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**COMMISSION STAFF WORKING DOCUMENT**

**on small mid-cap companies**

***Accompanying the documents***

**Proposal for a**
**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
**amending Directives 2014/65/EU and (EU) 2022/2557 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplifying measures**
**Proposal for a**
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
**amending Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures**

{COM(2025) 501 final} - {COM(2025) 502 final}

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## Glossary of acronyms

| Acronym | Meaning or definition |
|---|---|
| CS3D /CSDDD | Corporate Sustainability Due Diligence Directive (Directive (EU) 2024/1760) |
| CSRD | Corporate Sustainability Reporting Directive (Directive (EU) 2022/2464) |
| ECB | European Central Bank |
| EIB | European Investment Bank |
| EU | European Union |
| GBER | General Block Exemption Regulation (Regulation (EU) No 651/2014) |
| GDPR | General Data Protection Regulation (Regulation (EU) 2016/679) |
| JRC | Joint Research Centre |
| SMC | Small mid-cap company |
| SME | Small or medium-sized enterprise |
| SWD | Staff working document |
| Taxonomy | Taxonomy Regulation (Regulation (EU) 2020/852) |
| TFEU | Treaty on the Functioning of the European Union |

# 1 INTRODUCTION

## 1.1 Policy context

European businesses create employment, innovation and prosperity. Competitiveness and productivity are essential conditions for businesses to flourish; they have been at the heart of EU policy for decades[1]. To set the EU economy on a sustainable growth path, the EU and its Member States need to make structural improvements to the business environment, including through well-focused investment and regulatory measures.

President von der Leyen has set out a plan for Europe's sustainable prosperity and competitiveness in the political guidelines for the European Commission's 2024-2029 term[2]. Making business easier and deepening the Single Market are among the plan's key priorities.

The Commission's better regulation agenda[3] also supports the competitiveness of European enterprises by aiming to ensure that EU laws deliver on their objectives without imposing an unnecessary burden. In 2023, the Commission identified the need to rationalise and simplify reporting requirements for enterprises and administrations[4] by 25%, without undermining the policy objectives of the relevant legislation. This commitment was subsequently increased to a 25% reduction of all administrative costs and a 35% reduction for SMEs[5].

Mario Draghi in his report on 'The future of European competitiveness'[6], argues that EU regulation imposes a proportionally higher burden on SMEs and small mid-cap enterprises (SMCs)[7] than on larger enterprises. The report suggests that the Commission should extend the existing mitigation measures currently available to SMEs to small mid-caps to extend proportionality in EU law to

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[1] Long-term competitiveness of the EU: looking beyond 2030, COM/2023/168 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0168.

[2] https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf

[3] Better regulation: Joining forces to make better laws, COM(2021) 219 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:219:FIN.

[4] Long-term competitiveness of the EU: looking beyond 2030, COM(2023) 168 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0168.

[5] Mission letter to Stéphane Séjourné, Executive Vice-President-designate for Prosperity and Industrial Strategy, available at: https://commission.europa.eu/document/download/6ef52679-19b9-4a8d-b7b2-cb99eb384eca_en?filename=Mission%20letter%20-%20S%C3%89JOURN%C3%89.pdf. See also Communication on implementation and simplification, https://commission.europa.eu/document/download/8556fc33-48a3-4a96-94e8-8ecacef1ea18_en?filename=250201_Simplification_Communication_en.pdf

[6] M. Draghi, The future of European competitiveness, 2024, available at: https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en#paragraph_47059, p. 65.

[7] Companies that have outgrown the SME definition.

small mid-caps. The Draghi report also observes that EU lacks a commonly agreed definition of small mid-caps and readily available statistical data.

According to Enrico Letta's 'Much more than a market' report, distinguishing between mid-caps and large corporations in EU regulations will enable more suitable rules, fostering their growth and equitable participation in the Single Market, especially during crises[8]. Mid-cap enterprises can therefore contribute to building the Single Market and making it work better.

On 12 September 2023, the Commission published the SME Relief Package[9], announcing its goal to help small and medium-sized enterprises compete and grow, for example, by being attentive to the needs of enterprises that outgrow the thresholds of the SME definition[10] and those in the broader range of small mid-cap enterprises (SMCs). Action 18 of this relief package announced that the Commission would 'develop a harmonised definition for small mid-cap companies, build a dataset based on such definition and assess possible measures to support these companies in their growth (including potential application in adapted form of certain measures favouring SMEs)'.

A study to 'Map, measure and portray the EU mid-cap landscape'[11] showed that mid-cap enterprises that have outgrown the SME definition play a vital role in the EU economy, providing 13% of overall employment. They are prominently present in industrial ecosystems that are key to the EU's competitiveness and technological sovereignty, such as electronics, aerospace and defence, energy, energy-intensive industries and health. Around 20% of all mid-cap enterprises were SMEs three years earlier. Compared to SMEs, they tend to demonstrate a higher pace of growth, level of innovation and digitisation, although they face certain similar challenges such as administrative burden and share the need for more proportionality in new legislation and for targeted support. These challenges must be addressed in a consistent manner to help SMEs transition smoothly into small mid-cap enterprises.

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[8] E. Letta, Much more than a market, 2024, available at: https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf, p. 107.

[9] SME Relief Package, COM/2023/535 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:535:FIN;.

[10] SMEs are currently defined as companies with under 250 employees, combined with an annual turnover up to 50 million euro or a balance sheet total up to 43 million - Recommendation 2003/361/EC - https://single-market-economy.ec.europa.eu/smes/sme-definition_en.

[11] B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

A report by the European Investment Bank[12] also found that mid-caps – defined in that report as firms with 250 to 3 000 employees – contribute significantly to employment and value creation in the European economy. They are vital components of key industrial ecosystems, including electronics, health, energy, renewables, and aerospace and defence, underpinning Europe's competitiveness. Mid-caps are more likely to invest than SMEs and large firms and their investment volumes are also larger. Around 87% of them invested in training and skills between 2018 and 2023, and 65% of small mid-caps are likely to do so. The report calls for a standardised definition and better understanding of mid-caps' specific needs to unlock their full potential.

A definition for small mid-cap enterprises is already in use under the General Block Exemption Regulation[13] and the Guidelines on State aid to promote risk finance investments[14]. In the Annual Single Market and Competitiveness Report[15], adopted on 14 February 2024, the Commission committed to monitoring – based on this definition[16] – outcomes for both SMEs and small mid-caps under relevant financial programmes and deepening its understanding of barriers impeding the growth and transition of medium-sized enterprises into SMCs.

This Omnibus proposal follows in the context of a series of Omnibus simplification packages. The first of these was adopted on 26 February 2025 and concerned the Corporate Sustainability Reporting Directive (CSRD), the Corporate Sustainability Due Diligence Directive (CSDDD), the Carbon Adjustment Mechanism (CBAM), and the InvestEU Regulation. It was accompanied by a draft Taxonomy Delegated Act for public consultation.

The savings from that Omnibus package amounted to EUR 6.3 billion for all enterprises, and the potential savings for SMCs from these acts are significant. This proposal comes on top of these packages and allows for further simplification specifically aimed at small mid-caps, enabling enterprises to scale up.

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[12] L. Maurin, J. Delanote, H. Tran, G. Riekeles, P. Lausberg,, *Hidden Champions, missed opportunities*, EIB, 2024, available at: https://www.eib.org/en/publications/20230277-hidden-champions-missed-opportunities-mid-caps-crucial-role-in-europe-s-economic-transition.

[13] Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, available at: https://eur-lex.europa.eu/EN/legal-content/summary/general-block-exemption-regulation.html.

[14] Guidelines on State aid to promote risk finance investments, OJ C 508 of 16.12.2021, p.1.

[15] The 2024 Annual Single Market and Competitiveness Report, COM(2024) 77 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52024DC0077.

[16] 'Small mid-cap' means an undertaking that is not an SME and whose number of employees does not exceed 499, calculated under Articles 3 to 6 of Annex I to the General Block Exemption Regulation, and the annual turnover of which does not exceed EUR 100 million or the annual balance sheet of which does not exceed EUR 86 million. For the application of this definition, several entities will be considered as one undertaking if any of the conditions listed in Article 3(3) of Annex I to the General Block Exemption Regulation is fulfilled.

## 1.2 Consultation with stakeholders

The idea of formalising a definition for small mid-cap enterprises, as a first step towards policy support that would focus on enterprises that manage to scale up out of the SME population, has received growing attention. Calls have multiplied at all levels, from business organisations (Mouvement des Entreprises de taille intermédiaire - METI, France; Bundesverband der Deutschen Industrie e. V. – BDI; European Family Businesses) and Member States (Franco-German paper on Better Regulation and Modern Administration in Europe in October 2023)[17] to think tanks (European Policy Centre) and financial institutions (EIB), and from Enrico Letta in his 'Much more than a market' report.

The Commission has engaged with and listened to the business community to identify how such a small mid-cap company definition could be used for cross-cutting policy purposes and to identify fields for proportionate regulatory, funding or policy measures.

Position papers sent by stakeholders give a number of recommendations for this, such as 'considering the specific characteristics of mid-caps in the better regulation context', or 'ensuring that EU regulation is more sensitive to business size'. These papers further indicate that, while SMEs are often targeted with support or spared the burden of regulation, mid-caps are treated as similar to very large firms, which stakeholders do not see as an optimal policy choice.

The Commission also consulted representatives of European industry on specific ideas for providing tailored support to small mid-cap companies, both in bilateral meetings and in a 'roundtable on simplification' on the necessary policy support for small mid-cap enterprises held on 6 February 2025. The results of all these discussions have contributed to the list of proposals put forward in this document.

The Commission validates the registrations in the F-gas Portal and has through this process been in direct contact with the stakeholders that were impacted by the extended registration requirements in the F-gas Regulation that entered into force in 2024. Moreover, one Member State contacted the Commission to request that the rules be simplified.

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[17] Reducing bureaucracy in these unprecedented times – French-German Paper on Better Regulation and Modern Administration in Europe, Bundesministerium für Wirtschaft und Klimaschutz, Bundesministerium der Justiz, Ministère de l'Économie des Finances et de la Souveraineté industrielle et numérique, available at: https://www.bmwk.de/Redaktion/EN/Downloads/B/french-german-paper-on-better-regulation-and-modern-administration-in-europe.pdf?__blob=publicationFile&v=8.

## 2 MAIN ISSUES AT STAKE AND THE WAYS TO ADDRESS THEM

### 2.1 Main issues at stake

Mid-caps play a key role in industrial ecosystems that are essential to the competitiveness of the European Union[18] and in several Member States mid-cap enterprises provide a significant number of jobs[19].

A mid-cap study[20], based on the Orbis database[21], provided estimates for the number of enterprises under different definitions (by Member State and industry) and extrapolations of the sample given the varying availability of data across the Member States.

Based on these estimations, in absolute terms, there are around 31 000 mid-cap firms with 250 – 499 staff and another 18 000 mid-caps with 500-1 499 staff in the EU[22]. Mid-cap firms can be found in all EU Member States. There are also around 3 600 very large mid-cap firms (1 500-2 999 employees) in the EU. Due to inherent limitations in the available data[23], these estimates may not fully reflect the total number of mid-cap enterprises in the EU.

The above figures are generally confirmed by more recent analyses. Eurostat recently collected 2023 data on companies with 250-499 employees on a voluntary basis from Member States. While only eight Member States participated in the data collection[24], the average share of small mid-caps

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[18] Electronics, Aerospace & Defence, Energy, Energy-intensive Industries and Health; B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

[19] Mid-caps employ around 20% of all employees in the business sector of the Nordic countries, in Luxembourg, Germany and Austria; B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

[20] B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

[21] Sample base of companies with employment data for 2019 and still active in April 2022.

[22] For the estimation here, relying only on staff headcount.

[23] ESTAT divides businesses into categories based on staff headcount classified in four groups: 0-9, 10-49, and 50-249 and 250 and more employees. The size-class with 250 staff or more, does not offer further breakdowns based on headcount and all companies are considered as one group. The available data does not make it possible to calculate how many companies would match a particular segment of a size-class. Private databases, e.g. Orbis, allow for more granulated subdivisions. An additional limitation is the fact that the staff headcount is the only criterion, and there is no one-on-one relationship with the turnover of the company, or the ownership (all elements that are considered in the SME definition). As a result, a company is put into a segment solely based on the headcount. Orbis considers a company's ownership to a limited extent.

[24] The Member States that submitted data were Bulgaria, Germany, Croatia, Italy, Latvia, Lithuania, Malta, and Finland.

in the total number of enterprises in this sample was 0.12%[25], representing around 31 200 enterprises when extrapolated to the EU's enterprise population of approximately 26 million as given by the Annual Report on European SMEs[26]. A recent JRC analysis[27], based on both the above-mentioned Eurostat data and an Orbis analysis, also arrives at similar numbers.

The share of mid-caps varies significantly between countries (ranging from a share of 0.42% of all enterprises to barely 0.06%, source: JRC) and industrial ecosystems. According to the JRC analysis, the industrial ecosystems with the highest share of mid-caps are electronics and energy – renewables, whereas those with the lowest shares are cultural & creative industries, construction and tourism.

Despite the small share in numbers, mid-caps account for a sizeable share of employment and turnover in the EU economy. The shares vary depending on the study; the 2021 mid-cap study[28] found that mid-caps with 250-499 employees provide 6% of all employment, while the JRC analysis found this share to be around 9%. Their share of turnover represents 13% of all business turnover[29].

All these figures mainly look at companies with 250 to 499 employees. In the current economic context, to better accompany scaling up of enterprises and to cover a larger number of companies, the new definition will, however, cover enterprises that are three times the size of SMEs:

Based on the available figures for the 250-499 and the 500-1,499 brackets (where the 2021 mid-cap study estimates around 31,000 and 18,000 companies, respectively), it can be estimated that around 35-40% of companies in the 500-1499 bracket have 500-749 employees. This would lead to an estimate of around 38,000 SMCs defined as 250-749 employees.

Applying the same method of estimation to different industrial ecosystems, in terms of total numbers, the highest numbers of small mid-caps can be found in construction, retail and mobility – transport – automotive. These figures, however, reflect the large sizes of these ecosystems in

[25] Eurostat, Enterprises by extended size classes (including small mid-caps) and NACE Rev. 2 activity, https://ec.europa.eu/eurostat/databrowser/view/sbs_ovw_smc/default/table?lang=en&category=bsd.sbs.sbs_ovw.
[26] https://single-market-economy.ec.europa.eu/smes/sme-strategy-and-sme-friendly-business-conditions/sme-performance-review_en..
[27] European Commission: Joint Research Centre, Lagüera Gonzalez, J., Di Bella, L., Katsinis, A.A. and Schulze Brock, P., A comprehensive analysis of mid-cap enterprises in the EU business economy, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/9616331, JRC141271.
[28] B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.
[29] European Commission: Joint Research Centre, Lagüera Gonzalez, J., Di Bella, L., Katsinis, A.A. and Schulze Brock, P., A comprehensive analysis of mid-cap enterprises in the EU business economy, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/9616331, JRC141271.

general, while percentage shares give a better picture of the importance of small mid-caps to each industrial ecosystem.

| | *250-499* | *500-749* | *Small mid-caps (250-749)*[30] |
|---|---|---|---|
| *Retail* | 4124 | 850 | 4974 |
| *Construction* | 3779 | 732 | 4511 |
| *Mobility Transport Automotive* | 2860 | 556 | 3416 |
| *Tourism* | 2206 | 410 | 2616 |
| *Agri food* | 2084 | 364 | 2447 |
| *Digital* | 1898 | 379 | 2277 |
| *Energy Intensive Industries* | 1644 | 377 | 2022 |
| *Proximity Social Economy & Civil Security* | 1307 | 276 | 1584 |
| *Aerospace and Defence* | 1216 | 262 | 1478 |
| *Cultural & Creative Industries* | 821 | 134 | 955 |
| *Health* | 648 | 167 | 815 |
| *Energy Renewables* | 626 | 111 | 737 |
| *Electronics* | 571 | 118 | 689 |
| *Textile* | 509 | 69 | 578 |

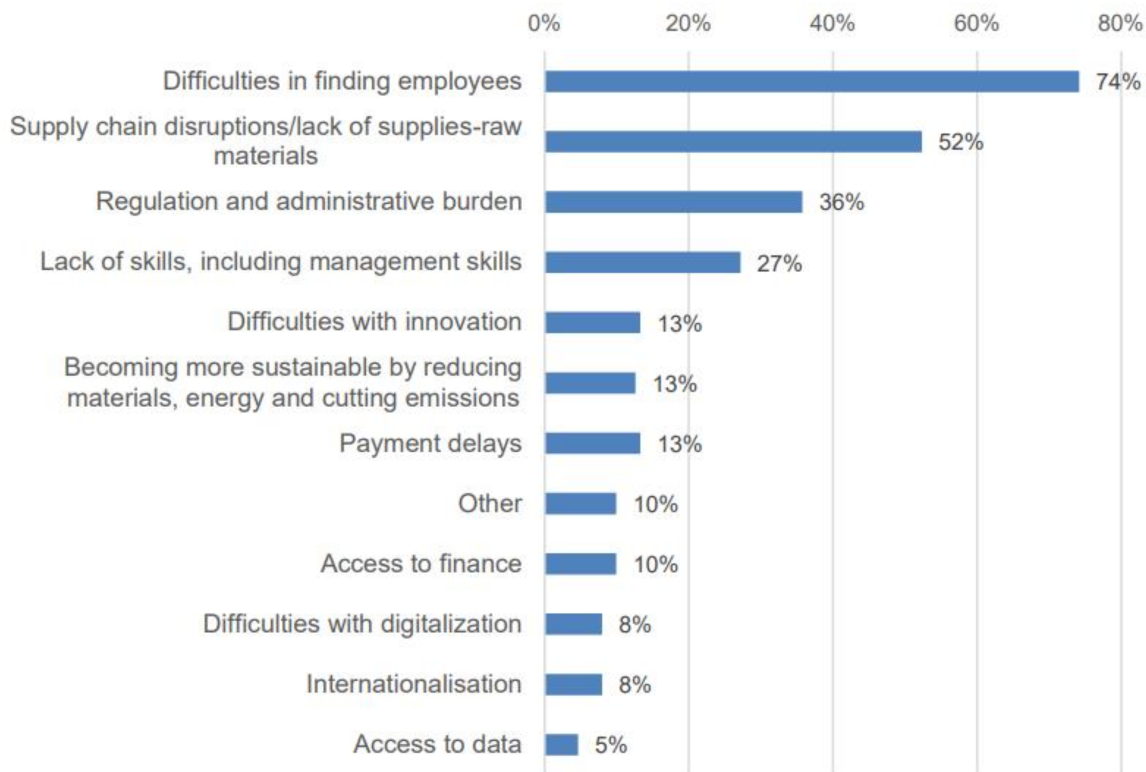
In terms of percentage shares, the highest shares of small mid-caps with 250-749 employees are found in electronics, energy renewables and aerospace and defence[31].

The SMC definition should allow for targeted policy support, especially in relevant sectors. This is why the bracket 250-749 seems appropriate to reach a sufficiently large number of companies and alleviate the challenges they face.

Although small mid-caps usually grow faster, are more innovative and deal better with digitalisation than SMEs, they still face certain challenges[32]. Different factors may adversely affect the speed of their growth.

[30] Due to data limitations and missing data for certain NACE codes, the numbers by ecosystems do not fully add up to the 38 000 SMCs identified above.
[31] Small mid-caps represent 0.61% of all companies in electronics, 0.58% in Energy Renewables and 0.47% in Aerospace and Defence; European Commission: Joint Research Centre, Lagüera Gonzalez, J., Di Bella, L., Katsinis, A.A. and Schulze Brock, P., A comprehensive analysis of mid-cap enterprises in the EU business economy, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/9616331, JRC141271.
[32] SME Relief Package, COM(2023) 535 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A535%3AFIN.

*Figure 1: Main challenges for mid-caps in the European Union*[33]




The main difficulties for small mid-cap enterprises concern finding employees, dealing with supply chain disruptions, and complying with regulation and administrative requirements, as outlined in the interviews carried out for the 2022 mid-cap study[34]. Rising energy prices and other production inputs have been another major challenge for mid-caps in recent months.

The Commission proposal also includes an amendment of Regulation (EU) 2024/573 on fluorinated greenhouse gases (F-gas Regulation). The F-gas Regulation that entered into force in 2024 expands a registration requirement in the F-gas Portal to all imports of products and equipment, including those not subject to reporting requirements, and includes a new registration obligation for exports of products and equipment containing F-gases, including for products and

[33] B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

[34] B. Dachs, I. Siedschlag, W. Yan, M. Yoveska, F. Boeira, S. Ivory, Study to map, measure and portray the EU mid-cap landscape, European Union, 2022, available at: https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461.

equipment for which no export restrictions exist. If a trader is not able to present a valid registration in the F-gas Portal, customs should block the goods.

This Commission received many new registration requests from traders in products and equipment containing F-gases. They mostly concern relatively small enterprises that trade with used cars that have F-gases in the air-conditioning equipment and that were not covered by any obligations under the previous F-gas Regulation. To register, importers and exporters must submit an electronic application form to the Commission and provide the required information related to their business activities and their legal and financial identity. The Commission validates the registration in the F-gas Portal. It appears that this requirement is not fully proportionate.

### 2.2 Ways to address the main issues

The Draghi report calls for ensuring proportionality for mid-caps in EU law and extending some mitigation measures, which benefit SMEs, to mid-cap enterprises. The Letta report also advocates recognising mid-caps distinctly from large corporations in EU regulations.

To help small mid-caps tap their growth potential and scale up their contribution to European competitiveness, welfare, and prosperity, the Commission is proposing to:

1) formalise the definition of a European small mid-cap company, by adopting a recommendation on an 'EU definition of small mid-cap enterprises', and

2) extend some mitigating measures currently available to small and medium-sized enterprises to this new category of small mid-caps by adopting an Omnibus proposal amending certain EU legislation. This SWD provides the evidence and analysis supporting such an Omnibus proposal.

Once the definition is adopted, this will allow SMCs' needs to also be considered in pending and upcoming Commission proposals.

1) *Formalising the definition of a European small mid-cap company*

The General Block Exemption Regulation and the Guidelines on State aid to promote risk finance investments include already a definition of small mid-caps, covering enterprises up to a size that is twice that covered by the SME definition (up to 499 staff, combined with EUR 100 million turnover or EUR 86 million balance sheet total). As seen above, estimations point to some 31 000 enterprises in this size category. The purpose of a general SMC definition is, however, not to replicate the definition used in State aid rules per se, which are determined for the purpose of identified market failures susceptible to be addressed through targeted public financial support from national resources, but to allow for a basis for targeted policy support that can help companies to scale in relevant and important sectors. In the current economic context and with a view to the sectors with high shares of companies in the bracket 250-749 employees, , the definition is therefore deemed most effective when covering enterprises that are three times the size of SMEs to better accompany scaling up of enterprises and to cover a larger number of companies. This is expected to yield significant benefits, as demonstrated by the amendments to the acts that are part of this package and will be complemented by future use cases. This remains, of course, without prejudice to the thresholds deemed appropriate in the State aid context.

2) *Extending certain mitigating measures currently available to SMEs to this new category of small mid-caps*

Following the commitment made in the SME Relief Package[35] to assess possible measures to help small mid-cap enterprises grow, the Commission has analysed the *acquis* with a particular focus on initiatives considered as burdensome and on including dedicated lighter regimes or mitigating measures for SMEs. Extensive consultations with industry and business stakeholders and actors (see also section 1.2 for details) have contributed to setting up the list of proposals for amendment. The screening has revealed a range of possibilities to ensure better proportionality for small mid-cap enterprises.

Initial amendments to the pieces of legislation presented below will be made through Omnibus proposals (one for Regulations and one for Directives).

For each act, an attempt is made to estimate potential savings despite the inherent difficulties. General order-of-magnitude figures have been derived from both the information provided in the impact assessment reports underlying each of the acts concerned and other available relevant information from the implementation of the acts. While these impact assessments reflect the content of the initial Commission proposal rather than the act ultimately adopted by the co-legislators, they can nonetheless provide an approximation of what costs small mid-caps currently incur and what savings extending the mitigating measures for SMEs to SMCs could bring. However, none of the impact assessments specifically look at effects on small mid-caps, or at the number of small mid-caps affected, and data used to estimate costs for SMEs are also extrapolated for the purpose of this exercise.

Wherever possible, the cost per company as currently incurred was estimated, based on the impact assessment report figures or *ex post* evaluations. In a second step, the number of small mid-caps

[35] SME Relief Package, COM(2023) 535 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A535%3AFIN.

the particular requirement may apply to was estimated. Based on these, the total cost savings per measure was calculated. This approach is necessarily limited to the data available.

### *2.2.1 General Data Protection Regulation (GDPR) - Regulation (EU) 2016/679*

The GDPR contains a derogation from the obligation to maintain records of processing activities for enterprises and organisations employing fewer than 250 persons. This derogation applies if their processing is only occasional, not likely to cause risk to data subjects, and does not involve special categories of personal data or data on criminal offences. The Omnibus proposal proposes that this derogation be extended to SMCs and organisations with fewer than 750 employees and be simplified by limiting the obligation to maintain records only for ‘high risk’ processing under Article 35 GDPR.

In addition to SMCs and organisations with fewer than 750 employees, the extended derogation would benefit those SMEs and organisations with less than 250 employees which are not, despite their size, covered by the current SME derogation and are therefore already maintaining records.

A new threshold of ‘high risk’ processing would mean that any enterprise or organisation that employs less than 750 people is no longer obliged to create records of processing or update their existing records unless their processing activities are likely to present a ‘high risk’ to data subjects.

According to Eurostat business demography statistics, the number of enterprises with 0 employees is around 62%. Based on this, it could be assumed that at least 38% of SMEs have processing activities for which they have to keep records, as they have to process employees’ data regularly rather than occasionally, which means they are not covered by the derogation under Article 30(5) GDPR.

Given that there are around 26 million SMEs, this would translate into around 10 million SMEs [38% out of 26 million =9.8 million] that are affected by the proposed amendment, provided that their processing is not likely to result in a ‘high risk’ to data subjects.

Assuming that 90% of those SMEs, i.e. <u>around 9 million SMEs</u>, do not carry out ‘high risk’ processing, which would exclude them from the scope of the proposed extended derogation, and that <u>around half of those 9 million SMEs</u> [=4.5 million SMEs] would each need to use <u>around 0.5 hours</u> <u>every year</u> to comply with the record-keeping obligation, mainly to update their already existing records when their processing activities change, an annual saving of *approximately EUR 66 million* could be expected, based on the hourly rate from the ‘one in, one out’ calculator [= EUR 29.4 x 4.5 million SMEs x 0.5 hour = +/- EUR 66 million].

Given the very small population of SMCs compared to that of SMEs, those savings will not be of an order of magnitude that significantly impacts the rounded global figure of EUR 60 million estimated for SMEs and SMCs together. Applying the same calculation as for all SMEs above would lead to a saving of around EUR 560 000 for small mid-caps [= EUR 29.4 x 38 000 SMCs x 0.5 hour].

However, several caveats apply that could affect the expected saving. These include at least the following:

A considerable number of the 26 million SMEs are likely to carry out processing activities other than the processing of employees' data that could fall in the scope of the current record-keeping obligation. An example of this is processing on a regular basis of customer data. Also those SMEs would thus be 'affected' and they could profit from the proposed extended derogation if their processing is not 'high risk'.

There is no factual data supporting the assumption that most SMEs would fall in the scope of the extended derogation and that half of them currently use half an hour for maintaining records of processing per year. The exact number of SMEs obliged to maintain/update their records depends on whether those enterprises introduce new processing activities requiring record-keeping or change their ongoing processing in a way that requires updating the information in their existing records. Furthermore, the number of hours used to comply with this obligation depends on factors such as the expertise within the organisation and the availability of support measures, such as simplified templates provided by data protection authorities or the industry. This is likely to vary from one SME to another and possibly from one Member State to another.

In addition to possible savings for SMCs and organisations of the same size, the estimated saving does not include the saving for organisations with fewer than 250 employees, which are covered under certain conditions by the current derogation. Also some of those entities could be affected if their processing is not likely to result in a 'high risk'.

The estimated saving does not take into account the possibility that the costs of complying with the record-keeping obligation may be balanced out to some extent by possible savings in non-compliance costs, such as the loss of reputation, administrative fines, or compensation for damage, because the record-keeping obligation supports the general compliance with the GDPR.

#### *2.2.2 Basic anti-dumping and anti-subsidy regulations – Regulation (EU) 2016/1036 and Regulation (EU) 2016/1037*

These two regulations are part of the EU's trade defence system, allowing the EU to investigate and address dumping and subsidisation by non-EU countries and restore a level playing field in the EU market. If an investigation confirms the existence of such practices harmful to EU industry, the Commission imposes an anti-dumping or countervailing duty, provided this is not against the EU interest.

Given the technical nature of trade defence, and the fact that investigations require active involvement from companies in the EU, Regulations (EU) 2016/1036 and (EU) 2016/1037 include provisions to overcome the barriers that stop smaller companies from accessing and using trade defence. A dedicated helpdesk offers general, no-case-specific information on trade defence to SMEs, for example on procedures or on how to submit complaints to initiate cases. Another provision provides that, in investigations where EU industry is fragmented and largely composed of SMEs, the investigation period should, whenever possible, coincide with the companies' financial year, which facilitates the investigations for companies as much of the data required would be readily available from their financial statements. The Omnibus proposal proposes that these provisions be extended to SMCs. This is consistent with the objective of helping small enterprises understand and gain access to trade defence instruments.

Since those provisions mainly focus on awareness raising and providing general information about trade defence, as well as facilitating companies' involvement in investigations by, whenever possible, aligning the periods for investigation with the financial year, there is no quantified estimate of how much SMCs may save.

### *2.2.3 Markets in financial instruments – Directive (EU) 2014/65 and Regulation (EU) 2017/1129 (the 'Prospectus Regulation')*

Regulation (EU) 2017/1129, as amended by Regulation (EU) 2024/2809, introduced the EU growth issuance prospectus, a new short-form and standardised prospectus primarily focusing on SMEs and companies listed or to be listed on an SME growth market. While SMCs listed on an SME growth market can already benefit from the lighter EU growth issuance prospectus, its use could be further extended to all offers of securities to the public made by SMCs, irrespective of whether those offers are accompanied by a listing on a multilateral trading facility or an SME growth market. This would reduce their regulatory compliance burden and potentially make them more attractive to investors (as an EU growth issuance prospectus is shorter than a standard prospectus and hence easier for investors to navigate).

The Markets in Financial Instruments Directive (MiFID II) would be amended to ease the authorisation of multilateral trading facilities as SME growth markets, by enabling them to list all small mid-caps and still be eligible for the SME growth market status. That means that all SMCs could now potentially benefit from the less stringent disclosures requirements under the EU Growth issuance prospectus regime. While it would be impossible to estimate the actual future number of SMCs that will list on SME growth markets (and not all SMCs may want to do so, opting for listing, for example, on a regulated market), it is possible to calculate the hypothetical maximum cost savings that could be achieved if it were assumed that: (i) all currently listed SMCs would list on SME growth markets, and: (ii) all of those SMCs would otherwise list on regulated markets, being subject to more stringent disclosure requirement (such as a full prospectus).

Under this assumption, the alleviation would apply to approx. 635 companies (or 14% of all listed companies, based on the annual average market capitalisation for 2022-2024, source: Orbis) that would fall under the definition of an SMC (companies with a market capitalisation of up to EUR 1 billion). The impact assessment report accompanying the Listing Act proposal estimated that SMEs and other companies that are eligible to use the EU growth issuance prospectus[36] could save up to 40% of their costs (EUR 20 000 out of EUR 50 000) for drawing up the EU growth prospectus that pre-dated the EU growth issuance prospectus (the Listing Act considerably alleviated the requirements for the EU growth prospectus)[37]. Savings would be of an even greater magnitude (70%) for SMCs that are currently using a standard prospectus and that would now be able to benefit from an EU growth issuance prospectus (about EUR 35 000)[38].

Therefore, if it were assumed that drawing up an alleviated form of an EU growth issuance prospectus instead of a full prospectus would generate a cost saving of approximately EUR 20 000 per company, 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). This number is however likely to overestimate the actual number of 'new uses' of the EU growth issuance prospectus by SMCs, as some SMCs that are listed on an SME growth market (but not on a multilateral trading facility) can already benefit from this alleviated form of prospectus and some may continue to draw up a full prospectus when they list on a regulated market.

The Prospectus Regulation would be further amended to include a new exemption from the obligation to publish a prospectus for offers of securities to the public where such offers result from actions taken by EU resolution authorities under the EU framework for the resolution of banks or insurers (Directives 2014/59/EU and (EU) 2025/1) or by third-country authorities under a comparable legal framework. Additionally, the existing resolution-specific exemption from the obligation to publish a prospectus for the admission of securities to trading on an EU regulated market would be extended to similar actions taken by third-country resolution authorities. These amendments introduce simplification and burden reduction for complying entities and they ensure that resolution authorities can implement resolution actions within a timeframe in which the preparation and publication of a prospectus would not be possible. SMCs will benefit from the improvements brought forward by these amendments in their capacity as clients and beneficiaries of the services provided by banks and insurers.

[36] At the time of the impact assessment report, this was still referred to as an 'EU admission document'.
[37] See Table 4 and Table 12 of the impact assessment report.
[38] See Table 6 of the impact assessment report.

A key objective of resolution action is to preserve critical functions provided by banks and insurers to the real economy, such as lending, payment and cash services and insurance coverage where it is a precondition of economic activity. Resolution action ensures the smooth continuity of these functions provided to SMCs, without interruption or impact on their daily activities. This particularly benefits SMCs that obtain their services from only one bank and/or insurer instead of a diversified range of business partners. Additionally, SMCs benefit from the financial stability provided by resolution action, as the disorderly failure of a bank or an insurer can disrupt the normal function of the financial system and subsequently of the real economy.' Despite a rather limited number of resolution cases in the EU, potentially all of the 26 million SMEs and 38,000 SMCs in the EU could be at risk of falling short of credit facilities or access to cash if the timely resolution of a bank or insurer could not be implemented due to the obligation to prepare and publish a prospectus.

#### *2.2.4 Batteries Regulation - Regulation (EU) 2023/1542*

SMEs' exemption from the rules on due diligence rules and tracing back supply chains could be extended to SMCs. The exemption was based on the definition of the high-impact sectors in the Commission proposal for a Directive on Corporate Sustainability Due Diligence, but the provisions on high-impact sectors were not included in the final Directive.

The impact assessment report estimates EUR 40 000 - 500 000 per year for each company for due diligence requirements. It estimated around 50 companies are affected, but the scope substantially changed in co-decision and may now affect more than 250 companies. Only a small share of those are expected to have a turnover between EUR 40 and 150 million. Since much larger companies account for the vast majority of raw materials and volumes of batteries placed on the market, the impact of this exemption on the policy objectives is negligible.

As the number of SMCs affected is estimated to be small, the total savings are likely to be low considering the current market situation.

#### 2.2.5 *F-gas Regulation – Regulation (EU) 2024/573*

The registration requirement should be better targeted to companies that perform activities that are covered by other obligations in the F-gas Regulation to serve the purpose of facilitating the enforcement. It is therefore proposed to limit the obligation to imports subject to a reporting obligation for companies to the Commission under the F-gas Regulation and to exports of products and equipment that are covered by limitations on the global warming potential of the F-gas contained.

By better targeting the registration requirement for imports and exports of products and equipment containing F-gases to trades for which other requirements exist in the F-gas Regulation, the administrative costs on traders, in particular small enterprises, will decline without compromising the objectives of the Regulation. On the contrary it will allow Member States' authorities, customs and the Commission to focus more on cases relevant for enforcement.

The registration requirement results in one-off costs and costs to keep information and documentation up to date. In cases where the trader is not aware of the obligation to register, there are costs associated with having goods stopped at the border until the company has obtained a valid registration by the Commission. Based on experience, this concerns typically smaller enterprises that are not covered by the F-gas Regulation for other reasons and thus not familiar with the legislation.

It is very difficult to estimate how many companies would be impacted in the future by the simplification. The impact assessment for the F-gas Regulation proposal in 2022 estimated that if all exporters had to be registered it would affect a high number of companies (approximately 2000) and it was not part of the preferred option. Based on recent experience it is clear that the original impact assessment underestimated the number. In the first months of 2025 there were more than 2000 registration requests and modifications per month, many of which are linked to imports or exports of relatively few (used) cars. Currently, they are mostly in one Member State and it can be expected that a similar situation will gradually occur in other Member States too.

Hence, assuming conservatively that 2000 new registrations per month will take place also in the remaining months of year 2025, there would be 24 000 new registrations in 2025. A conservative assumption is a decline of this number to 12 000 in 2026, and to 1 200 registration requests in 2027. If the proposed simplification would reduce these requests by 80%, it would result in 6 400 fewer registrations in 2025[39], 9 600 in 2026 and 960 in 2027.

Further, it is assumed that the time used by those companies is equivalent to 1.5 full working days per registration/intervention at a cost of EUR 352.8 per registration[40]. Consequently, the simplification option is estimated to save 9 600 working days in 2025, 14 400 working days in 2026 and 1 440 working days in 2027, generating estimated cost savings of EUR 3.4 million in 2025, EUR 5.1 million in 2026 and EUR 508 000 in 2027. After that time, very few new initial registrations would be expected and costs would only remain for updating and completing existing registrations, so that cost savings from 2028 would be more limited.

The amendment is not expected to have any environmental or social impacts. Moreover, the change is in line with the preferred option and with the intervention logic in the Impact

[39] Provided the amendment starts to apply from September 2025.
[40] Using the estimated hourly cost of EUR 29.4 from the Administrative Burden Calculator.

Assessment that accompanied the Commission proposal in 2022[41], since the preferred option did not include any extended obligation for importers and exporters of products and equipment, while taking into account the principle that it is useful to facilitate the enforcement of a new limitation that was introduced by the co-legislators on certain exported products and equipment.

### *2.2.6 Critical entities resilience – Directive (EU) 2022/2557*

Each Member State must adopt a strategy for enhancing the resilience of critical entities by 17 January 2026. In this strategy, Member States have to provide a description of measures already in place which aim to facilitate the implementation of the obligations by the SMEs that are identified as critical entities.

The Omnibus proposes that any facilitating measures that exist for SMEs and SMCs in the Member States should be described in the strategy.

## 3 CONCLUSIONS – GLOBAL IMPACT OF THE PROPOSAL

Amending the above-mentioned acts to extend SME mitigating measures to small mid-caps is likely to lead to savings not only for SMCs, but also for SMEs and the wider enterprise population.

While some acts cover all or a large proportion of the enterprise population and are likely to apply to most small mid-caps (e.g. the GDPR), other acts only apply to a small sub-section of enterprises (e.g. the Prospectus Act). Section 2 of this document includes estimations of how many SMCs might be concerned by each act, to the extent possible.

Using the figures from Section 2.2 on the potential savings for each act, as well as the number of potentially affected SMCs, EUR 20 000-35 000 per company incurred by 635 SMCs per year was estimated, stemming from the Prospectus Act. These figures would lead to a yearly saving for SMCs on the whole of EUR 12.7 million per year using the lower bound estimates, or EUR 22.2 million using the upper bound estimates.

In addition, some simplifications will bring savings for both SMEs and SMCs by making compliance with certain obligations easier. This is notably the case for the GDPR and F-gases. On the GDPR, despite the lack of first-hand data, based on a number of assumptions and hypothesis, we can estimate that the proposed amendment could save SMEs and SMCs across the EU around

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[41] SWD(2022) 96 final.

EUR 66 million per year. The F-gas amendment is further estimated to save companies EUR 5.1 million decreasing over time to 0.51 million per year.

Taking all these different impacts together, it is estimated that this Omnibus package will save EU enterprises between **EUR 79.2-93.3 million** per year. It has to be stressed that these figures are conservative and the true savings are likely to be much larger.

It should be noted that some acts listed above are not included in this calculation due to insufficient data. This is the case for the Trade Defence regulations and the Batteries Regulation. However, the revised Regulations and the Critical Entities Resilience Directive will offer qualitative benefits for small mid-caps beyond the monetary impact. These largely concern clearer and simpler legal obligations and making additional guidance or support structures already available to SMEs also available to small mid-caps.

The savings presented here can be achieved with no negative impact on the associated policy objectives. The proposed simplifications focus on simplifying existing rules or making it easier for enterprises to apply these rules, rather than removing obligations necessary to achieve the policy objectives. Importantly, the proposed amendments will not affect the obligations of enterprises to continue complying with each act. For instance, the amendment proposed to the GDPR derogation from the record-keeping obligation would not affect the enterprises and organisations' duty to comply with other GDPR obligations, and it would not compromise the risk-based approach underlying this act. Therefore, the proposed measures would still ensure a proportionate and fair balance between the achievement of policy objectives and the interests of smaller enterprises and organisations.