance easier for what is *already* regulated, not about extending regulations to new domains via the back door.

By anchoring laws to a shared set of definitions and concepts, the Omnibus will reduce compliance confusion and legal risk on uncertainty. It will also help regulators enforce rules more uniformly.

In short: All digital regulations should "speak the same language," but in doing so, we must maintain the existing perimeter of application. Consistent language will help companies more easily understand their duties and reduce the risk of inconsistent enforcement.

3. Mutual recognition of compliance efforts across laws

We urge the Commission to embed a principle of "recognise one, satisfy all" for similar compliance obligations. If a company has undertaken a certain compliance task under one regulation, that should be counted as fulfilling analogous requirements under another. For example, a company that conducts a robust data protection impact assessment (DPIA) for a new AI-based service under GDPR should not be required to conduct an essentially duplicative impact assessment under the AI Act, one well-documented assessment ought to suffice. Similarly, if a cloud service provider has obtained a cybersecurity certification under an EU-wide scheme (Cybersecurity Act), that achievement should give presumptive compliance under related security requirements in laws like NIS2 or the CRA.

This kind of mutual recognition would directly eliminate redundancies and cut down duplicative compliance costs, encouraging businesses to aim for high standards (knowing they won't have to redo the exercise for each law). It sends a powerful signal that EU regulators coordinate with each other just as they expect companies to. Concretely, the Omnibus could introduce clauses that explicitly allow documentation or certificates from one law to be reused for another, where the objectives overlap. This improves efficiency and encourages companies to pursue the highest-standard compliance In regulatory terms, it's simply **common sense**: avoid making companies reinvent compliance processes when the end-goal of different rules is comparable. It is important for keeping compliance costs proportional: without mutual recognition, mid-sized firms in particular face layer upon layer of similar audits and paperwork. FEDIL believes "one process, multiple compliance" is a cornerstone of smarter regulation.

In short: Embracing the mutual recognition principle will foster a more *coherent* regulatory environment and reward proactive compliance.

4. Proportionality, predictability and simplification for all companies

Simplification should not be seen as a concession only for small businesses, it must be about right-sizing regulations for all enterprises, while still achieving regulatory goals. Indeed, while SMEs warrant particular support, we caution against a narrative that only addresses SME needs and assumes bigger firms can indefinitely shoulder complexity. Many large companies, especially those operating globally, are also calling for relief from unnecessary bureaucracy. FEDIL cautions against a trend of differentiating too starkly by company size (e.g., simply exempting SMEs but making requirements even stricter for large companies). Instead, we advocate approaches that scale obligations to actual risk and capacity without creating loopholes. Simplification must be "throughout the board".

We recommend embedding proportionality in enforcement: regulators should focus on the substance (risk and harm) rather than formalistic compliance, and adjust expectations based on company capacities where appropriate. For example, provide simplified compliance pathways or templates that any company can use if their situation is low-risk or standard, this helps SMEs but can also streamline processes for larger entities. Conversely, avoid imposing extra layers exclusively on large firms as a trade-off for easing SMEs; such an approach could penalize success and deter growth. Instead, aim for a net reduction of burden across all tiers.

A practical recommendation is to enable group-level compliance for corporate groups: if several affiliated companies fall under the same requirement, allow a parent or centralized function to handle certain compliance obligations once for the entire group in a centralized way. This avoids needless duplication of effort and leverages internal expertise. Under NIS2, for instance, a multinational group with many subsidiaries should be permitted to file *one* consolidated cyber incident report (via its headquarters or lead entity) instead of dozens of identical reports from each affiliate. Similarly, intra-group service arrangements shouldn't trigger the same external oversight as third-party outsourcing. By recognizing integrated compliance setups, the EU can eliminate internal redundancies and make enforcement more efficient as well.

Overall, the Commission should signal clearly that the aim is a leaner rulebook for everyone, resulting in a more competitive Europe.

The overarching message is one of fairness and competitiveness: Europe's regulatory environment should be manageable for its champions and newcomers alike. Simplifying "throughout the board" will make the entire ecosystem more agile and competitive. As the Commission pursues relief for SMEs, which we strongly support, it should concurrently identify and prune burdens that affect larger companies without commensurate benefit.

In short: Better regulation is an economy-wide necessity, not a zero-sum game between big and small players. *"If we simplify for all, we all benefit."*

5. Strengthen safeguards for trade secrets and cybersecurity in data-sharing regimes

FEDIL calls for strengthened protections for confidential business information in any data-sharing obligations revised by the Omnibus. Industry fully understands the value of data sharing and supports the goals of the Data Act to spur innovation and competition. However, these goals must not come at the cost of companies' legitimate intellectual property and security.

The Omnibus should clarify and enhance the provisions that allow data holders to deny or condition access to data that would expose trade secrets or critical know-how. The so-called "trade secrets handbrake" in the Data Act, for example, should be made more robust and easier to invoke – essentially a clear exemption for bona fide trade secrets and cybersecurity-sensitive information, rather than a complex arbitration process. This will reassure businesses that sharing usage data with customers or competitors (through user-authorized third parties) will not equate to handing over their "crown jewels."

Additionally, "security" exceptions should explicitly include cybersecurity risks: if sharing certain data could open doors to cyber attacks or vulnerabilities, companies should have the right to refuse until safeguards are in place. These clarifications will prevent an unintended chilling effect where companies, fearing loss of their crown jewels, might resist participating in data-driven ecosystems.

We also urge caution in defining the scope of data-sharing mandates. The Omnibus should precisely delineate terms like "data from related service" (in the Data Act's context of products). We propose limiting services inextricably linked to the core functioning of a product. This prevents overreach and gives companies certainty about which data must be shared and which

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falls outside the law's purview, while aligning with the original intent of facilitating maintenance and interoperability, not exposing proprietary troves.

In short: Data availability should be balanced with data responsibility. The Omnibus should ensure that European companies can share data to innovate, while firmly protecting the competitive advantages and security integrity that drive them to innovate in the first place.

6. **Introduce systematic mandatory impact assessments for new obligations ("Think Twice" principle)**

A crucial forward-looking recommendation is that the EU's law-making process incorporate a rigorous compliance cost assessment for any new regulatory obligation to avoid repeating the accumulation of burdens.

FEDIL proposes that the Digital Omnibus not only fix current issues but also embed mechanisms to avoid future complexity creep. Specifically, before any new reporting duty, certification requirement, or other administrative obligation is introduced (whether via delegated act, implementing act, or new primary legislation), the Commission should conduct a Regulatory Impact Assessment focusing on cumulative compliance cost, practicability and potential overlap with existing requirements. This assessment should involve consultation with industry to gauge real-world feasibility and should be made public. Such a "think twice" principle will instill discipline in regulatory drafting: is a given obligation truly necessary and worth the burden it imposes? Could the objective be met in a simpler way or using an existing channel? The Commission's Better Regulation toolbox should be updated to include an explicit checklist for cumulative impact in the digital sector.

Moreover, the Omnibus should consider empowering a central body (for example, the Commission's own Regulatory Scrutiny Board or a dedicated task force) to review digital regulations holistically for coherence. Many of the overlapping issues today might have been caught earlier with a more silo-breaking review process.

By institutionalizing these practices, the EU can ensure that after cleaning up the rulebook via the Omnibus, it stays clean and navigable.

Going forward, European digital legislation needs a continuous simplification mindset, much like code refactoring in software, to prevent the accumulation of technical debt (or in this case, regulatory debt). By instituting mandatory cost-of-compliance evaluations and sunset or review clauses for reporting requirements, the EU can avoid repeating the mistakes that made a Digital Omnibus necessary in the first place. This aligns with the Commission's broader Better Regulation agenda and the commitment to reduce administrative burden by 25%.

In short: Future regulatory initiatives should be *stress-tested* for simplicity and coherence. "*Prevention is better than cure*" when it comes to avoiding undue compliance burdens.

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7. Keep fragmentation to a minimum

While the Digital Omnibus will primarily adjust EU-level rules, FEDIL encourages the Commission to use this moment to also promote consistency in enforcement across Member States.

One aspect could be favoring regulations over directives for future horizontal digital laws (where appropriate), since regulations have direct effect and leave less room for divergent national implementation and actively coordinate enforcement among national authorities so that businesses see a consistent approach across the single market.

We acknowledge this may be beyond the strict scope of the Omnibus, but it is an important contextual message: harmonization should be achieved not just in legal texts but in practice on the ground.

Whether through regulations, better coordination among national authorities, or enhanced oversight by EU agencies, ensuring a level playing field across the single market remains a key industry ask. Every deviation at national level increases costs and complexity for businesses operating Europe-wide, effectively undoing some of the Omnibus's simplification gains. We therefore support any Omnibus provisions or accompanying measures that push for uniform interpretation and application of rules (for example, commitments to develop common guidelines, or mechanisms for joint enforcement actions).

In short: The principle is simple: "*One Europe, one rulebook, one approach*".

8. Forward-looking considerations

While the objective of establishing a single reporting entry point is essential, this endeavour is of scale. Thus, a phased structured implementation structured around a long-term vision ensures feasibility and stakeholder alignment:

- Short term:
- Achieve progressive harmonisation of definitions, thresholds, and reporting timelines across Member States to eliminate inconsistencies and overlapping obligations under NIS2, GDPR, and sectoral frameworks.
- Medium term:
- Develop an interoperability framework for existing national portals, including common data models and secure APIs, to enable automated and secure information exchange between competent authorities.
- Conduct a feasibility assessment for a fully centralised EU reporting entry point, supported by a robust governance architecture and operational coordination with ENISA.
- Long term:
- Deployment and operationalisation of the EU-level portal, ensuring resilience, cybersecurity assurance, and sustainable governance mechanisms.

The success of this initiative will depend on strong engagement from Member States and specialised institutions such as national CERTs. Luxembourg, given its experience and central role in EU digital policy, is well positioned to foster dialogue and coordination among stakeholders.

Additionally, while the Digital Omnibus Package focuses on targeted amendments to existing regulations, the sustainability of a centralized EU reporting entry point will require adequate and predictable resourcing to ensure security, resilience, and long-term operational continuity.

This will require sufficient financial resources to cover operational expenditure for maintaining a secure, resilient, and continuously updated platform.

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It will also include the technical resources necessary for the development and integration of interoperable systems, as well as the implementation of robust governance and independent assurance mechanisms, including conformity assessments and resilience testing to guarantee trust and accountability across Member States.

These aspects should be addressed within the context of the EU Multiannual Financial Framework (MFF) and through public-private cooperation mechanisms, ensuring that financial and operational commitments remain proportionate and aligned with the strategic objectives of the Digital Omnibus.

V. Conclusion and call to action

FEDIL strongly believes that the Digital Omnibus initiative comes at a pivotal time. It is essential to recalibrate the EU's digital regulations to ensure they truly support, and do not inadvertently hinder, Europe's twin transitions to digital leadership and global competitiveness. A bold and well-crafted Digital Omnibus will help maintain Europe's high standards while eliminating unnecessary friction, thereby unleashing the full potential of European companies, big and small, to innovate, compete, and deliver value to society.

We do not call for deregulation or lowering of standards, but for intelligent adjustments that make the existing high standards work better in practice. We urge the European Commission to embrace the recommendations above, from the once-only reporting principle to cross-referenced definitions and careful impact assessments, as guiding tenets of the Omnibus.

Ultimately, what's at stake is more than administrative streamlining; it is Europe's ability to foster innovation, streamline compliance, and remain an attractive place to do business in the digital era. By implementing these simplification measures, the Digital Omnibus will send a powerful signal that the EU is serious about Better Regulation, that it listens to businesses' experiences and is willing to course-correct for the sake of a stronger Digital Single Market.

We are committed to supporting this initiative throughout the legislative process and look forward to a Digital Omnibus that truly achieves its promise of a more coherent, business-innovation-friendly EU digital framework. We count on the Commission to deliver an Omnibus proposal that reflects these common-sense adjustments and on the co-legislators to swiftly turn it into law.

In conclusion, our message is clear: "**Make EU digital regulation an enabler, not a barrier**". The Digital Omnibus is the right vehicle to ensure that Europe's digital legislation remains effective without being excessive. Europe has been a pioneer in digital governance; now it must pioneer in regulatory smartness and simplicity.

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