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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 2)
No. prev. doc.:	12525/25; 12526/25; 12748/25
Subject:	<p>Omnibus IV</p> <p>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</p> <p>Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2014/65/EU and (EU) 2022/2557 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplifying measures</p>

- Mandate for negotiations with the European Parliament

I. BACKGROUND

1. The Commission put forward a fourth Omnibus package ('Omnibus IV') on 21 May 2025. It contains two proposals aiming to extend certain mitigating measures for small and medium-sized enterprises (SMEs) to small mid-cap enterprises (SMCs), two proposals regarding digitalisation and alignment of common specifications, and a 'stop-the-clock' proposal on

certain obligations regarding battery due diligence. This note concerns the proposal for a Regulation and a Directive on SMCs.

2. The proposals aim to amend several pieces of legislation by extending certain mitigating and supporting measures provided in the initial legislative acts for SMEs to SMCs, alongside further simplification measures. The main objective of these changes is to avoid that enterprises outgrowing their status as an SME are faced with a sudden and dramatic increase in administrative burdens, thereby lowering the administrative costs for such companies and supporting their growth and innovation. The Commission has therefore proposed that a number of existing acts which provide for specific mitigating rules and support measures for SMEs should be adapted to extend the scope of those provisions and include SMCs, alongside further simplification measures.

II. STATE OF PLAY

3. The Antici Group on Simplification (AGS) met on 28 May, 4, 10, 16 and 25 June, 24 July and 1 and 11 September to examine the Commission proposals and prepare Presidency compromise texts. Following a swift procedure applied with the utmost priority by both co-legislators, the ‘stop-the-clock’ text on certain battery due diligence obligations was approved by the Council on 18 July 2025¹.

III. KEY COMPROMISE ELEMENTS

4. During the discussions in the AGS, delegations stressed the need to ensure that the current level of support and possibilities to SMEs is not undermined by extending some measures also to SMCs. The Presidency therefore introduced clarifications in several recitals with the purpose of underlining that extending the scope of certain tools and support measures or exemptions from SMEs to SMCs should not undermine the current level of support and possibilities for SMEs.
5. Delegations also requested further clarifications as regards the amendments to the General Data Protection Regulation (GDPR)², notably concerning the scope of the exemption from

¹ PE-CONS 28/1/25 REV 1.

² 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

records keeping obligation, the processing of special categories of personal data in the field of employment and the development of code of conducts. Overall, these clarifications aim at ensuring a practical and effective application of the foreseen amendment for the benefits of SMEs and SMCs.

6. Regarding the Regulation on batteries and waste batteries³, delegations asked for clarifications regarding the proposed additional simplification measures on the obligations regarding economic operators' battery due diligence policies. While delegations supported the simplification of certain reporting requirements, they asked for the introduction of a clause requiring economic operators to review their due diligence policies without undue delay in the case of a significant change in the sourcing of their raw materials.
7. When it comes to the Regulation on F-gases⁴, delegations requested clarifications on the provisions on import and export, including on the thresholds, the relevant time period for reporting and that licensing is required only for exports exempted from the export ban.

IV. OPEN ISSUES

8. The main open issue relates to the maximum size companies should have in order to be considered SMCs.
9. The Commission proposes that the SMC definition should cover enterprises up to the size of three times that of SMEs. By reference to its Recommendation on the definition of small mid-cap enterprises⁵, the Commission proposes that small mid-caps would mean companies with fewer than 750 employees and that have an annual turnover not exceeding EUR 150 million or an annual balance sheet total not exceeding EUR 129 million. In its Annex to the Recommendation (point 1 and 3-6), the Commission describes several calculation methods on

free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

³ 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

⁴ 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.

⁵ Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises.

these various thresholds e.g., reference years and annual work units, as well as defining various specific enterprises e.g., ‘partner enterprises’ and ‘linked enterprises.’

10. During the discussions in the AGS, some delegations requested an increase of the thresholds for defining SMCs, to cover enterprises with fewer than 1000 employees and a turnover of up to EUR 450 million. The aim is to ensure coherence with the Coreper mandate for negotiations with the European Parliament on the scope of the Corporate Sustainability Reporting Directive, part of ‘Omnibus I’⁶. Most other delegations expressed a preference for retaining the thresholds as proposed by the Commission.
11. The Presidency decided to seize Coreper for further guidance. The discussion on 17 September showed that a number of delegations have strong concerns about possible negative implications for the supporting favourable conditions for SMEs from a significant increase of the thresholds for employee numbers and annual turnover for the definition of SMCs as compared to the Commission proposal. Following consultations with delegations, the Presidency proposes that as a compromise, the thresholds for SMCs be set at fewer than 1000 employees and an annual turnover of up to EUR 200 million, and/or an annual balance sheet total not exceeding EUR 172 million. These values would define SMCs as up to four times the size of SMEs. In parallel, it is foreseen that the Commission and the Council will make statements intended to reassure those delegations that these thresholds will not serve as a precedent for future discussions in the Multiannual Financial Framework or state aid files, nor have immediate financial implications.
12. The Presidency compromise text on the Regulation is set out in Annex I and the Presidency compromise text on the Directive is set out in Annex II. Changes compared to the Commission proposal are marked in **bold**, deletions in ~~striketrough~~. All references to the Commission’s Recommendation and other thresholds in the text are in squared brackets and will be changed to the higher thresholds, should Coreper decide to do so. Such a change would also require consequential technical changes to incorporate the crucial calculation elements in the Annex of the Commission’s Recommendation.

⁶ ST 10276/25.

V. CONCLUSION

13. The Permanent Representatives Committee is invited to discuss and decide the Council's position regarding the thresholds for SMCs, in order to agree on a mandate with regard to the proposed Regulation and Directive, as set out in the Annexes to this note, and to invite the Presidency to conduct negotiations with the European Parliament on the basis of this mandate.
14. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2023, and in full consistency with Regulation (EC) 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

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 Committee⁷,

Having regard to the opinion of the Committee of the Regions⁸,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) In the political guidelines for the European Commission's 2024-2029 term⁹, President von der Leyen set out a plan for the Union's sustainable prosperity and competitiveness.

⁷ OJ C , , p. .

⁸ OJ C , , p. .

⁹ 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 agenda¹⁰ also supports the competitiveness of Union enterprises by aiming to ensure that Union laws deliver on their objectives at a minimum cost. In 2023, the Commission identified the need to rationalise and simplify reporting requirements for enterprises and administrations¹¹ and committed to reduce administrative burdens by 25%.
- (3) On 12 September 2023, the Commission published the SME Relief Package¹², 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 definition¹³, 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)'.]
- (4) Enterprises outgrowing the SME definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy¹⁴. 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 earlier¹⁵.

¹⁰ 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>

¹¹ 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>

¹² SME Relief Package (europa.eu). See also annex 3A to this report SME relief package policy tracker.

¹³ SMEs are defined as enterprises with under 250 employees, combined with an annual turnover up to 50 million euro or a balance sheet total up to 43 million - Recommendation 2003/361/EC - https://single-market-economy.ec.europa.eu/smes/sme-definition_en

¹⁴ Study to map, measure and portray the EU mid-cap landscape - <https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461>

¹⁵ <https://www.esri.ie/system/files/publications/BKMNEXT429.pdf>

- (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 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, **while still supporting SMEs and 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.**
- (6) Regulations (EU) 2016/679¹⁶, (EU) 2016/1036¹⁷, (EU) 2016/1037¹⁸, (EU) 2017/1129¹⁹ and (EU) 2023/1542²⁰ 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

¹⁶ 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>).

¹⁷ 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>).

¹⁸ 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>).

¹⁹ 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>).

²⁰ 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>).

economic and social impacts of those obligations, providing dedicated guidance, support and assistance to SMEs.

- (7) To ensure consistency and legal certainty, a definition of SMCs should be introduced in those acts. While the definition of SMCs should in principle correspond to [the definition in Commission ~~Recommendation of 21.5.2025~~ **Recommendation 2025/1099 of 21 May 2025** on the definition of small mid-cap enterprises—~~C(2025) 3500 final~~] and cover enterprises that are up to [three] times the size of SMEs, it should, where appropriate, build on the definitions of SMEs that are already provided in the acts that are being amended, which were considered fitting by the legislators.
- (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~~ **the derogation** applies to all enterprises and organisations with fewer than **[750]**~~750~~ employees, provided that their processing activities are not likely to result in a high risk to the data subjects' rights and freedoms.
- (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 ~~SMC~~**enterprises** and organisations with fewer than **[750]**~~750~~ employees to allow ~~also~~ them to ~~profit~~**also benefit** from that derogation and by providing that the derogation applies unless the processing, **upon assessment**, 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 records of ~~it~~**those** processing activities. **Furthermore, it should be clarified that enterprises and organisations with fewer than [750] 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 an assessment indicates that the processing is likely to result in a high risk.**

- (11) Furthermore, ~~in order to extend to SMCs, the provisions that are available~~ **definitions should be added** for micro, small and medium-sized enterprises ~~under~~ **and for SMCs in Article 4 of Regulation (EU) 2016/679, the following. 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 also be amended: be extended to include the specific needs of SMCs. It is important that these codes of conduct comply inter alia with the principles of regulatory burden minimisation and digitalisation.**
- ~~Article 4, which contains the definitions applicable for the purpose of Regulation (EU) 2016/679. For reasons of clarity, definitions should be added for micro, small and medium-sized enterprises, and for small mid-cap enterprises. For small and medium-sized enterprises, it is appropriate to follow the choice of the co-legislator as expressed in recital (13) of the preamble to Regulation (EU) 2016/679. For SMCs, reference should be made to point 2 of Commission Recommendation of 21.5.2025 on the definition of small mid-cap enterprises — C(2025) 3500 final.~~
 - ~~Article 40, which provides that Member States, the supervisory authorities, the Board and the Commission are to encourage associations and other bodies representing categories of controllers or processors to draw up codes of conduct, and that the specific needs of micro, small and medium-sized enterprises are to be taken into account when doing so. This requirement should be extended to include the specific needs of SMCs.~~
 - ~~Article 42, which provides that when Member States, the supervisory authorities, the Board and the Commission are to encourage, in particular at Union level, the establishment of data protection certification mechanisms and of data protection seals and marks by certification bodies referred to in Article 43 of that Regulation or by competent supervisory authorities, the specific needs of micro, small and medium-sized enterprises are to be taken~~

into account. ~~This requirement should also be extended to include the specific needs of SMCs.~~

- (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 ~~[XXX, date]~~ **8 July 2025**.
- (13) Regulations (EU) 2016/1036 and (EU) 2016/1037 are part of the Union's trade defence system. They 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 anti-subsidy 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~~ **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 still supporting SMEs and maintaining the existing approach**.
- (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.

- (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. ~~Where~~ Resolution authorities **may be required 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 Council²¹ and Directive (EU) 2025/1 of the European Parliament and of the Council²² and securities resulting from a conversion due to the

²¹ 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>**.

²² 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

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.

- (17) The provision in Regulation (EU) 2017/1129 concerning the EU Growth issuance prospectus will apply as of 5 March 2026, as the Commission is required to ~~develop~~**adopt** delegated acts to specify the reduced content and the standardised format and sequence of that prospectus. It is therefore appropriate to defer the application of the amendments to Regulation (EU) 2017/1129 concerning the EU Growth issuance prospectus set out in this Regulation to 5 March 2026.
- (18) Regulation (EU) 2023/1542 establishes rules concerning batteries and waste batteries. 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 ~~bearing in mind that they are entities up to three times the size of SMEs~~**[whilst aligning with Commission Recommendation 2025/1099 of 21 May 2025 concerning the definition of small mid-cap enterprise]**, i.e. **exempting SMCs** with a net turnover which should thus be less than EUR **[150]150** 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~~**available** their due diligence policy ~~only~~ only every three years instead of annually. This burden reduction should apply to all economic operators. **In between the three years, economic operators should be**

806/2014 and (EU) 2017/1129 (OJ L, 2025/1, 8.1.2025,
ELI: <http://data.europa.eu/eli/dir/2025/1/oj>).

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 SMCsin particular a change in sourcing of the raw materials covered by the battery due diligence policy or components that contain such raw materials.

- (20) The requirement in Article 20(4), point (a) of Regulation (EU) 2024/573 of the European Parliament and of the Council²³ 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 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~~**requirements** apply and to exports for which **a derogation to** an export limitation ~~exists~~**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. **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. The amendments to Regulation (EU) 2017/1129 are also based on Article 114 TFEU.**
- (20a) **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**

²³ 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>).

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,

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 as defined in [point (2) of the Annex to Commission Recommendation of 21.5.2025 **Recommendation 2025/1099** on the definition of small mid-cap enterprises—C(2025) 3500 final**];

* 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 of 21.5.2025 **Recommendation 2025/1099 of 21 May 2025** on the definition of small mid-cap enterprises —C(2025) 3500 final.’ 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 **[750]750** persons, unless **and to the extent that** the processing it carries out is likely to result in a high risk to the rights and freedoms of data subjects, within the meaning of Article 35.;’

(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) ~~No 2016/1036~~**2016/1036** is amended as follows:

(1) in Article 5-(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-cap enterprises (‘SMCs’)[**]**, through a dedicated 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.’

* 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 of 21.5.2025 on~~**Recommendation 2025/1099 of 21 May 2025 concerning** the definition of small mid-cap enterprises —~~C(2025) 3500 final.~~²
~~;~~**OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>.**²~~;~~]

(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~~**2016/1037** is amended as follows:

(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, 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.’~~

* 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 of 21.5.2025 on~~**Recommendation 2025/1099 of 21 May 2025 concerning** the definition of small mid-cap enterprises —~~C(2025) 3500 final.~~²
~~;~~**OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>.**²~~;~~]

(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 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 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or 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 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 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or 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) ~~in Article 2,~~ the following point (fa) is inserted:

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

(i) companies which, 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 [750]750, a total balance sheet not exceeding EUR [129 000 000] and an annual net turnover not exceeding EUR [150 000 000];

(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 [150]450 million in the financial year preceding the last financial year, and that are not part of a group, consisting of parent and subsidiary undertakings, **the net turnover of which group, on a consolidated basis, equals or exceeds the limit of EUR [150]450 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 three 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.’

Article 6

Amendment 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 ~~products and equipment containing~~**10 tonnes of CO₂ equivalent or more of hydrofluorocarbons or 100 tonnes of CO₂ equivalent or more of other** fluorinated greenhouse gases ~~that requires reporting under Article 26;~~**, 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 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.

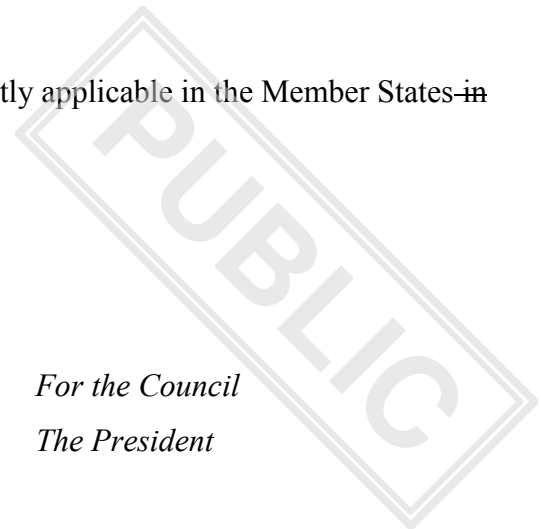
Article 4, points (2)(b) and (3), shall apply as of 5 March 2026.

This Regulation shall be binding in its entirety and directly applicable in the Member States ~~in accordance with the Treaties~~.

Done at Brussels,

For the European Parliament
The President

For the Council
The President



2025/0131 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2014/65/EU and (EU) 2022/2557 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplifying measures with a view to simplification

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 53(1); **and** Article 114 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,²⁴

~~Having regard to the opinion of the Committee of the Regions²⁵,~~

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) In the political guidelines for the European Commission's 2024-2029 term²⁶, President von der Leyen set out a plan for the Union's sustainable prosperity and competitiveness.

²⁴ OJ C , , p.

²⁵ ~~OJ C , , p.~~

²⁶ 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 agenda²⁷ also supports the competitiveness of Union enterprises by aiming to ensure that Union laws deliver on their objectives at a minimum cost. In 2023, the Commission identified the need to rationalize and simplify reporting requirements for enterprises and administrations²⁸ and committed to reduce administrative burdens by 25%.
- (3) On 12 September 2023, the Commission published the SME Relief Package²⁹, 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 definition³⁰, 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)'.
- (4) Enterprises outgrowing the SME definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy.³¹ 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 earlier³².

²⁷ 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>

²⁸ 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>

²⁹ SME Relief Package (europa.eu). See also annex 3A to this report SME relief package policy tracker.

³⁰ SMEs are defined as companies with under 250 employees, combined with an annual turnover up to 50 million euro or a balance sheet total up to 43 million - Recommendation 2003/361/EC - https://single-market-economy.ec.europa.eu/smes/sme-definition_en

³¹ Study to map, measure and portray the EU mid-cap landscape - <https://op.europa.eu/en/publication-detail/-/publication/ad5fdad5-6a33-11ed-b14f-01aa75ed71a1/language-en/format-PDF/source-277396461>

³² <https://www.esri.ie/system/files/publications/BKMNEXT429.pdf>

- (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, two**~~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~~ **adjusted. In particular, to make business easier for SMCs and reduce their administrative burden, those acts should be adapted to extend the scope of those provisions and include SMCs, while still supporting SMEs and maintaining the existing approach.**
- (6) Directive 2014/65/EU³³ of the European Parliament and of the Council³³ contains certain provisions that aim at providing simplification or mitigating measures to SMEs. More specifically, those provisions aim at alleviating administrative burden and reducing or eliminating market entry barriers or draw Member States' attention to the benefits that SMEs derive from dedicated guidance, support and assistance. Directive (EU) 2022/2557³⁴ of the European Parliament and the Council provides that Member States should support critical entities, including those that qualify as small or medium-sized enterprises, in strengthening their resilience. The Directive requires Member States to include in their resilience strategies a description of measures that are already in place at national level which aim to facilitate the implementation of the obligations of SMEs that were identified as critical entities.
- (7) To ensure consistency and legal certainty, a definition of SMCs should be introduced in those acts. While the definition of SMCs should in principle correspond to the definition in

³³ 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>eu/eli/dir/2014/65/oj).

³⁴ Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: <http://data.europa.eu/eli/dir/2022/2557/oj>).

[Commission recommendation—insert full title and reference)**Recommendation**

2025/1099 of 21 May 2025 concerning the definition of small mid-cap enterprises] and

cover enterprises that are up to [three] times the size of SMEs, it should, where appropriate, build on the definitions of SMEs that are already provided in the acts that are being amended, which were considered fitting by the legislators.

- (8) Directive 2014/65/EU identifies a subcategory of multilateral trading facilities ('MTF') known as SME growth markets. Article 33 (3), point (a), of that Directive lays down specific conditions to ensure that those trading venues effectively benefit SMEs by facilitating their access to capital and the further development of specialist markets that cater for SMEs' needs. That provision should be extended to include SMCs, to also allow those companies to access capital markets through those SME growth markets, **while still supporting SMEs and maintaining the existing approach.**
- (9) Directive (EU) 2022/2557 obliges the Member States to support critical entities that qualify as SMEs in strengthening their resilience. In doing so, Member States are to prevent excessive administrative burdens. To this purpose, Member States are to adopt strategies for enhancing the resilience of critical entities. Pursuant to Article 4 of that Directive, each strategy is to contain a description of measures that are already in place to facilitate the implementation of certain obligations by the SMEs that are identified as critical entities by the Member States. The scope of that provision should be extended to include SMCs, so that Member States should include a description of any facilitating measures for SMC in their strategies.
- (9a) **Since the objective of this Directive, namely to reduce the administrative burden for SMCs by extending to them mitigation measures that currently benefit SMEs, 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 Directive does not go beyond what is necessary in order to achieve that objective.**
- (10) Directives 2014/65/EU and (EU) 2022/2557 should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2014/65/EU

Directive 2014/65/EU is amended as follows:

- (1) in Article 4(1), the following point (13a) is inserted:

‘(13a) ‘small mid-cap enterprises’ or ‘SMCs’, for the purposes of this Directive, means companies that had an average market capitalisation equal to or higher than EUR 200 000 000 and lower than EUR [1 000 000 000] on the basis of end-year quotes for the previous three calendar years;’²

- (2) in Article 33(3), point (a) is replaced by the following:

‘(a) at least 50% of the issuers whose financial instruments are admitted to trading on the MTF are SMEs or SMCs or both, at the time when the MTF is registered as an SME growth market and in any calendar year thereafter;.’

Article 2

Amendment to Directive (EU) 2022/2557

In Article 4(2) of Directive (EU) 2022/2557, point (h) is replaced by the following:

- ‘(h) a description of measures already in place which aim to facilitate the implementation of obligations under Chapter III of this Directive by small and medium-sized enterprises within the meaning of the Annex to Commission Recommendation 2003/361/EC* and by small mid-cap enterprises within the meaning of the [Annex to Commission ~~Recommendation XX~~**Recommendation 2025/1099**]* that the Member State in question has identified as critical entities.’²

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

Article 3

Transposition

1. **By ... [18 months after the date of entry into force of this Directive],** Member States shall adopt and publish, by ~~[Note to PO: insert exact date — [...]]~~ **12 months after entry into force of this Directive]** at the latest, the laws, regulations and administrative provisions **the measures** necessary to comply with this Directive. They shall ~~forthwith~~ **communicate to immediately inform** the Commission the text of those provisions ~~thereof~~.

They shall apply those ~~provisions from [Note to PO: insert exact date — [...]]~~ **12 measures from ... [18 months and one day after the date of entry into force of this Directive]**.

When Member States adopt those ~~provisions~~ **measures**, they shall contain a reference to this Directive or **shall** be accompanied by such a reference on the occasion of their official publication. ~~Member States shall determine how~~ **The methods of making** such reference is ~~to be made~~ **shall be laid down by Member States.**

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into force

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

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President