Key Takeaways

- The Omnibus IV package defines small-mid cap (SMC) companies as those with between 250 and 750 employees, with an annual turnover between €50 million and €150 million and a balance sheet between €43 million and €129 million.
- By using this definition to better tailor compliance requirements, the Commission says annual administrative costs for these businesses will be cut by €400 million.
- Over 38,000 business will now benefit from exemptions and lower requirements that were previously dedicated for SMEs.
- Several pieces of EU legislation will be amended across different sectors, including data protection, trade defence, batteries, financial markets, and fluorinated greenhouse gases.
- On the GDPR, the Commission proposes amending provisions relating to record-keeping, drafting sectoral codes of conduct, and data protection certification mechanisms.
- SMCs will also be subject to lighter obligations on trade defence, particularly on the protection of dumped imports and protection against subsidised imports.
- The Commission also revealed plans to tweak the Batteries Regulation and the F-gas Regulation to relieve SMCs from some due diligence and reporting duties.
- The Commission has stated that the list of regulations and directives to be brought in line through Omnibus IV is not exhaustive, and other laws may be targeted further down the road.
- There are concerns about the efficacy of legislation in light of growing exemptions for certain companies, with a lot of voices urging against reopening the GDPR laws.
- Questions also remain on the enforcement and oversight of the newly established SMC category.
- There are also measures to eliminate paper-based requirements and move to digital to enhance efficiency, facilitate compliance verification by national authorities, and promote environmental sustainability.

Omnibus IV: small mid-cap simplification

The DeHavilland guide

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Context

The latest Omnibus package, published on 21 May, is the Commission's fourth simplification package. The first three looked at corporate reporting legislation (CS3D, CBAM and CSRD), the European investment framework (InvestEU), and the Common Agricultural Policy (CAP). This one focuses on small mid-caps (SMCs) and cutting paper requirements.

While previous Omnibus packages spotlight simplification and slashing requirements, Omnibus IV defines SMC enterprises to reduce administrative burdens and boost competitiveness by ensuring they benefit from more proportional reporting duties.

This initiative finally defines the bounds of SMCs, a new category of companies, laying between small and medium-sized enterprises (SMEs) and large corporations. SMCs and SMEs represent 99% of all businesses in the EU, provide 75% of all jobs and are an integral part of the EU's economy. Mid-caps are particularly relevant to the EU's competitiveness as they represent a large share of employment in key industrial sectors, such as energy, electronics, energy intensive industries, textiles, aerospace and defence, and construction.

As highlighted in the Draghi Report, SMEs and SMCs face a disproportionately high regulatory burden, hindering competitiveness and an innovative business environment. Additionally, SMCs do not benefit from the same exemptions as SMEs concerning reporting obligations. The lack of a clear and harmonised definition of SMCs has led to unequal treatment across national jurisdictions, increased regulatory and administrative burdens, for example in funding programmes, fragmented access to financial markets, and an uneven application of reporting requirements.

Following the 2025 Work Programme, this Omnibus package plays an integral part in relieving smaller enterprises of excessive administrative burdens and cutting red tape. The Commission says under the new definition — enterprises which are not SMEs but employ fewer than 750 persons and have an annual turnover not exceeding €150 million or an annual balance sheet total not exceeding €129 million — over 38,000 companies would be classified as SMCs and be able to make use of exemptions and simpler reporting obligations, following the SME approach.

This comes on top of measures in the Omnibus I package to remove the reporting obligations of SMCs under CSRD by addressing the "trickle-down" effect and the indirect obligations stemming from the CSDDD.

The Omnibus IV package also targets the removal of paper requirements in an effort to speed up digitalisation and the transition to a data-driven internal market, underpinned by the broader goal to reduce administrative burdens, especially for SMCs. As such, the digitalisation of compliance procedures is key.

Overview

With this package, the Commission introduces a new category for small-mid cap companies (SMCs) to better tailor compliance requirements, reducing annual administrative costs for these businesses by €400 million. This builds on earlier simplification efforts worth €8 billion.

The reforms are set to ease regulatory burdens, encourage investment, and make it easier for companies to grow and innovate across the Single Market. By digitising procedures and cutting red tape, the Commission moves closer to its target of a 25% reduction in administrative burdens overall, and 35% for SMEs, by the end of its mandate.

The three core elements of the package are:

- New EU category for small mid-caps and targeted support
- Increased digitalisation and legal certainty
- Postponement of battery due diligence requirements

New EU category for small mid-caps and targeted support

The Commission proposes a definition for SMCs in its Recommendation referring to them as "enterprises which are not small and medium-sized enterprises in accordance with Recommendation 2003/361/EC, employ fewer than 750 persons and have an annual turnover not exceeding €150 million or an annual balance sheet total not exceeding €129 million." This means that any companies which exceed the SME definition (enterprises with fewer than 250 employees and either an annual turnover not exceeding €50 million or a balance sheet total not exceeding €43 million), but fall below the thresholds mentioned above will be treated as SMCs.

It has chosen these parameters to strike a balance between being broad enough to cover companies with significant growth potential, but small enough to address their unique challenges compared to larger, established mid-cap companies. This differentiation allows the Commission to create more precise and effective regulatory and market support measures.

This definition is then used to expand a number of exemptions and lower requirements previously open to SMEs to businesses within the new definition, with the Commission saying this will benefit 38,000 companies.

Proposed legislation

The Commission's proposals for a regulation and a directive on SMCs will amend six regulations and two directives, impacting data protection, trade defence, batteries, MiFID, and fluorinated greenhouse gas registration.

Data protection

The 2020 and 2024 GDPR application reports show that despite some challenges, stakeholders generally agreed it has had positive outcomes. However, SMEs voiced concerns that the exemption from record-keeping requirements under Article 30(5) is too limited.

To address this concern, and allow for the exemptions for SMCs, the Commission proposes amending Regulation (EU) 2016/679 on general data protection (GDPR).

Article 30 currently exempts SMEs and organisations with fewer than 250 employees from the obligation to keep records of processing activities, under certain conditions. The revised provision will make record-keeping mandatory only when the processing is likely to result in a high risk to individuals' rights and freedoms. At the same time, the exemption will be extended to SMCs and organisations with fewer than 750 employees, easing the burden on a wider range of entities.

Article 40, which encourages the development of sector-specific codes of conduct tailored to the needs of SMEs, will be also modified. This obligation will now be extended to also cover SMCs, ensuring their specific characteristics are considered when such codes are drawn up.

Article 42, addressing data protection certification mechanisms, will be amended to require that the needs of SMCs, alongside those of SMEs, are taken into account in the design and implementation of certification schemes, seals, and marks.

Trade defence

The proposal aims to amend two regulations related to trade defence: Regulation (EU) 2016/1036 on protection against dumped imports from countries not members of the European Union, and Regulation (EU) 2016/1037 on protection against subsidised imports from countries not members of the European Union.

Both regulations allow the European Union to investigate and address dumping and the granting of subsidies by non-EU countries and restore a level playing field in the Single Market and will be simplified by the proposed amendments.

Protection of dumped imports

Article 5(1a), which provides assistance to SMEs through a dedicated helpdesk offering guidance on trade defence procedures, will be updated to include SMCs within its scope.

Additionally, **Article 6(9)**, which encourages aligning investigation periods with the financial year in sectors largely composed of SMEs, will also be extended to SMCs**,** enhancing procedural predictability for a broader range of companies.

Protection against subsidised imports

Article 11(9), which encourages aligning investigation periods with the financial year for sectors largely made up of SMEs, will be extended to include SMCs**,** improving predictability and procedural alignment for a wider group of companies.

Prospectus Regulation

There are also proposed amendments to Regulation (EU) 2017/1129, as amended by Regulation (EU) 2024/2809, which aim to reduce listing costs for SMCs and improve their access to funding by making them more attractive to investors. New prospectus exemptions will allow authorities to act quickly during banking or insurance crises by helping speed up the resolution of failing firms, maintaining their essential services, and ensuring that SMCs can still access those services as clients.

Amendments to **Article 1(4) and (5)** introduce a new exemption from the prospectus obligation for securities issued following liability conversions under EU or equivalent third-country bank/insurer resolution frameworks. It also extends the existing resolution-specific exemption for admissions to trading to include third-country authorities.

Article 2 sets out relevant definitions of the Regulation**,** and would be amended to include those for SMCs, relevant third-country authorities, and third-country resolution proceedings via cross-references to relevant directives.

Article 15a expands the eligibility for the EU Growth issuance prospectus to include SMCs, aiming to reduce their listing costs and improve access to funding.

Given that the relevant provisions introduced by Regulation (EU) 2024/2809 will apply from 5 March 2026, the proposal also aligns the application date of the new amendments to that same date.

Batteries

Regulation (EU) 2023/1542 aims to strengthen the functioning of the EU internal market while mitigating the environmental and human health impacts of batteries throughout their life cycle, including production, use, and end-of-life management. Central to this framework are due diligence requirements for economic operators placing batteries on the EU market, particularly concerning the ethical and sustainable sourcing of raw materials.

This proposal modifies that Regulation to reduce the burden on SMCs. While few SMCs are affected by these changes, those that are could save around €40,000 annually. The Commission also stressed that overall environmental ambition remains unchanged, as most batteries on the EU market are sold by large companies.

Article 47 currently exempts SMEs from certain due diligence requirements, such as adopting a due diligence policy to address environmental and social risks in the supply chain and establishing internal management systems. This will now be extended to SMCs.

It also amends the obligation in **Article 52** requiring economic operators referred to in **Article 48(1),** namely those who place batteries on the EU market or put them into service, to review and publish their battery due diligence policy annually. The proposal changes this frequency to every three years**.** This change applies to all economic operators, including SMCs.

Fluorinated greenhouse gases

The goal of Regulation (EU) 2024/573 is to significantly reduce emissions of fluorinated greenhouse gases, particularly hydrofluorocarbons (HFCs), which have a high global warming potential and contribute to climate change. To achieve this, it introduces stricter limits on the production and use of F-gases, mandates a gradual phase-down of HFCs, and establishes new requirements for equipment standards, leakage prevention, and enforcement measures.

In order to reduce the burden, the proposal amends this Regulation with the intention of narrowing the scope of the registration obligation in the F-gas Portal for importers and exporters of products and equipment containing fluorinated gases.

Currently, the Regulation requires all such imports and exports, regardless of whether they are subject to reporting or restriction, to be registered.

Article 20(4)(a) will be amended to limit this obligation to imports that are also subject to reporting requirements, and exports that are covered by restrictions based on the global warming potential of the F-gases contained.

MiFID

Amendments to the Directive 2014/65/EU on markets in financial instruments intend to facilitate broader access for SMCs to SME growth markets and improve their funding opportunities.

Article 4(1) would be changed to introduce the new definition of SMCs, distinguishing them from the existing category of SMEs.

Article 33(3), which currently requires at least 50% of issuers on a multilateral trading facility (MTF) be SMEs in order for the MTF to be registered as an SME growth market, will be amended. The revised provision will allow MTF operators to count both SMEs and SMCs when demonstrating compliance with this threshold.

Critical entities

Under Directive (EU) 2022/2557, critical entities are organisations that provide essential services across key sectors, such as energy, transport, banking, health, water supply, digital infrastructure, and public administration, whose disruption could seriously impact the economy, society, public health, or safety.

According to the directive, Member States are required to assist critical entities by offering guidance, developing methodologies, organising resilience exercises, providing training, and facilitating voluntary information sharing. Additionally, the directive encourages the Commission to support these efforts by developing best practices, guidance materials, and cross-border training activities. This collaborative approach aims to enhance the resilience of critical entities across the EU.

Amendments to this directive intend to ensure that SMCs, alongside SMEs, receive appropriate support if identified as critical entities.

Article 4 requires each Member State to adopt, by 17 January 2026, a strategy to enhance the resilience of critical entities. This strategy must describe existing measures that help SMEs identified as critical entities comply with certain obligations. The proposal aims to extend this requirement to also include SMCs, so Member States must describe any facilitation measures available for SMCs as well. Additionally, the proposal suggests adding a definition of SMCs alongside the existing definition of SMEs in Article 4.

Increased digitalisation and legal certainty

The Commission's proposals aim to modernise and streamline EU product legislation by embracing digital transformation. By eliminating outdated paper-based requirements such as declarations of conformity and instructions for use, the initiative seeks to reduce administrative burdens, particularly for SMEs.

This shift to digital formats is expected to enhance efficiency, facilitate compliance verification by national authorities, and promote environmental sustainability by reducing paper consumption.

The proposals reference the upcoming European Business Wallet initiative as a solution to key challenges faced by economic operators and public administrations. It will establish a secure digital identity for all economic operators and provide a framework for interoperable Business Wallets that share verified data and credentials. To support its development, the European Commission has launched a call for evidence running from 15 May to 12 June 2025, seeking input from a wide range of stakeholders, to identify challenges the wallet should address and to guide its implementation.

In addition to digitisation, the proposals address the need for legal certainty through the establishment of common specifications. In scenarios where EU-wide harmonised standards are absent, these common specifications will offer companies a clear framework to demonstrate compliance with EU requirements. This approach is intended to reduce costs, enhance competitiveness, and prevent market fragmentation by ensuring uniform application of standards across Member States.

Proposed legislation

To achieve both objectives, the Commission presented a proposal for a directive and a proposal for a regulation.

The proposal for a directive aims to modernise and simplify existing EU product legislation by enabling the use of digital documentation instead of paper-based paperwork. This directive targets several existing product-related directives, facilitating easier market access through streamlined compliance processes. The files included in this proposal are:

- Machinery Directive (2006/42/EC)
- Electromagnetic Compatibility Directive (2014/30/EU)
- Pressure Equipment Directive (2014/68/EU)
- Radio Equipment Directive (2014/53/EU)
- Low Voltage Directive (2014/35/EU)
- General Product Safety Directive (2001/95/EC)

Meanwhile, the proposal for a regulation complements this by mandating the adoption of digital tools and platforms for product compliance across the EU. It focuses on two proposals:

- Regulation (EC) No 765/2008 on accreditation and market surveillance
- Regulation (EU) 2019/1020 on market surveillance and compliance of products

Together, both proposals push for a “digital by default” approach to product compliance, fostering a more efficient, transparent, and sustainable internal market that benefits businesses and supports the EU’s broader goals of innovation and competitiveness.

The Omnibus proposes a uniform approach to alignment across these files as regards definition, legal effect, conditions, and procedure for adoption for the acts.

Postponement of battery due diligence requirements

The package also includes a two-year postponement of sustainability due diligence requirements in relation to batteries, to give companies more time and flexibility to transition smoothly. It implies that the application date changes from 18 August 2025 to 18 August 2027.

Proposed legislation

The Commission presented a proposal for a regulation amending Regulation (EU) 2023/1542 on battery due diligence requirements.

This delay also intends to enable the development and recognition of due diligence schemes and the designation of notified bodies, which are progressing slower than expected.

One of the main reasons for the postponement is the fact that key enforcement mechanisms, such as third-party verification and national authority appointments, were not yet in place, and companies lacked official guidance, putting many at risk of non-compliance by August 2025. Moreover, the amendment does not alter the substantive provisions of Regulation (EU) 2023/1542 but addresses practical implementation issues.

Analysis

This package comes as part of a broader push by the Commission to simplify EU rules for businesses, and particularly targets SMCs that have often been overlooked between SME exemptions and regulations for larger firms. Creating a distinct SMC category and extending certain SME reliefs to 38,000 companies represent a notable adjustment in the regulatory framework.

The extension of exemptions raises questions about the potential impact on regulatory effectiveness. While the simplification is intended to alleviate burdens on smaller companies, it is essential to ensure that critical regulatory objectives, such as data protection and environmental sustainability, are not compromised. Some may see the creation of a new company category less as simplification and more as a narrowing of regulatory scope, being perceived by critics as part of a broader deregulation agenda. The Commission has indicated that these amendments are illustrative and that further regulatory adjustments may be considered in the future.

In addition, the package leaves questions unanswered around enforcement and oversight of the new SMC category. Without clear mechanisms, compliance monitoring could become inconsistent across Member States, increasing the risk of regulatory fragmentation and uneven application within the Single Market.

The proposal to modernise product legislation through digital transformation addresses long-standing calls for greater simplification and efficiency. By replacing paper-based requirements with digital documentation, it aims to reduce administrative burdens. Eurochambres' 2024 position on SME digitalisation highlighted the need for tailored digital solutions to ease these costs and enhance competitiveness, reinforcing the Commission's digital-by-default approach.

The upcoming introduction of the European Business Wallet signals an important innovation, aiming to provide secure digital identities and interoperable tools for economic operators and authorities. However, its success will depend on effective stakeholder engagement and the resolution of technical challenges during implementation.

The establishment of common specifications addresses a gap where harmonised standards are lacking, aiming to ensure legal certainty and avoid fragmentation across Member States. While this could enhance competitiveness and reduce costs, the practical impact will hinge once again on the consistent application of these specifications.

The postponement of battery due diligence requirements is a pragmatic response to practical challenges. This delay mirrors earlier postponements, notably the 'Stop the clock' mechanism introduced under Omnibus I. Presented by the Commission in February 2025, this measure progressed swiftly, reaching publication in the Official Journal by 16 April 2025. This rapid adoption highlighted the political priority given to providing legal certainty through the deferral of certain obligations.

Looking ahead, the legislative process will continue with the planned adoption of Omnibus V on Defence, scheduled for 17 June 2025. Additionally, further Omnibus packages addressing the chemical industry and a broader digital package are expected by the end of the year.

Reaction

Petri Salminen, President, SMEunited said: "SMEs remain cautious and concerned about the impact the introduction of a new company category "small mid-caps" will have on SMEs and SME policy in Europe."

Agustín Reyna, Director General, BEUC, said: "Making rules simpler can make Europe act faster and benefit both companies and consumers. However, simplification must in no way equal watering down standards. Opening the GDPR could not only put consumer's rights at risk but also create legal uncertainty for companies, raising their costs if they would need to adapt to new rules."

Political groups

Dolors Montserrat MEP, EPP Group Vice-Chair for Economy and Environment, said: "Life for small companies needs to be made easier. A clear definition of small mid-cap companies is essential to ease reporting and monitoring obligations and simply allow them to concentrate on what they do best: building their business."

Bas Eickout, Co-President of the Greens-EFA, said: "This new omnibus does not address the main challenges faced by "small mid-caps." Indeed, the administrative burden is not the primary cause of the slowdown in their growth. This ranks far behind difficulties in finding staff, supply chain disruptions, and raw material shortages. However, the Commission does not provide any answers on these issues."

Svenja Hahn, Renew coordinator in the Internal Market and Consumer Protection committee, said: "The Commission's proposal would ease the bureaucratic burden on many companies in the EU. This is an important step to give European companies the breathing space they need, so they can focus on what they do best: to innovate and produce."