



C/2026/29

16.1.2026

Opinion of the European Economic and Social Committee

a) Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures

(COM(2025) 501 *final* – 2025/0130 (COD))

and

b) 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

(COM(2025) 502 *final* – 2025/0131 (COD))

and

c) Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

(COM(2025) 503 *final* – 2025/0133 (COD))

and

d) Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

(COM(2025) 504 *final* – 2025/0134 (COD))

(C/2026/29)

Rapporteur: **Katrina ZARIŇA**

Co-rapporteur: **Panagiotis GKOFAS**

Advisors	Giacomo FERSINI (for the rapporteur) Dimitris BIMPAS (for the co-rapporteur)
Legislative procedure	(a) EU Law Tracker (b) EU Law Tracker (c) EU Law Tracker (d) EU Law Tracker
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Legal basis	(a) Articles 114 (1) and 192 (1) of the Treaty on the Functioning of the European Union (b) Article 114 of the Treaty on the Functioning of the European Union (c) Article 114 of the Treaty on the Functioning of the European Union (d) Article 114 of the Treaty on the Functioning of the European Union

European Commission documents	COM(2025) 501 final – 2025/0130 (COD) COM(2025) 502 final – 2025/0131 (COD) COM(2025) 503 final – 2025/0133 (COD) COM(2025) 504 final – 2025/0134 (COD) Summary
Relevant Sustainable Development Goals (SDGs)	SDGs 7, 8, 9 and 13
Section responsible	Single Market, Production and Consumption
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Outcome of vote (for/against/abstentions)	142/0/1

1. RECOMMENDATIONS

Small mid-cap enterprises and simplification measures

1.1. The Economic and Social Committee (EESC) welcomes the European Commission's efforts to simplify legislation and reduce specific administrative burdens, while ensuring that standards are maintained. The Committee takes note of the fourth Omnibus Simplification package, presented on 21 May, as an initiative that aims to enhance the competitiveness of European businesses within the newly proposed small mid-cap (SMC) category and makes proposals on digitalisation and common specifications. The Committee, however, expresses concerns regarding the inadequacy of the consultation process, the limited debate on the proposed changes, the lack of impact assessments and the lack of ex-post measurement of impact for the proposed measures.

1.2. The EESC considers the SMC category to be a small step towards more proportionate application of EU legislation, while at the same time ensuring a level playing field. Despite this, the Commission's Single Market Strategy ⁽¹⁾ acknowledges the limited scope of this category, which is estimated to include approximately 38 000 companies across the EU. The EESC invites the Commission to comprehensively map the EU business landscape by company size and according to specific Member States' characteristics. This data would be a more robust foundation for assessing the appropriateness of thresholds and their scope.

1.3. The EESC notes that a deeper analysis should have been carried out to support the Commission Recommendation and better understand the short, medium and long-term costs and benefits associated with this new category to avoid compromising the data relevance, reliability and consistency necessary for securing EU objectives on energy transition. The EESC also highlights that such a new category may have negative effects on public authorities, standards and competition conditions across different Member States and sectors.

1.4. In order to ensure that an appropriate number of companies can benefit from SMC status, the EESC asks the Commission to better adjust the definition of SMC to the realities of the different Member States. Moreover, it encourages the performance of ex-post reviews of possible reverse effects benefitting larger companies or groups of companies to avoid jeopardising the local productive capacity of countries or market concentration in certain sectors or other possible negative effects.

1.5. The EESC highlights that definitions, if not harmonised across Member States, risk increasing the fragmentation of the Single Market and uncertainty for businesses operating across borders. The Committee further notes that amendments to individual legislation may exacerbate legal complexity and hinder the achievement of regulatory coherence objectives.

⁽¹⁾ Single market strategy.

1.6. The EESC emphasises the importance of a regulatory framework that supports business growth and scaling, especially for SMEs. It therefore encourages the Commission to take more substantive measures to support the remaining 26 million SMEs across the EU to comply with legislation, at both EU and national levels. The Committee emphasises that the most effective way to ensure a fit-for-purpose regulatory framework, in line with the 'think small first' principle, is to design legislation with smaller businesses in mind from the outset and compliance instruments ⁽²⁾ that meet their needs. This proactive approach would help prevent adverse and unforeseen impact on smaller enterprises rather than relying on subsequent omnibus simplification measures to amend legal texts that have already been adopted, while maintaining an even playing field for business competitiveness and an environment open to sustainable investment.

1.7. Special attention is required to improve the core indicators of access to finance, public procurement and state aid for SMEs, and incentives for scale-up. Improving the administrative framework for issues such as second chance and early warning for businesses in distress should also be a high priority for the Commission. Constant and reliable data has the potential to improve management decisions for SMEs and the predictability of the overall economic environment.

1.8. The EESC reiterates that no simplification measure should exempt employers from obligations related to occupational health and safety, working conditions, or worker participation, environmental and sustainability criteria, which could become relevant for the further application of the new SMC category.

General Data Protection Regulation (GDPR) – Regulation (EU) 2016/679 ⁽³⁾

1.9. The EESC takes note of the proposed extension of derogations under Article 30(5) exempting SMCs, in addition to SMEs. The EESC considers the proposed changes to be positive, particularly the fact that SMCs are now exempt from the record-keeping obligation and that this exemption has been made more accessible to SMEs. However, as the other GDPR obligations, such as accountability and transparency, remain fully applicable, the suggested change to Article 30(5) could have very limited practical effect. The EESC reiterates that data protection, especially concerning workers' data, should not be weakened.

1.10. Reducing record-keeping obligations for SMEs must necessarily be accompanied by simplification of the information, accountability and transparency obligations imposed on SMEs. All these adjustments must be geared towards paying greater attention to the risk-based approach and eliminating existing legal uncertainties. Recital 13 of the GDPR, which recognises the special situation of SMEs, has hardly played any role in practice to date.

1.11. With many companies still facing disproportionate compliance requirements, including extensive record-keeping, detailed documentation of data processing activities and ongoing obligations to monitor and report on their data practices, the EESC invites the Commission to present further targeted GDPR simplification measures, including clearer guidance on what constitutes 'high-risk processing' and enhance the practical application of the GDPR's risk-based approach, as this remains a significant concern for businesses and organisations. The Committee stresses the need for more accessible and user-friendly guidance, particularly for SMEs as they often lack the resources to hire specialised legal support or to benefit from training on management of sensitive data.

1.12. The EESC highlights that simplifying the GDPR should not come at the expense of citizens, employees and consumer rights, especially concerning activities and sensitive data related to health, social screening, defence, critical raw materials and the informatics and digital sector, nor should it impede research and evidence-based policy-making.

⁽²⁾ Such as a single electronic reporting format for greater harmonisation, improved guidance for companies and compliance auditors, awareness raising on reporting benefits and cost reduction procedures, particularly at initial implementation stages.

⁽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).

Market in Financial Instruments Directive – Directive 2014/65/EU ⁽⁴⁾

1.13. The EESC welcomes the proposed changes to Article 4(1) and Article 33 to extend mitigating measures to SMCs under MiFID II.

1.14. The EESC suggests raising the SME threshold under MiFID II, currently set at a market capitalisation of EUR 200 million, to include companies in the SMC category.

Regulation on protection against dumped imports – Regulation (EU) 2016/1036 ⁽⁵⁾ and Regulation on protection against subsidised imports – Regulation (EU) 2016/1037 ⁽⁶⁾

1.15. The EESC agrees with the extension of the scope of provisions under Article 5(1)(a) of Regulation (EU) 2016/1036, whereby both SMEs and SMCs have facilitated access to the trade defence instrument.

1.16. Similarly, with regard to Regulation (EU) 2016/1037 the EESC agrees with the extension of the assistance provided for SMEs through a dedicated helpdesk to SMCs as well.

Prospectus Regulation – Regulation (EU) 2017/1129 ⁽⁷⁾

1.17. The EESC agrees on the extension of the use of an EU growth issuance prospectus, currently typically drawn up by SMEs, also to SMCs. At the same time, there is a counter-risk that SMCs will be screened by investors and banking institutions and penalised because of the simplified reporting, thus leading to poorer access to finance and comparability in markets. Critical audit and financial information relating to entities should be publicly available, making it easier for investors and households to make decisions. Core investors' data should be uploaded once and be retrievable only electronically by interested parties.

Critical Entities Resilience Directive – Directive (EU) 2022/2557 ⁽⁸⁾

1.18. The EESC welcomes the changes to Article 4 of Directive (EU) 2022/2557. However, such minor changes risk resulting in additional administrative burdens for Member States and public authorities. This is ultimately likely to result in an additional burden for businesses whenever information is not already easily available.

Fluorinated Greenhouse Gas Regulation – Regulation (EU) 2024/573 ⁽⁹⁾

1.19. The EESC is concerned that the proposed amendment to the Fluorinated Greenhouse Gas (F-gas) Regulation may create a loophole in the legislative framework dealing with highly damaging climate substances, and as an unintended consequence promote illegal trade, and miss the objectives declared by the proposal.

⁽⁴⁾ 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 (OJ L 173, 12.6.2014, p. 349).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ 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).

⁽⁸⁾ 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).

⁽⁹⁾ 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>).

Digitalisation and common specifications

1.20. The EESC takes note of the Commission's intention to encourage the use of interoperable digital solutions with the ultimate goal of lowering compliance costs. At the same time, achieving 'digital-by-default' should not impose additional costs on companies that have invested in alternative compliance solutions. The adoption of a transition period is essential, especially for some emerging sectors, but also traditional ones. The EESC stresses the need for consumers to be able to receive and analyse the digital information on certain products that might be important for their lives, daily routine, or even leisure time.

1.21. The EESC welcomes the Commission's proposal to remove references to paper format for communication between manufacturers and market surveillance authorities.

1.22. At the same time, the EESC expresses concerns regarding the proposal to introduce digital-only product instructions for end users, as both paper and digital instructions will need to be provided in parallel for a transitional period. Furthermore, the EESC is concerned about the proposed six-month period after a purchase during which end users would be entitled to request paper instructions. The regulation lacks clarity as to how this requirement would be implemented in practice.

1.23. The EESC expresses reservations about the Proposal for a Directive and a Regulation as regards the digitalisation and alignment of common specifications. The Committee highlights the importance of an open, inclusive, transparent industry-led European Standardisation System, involving all relevant stakeholders, promoting European values internally and globally. In this regard, common specifications would be likely to promote a parallel system, undermining Europe's global leadership position, and to reduce the competitiveness of European companies.

1.24. The process triggering the development and adoption of common specifications lacks clarity and is not fully transparent. The EESC highlights that common specifications should be based on a harmonised approach. It must be clearly stated that they are a fallback option which is subject to strict criteria, in order to prevent the establishment of a parallel system.

2. EXPLANATORY NOTES

Arguments in support of recommendations 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7 and 1.8

2.1. The EESC stresses the importance of consistent, relevant, proportionate and reliable data to enhance decision-making processes for SMEs and help bring about greater predictability in the overall economic environment, while supporting the EU's competitiveness and environmental objectives. The EESC should be a reference point for the Commission's simplification agenda. Optimising the quality of EU policies and legislation is at the core of the EESC's work and it therefore calls on the Commission to systematically consult organised civil society in Europe on all future simplification initiatives.

2.2. The importance of ensuring greater emphasis on SMCs was stressed in the high-level reports of Mario Draghi and Enrico Letta. Both indicated that extending SME-supporting measures to SMCs would benefit the operation of the Single Market and European competitiveness. The EESC supports the Commission's objective of addressing the difficulties of SMEs when they exceed the SME ceiling and addressing the 'cliff-edge' effect that discourages growth and limits competitiveness.

2.3. This new category recognises companies that are larger than SMEs but still face significant barriers in complying with regulatory requirements. By creating a distinct SMC category, the Commission acknowledges their potential contribution to economic growth, innovation and employment. The EESC considers this an important step toward a more nuanced and proportionate application of EU legislation, and a first step in ensuring that policies reflect the diverse structure of the European economy.

2.4. To ensure a proportionate regulatory framework, the Commission often resorts to mitigating measures and exemptions for SMEs. The EESC notes that formally exempting SMEs from complying with legislation does not, in many cases, align with the reality on the ground, as these businesses continue to be indirectly impacted by financing conditionalities legislation and reporting obligations.

Arguments in support of recommendations 1.9, 1.10, 1.11 and 1.12

2.5. The proposed exemption might offer a certain degree of relief but only for a limited number of companies. In practice, many companies that will fall under the scope of this provision are classified as engaging in high-risk processing. It therefore remains unclear how this exemption will benefit SMCs. There is therefore an urgent need to ease the documentation and information obligations, as the existing extensive obligations are disproportionate and not appropriate to the risk in the case of data-poor processing or data processing with low or normal risk.

2.6. The inconsistent interpretation of the notion of 'high-risk' processing continues to heavily impact businesses. Fragmented guidance from supervisory authorities further contributes to the existing uncertainty.

Argument in support of recommendations 1.13, 1.14, 1.15, 1.16 and 1.17

2.7. The Committee generally agrees with the Commission's proposals.

Arguments in support of recommendation 1.18

2.8. The proposal to amend the F-gas Regulation is broader than its purported purpose. A better approach would have been to exempt only exporters of used vehicles from the obligation to register, and not to offer a blanket exemption in Article 20(4)(a)(iii) to a wide array of other market participants.

2.9. The proposal creates a loophole that weakens enforcement of Article 22(3) of the F-gas Regulation and may enable illegal trade. Article 22(3) prohibits, from 12 March 2025, the export of certain equipment and products containing or relying on fluorinated gases with a GWP of 1 000 or more. However, the proposed Article 20(4)(a)(iii) only requires registration for exporters of such products explicitly containing GWP $\geq$ 1 000. This could allow exporters to mislabel items as containing GWP $<$ 1 000 to avoid registration and licensing. A more effective approach would require all exporters of products covered under Article 22(3) to register, regardless of GWP claims.

Arguments in support of recommendations 1.19, 1.20, 1.21, 1.22 and 1.23

2.10. The EESC expresses concern at the move towards purely digital product instructions for end users. This shift may exclude vulnerable groups such as older people, those with limited digital access or individuals with low digital literacy. For the sake of inclusiveness, information must remain accessible in both digital and paper formats, at least for a carefully-managed transition period.

2.11. The coexistence of digital and paper instructions during this transition may cause confusion among market participants – including manufacturers, retailers and wholesalers – regarding their responsibilities to consumers. The unclear definition of roles and responsibilities, combined with the proposed six-month period for end users to be able to request printed instructions, creates legal uncertainty and may lead to uneven enforcement across Member States. The lack of a defined implementation mechanism adds to the compliance challenges and could generate additional administrative and financial burdens, particularly for SMEs.

2.12. Finally, the six-month period for requesting paper instructions is disputable, especially for long-life products where consumers often need guidance beyond that timeframe. The EESC therefore recommends ensuring more regulatory clarity, stakeholder preparedness and consumer protection.

2.13. The introduction of common specifications could weaken Europe's global leadership and reduce the competitiveness of European companies by potentially diverging from established international frameworks such as ISO, IEC and ITU. Rather than moving away from alignment with these international standards, Europe should strengthen its collaboration with like-minded international standards development organisations (SDOs). Initiating standard-setting at international level not only aligns with the goals of the European Standardisation Strategy but also enhances the global competitiveness of European companies –a benefit that could otherwise be lost.

Brussels, 18 September 2025.

The President
of the European Economic and Social Committee
Oliver RÖPKE
