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LIMITE

SIMPL 142
ANTICI 146
ECOFIN 808
EF 179
MI 627
ECO 22
ENT 144
IA 163
IND 411
TELECOM 315

POLCOM 219
ENV 721
CLIMA 327
TRANS 418
ENER 395
CODEC 1163
FIN 872
JAI 817
DATAPROTECT 197

NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee

Subject: Omnibus IV

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

- Final compromise text

Delegations will find enclosed the final compromise text on the Regulation on small mid-caps.

2025/0130 (COD)

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16, Article 114, Article 192 (1) and Article 207 (2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) In the political guidelines for the European Commission's 2024-2029 term³, President von der Leyen set out a plan for the Union's sustainable prosperity and competitiveness.

¹ OJ C , , p. .

² OJ C , , p. .

³ https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf

Making business easier and deepening the Single Market are among the plan's key priorities.

- (2) The Commission's better regulation agenda⁴ also supports the competitiveness of Union enterprises by aiming to ensure that Union ***legislation achieves its objectives without imposing unnecessary costs and burden, while positively contributing to consumers' lives and the internal market, thereby helping the Union address current and future challenges***. In 2023, the Commission identified the need to rationalise and simplify reporting requirements for ***both*** enterprises and ***public*** administrations⁵ and committed to reduce administrative burdens by 25% ***and 35% for SMEs***.
- (3) On 12 September 2023, the Commission published the SME Relief Package ***■***, announcing its goal to help small and medium sized enterprises ('SMEs') compete and grow, by being attentive to the needs of enterprises that outgrow the thresholds of the SME definition ***■***, and those in the broader range of small mid-cap enterprises. Action 18 of this relief package announced that the Commission would 'develop a harmonised definition for small mid-cap enterprises, build a dataset based on such definition and assess possible measures to support these enterprises in their growth (including potential application in adapted form of certain measures favouring SMEs)'. ***It is important to ensure that any support for small mid-cap enterprises is designed in a manner that upholds the principles of fair competition, non-discrimination, high level of consumer protection as well as the integrity of the internal market.***

⁴ 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>

⁵ 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>

- (4) *SMEs represent 99% of all Union companies . Micro and small enterprises, which represent the vast majority of SMEs, continue to face significant challenges in scaling up their businesses within the Union. These challenges risk undermining the effectiveness and proper functioning of the internal market. The Union should therefore support enterprises, entrepreneurship and a competitive market economy by promoting a predictable regulatory framework and appropriate compliance support, with a view to facilitating the growth and scaling-up of micro and small enterprises within the internal market. Those enterprises that outgrow the SME definition – the ‘small mid-cap enterprises’ (‘SMCs’) – also play a vital role in the Union’s economy ■ . They are prominently present in industrial ecosystems that are key to the competitiveness of the Union and its technological sovereignty, in fields including electronics, aerospace and defence, energy, energy-intensive industries and health. Around 20% of all small mid-cap enterprises were SMEs three years earlier ■ . Both categories of businesses, while important and needing similar support in some respects, have different needs and requirements linked to their size and growth. Support for those categories should therefore be tailored accordingly, with particular attention paid to the specific and continuous challenges faced by SMEs.*
- (5) Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, where administrative burden is concerned, they face similar challenges as SMEs, leading to a need for proportionality in legislation and for targeted support. To enable the smooth transition of SMEs into SMCs, it is important to address in a coherent manner the cliff-effect that may arise once they outgrow the segment of SMEs and are faced with rules that apply to large enterprises. *In order to achieve the overarching objective of facilitating the operation of businesses and the internal market, with a particular focus on SMCs, a number of existing acts should be adjusted. In particular, to enhance the conditions for economic growth in the Union and to make business easier for SMCs and reduce their administrative burden, a number of existing acts which provide for specific mitigating rules for SMEs should be adapted to extend the scope of those provisions and include SMCs. Reducing administrative and reporting obligations is essential to strengthen the competitiveness of Union enterprises, particularly where such reductions can have the greatest positive impact on innovation and digital transformation, while maintaining the level of ambition of the relevant existing Union acts.*

This simplification exercise must be done in a balanced and proportionate manner, by ensuring that the Union's overarching rules on investor protection are maintained and while still supporting SMEs by maintaining the existing approach. In addition, certain other adjustments should be made with a view to reducing the burden on businesses, including in particular SMCs.

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- (6) Regulations (EU) 2016/679¹⁰, (EU) 2016/1036¹¹, (EU) 2016/1037¹², (EU) 2017/1129¹³ and (EU) 2023/1542¹⁴ of the European Parliament and of the Council contain a number of provisions that aim at providing support, simplification or mitigating measures to SMEs. More specifically, those provisions are aimed at alleviating administrative burdens, reducing or eliminating market entry barriers, facilitating compliance, considering the specific situation of SMEs when implementing their obligations and when assessing the economic and social impacts of those obligations, providing dedicated guidance, support and assistance to SMEs.

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- ¹⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>)
- ¹¹ Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union (OJ L 176, 30.6.2016, p. 21, ELI: <http://data.europa.eu/eli/reg/2016/1036/oj>)
- ¹² Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union (OJ L 176, 30.6.2016, p. 55, ELI: <http://data.europa.eu/eli/reg/2016/1037/oj>)
- ¹³ Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC (OJ L 168, 30.6.2017, p. 12, ELI: <http://data.europa.eu/eli/reg/2017/1129/oj>)
- ¹⁴ Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).

- (7) *For the purpose of the Omnibus IV package, SMCs should, in principle, be defined as enterprises that are not SMEs, that employ fewer than 1000 persons, and that either have an annual turnover not exceeding EUR 200 million or an annual balance sheet total not exceeding EUR 172 million, those numbers and amounts being calculated in accordance with points 1 and 3-6 of the Annex to that Commission Recommendation 2025/1099 of 21 May 2025. That scope covers enterprises that are up to four times the size of SMEs without extending to large mid-caps or large enterprises. References in this Regulation to Commission Recommendation 2025/1099 of 21 May 2025 and Commission Recommendation 2003/361/EC should be understood as referring to the original version of those recommendations. To ensure a coherent and evidence-based approach to SMCs, the Commission should, within five years from the date of entry into force of this Regulation, submit a report to the European Parliament and the Council on the review of the application of the SMC definition, on the implementation of the provisions of the regulations amended by this Regulation, including the impact on the reduction of administrative burden, and on competitiveness of SMCs, considering also economic, social and environmental aspects, where appropriate. As part of that review, the Commission should compile an overview of existing definitions of SMCs in Union legislative acts. The report should, in particular, focus on any need to review the thresholds defining SMCs in light of inflation, scope, and economic and market developments, with a view to considering further harmonisation of the application of the SMC definition across Union legislation, where appropriate. The report should also focus on the existing derogations, simplifications, exemptions and other preferential treatments granted to SMCs across the Union legislation, and should be accompanied, where appropriate, by a legislative proposal.*

1. Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises  (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>).

- (8) Regulation (EU) 2016/679 provides for the protection of natural persons with regard to the processing of personal data and free movement of such data. ***To take account of the specific situation of micro, small and medium-sized enterprises and small midcap enterprises*** the obligation to maintain records of processing ***activities*** should be simplified so that ***the derogation*** applies to all enterprises and organisations with fewer than ***1000*** employees, provided that their processing activities are not likely to result in a high risk to the data subjects' rights and freedoms. ***Furthermore, it is important to clarify that public authorities and bodies are not concerned by the objectives of this Regulation amending Regulation (EU) 2016/679, and therefore should not benefit from that derogation.***
- (9) In order to reflect the above, it is necessary to amend Article 30(5) of Regulation (EU) 2016/679, by extending the scope of the derogation from the record-keeping obligation to ***enterprises*** and organisations with fewer than ***1000*** employees to allow ■ them to ***also benefit*** from that derogation and by providing that the derogation applies unless ***it is assessed that a given*** processing ***activity*** is likely to result in a 'high risk' to data subjects' rights and freedoms, within the meaning of Article 35 of Regulation (EU) 2016/679. In particular the processing of personal data referred to in paragraph 3 of that provision should be considered as requiring the data controller or the processor to maintain ***up-to-date*** records of ***those*** processing activities. ***Furthermore, it should be clarified that enterprises and organisations with fewer than 1000 employees carrying out high-risk processing of personal data are only required to maintain a record of those specific processing activities which are likely to result in a high risk to data subjects' rights and freedoms within the meaning of Article 35 of Regulation (EU) 2016/679.***
- (10) In this context, the processing of special categories of personal data ***by such enterprises and organisations*** which is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law, as referred to in Article 9(2), point (b), of Regulation (EU) 2016/679, ***would not always likely result in a high risk to data subjects, and*** should not as such require that records of processing ***activities*** be maintained , ***unless it is assessed that the processing is likely to result in a high risk.***

- (10a) *Furthermore, the obligation to keep records of processing activities should continue to apply where the controller or processor is required to designate a data protection officer pursuant to Article 37(1), points (b) and (c), of Regulation (EU) 2016/679. Those cases bear particular importance where personal data processing presents structural or recurring risks and should therefore require that records of related processing activities are always maintained. In particular, those cases concern processing operations involving regular and systematic monitoring of data subjects on a large scale or large-scale processing of special categories of data or personal data relating to criminal convictions and offences. However, it is important to recall that core activities of a controller or processor relate to its primary activities and do not relate to the processing of personal data as ancillary activities. For example, in the private sector, where the processing of personal data would constitute an ancillary activity and would not result in a high risk to data subjects, no records for that particular processing activity would be required to be maintained.*
- (11) *Furthermore, definitions should be added for micro, small and medium-sized enterprises and for SMCs in Article 4 of Regulation (EU) 2016/679. The requirements provided for in Articles 40 and 42 of that Regulation to take into account the specific needs of micro, small and medium-sized enterprises as regards the drawing-up of codes of conduct and the establishment of data protection certification mechanisms and of data protection seals and marks should be extended to include the specific needs of SMCs. It is important that these codes of conduct comply inter alia with the objectives of minimising regulatory burden and promoting digitalisation.*

- (12) The European Data Protection Supervisor and the European Data Protection Board were consulted, in accordance with Article 42(1) and (2) of Regulation (EC) 2018/1725, and they delivered a joint opinion on **8 July 2025**.

- (13) Regulations (EU) 2016/1036 and (EU) 2016/1037 are part of the Union's trade defence system. *Effective implementation of trade defence measures is vital for maintaining the competitiveness of key Union industrial ecosystems and securing quality jobs. Those Regulations* allow the Union to investigate and address dumping and subsidisation by third countries and restore a level playing field in the Union market. If an investigation confirms the existence of such practices and resulting injury to the Union industry, the Commission imposes an anti-dumping or countervailing duty, provided such imposition is not against the Union interest. Anti-dumping and *antisubsidy* investigations require active involvement from enterprises. Investigations are normally initiated on the basis of a formal complaint from the affected Union industry that must contain evidence of the unfair practice and of the injury it has caused. Investigations require active involvement of, and data from, producers, importers and users of the product in the Union. Mainly because of their fragmentation and lack of resources, it is often very difficult for SMEs to understand trade defence and cooperate in trade defence proceedings. This is why Regulations (EU) 2016/1036 and (EU) 2016/1037 include provisions to overcome the barriers that stop smaller enterprises from accessing and using trade defence, namely through a dedicated helpdesk, and by, whenever possible, aligning investigation periods with the financial year. It is considered appropriate to ensure that SMCs also benefit from those provisions, *while maintaining the same level, quality, capacity and timeliness of services to SMEs. To mitigate the impact of unfair practices on SMEs and SMCs, it is important, to the extent possible, that the investigation procedures are conducted without undue delay, preserving the principle of due process and ensuring legal certainty.*

- (14) Regulation (EU) 2017/1129 sets out requirements for drawing up of a prospectus in cases where securities are offered to the public or admitted to trading on a regulated market. That Regulation, as amended by Regulation (EU) 2024/2809, provides for a streamlined EU Growth issuance prospectus that has lighter requirements, compared to a standard prospectus, to make the listing process less burdensome and less costly for certain types of enterprises and in certain cases. The main categories of beneficiaries of such streamlined prospectus are enterprises with a growth potential, notably SMEs and other enterprises whose securities are admitted or are to be admitted to trading on an SME growth market. In order to reduce the burden for SMCs and potentially make them more attractive to investors, it is appropriate to also enable SMCs to draw up an EU Growth issuance prospectus for their offers of securities to the public, including when such offers are accompanied with an admission to trading on a multilateral trading facility. ***It is important that simplification be implemented in a way that balances reduced administrative requirements for enterprises with the need to preserve financial market integrity, investor protection and confidence in Union capital markets.***
- (15) In order to clarify the treatment of SMCs in Regulation (EU) 2017/1129, it is necessary to introduce in its Article 2 a definition of SMC, distinct from the definition of an SME. Small mid-cap enterprises for the purpose of that Regulation should be defined either as enterprises that meet at least two out of the three criteria based on the average number of employees, a total balance sheet and an annual net turnover, or as enterprises that meet the definition of small mid-cap enterprises set out under Directive 2014/65/EU.

- (16) SMEs and SMCs are particularly dependent on services provided by credit institutions and insurers, often relying on only one or few principal providers of these services. Resolution regimes ensure uninterrupted access to deposits and critical functions where a financial institution fails. ■ Resolution authorities *may decide to* use their power to convert liabilities of a financial institution to resolve it in a timely manner and ensure the continuity of critical functions. ***The operationalisation of this power varies across Union and third-country resolution proceedings, and it cannot be excluded that its exercise may entail an offer of securities to the public, in particular where there is an element of choice for the recipient of those securities. However,*** prior preparation and publication of a prospectus is not feasible due to the short timeframe imposed in the context of a resolution. It is therefore important to introduce an exemption from the obligation to publish a prospectus that applies to an offer to the public of both securities resulting from a conversion due to the exercise of powers under Directive 2014/59/EU of the European Parliament and of the Council¹⁵ and Directive (EU) 2025/1 of the European Parliament and of the Council¹⁶ and securities resulting from a conversion due to the exercise of a comparable power in third-country resolution proceedings that implements the Financial Stability Board’s ‘Key Attributes of Effective Resolution Regimes for Financial Institutions’, published in October 2011. Equally, the existing exemption for the admission to trading on a regulated market of securities resulting from a conversion due to the exercise of powers under Directive 2014/59/EU and Directive (EU) 2025/1 from the obligation to publish a prospectus should be extended to securities resulting from a conversion due to the exercise of a comparable power in third-country resolution proceedings that implements those internationally agreed standards.

¹⁵ Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190, **ELI:** <http://data.europa.eu/eli/dir/2014/59/oj>).

¹⁶ Directive (EU) 2025/1 of the European Parliament and of the Council of 27 November 2024 establishing a framework for the recovery and resolution of insurance and reinsurance undertakings and amending Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132 and Regulations (EU) No 1094/2010, (EU) No 648/2012, (EU) No 806/2014 and (EU) 2017/1129 (OJ L, 2025/1, 8.1.2025, ELI: <http://data.europa.eu/eli/dir/2025/1/oj>).

- (18) Regulation (EU) 2023/1542 establishes rules concerning batteries and waste batteries. ***The amendments to Regulation (EU) 2023/1542, which only affect the parts of that Regulation based on Article 114 TFEU, are based on Article 114 TFEU.*** Article 47 of that Regulation exempts SMEs from certain obligations regarding battery due diligence policies. The scope of that provision should be extended to SMCs, so that they are also exempted from those obligations. To ensure consistency, it is appropriate to refer to SMCs in the same way ***whilst aligning with the Omnibus IV definition of SMCs referred to in recital 7, i.e. exempting SMCs with an annual*** net turnover which should thus be less than EUR 200 million.
- (19) Pursuant to Article 52 of Regulation (EU) 2023/1542, economic operators referred to in Article 48(1) of that Regulation are required - on an annual basis – to review and make publicly available, including on the internet, a report on their battery due diligence policy. With a view to reducing the administrative burden on economic operators, operators should be required to review and make publicly ***available*** their due diligence policy only every ***five*** years instead of annually. This burden reduction should apply to all economic operators. ***In between the five years, economic operators should be required to review, and make publicly available their due diligence policy without undue delay after a significant change occurs. A significant change should be understood as a change to the status quo of the company's own operations, operations of its subsidiaries or business partners, the legal or business environment or any other substantial shift from the situation of the company or its operating context, including in particular a change in sourcing of the raw materials covered by the battery due diligence policy or components that contain such raw materials. In addition, in order to ensure coherence with other Union frameworks, economic operators are allowed to fulfil their reporting obligations through the submission of a single consolidated report. Doing so would avoid the duplication of reporting requirements and further reduce unnecessary administrative burden.***

- (20) The requirement in Article 20(4), point (a) of Regulation (EU) 2024/573 of the European Parliament and of the Council¹⁷ to register in the F-gas Portal prior to carrying out any imports and exports of products and equipment containing fluorinated greenhouse gases, is intended to facilitate enforcement. However, the burden resulting from that requirement may be disproportionate compared to its benefit, in particular for SMEs and SMCs. Therefore, the registration requirement should be limited to imports for which reporting *requirements* apply and to exports for which *a derogation to* an export limitation *applies*. ***Article 22(1) of Regulation (EU) 2024/573, concerning the obligation to present a licence to customs authorities, should also be amended accordingly.*** To the extent that this Regulation amends Regulation (EU) 2024/573 the appropriate legal basis, in so far as those amendments are concerned, is Article 192(1) TFEU.

(20b) Since the objective of this Regulation, namely to adjust a number of existing acts so as to facilitate the operation of businesses and the internal market, with a particular focus on SMCs, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

- (21) Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 should therefore be amended accordingly,

¹⁷ Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (OJ L 2024/573, 20.02.2024, ELI: <http://data.europa.eu/eli/reg/2024/573/oj>).

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2016/679

Regulation (EU) 2016/679 is amended as follows:

(1) in Article 4, the following points (27) and (28) are added:

‘(27) ‘micro, small, and medium-sized enterprises’ means enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC*;

(28) ‘small mid-cap enterprises’ means enterprises ***which are not micro, small and medium-sized enterprises, that employ fewer than 1000 persons, and either have an annual turnover not exceeding EUR 200 million or an annual balance sheet total not exceeding EUR 172 million, those numbers and amounts being calculated in accordance with points (1) and (3)-(6) of the Annex to Commission Recommendation 2025/1099 on the definition of small mid-cap enterprises**;***

* Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

[** Commission ***Recommendation 2025/1099 of 21 May 2025*** on the definition of small mid-cap enterprises ■ (***OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>***).’];

(2) in Article 30, paragraph 5 is replaced by the following:

- ‘5. The obligations referred to in paragraphs 1 and 2 shall not apply to an enterprise or an organisation employing fewer than **1000** persons unless ***and to the extent that a specific processing activity they carry out is likely to result in a high risk to the rights and freedoms of data subjects, within the meaning of Article 35, in particular with regard to the cases referred to in paragraph 3 of that Article and, in any event, where the processing activity constitutes a core activity requiring the appointment of a data protection officer pursuant to Article 37(1), point (b) or (c).*** The obligations referred to in paragraphs 1 and 2 of this Article shall only apply to the specific processing activity that meets the conditions established in this paragraph. ’

(3) in Article 40, paragraph 1 is replaced by the following:

- ‘1. The Member States, the supervisory authorities, the Board and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper application of this Regulation, taking account of the specific features of the various processing sectors and the specific needs of micro, small and medium-sized enterprises and of small mid-cap enterprises.;

(4) in Article 42, paragraph 1 is replaced by the following:

- ‘1. The Member States, the supervisory authorities, the Board and the Commission shall encourage, in particular at Union level, the establishment of data protection certification mechanisms and of data protection seals and marks, for the purpose of demonstrating compliance with this Regulation of processing operations by controllers and processors. The specific needs of micro, small and medium-sized enterprises and of small mid-cap enterprises shall be taken into account.’

Article 2

Amendments to Regulation (EU) 2016/1036

Regulation (EU) 2016/1036 is amended as follows:

- (1) **Article 5(1a) is amended as follows:**

‘(a) the first subparagraph is replaced by the following:

The Commission shall facilitate access to the trade defence instrument for diverse and fragmented industry sectors, largely composed of small and medium-sized enterprises (‘SMEs’)* or small mid-cap enterprises (‘SMCs’)**, through a dedicated Helpdesk (*the ‘SME and SMC Helpdesk’*), for example by awareness raising, by providing general information and explanations on procedures and on how to submit a complaint, by releasing standard questionnaires in all official languages of the Union and by replying to general, non-case-specific queries.’

(b) the following subparagraphs are inserted before the second subparagraph:

For the purposes of the first subparagraph, ‘small and medium-sized enterprises’ are enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/61/EC*.

For the purposes of the first subparagraph, ‘small mid-cap enterprises’ are enterprises which are not micro, small and medium-sized enterprises, that employ fewer than 1000 persons, and that either have an annual turnover not exceeding EUR 200 million or an annual balance sheet total not exceeding EUR 172 million, those numbers and amounts being calculated in accordance with points (1) and (3)-(6) of the Annex to Commission Recommendation 2025/1099**.

* Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

**** Commission *Recommendation 2025/1099 of 21 May 2025 concerning* the definition of small mid-cap enterprises** **■** **(OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>).’ ;’**

(1a) in Article 5(1a), the second subparagraph is replaced by the following:

‘ The SME and SMC Helpdesk shall make available standard forms for statistics to be submitted for standing purposes and questionnaires.; ’

(2) in Article 6, paragraph 9, is replaced by the following:

‘9. For proceedings initiated pursuant to Article 5(9), an investigation shall, whenever possible, be concluded within one year. In any event, such investigations shall in all cases be concluded within 14 months of initiation, in accordance with the findings made pursuant to Article 8 for undertakings or the findings made pursuant to Article 9 for definitive action. Investigation periods shall, whenever possible, especially in the case of diverse and fragmented sectors largely composed of SMEs or SMCs, coincide with the financial year..’

■

Article 3

Amendments to Regulation (EU) 2016/1037

Regulation (EU) No 2016/1037 is amended as follows:

(-1) In Article 2, the following points are added:

- (e) ‘small and medium-sized enterprises’ means enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC*;**
- (f) ‘small mid-cap enterprises’ means enterprises which are not micro, small and medium-sized enterprises, that employ fewer than 1000 persons, and that either have an annual turnover not exceeding EUR 200 million or an annual balance sheet total not exceeding EUR 172 million, those numbers and amounts being calculated in accordance with points (1) and (3)-(6) of the Annex to Commission Recommendation 2025/1099****

* Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

** Commission *Recommendation 2025/1099 of 21 May 2025 concerning* the definition of small mid-cap enterprises **■** (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>.’ ;’

(1) in Article 10 (1a, the first subparagraph is replaced by the following:

■ The Commission shall facilitate access to the trade defence instrument for diverse and fragmented industry sectors, largely composed of small and medium-sized enterprises (SMEs) ■ or small mid-caps enterprises (SMCs) ■ , through a dedicated Helpdesk (*the ‘SME and SMC Helpdesk’*), for example by awareness raising, by providing general information and explanations on procedures and on how to submit a complaint, by releasing standard questionnaires in all official languages of the Union and by replying to general, non-case-specific queries.’

■

(1a) in Article 10(1a), the second subparagraph is replaced by the following:

‘The SME and SMC Helpdesk shall make available standard forms for statistics to be submitted for standing purposes and questionnaires.; ’

(2) in Article 11, paragraph 9 is replaced by the following:

‘9. For proceedings initiated pursuant to Article 10(11), an investigation shall, whenever possible, be concluded within one year. In any event, such investigations shall in all cases be concluded within 13 months of their initiation, in accordance with the findings made pursuant to Article 13 for undertakings or the findings made pursuant to Article 15 for definitive action. Investigation periods shall, whenever possible, especially in the case of diverse and fragmented sectors largely composed of SMEs or SMCs, coincide with the financial year..’

■

Article 4

Amendments to Regulation (EU) 2017/1129

Regulation (EU) 2017/1129 is amended as follows:

(1) Article 1 is amended as follows:

(a) in paragraph 4, the following point (dc) is inserted:

‘(dc) an offer of securities resulting from ***either of the following: (i) the conversion or exchange of other securities, own funds or **bail-inable** liabilities by a resolution authority due to the exercise of a power referred to in Article 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings;***

(ii) the conversion or exchange of other securities, own funds or eligible liabilities by a resolution authority due to the exercise of a power referred to in Article 35(1), Article 39(2) or Article 42(1) of Directive (EU) 2025/1 of the European Parliament and of the Council (*) or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings; ■

(*) Directive (EU) 2025/1 of the European Parliament and of the Council of 27 November 2024 establishing a framework for the recovery and resolution of insurance and reinsurance undertakings and amending Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132 and Regulations (EU) No 1094/2010, (EU) No 648/2012, (EU) No 806/2014 and (EU) 2017/1129 (OJ L, 2025/1, 8.1.2025, ELI: <http://data.europa.eu/eli/dir/2025/1/oj>).’

(b) in paragraph 5, point (c) is replaced by the following:

- ‘(c) securities resulting from ***either of the following: (i) the conversion or exchange of other securities, own funds or **bail-inable** liabilities by a resolution authority due to the exercise of a power referred to in Article 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings;***
- (ii) the conversion or exchange of other securities, own funds or eligible liabilities by a resolution authority due to the exercise of a power referred to in Article 35(1), Article 39(2) or Article 42(1) of Directive (EU) 2025/1 or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings;*** █

(2) Article 2 is amended as follows:

(a) the following points (dc) and (dd) are inserted:

- ‘(dc) ‘relevant third-country authority’ means a relevant third-country authority as defined in Article 2(1), point (90), of Directive 2014/59/EU or a relevant third-country authority as defined in Article 2, point (74), of Directive (EU) 2025/1;
- (dd) ‘third-country resolution proceedings’ means third-country resolution proceedings as defined in Article 2(1), point (88), of Directive 2014/59/EU or third-country resolution proceedings as defined in Article 2, point (72), of Directive (EU) 2025/1;’

(b) ■ the following point (fa) is inserted:

“(fa) ‘small mid-cap enterprises’ or ‘SMCs’ means any of the following:

- (i) companies which *are not SMEs and that*, according to their last annual or consolidated accounts, meet at least two of the following three criteria: an average number of employees during the financial year of less than **1000**, a total balance sheet not exceeding EUR **172 000 000** and an annual net turnover not exceeding EUR **200 000 000**;
- (ii) small mid-cap enterprises as defined in Article 4(1), point (13a), of Directive 2014/65/EU;;’

(3) in Article 15a, paragraph 1 is replaced by the following:

‘1. Without prejudice to Article 1(4) and Article 3(2) and (2a), the following persons may draw up an EU Growth issuance prospectus in the case of an offer of securities to the public, provided that they have no securities admitted to trading on a regulated market:

- (a) SMEs;
- (b) SMCs;
- (c) issuers, other than SMEs and SMCs, whose securities are, or are to be admitted to trading on an SME growth market;
- (d) offerors of securities that have been issued by issuers referred to in points (a), (b), and (c)..’

■

Article 5

Amendments to Regulation (EU) 2023/1542

Regulation (EU) 2023/1542 is amended as follows:

- (1) in Article 47, the first paragraph is replaced by the following:

‘This Chapter does not apply to economic operators that had a net turnover of less than EUR **200** million in the financial year preceding the last financial year, and that are not part of a group, consisting of parent and subsidiary undertakings, **whose net turnover** on a consolidated basis, **equals or** exceeds the limit of EUR **200** million **in the financial year preceding the last financial year.** █

- (2) in Article 52(3), the first sentence is replaced by the following:

‘The economic operator referred to in Article 48(1) shall, by the latest one year after the date specified in Article 48(1) and at least every **five** years thereafter, **and without undue delay after a significant change occurs**, review, **and where necessary, update** and make publicly available, including on the internet, a report on its battery due diligence policy. █

(2a) After article 52(3), the following paragraph is inserted:

‘3a. Economic operators may comply with their reporting obligations in paragraph 3 by including the necessary information together with the sustainability information referred to in Articles 19a and 29a of Directive 2013/34/EU, including through a single consolidated report.’

Article 6

Amendment to Regulation (EU) 2024/573

– Regulation (EU) 2024/573 is amended as follows:

in Article 20(4), point (a) is replaced by the following:

- ‘(a) the following imports and exports, except in the case of temporary storage as defined in Article 5, point (17), of Regulation (EU) No 952/2013:
- (i) the import or export of fluorinated greenhouse gases;
 - (ii) the placing on the market of ***10 tonnes of CO₂ equivalent or more of hydrofluorocarbons or 100 tonnes of CO₂ equivalent or more of other*** fluorinated greenhouse gases, ***during the calendar year, contained in products and equipment***
 - (iii) the export of products and equipment as referred to in Article 22(3) containing or whose functioning relies upon, fluorinated greenhouse gases with a GWP of 1000 or more as from the prohibition date stated in Annex IV ***where the export is allowed pursuant to Article 22(3), second subparagraph, or Article 22(4);*** ■

(2) ***In Article 22(1), the first subparagraph is amended as follows:***

‘The import and export of fluorinated greenhouse gases, and products and equipment containing those gases or whose functioning relies upon those gases shall be subject to the presentation of a valid licence to customs authorities issued by the Commission, pursuant to Article 20(4) and (5), where registration is required pursuant to Article 20(4), point (a).’

Article 6a

Review

By ... [five years from the date of entry into force of this amending Regulation],],the Commission shall submit a report to the European Parliament and the Council on the review of the application of the SMC definition, as foreseen by Commission Recommendation 2025/1099 of 21 May 2025¹, on the implementation of the provisions of Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as amended by this Regulation, including the impact on the reduction of administrative burden, and on competitiveness of SMCs, considering also economic, social and environmental aspects, where appropriate. As part of that review, the Commission shall compile an overview of existing definitions of small mid-cap enterprises in Union legislative acts. The report shall in particular focus on any need to review the thresholds defining SMCs in light of inflation, scope, and economic and market developments, with a view to considering further harmonisation of the application of the SMC definition across Union legislation, where appropriate. The report shall also focus on the existing derogations, simplifications, exemptions and other preferential treatments granted to SMCs across the Union legislation. The report shall be accompanied, where appropriate, by a legislative proposal.

Article 7

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

■

This Regulation shall be binding in its entirety and directly applicable in the Member States ■ .

Done at Brussels,

For the European Parliament
The President

For the Council
The President