European Parliament
2024-2029

TEXTS ADOPTED

P10_TA(2026)0382

Amending certain Regulations as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures (Omnibus IV)

European Parliament legislative resolution of 24 November 2026 on the 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)0501 – C10-0092/2025 – 2025/0130(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2025)0501),

– having regard to Article 294(2) and Article 16, Article 114, Article 192(1) and Article 207(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C10-0092/2025),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 18 September 2025[1],

– after consulting the Committee of the Regions,

– having regard to the provisional agreement approved by the committees responsible under Rule 75(4) of its Rules of Procedure, and the undertaking given by the Council representative by letter of 26 June 2026 to approve Parliament’s position, in accordance with

[1] OJ C, C/2026/29, 16.1.2026, ELI: http://data.europa.eu/eli/C/2026/29/oj.

Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rule 60 of its Rules of Procedure,

– having regard to the joint deliberations of the Committee on Economic and Monetary Affairs, the Committee on the Environment, Climate and Food Safety and the Committee on Civil Liberties, Justice and Home Affairs under Rule 59 of the Rules of Procedure,

– having regard to the opinions of the Committee on International Trade and the Committee on the Internal Market and Consumer Protection,

– having regard to the report of the Committee on Economic and Monetary Affairs, the Committee on the Environment, Climate and Food Safety and the Committee on Civil Liberties, Justice and Home Affairs (A10-0041/2026),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P10_TC1-COD(2025)0130

Position of the European Parliament adopted at first reading on 24 November 2026 with a view to the adoption of Regulation (EU) 2026/... 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

(Text with EEA relevance)

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 Committee[1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[2],

---

1 OJ C, C/2026/29, 16.1.2026, ELI: http://data.europa.eu/eli/C/2026/29/oj.

2 Position of the European Parliament of 24 November 2026.

Whereas:

(1) ‘Europe's Choice: Political Guidelines for the next European Commission 2024-2029’ sets out a plan for the Union’s sustainable prosperity and competitiveness. Making business easier and deepening the internal market are among the plan’s key priorities.

(2) The Commission’s communication of 29 April 2021 entitled ‘Better regulation: Joining forces to make better laws’ also supports the competitiveness of Union enterprises by aiming to ensure that Union ***legal acts achieve their*** objectives ***without imposing unnecessary costs and burdens on enterprises, while making a positive contribution to consumers’ lives and to the internal market, thereby helping the Union address current and future challenges***. In its communication of 16 March 2023 entitled ‘Long-term competitiveness of the EU: looking beyond 2030’ and its communication of 29 January 2025 entitled ‘A Competitiveness Compass for the EU’, the Commission identified the need to rationalise and simplify reporting requirements for ***both*** enterprises and ***public*** administrations and committed to reducing administrative burden by at least 25% ***for all enterprises and at least 35% for small and medium-sized enterprises (‘SMEs’)***.

(3) On 12 September 2023, the Commission published a communication entitled ‘SME Relief Package’ ▌, announcing its goal to help SMEs compete and grow by being attentive to the needs of enterprises that, due to their growth, exceed the thresholds set out in the definition of SMEs ▌, and the broader range of small mid-cap enterprises (‘SMCs’). Action 18 of that communication provided that the Commission would develop a harmonised definition for SMCs, build a dataset based on that definition and assess possible measures to support SMCs in their growth, including the potential application, in adapted form, to SMCs of certain measures favouring SMEs. ***It is important to ensure that any support for SMCs is designed in a manner that upholds the principles of fair competition, non-discrimination and a high level of consumer protection, as well as the integrity of the internal market.***

(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. Those 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. Enterprises that, due to their growth, no longer fall within*** the definition of SMEs, in particular SMCs, ***also*** play a vital role in the Union economy ▌. SMCs are prominently present in industrial ecosystems that are key to Union competitiveness and its technological sovereignty, including electronics, aerospace and defence, energy, energy-intensive industries and health. Approximately 20% of all SMCs were SMEs three years earlier ▌. ***Both SMEs and SMCs, while important and requiring similar support in some respects, have different needs and requirements linked to their size and growth. Support for SMEs and SMCs should therefore be tailored accordingly, with particular attention paid to the specific and continuous challenges faced by SMEs.***

(5) Regulations (EU) 2016/679[3], (EU) 2016/1036[4], (EU) 2016/1037[5], (EU) 2017/1129[6] and (EU) 2023/1542[7] of the European Parliament and of the Council contain a number of provisions that aim to provide support as well as simplification or mitigating measures for SMEs. More specifically, those provisions aim to alleviate the administrative burden, reduce or eliminate market entry barriers and facilitate compliance, taking into consideration the specific situation of SMEs when implementing their obligations and when assessing the economic and social impact of those obligations, and also provide dedicated guidance, support and assistance to SMEs.

(6) Compared to SMEs, SMCs tend to demonstrate a higher pace of growth and a higher level of innovation and digitisation. Nevertheless, as far as the administrative burden is concerned, they face similar challenges to SMEs, leading to a need for proportionality in legislation and for targeted support. To enable the smooth transition of an enterprise from SME to SMC, it is important to address, in a coherent manner, the ‘cliff effect’ that

---

3 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).

4 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).

5 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).

6 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).

7 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).

might arise once an enterprise, due to its growth, is no longer an SME and is faced with rules that apply to larger 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 Union legal acts should be amended. In particular, in order to enhance the conditions for economic growth in the Union and*** to make business easier for SMCs and reduce their administrative burden, Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129 and (EU) 2023/1542, which provide for specific mitigating rules for SMEs, should be adapted so as to extend the scope of those rules to include SMCs.

(7) Reducing administrative and reporting obligations is essential to strengthening 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 legal acts. Such a simplification exercise should 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 amendments should be made with a view to reducing the burden on businesses, including, in particular, SMCs.

(8) ***For the purposes of this amending Regulation, which is part 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, with those numbers and amounts being calculated in accordance with point 1 and points 3 to 6 of the Annex to Commission Recommendation (EU) 2025/1099[8]. The scope of that definition covers enterprises that are up to four times the size of SMEs without extending to large mid-caps or large enterprises. References in this amending Regulation to Recommendation (EU) 2025/1099 and Commission Recommendation 2003/361/EC[9] should be understood as referring*** to the ***original version of those recommendations.***

(9) ***To ensure a coherent and evidence-based approach to SMCs, the Commission should, within five years of 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 definition of SMCs and on the implementation of the provisions of Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129 and (EU) 2023/1542 and of Regulation (EU) 2024/573 of the***

---

[8] ***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***).

[9] ***Commission Recommendation 2003/361/EC 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).***

European Parliament and of the Council[10]amended by this Regulation, including the impact on the reduction of the administrative burden as well as on the 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 legal acts.

10 ***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, 20.2.2024, ELI: http://data.europa.eu/eli/reg/2024/573/oj).***

That report should focus, in particular, on any need to review the thresholds by which SMCs are defined in light of inflation, scope, and economic and market developments, with a view to considering further harmonisation of the application of the definitions of SMCs across Union legal acts, where appropriate. That report should also focus on the existing derogations, simplifications, exemptions and other preferential treatment granted to SMCs in Union legal acts, and should be accompanied, where appropriate, by a legislative proposal.

(10) Regulation (EU) 2016/679 provides for the protection of natural persons with regard to the processing of personal data and the free movement of such data. ***To take account of the specific situation of micro, small and medium-sized enterprises and SMCs,*** the derogation from the obligation to maintain records of processing ***activities*** should be simplified and applied to all enterprises and organisations employing fewer than ***1000*** employees, provided that their processing activities are not likely to result in a high risk to the rights and freedoms of data subjects. ***Furthermore, it is important to clarify that public authorities and bodies are not concerned by the objectives of that amendment to Regulation (EU) 2016/679 set out in this amending Regulation, and therefore should not benefit from that derogation.***

(11) It is necessary to amend Article 30(5) of Regulation (EU) 2016/679, to extend the scope of the derogation from the obligation to maintain a record of processing activities to all ***enterprises*** and organisations employing fewer than ***1000*** employees to allow ▌ them to ***also benefit*** from that derogation and to provide that the derogation applies unless ***it is assessed that a specific*** processing ***activity*** is likely to result in a high risk to the rights and freedoms of data subjects, as referred to in Article 35 of Regulation (EU) 2016/679. In particular, the processing of personal data referred to in Article 35(3) of that Regulation 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 employing fewer than 1000 employees and carrying out high-risk processing of personal data are only required to maintain a record of the specific processing activities which are likely to result in a high risk to the rights and freedoms of data subjects, as referred to in Article 35 of Regulation (EU) 2016/679.***

(12) The processing of special categories of personal data ***by enterprises and organisations employing fewer than 1000 employees*** where such processing 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 be likely to result in a high risk to the rights and freedoms of data subjects, and*** should not, as such, require that records of those processing ***activities*** be maintained***, unless it is assessed that the processing is likely to result in a high risk to the rights and freedoms of data subjects***.

(13) Furthermore, the obligation to maintain a record 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), point (b) or (c), of Regulation (EU) 2016/679. Article 37 of that Regulation applies to cases where the core activities of a controller or processor consist of 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. Those cases bear particular importance, since the processing of personal data presents structural or recurring risks and should therefore require that records of related processing activities are always maintained. However, it is important to note that the 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 the rights and freedoms of data subjects, it would not be required to maintain records for that particular processing activity.

(14) ***Definitions*** of micro, small and medium-sized enterprises ***and of SMCs should be added to 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 take into account the specific needs of SMCs. It is important that those codes of conduct comply inter alia with the objectives of minimising the regulatory burden and promoting digitalisation.***

▌

(15) 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 of the European Parliament and of the Council[11], and they delivered a joint opinion on ***8 July 2025***.

---

11 ***Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).***

(16) 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 a resulting injury to the Union industry, the Commission is to impose an anti-dumping or countervailing duty, provided that such an anti-dumping or countervailing duty is not against the Union interest. Anti-dumping and ***anti-subsidy*** investigations require the active involvement of enterprises. Investigations are generally initiated on the basis of a written complaint from the affected Union industry that must contain evidence of the unfair practice and of the injury it has caused. Investigations require the active involvement of, and data from, producers, importers and users of a like product in the Union. Largely due to their fragmentation and lack of resources, it is often very difficult for SMEs to understand trade defence and cooperate in trade defence proceedings. It is for that reason that Regulations (EU) 2016/1036 and (EU) 2016/1037 include provisions to overcome the barriers that stop SMEs 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 investigations be conducted without undue delay, preserving the principle of due process and ensuring legal certainty***.

(17) Regulation (EU) 2017/1129 sets out requirements for the drawing up of a prospectus in cases where securities are offered to the public or admitted to trading on a regulated market. That Regulation provides for a streamlined EU Growth issuance prospectus that has lighter requirements, compared to a standard prospectus, in order 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 a streamlined prospectus are enterprises with growth potential, in particular 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 by 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.***

(18) In order to clarify the treatment of SMCs in Regulation (EU) 2017/1129, it is necessary to introduce a definition of SMCs in that Regulation, distinct from the definition of SMEs. SMCs for the purposes 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, the total balance sheet and the annual net turnover, or as enterprises that fall within the

definition of small mid-cap enterprises set out in Directive 2014/65/EU of the European Parliament and of the Council[12].

12 Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (recast) (OJ L 173, 12.6.2014, p. 349, ELI: http://data.europa.eu/eli/dir/2014/65/oj)

(19) SMEs and SMCs are particularly dependent on services provided by credit institutions and insurers, often relying on only one or a few principal providers of those services. Resolution regimes ensure uninterrupted access to deposits and critical functions where a financial institution fails. ▌Resolution authorities ***can 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 that 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***, the prior preparation and publication of a prospectus is not feasible due to the short timeframe imposed in the context of resolution proceedings. 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 Directives 2014/59/EU[13] and (EU) 2025/1[14] of the European Parliament and of the Council and securities resulting from a conversion due to the exercise of a comparable power in third-country resolution proceedings that implement the Financial

---

13 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).***

14 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).

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 Directives 2014/59/EU and (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 implement those internationally agreed standards.

▌

(20) Regulation (EU) 2023/1542 establishes rules concerning batteries and waste batteries***. The amendments in this Regulation to Regulation (EU) 2023/1542, which only affect the parts of that Regulation based on Article 114 of the Treaty on the Functioning of the European Union (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 Regulation (EU) 2023/1542 in a way that aligns with the ***definition of SMCs introduced by this amending Regulation***, thereby ***exempting SMCs with an annual*** net turnover of less than EUR ***200*** million.

(21) Pursuant to Article 52 of Regulation (EU) 2023/1542, the 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 their administrative burden, economic operators should, after issuing their first report on battery due diligence policy, only be required to review their due diligence policy and make the report on that policy publicly ***available*** at least every ***five*** years rather than every year. That burden reduction should apply to all economic operators***. At the same time, economic operators should be required to review their due diligence policy and make the report on that policy publicly available, without undue delay, whenever a significant change occurs. A significant change should be understood as a change to the status quo of the company's own operations or the operations of its subsidiaries or business partners, or as a change to the legal or business environment, or as any other substantial shift in the company's existing situation or its operating context***, including, ***in particular, a change in the 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 should be allowed to comply with their reporting obligations by making a single consolidated report publicly available. Making such a report publicly available would avoid duplication of reporting requirements and further reduce any unnecessary administrative burden.***

(22) The requirement in Article 20(4), point (a), of Regulation (EU) 2024/573 to register in the F-gas Portal prior to carrying out any imports and exports of products and equipment containing fluorinated greenhouses gases, is intended to facilitate enforcement. However, the burden resulting from that requirement can be disproportionate when compared to its benefit, in particular for SMEs and SMCs. Therefore, that registration requirement should be amended so that it is limited to imports for which reporting ***requirements*** apply and to exports for which ***a derogation from*** 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, insofar as those amendments are concerned, is Article 192(1) TFEU.

(23) Since the objective of this Regulation, namely to amend Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 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.

(24) 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,

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 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 ***that 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, with those numbers and amounts being calculated in accordance with point (1) and points (3) to (6)*** of the Annex to Commission ***Recommendation (EU) 2025/1099***** .

---

* Commission Recommendation 2003/361/EC 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 ***(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).’***;

(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 carried*** out by that enterprise or organisation is likely to result in a high risk to the rights and freedoms of data subjects, as referred to in 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) ▌ in Article 5, paragraph ***1a is replaced by the following***:

‘1a. 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.

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 2003/361/EC*.

For the purposes of the first subparagraph, 'small mid-cap enterprises' are enterprises that 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, with those numbers and amounts being calculated in accordance with point (1) and points (3) to (6) of the Annex to Commission Recommendation (EU) 2025/1099**.

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

---

* Commission Recommendation 2003/361/EC 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 ***(EU) 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***).';

(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.’;

(3) in Article 23(1), the second subparagraph is replaced by the following:

‘That report shall include information about the application of provisional and definitive measures, the termination of investigations without measures, undertakings, reinvestigations, reviews, significant distortions and verification visits, and the activities of the various bodies responsible for monitoring the implementation of this Regulation and fulfilment of the obligations arising therefrom. The report shall also cover the use of trade defence instruments by third countries targeting the Union and appeals against the measures imposed. It shall include the activities of the Hearing Officer of the Commission’s Directorate General for Trade and Economic Security and those of the SME and SMC Helpdesk in relation to the application of this Regulation’.

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 that 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, with those numbers and amounts being calculated in accordance with point (1) and points (3) to (6) of the Annex to Commission Recommendation (EU) 2025/1099**.***

---

* Commission Recommendation 2003/361/EC 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 ***(EU) 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***.’;

(2) in Article 10, paragraph 1a is replaced by the following:

‘▌ 1a. 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.

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

(3) 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.’;

(4) in Article 32a(1), the second subparagraph is replaced by the following:

‘That report shall include information about the application of provisional and definitive measures, the termination of investigations without measures, undertakings, reinvestigations, reviews, significant distortions and verification visits, and the activities of the various bodies responsible for monitoring the implementation of this Regulation and fulfilment of the obligations

arising therefrom. The report shall also cover the use of trade defence instruments by third countries targeting the Union and appeals against the measures imposed. It shall include the activities of the Hearing Officer of the Commission’s Directorate General for Trade and Economic Security and those of the SME and SMC Helpdesk in relation to the application of this Regulation.’.

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 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 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 is inserted:

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

(i) companies that ***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 as 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) Article 52 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. The economic operator referred to in Article 48(1) shall, at the latest by 18 August 2028 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. That report shall contain, in a manner that is easily comprehensible for end-users and clearly identifies the batteries concerned, the data and information on steps taken by that economic operator to comply with the requirements laid down in Articles 49 and 50, including findings of significant adverse impacts in the risk categories listed in point 2 of Annex X, and how they have been addressed, as well as a summary report of the third-party verifications carried out in accordance with Article 51, including the name of the notified body, with due regard for business confidentiality and other competitive concerns. That report shall also cover, where relevant, access to information, public participation in decision-making and access to justice in

environmental matters in relation to the sourcing, processing and trading of the raw materials present in batteries.’;

(b) the following paragraph is inserted:

‘3a. Economic operators may comply with their reporting obligations set out in paragraph 3 by providing the necessary information as part of the sustainability reporting referred to in Articles 19a and 29a of Directive 2013/34/EU of the European Parliament and of the Council*, including through a single consolidated report.

**** Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19, ELI: http://data.europa.eu/eli/dir/2013/34/oj).’.***

Article 6

Amendments to Regulation (EU) 2024/573

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

(1) 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 CO_2 equivalent or more of hydrofluorocarbons or 100 tonnes of CO_2 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 replaced by the following:

'1. 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 7

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 definition of SMCs, as provided for in Commission Recommendation (EU) 2025/1099, and 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 amended by this Regulation, including the impact on the reduction of administrative burden as well as on the 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 SMCs in Union legal acts. The report shall focus, in particular, on any need to review the thresholds by which SMCs are defined in light of inflation, scope, and economic and market developments, with a view to considering further harmonisation of the application of the definition of SMCs across Union legal acts, where appropriate. The report shall also focus on the existing derogations, simplifications, exemptions and other preferential treatment granted to SMCs across Union legal acts. The report shall be accompanied, where appropriate, by a legislative proposal.

Article 8

Entry into force

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…,…

For the European Parliament	*For the Council*
The President	*The President*