



Questions and answers on simplification omnibus IV

Brussels, 21 May 2025

1. Why are you proposing this fourth Omnibus?

The Commission's recent Competitiveness Compass and Mario Draghi's report on the future of European competitiveness underline the need to boost Europe's competitiveness and long-term prosperity. To do so, the EU must ensure that regulation is proportionate, targeted, and supports business activity. Reducing regulatory burdens allows companies to grow, create quality jobs, attract investment, and secure the funding needed for the green and digital transitions.

To this end, the Commission is today presenting a Single Market Strategy focused on removing remaining barriers to trade in the Single Market. In parallel, this fourth simplification Omnibus delivers on the Commission's commitment to simplify EU rules and reduce administrative burdens.

This initiative forms part of a broader effort announced in the Commission's 11 February Work Programme: a series of "Omnibus" proposals targeting overlapping, excessive, or outdated rules that create unnecessary burden. The goal is to deliver at least a 25% reduction in administrative burdens – and at least 35% for SMEs – by the end of this mandate.

Today's proposals extend supportive measures for Small Mid-Cap companies (**SMCs**), in line with what is already available for Small and Medium-Sized companies (SMEs) in certain fields. It includes measures to reduce reporting requirements and administrative burdens for both SMEs and SMCs. It will also accelerate the shift to a digital regulatory framework, eliminating cumbersome paper-based format requirements in product legislation, and promote the use of common specifications to alleviate the challenges faced by businesses due to the lack of standards.

The proposals also include a postponement of sustainability due diligence requirements in relation to batteries. This delay will give companies more time and flexibility to smoothly transition and effectively implement due diligence obligations, with the help of guidelines to be published by the Commission.

Small mid-caps

2. Why are you proposing this new Small mid-cap definition?

Today small mid-caps are treated as large companies, having to meet exactly the same compliance obligations. The purpose of today's proposals is to recognise small mid-caps as a separate, intermediate company category and to avoid a cliff-edge in compliance obligations when companies outgrow the SME category.

The objective is also to allow SMCs to benefit from a supportive environment as they scale up and to provide SMEs with better incentives to grow. Finally, the definition will lay the ground for future proposals to allow for targeted policy support to SMCs.

The new definition also follows up on the recommendations set out in the Letta and Draghi reports. Both indicated that introducing such a new category of companies would have a positive impact on the functioning of the single market and on European competitiveness.

3. What type of benefits will be extended to small mid-cap companies?

The Commission is proposing to extend several existing supportive measures for SMEs, to cover also small mid-cap companies.

Examples of benefits we are proposing are as follows:

- a. The GDPR contains a derogation for enterprises and organisations employing fewer than 250 persons. It exempts them from the obligation to maintain records of data processing activities. We are now proposing to extend this derogation to small mid-caps and organisations with fewer than 750 employees. We are also pursuing simplification by proposing to limit the obligation to maintain records only for 'high risk' processing activities. The proposed changes should help companies save EUR 66 million per year.
- b. Currently SMEs listed and to be listed are entitled to issue a short-form and standardised prospectus. This simplified form will now be extended to all offers of securities to the public made by SMCs. We are expecting that any company drawing up a simplified form of an EU growth issuance prospectus (instead of a full prospectus) would save approximately EUR 20 000. The total maximum estimated cost savings for small mid-caps, resulting from the proposed amendments to the MiFID II Directive and the Prospectus Regulation, would amount to EUR 12 700 000.
- c. Under the Batteries Regulation, SMEs are exempted from the rules on due diligence and tracing back supply chains. This exemption is proposed to be extended to small mid-caps. This could help each mid-cap company falling under the scope of the Regulation save EUR 40 000.

Detailed benefits per each measure proposed have been detailed in the questions below.

4. How will this omnibus contribute to the 25% target to reduce administrative burden?

The Omnibus will amend several pieces of legislation in which supportive measures for SMEs already exist. A number of these measures will be extended to SMCs, leading to burden reduction for these companies. However, it is important to note that the Omnibus will also bring qualitative benefits such as a specific helpdesk or guidance for SMCs.

In parallel, there is an overall cutting of red tape brought about by the measures regarding the GDPR, the Batteries Regulation, and the f-gases Regulation.

This Omnibus is accompanied by a Staff Working Document which estimates the savings for companies to be achieved through the omnibus at between 79.2 and 93.3 million per year, drawing on the existing impact assessments of the amended acts. These savings will count towards the 25% target.

5. Which pieces of legislation are you amending today?

The Omnibus introduces targeted amendments to the following eight legislative acts:

- General Data Protection Regulation (GDPR) - Regulation (EU) 2016/679
- Regulation on protection against dumped imports - Regulation (EU) 2016/1036
- Regulation on protection against subsidised imports - Regulation (EU) 2016/1037
- Markets in financial instruments Directive – Directive (EU) 2014/65
- Prospectus Regulation - Regulation (EU) 2017/1129
- Batteries Regulation - Regulation (EU) 2023/1542
- Critical entities resilience Directive - Directive (EU) 2022/2557
- Fluorinated greenhouse gas Regulation - Regulation (EU) 2024/573

6. What will be the changes? What is the benefit for companies?

The Commission has reviewed a wide range of EU laws to identify overlapping, burdensome or disproportionate requirements, particularly for SMEs and small mid-cap companies (SMCs). The screening has revealed a range of possibilities to ensure better proportionality for small mid-cap enterprises and, in addition, extensive consultations with industry and business stakeholders have helped to set up the proposals for amendment.

The main changes and their expected benefits are as follows:

a. General Data Protection Regulation (GDPR) - Regulation (EU) 2016/679

Small mid-caps and organisations with fewer than 750 employees will no longer need to create or update their existing records of activities involving the processing of personal data in cases where these activities are not likely to result in a high risk to the rights and freedoms of data subjects.

b. Regulation on protection against dumped imports - Regulation (EU) 2016/1036 and Regulation on protection against subsidised imports - Regulation (EU) 2016/1037

These two regulations are part of the EU's trade defence system, allowing 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. Simplified procedures under the regulations will:

- provide a helpdesk offering information on trade defence to SMCs, for example on procedures or on how to submit complaints to initiate cases, and
- make it easier for SMCs to provide data in investigations where the EU industry is fragmented by, where possible, aligning investigation periods with the companies' financial year.

c. Markets in financial instruments Directive (Directive (EU) 2014/65 ("MiFiD")) and Regulation (EU) 2017/1129 (The 'Prospectus Regulation')

The proposed changes aim to extend:

- the support currently available for SMEs to access SME growth markets to SMCs, and
- the use of the EU Growth issuance prospectus, an alleviated form of prospectus introduced by the Listing Act, for public offers of securities made by SMCs, including with listing on multilateral trading facilities.

These will make the listing of SMCs simpler and less costly, potentially making investments in SMCs more attractive, and thus facilitating their access to funding.

New exemptions from the obligation to publish a prospectus will ensure that authorities can quickly implement resolution action in a banking or insurance crisis. They will help speed up the resolution of failing banks and insurers, preserve the critical services those companies offer, and make sure that SMCs continue to benefit from these services in their capacity as clients.

The total maximum estimated cost savings for SMCs would amount to EUR 12 700 000 (joined cost savings resulting from amendments to the MiFID II Directive and the Prospectus Regulation).

d. Batteries Regulation - Regulation (EU) 2023/1542

The proposal exempts SMCs, in the same way as SMEs, from the rules on due diligence and tracing back supply chains of battery raw materials. It also reduces the frequency of public reporting for all companies involved from yearly to once every three years.

The number of companies affected by the extension of the exemption is estimated to be small, but the annual savings for those SMCs are estimated at around € 40,000 per company.

At the same time, the ambition level will remain: the vast majority of batteries, small and large, are placed on the EU market by large companies.

e. Critical entities resilience Directive - Directive (EU) 2022/2557

Each Member State must adopt a strategy to enhance the resilience of critical entities by 17 January 2026. In this strategy, Member States must describe the measures they already have in place that facilitate the implementation of the obligations by the SMEs that are identified as critical entities.

In view of drawing attention to the potential needs of SMCs in this respect, the Omnibus proposes that Member States should also describe measures for SMCs.

f. Fluorinated greenhouse gas Regulation - Regulation (EU) 2024/573

The F-gas Regulation that entered into force in 2024 requires all importers and exporters of products

and equipment containing F-gases to register in the EU F-gas Portal. Currently, around 2,000 new companies request registration in the F-gas Portal every month, in particular SMEs such as small second-hand car dealers. The proposed amendment would limit F-gas Portal registration to:

- importers that exceed certain annual F-gas thresholds
- exporters of certain products and equipment with highly warming F-gases that are prohibited in the EU and are covered by an export restriction, e.g. mobile equipment such as cars are not covered by this restriction.

General Data Protection Regulation

6. Why are you proposing this change?

The [2020](#) and [2024](#) reports on the application of the GDPR found a broad consensus among stakeholders, data protection authorities and Member States that, despite some challenges, the GDPR has delivered important results for individuals and businesses.

However, in the process of the extensive consultations undertaken by the Commission when drafting these application reports, representatives of SMEs have been raising the issue that the derogation from the record-keeping obligation under Article 30(5) of the GDPR is too narrow. This is why the Commission announced in its [Competitiveness Compass](#) that a proposal would be issued to simplify record-keeping obligations under the GDPR.

7. What is exactly the derogation from record-keeping obligations?

Under the GDPR, the data controller and processor, that is the person or entity processing personal data, must maintain a record of their processing of personal data, including, among others, the purpose of processing, the type of data being processed, or whether the data is being transferred to a country outside the EU. This record needs to be available to data protection authorities.

Currently, the GDPR provides that this obligation is not mandatory for SMEs or organisations with fewer than 250 employees, unless that entity's processing is likely to result in a risk to data subjects' rights, the processing is not occasional, or the processing includes sensitive personal data or data on criminal offences.

The Single Market Simplification proposal would extend this derogation to SMCs and organisations with fewer than 750 people. The proposal would also simplify the record-keeping obligation for these entities by only requiring record-keeping in case of 'high risk' processing at large-scale. The proposal will help avoid situations where SMEs would still be obliged to maintain records, even though they are not processing data that is considered high risk.

8. How will you ensure a continued high level of data protection?

The proposal is limited to the record-keeping obligation of SMEs, SMCs and organisations with fewer than 750 employees. It does not affect any other provisions of the GDPR. The proposal also respects the GDPR risk-based approach: SMEs and SMCs and organisations with less than 750 employees will still be required to maintain records when their processing of personal data can be considered "high risk" under the GDPR.

Paper to digital

9. Why are you proposing this change?

While the Commission is promoting the 'digital by default' principle, there are still various pieces of EU product legislation that expect the use of paper format or that leave such an option to Member States. Removing mandatory paper requirements will encourage public authorities to rethink their processing of submissions or reporting by companies. Streamlining these submissions and reporting by promoting digital-by-default will create new incentives to invest in data collection and processing with eGovernment solutions. This can pave the way to a paper-free Single Market based on

interoperable structured data and the once-only principle.

10. What does it involve in practice/which products?

The proposal foresees the digitalisation of the EU declaration of conformity, as well as the exchanges between competent national authorities and economic operators. The proposal additionally gives the possibility for manufacturers to provide instructions for use to end users in digital format in lieu of paper; it also foresees the insertion of a "digital contact" in the manufacturer's information to be indicated on products placed on the market.

The sectors affected are: outdoor noise equipment, transportable pressure equipment, restriction of hazardous substances in electrical and electronic equipment, recreational crafts, simple pressure vessels, electromagnetic compatibility, non-automatic weighing instruments, measuring instruments, lifts, ATEX, low voltage, radio equipment, pressure equipment, marine equipment, cableways, personal protective equipment, gas appliances, machinery, batteries and ecodesign.

11. What is the benefit for companies?

We will accelerate our path to a digital regulatory environment and further reduce administrative burdens for companies so that they can concentrate their efforts on innovation and growth. If adopted and implemented as set out today, the proposals are conservatively estimated to bring total savings in annual administrative costs of at least € 300 million per year.

12. What is the benefit for consumers?

Providing instructions of use digitally will offer users the possibility of easier access to information related to the product, including in different languages, and make it easier for information to be updated. In addition, it will be more inclusive for some categories of consumers, with the possibility to include audio-visual material.

Common specifications

13. Why are you proposing these changes?

Harmonised EU legislation sets out different essential requirements (concerning health, safety, or other) for products that freely circulate in the Single Market. Harmonised standards are the most common and simple way for businesses to demonstrate that their products are in conformity with these essential requirements. Under EU law, compliance with harmonised standards creates a presumption that the product meets the essential requirements set out in relevant legislation. If harmonised standards are not available (in a timely manner or at all), businesses cannot benefit from the presumption of conformity. They must demonstrate conformity through other means, often involving costly and complex conformity assessment procedures.

The proposal introduces common specifications adopted by the Commission as a legally recognised fallback option that carries the same presumption of conformity.

14. What are the benefits?

While some legal acts already contain provisions on common specifications, the proposed changes introduce common specifications for the legislative acts that do not offer such an option in their current version. This alternative option is proposed in a uniform manner as regards definition, legal effect, conditions, and procedure for adoption for the acts in the Omnibus.

The proposed changes bring the following benefits:

- Provide an alternative means for demonstrating conformity with essential requirements set by EU rules, as a fall-back option;
- Increase legal certainty on compliance with EU requirements for businesses in situations where

harmonised standards do not exist, are not available or there is an urgent need to act;

- Eliminate for businesses the costs and regulatory complexity related to cumbersome methods for demonstration of conformity in the absence of harmonised standards.

For further information:

Consult our [press release](#) and [factsheet](#).

View the [texts of the proposal](#).

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