

EUROPEAN COMMISSION

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2025/0526 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions

(Text with EEA relevance)

{SWD(2025) 531 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

The chemical industry is one of the most strategically significant sectors in the European Union, forming the backbone of numerous industrial ecosystems and playing a pivotal role in innovation, employment, and sustainable growth. As the EU advances its twin transition towards climate neutrality and digital leadership, the resilience and global competitiveness of this sector have become even more essential.

Regulatory burdens are one of the two top problems named by businesses operating in the EU when it comes to the investment climate. The high-level reports of Enrico Letta¹ and Mario Draghi placed the reduction of the regulatory burdens and simplification of EU legislation among the top priorities. Overregulation is seen by more than 60% of EU companies as an obstacle to investment, with 55% of SMEs naming regulatory obstacles and the administrative burden as their greatest challenge².

In her political guidelines for the European Commission's 2024–2029 mandate³, President von der Leyen outlined a vision focused on driving sustainable prosperity and strengthening competitiveness across Europe. Central to this vision are efforts to streamline business operations and further integrate the Single Market.

Complementing this, the European Commission's better regulation agenda⁴ seeks to enhance the competitiveness of EU businesses by ensuring that legislation achieves its goals efficiently, without placing undue burdens on stakeholders.

Following those commitments, the European Commission put forward an initiative⁵ aiming at simplifying and streamlining certain requirements and procedures for chemical products laid down in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures⁶ ('CLP Regulation'), Regulation (EC) No 1223/2009 on cosmetic products⁷ and Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products⁸ identified as particularly burdensome by industry and

¹ E. Letta, Much more than a market, 2024, available at: <u>https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf</u>.

² M. Draghi, The future of European competitiveness, 2024, available at: <u>https://commission.europa.eu/topics/eu-competitiveness/draghi-report en#paragraph 47059</u>, p. 18.

³ Political guidelines for the next European Commission 2024-2029, available at:

https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en.

⁴ Better regulation: Joining forces to make better laws, COM(2021) 219 final, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:219:FIN</u>.

⁵ Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, COM(2025) 531.

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <u>http://data.europa.eu/eli/reg/2008/1272/oj</u>).

 ⁷ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59, ELI: <u>http://data.europa.eu/eli/reg/2009/1223/oj</u>).

⁸ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC)

authorities. These provisions would benefit from regulatory streamlining and modernisation, which would make chemical legislation more efficient and cost-effective for industry, while at the same time ensuring a high level of protection of human health and the environment.

With regard to the CLP Regulation, which requires economic operators to classify, label and package their hazardous chemicals appropriately before placing them on the market, the initiative is seeking to simplify the formatting rules laid down for the labelling of hazardous chemicals and make them more flexible. This includes rules on mandatory minimum font sizes and line spacing, which were identified being particularly burdensome and costly for industry⁹. It also aims to clarify rules on derogations from labelling requirements for smaller packages and rules on the labelling of fuel pumps. To alleviate the burden on businesses and improve the free circulation of substances and mixtures in the internal market without undermining the protection of human health and the environment, the initiative also seeks to reduce the scope of provisions on advertisements and distance sales that relate to products placed on the market for the general public, taking into account the fact that Regulation (EC) No 1907/2006¹⁰ ('REACH') already provides clear obligations on information flows in professional supply chains for substances and mixtures. Furthermore, it seeks to loosen obligations for advertisements of hazardous substances and mixtures by reducing the amount of information to be provided. In addition, it suggests removing the fixed six-month deadline for updating the label, while maintaining the more flexible requirement to ensure the label is updated without undue delay, as the period of six months appeared to be impossible to comply with in the complex supply chains. Finally, it proposes to broaden the use of digital labelling, allowing more pieces of information to be provided on the digital label only.

The current proposal aims to postpone the dates of application of the mandatory formatting requirements, provisions on advertisements and distance sales, obligations laying down sixmonth deadlines for the label update and rules on the labelling of fuel pumps introduced by Regulation (EU) 2024/2865¹¹ to provide legal certainty for businesses and to avoid having different application dates for the same type of obligations imposed on businesses by two amending acts to the CLP Regulation.

1.2. Consistency with existing policy provisions in the policy area

The proposal is part of a package of measures on simplification that aim to streamline certain procedures and reduce administrative burden and costs for industries to ensure a well-functioning Single Market for chemicals while ensuring the same level of protection of human health and of the environment.

No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1, ELI: <u>http://data.europa.eu/eli/reg/2019/1009/oj</u>).

⁹ Staff working document accompanying the document proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

¹¹ Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L, 2024/2865, 20.11.2024, ELI: <u>http://data.europa.eu/eli/reg/2024/2865/oj</u>).

This proposal contains provisions that are intended to reduce the burden for Member States and industry, with the aim of making the three amended pieces of legislation easier to apply and less burdensome.

1.3. Consistency with other EU policies

Under the regulatory fitness and performance programme (REFIT), the Commission ensures that its legislation is fit for purpose, is tailored to the needs of stakeholders and minimises burdens while achieving its objectives. This proposal is therefore part of the REFIT programme, aimed at reducing reporting burdens arising from EU legislation.

This proposal is part of a series of simplification packages.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

This proposal has as its legal basis Article 114 of the Treaty on the Functioning of the European Union in line with the original legal bases for the adoption of the legal acts which this proposal aims to amend.

2.2. Subsidiarity (for non-exclusive competence)

The Regulation (EU) 2024/2865 was adopted at EU level. Accordingly, amendments to this regulation need to be made at EU level.

2.3. Proportionality

The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction without lowering the protection of human health and environment.

2.4. Choice of the instrument

This proposal amends Regulation (EU) 2024/2865 adopted by ordinary legislative procedure and therefore the amendments of that Regulation need to be adopted by a regulation in accordance with the ordinary legislative procedure.

3. RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

3.1. *Ex post* evaluations/fitness checks of existing legislation

This proposal is accompanied by a Commission staff working document that includes a detailed overview of the impact of provisions of chemical legislation that are proposed to be amended. It also provides an analysis of the positive impacts of the proposed measures, based on existing data, information gathered during the various Reality Checks and written inputs received from stakeholders, also taking into account previous analyses, such as the Fitness Check of the most relevant chemicals legislation and the impact assessment for the CLP revision.

3.2. Stakeholder consultations

Various suggestions for simplifying or clarifying certain provisions of chemical legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals for the simplification of European chemical legislation¹².

On 16 May 2025, the European Commission held a Reality Check, aiming to gather practical feedback on the revised CLP Regulation. It was held online and draw over 570 participants from industry, consumer and environmental groups, legal practitioners, and national authorities. The event focused on identifying opportunities for simplification following the adoption of Regulation (EU) 2024/2865, while keeping the same level of protection of human health and of the environment. Stakeholders were invited to share concrete experiences and proposals on how to make the new rules more workable, particularly in operational and multilingual contexts.

Among various suggestions of stakeholders, strong calls to 'stop the clock' on implementation of certain provisions of Regulation 2024/2865 that create excessive administrative burden were repeated throughout the discussion. Stakeholders highlighted the need to ensure legal clarity for businesses until any Commission proposal for the revision of those rules is agreed by co-legislators

3.3. Collection and use of expertise

Different suggestions for clarifying certain provisions of chemical legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals for simplification of European chemical legislation. Furthermore, in response to the Reality Checks mentioned above, the Commission received more than 150 detailed position papers from stakeholders, supporting the views expressed during the event and providing additional suggestions, data and costs estimates. Detailed summaries of these consultation activities and the input received are attached to the staff working document accompanying this proposal.

3.4. Impact assessment

Given the urgent need to reduce administrative burden and excessive costs for businesses and the lack of policy options, it has not been possible to prepare a full impact assessment.

However, following better regulation principles, this proposal is accompanied by a Commission staff working document that includes an analysis of the proposed measures, based on existing data, inputs received from stakeholders and previous analyses, such as the Fitness Check of the most relevant chemicals legislation and the impact assessment for the CLP revision.

3.5. Regulatory fitness and simplification

This proposal is part of the European Commission's commitment to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU. The proposal aims to provide legal clarity for businesses and ensure that rules imposed by different EU acts to the same type of obligations are consistently taking effect from the same date.

¹² For example: Cefic, Towards a simpler, faster and more supportive legislative framework to help restore Europe's competitiveness, p. 2, available at <u>https://cefic.org/resources/cefic-views-towards-a-simpler-faster-and-more-supportive-legislative-framework-to-help-restore-europes-competitiveness/;</u> VCI, Omnibus proposal, p. 4, available at <u>https://www.vci.de/ergaenzende-downloads/vci-sectorial-omnibus-chemical-industry.pdf;</u> Business Europe, Reducing regulatory burden to restore EU's competitive edge, p. 12, available at: <u>https://www.businesseurope.eu/wp-content/uploads/2025/02/2025-01-22 businesseurope mapping of regulatory burden-d55-1.pdf</u>.

3.6. Fundamental rights

The proposal respects the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union¹³ and adheres to the principles recognised therein. The reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. At the same time, the proposal seeks to ensure a high level of protection of human health and of the environment.

4. **BUDGETARY IMPLICATIONS**

This initiative will not imply any additional costs for the Commission.

5. OTHER ELEMENTS

5.1. Implementation plans and monitoring, evaluation and reporting arrangements

The Commission will monitor the implementation and application of new provisions and compliance with them. This proposal does not require an implementation plan.

5.2. Detailed explanation of the specific provisions of the proposal

The proposal amends Article 2 of the Regulation (EU) 2024/2865 that sets the dates of entry into force and entry into application of the provisions of that Regulation.

Provisions amending Article 30 laying down timelines for relabelling, Article 48 on advertisements, Article 48a on distance sales and provisions on labelling of fuel pumps in Annex II are removed from the list of provisions that will apply as of 1 July 2026 as outlined in paragraph 2 of Article 2.

Similarly, provisions amending Article 31(3) and relevant sections of Annex I on mandatory formatting requirements are removed from the list of provisions that will apply as of 1 January 2027 as outlined in paragraph 3 of Article 2.

A new paragraph 3a is inserted in Article 2 laying down a new application date of 1 January 2028 for all abovementioned provisions.

Consequently, the provisions that are subject to extended deferred application dates are removed from the provision that allows the voluntary application of the provisions of Regulation (EU) 2024/2865 before their entry into application in paragraphs 4 and 5 of Article 2, and moved to a new paragraph 5a, aligning the date of the application of that provision with the new deferred application date.

The application dates of other provisions of Regulation (EU) 2024/2865 remain unchanged.

¹³

OJ C 326, 26.10.2012, p. 391, ELI: http://data.europa.eu/eli/treaty/char 2012/oj.

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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 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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council² contains certain requirements as regards the classification, labelling, and packaging of hazardous substances and mixtures. That Regulation was amended by Regulation (EU) 2024/2865 of the European Parliament and of the Council³, which *inter alia* introduced specific rules on the formatting of labels, deadlines for relabelling in case of classification changes, information requirements for advertisements and distance sales offers and labelling requirements for fuelling stations. Article 2 of Regulation (EU) 2024/2865 deferred the date of application of those rules.
- (2) The 2024 Draghi report⁴ highlighted that the number and the complexity of rules risk limiting the room for manoeuvre for Union undertakings and preventing them from remaining competitive. A detailed analysis of Regulation (EC) No 1272/2008⁵ also

¹ OJ C [...], [...], p. [...]

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <u>http://data.europa.eu/eli/reg/2008/1272/oj</u>).

³ Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L, 2024/2865, 20.11.2024, ELI: <u>http://data.europa.eu/eli/reg/2024/2865/oj</u>).

⁴ 2024 report by Mario Draghi on the future of European competitiveness: <u>https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059</u>

⁵ Detailed analysis of costs associated with new formatting requirements is provided in the Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as

pointed to excessive administrative burden and costs associated with requirements introduced by Regulation (EU) 2024/2865. Based on those findings, the Commission has laid down a proposal to simplify certain requirements and procedures for chemical products⁶. That proposal is, *inter alia*, intended to better balance, on the one hand, the need for label information to be clearly understood by consumers and, on the other hand, the need to reduce market barriers and administrative burden for industry⁷. In light of that proposal, it is necessary to further defer the obligations on label formatting, advertisements, distance sales offers and relabelling that were introduced by Regulation (EU) 2024/2865. Such further deferral would enable economic operators to prepare for changes to the formatting and labelling requirements, as well as new information requirements for advertisements and distance sales offers envisaged in the Commission's proposal.

- (3) Regulation (EU) 2024/2865 introduced specific provisions for the labelling of fuels supplied at fuelling stations. However, certain requirements, including the requirement to indicate the supplier, the nominal quantity, and the unique formula identifier, appeared to be impractical and costly for undertakings, without bringing benefits to the protection of human health and the environment. For that reason, the Commission proposal as regards simplification of certain requirements and procedures for chemical products intends to modify those requirements to make them more apt by removing unnecessary and burdensome labelling requirements. In light of those anticipated modifications, it is appropriate to further defer the date of application of those requirements.
- (4) Article 2(4) and (5) of Regulation (EU) 2024/2865 contain transitional provisions that enable undertakings to apply the provisions introduced by that Regulation before the dates of their application on a voluntary basis. To ensure consistency with the longer deferral and to provide legal clarity for economic operators, it is necessary to amend the dates of application of those transitional provisions on mandatory formatting requirements, relabelling, advertisements, distance offers and labelling of fuelling stations and align those dates with the extended deferred applicability dates.
- (5) To ensure a high level of protection of human health and the environment, the application dates of other provisions of Regulation (EU) 2024/2865 should remain unchanged.
- (6) Regulation (EU) 2024/2865 should therefore be amended accordingly,

https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

⁶ Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, COM(2025) 531.

⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, a strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2024/2865

Article 2 of Regulation (EU) 2024/2865 is amended as follows:

(1) paragraph 2 is replaced by the following:

⁶2. Article 1, point (3)(b), Article 1, points (4) to (7), Article 1, point (12)(a), Article 1, point (13), Article 1, points (15)(a) and (b), Article 1, points (17), (18), (22) and (23), points (4), (8), (10) and (11) of Annex I and point (1) of Annex II shall apply from 1 July 2026.';

(2) paragraph 3 is replaced by the following:

'3. Article 1, points (1) and (9), Article 1, points (24)(b) and (d) and Annex IV shall apply from 1 January 2027';

(3) the following paragraph 3a is added:

'3a. Article 1, points (14), (15)(c), (26) and (27), points (2) and (3) of Annex I and point (2) of Annex II shall apply from 1 January 2028';

(4) paragraph 4 is replaced by the following:

'4. By way of derogation from Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 10, Article 25(3), Articles 29, Article 31(1), Article 35, Article 40(1) and (2), Article 42(1), third subparagraph of Regulation (EC) No 1272/2008, section 1.2.1, section 1.5.1.2 and section 1.5.2.4.1 of Annex I and Part 3 of Annex II to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may until 30 June 2026 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (4) to (7), Article 1, point (12)(a), Article 1, point (13), Article 1, point (15)(a) and (b), Article 1, points (18) and (22), Article 1, point (23)(a) and points (4), (8) and (10) of Annex I and point (1) of Annex II to this Regulation.';

(5) paragraph 5 is replaced by the following:

'5. By way of derogation from Article 1(1), 18(3)(b), Article 45(1) and (3) of Regulation (EC) No 1272/2008 and part A, section 1 of Annex VIII, part A, section 2.1, of Annex VIII, part A, the first subparagraph of section 2.4 of Annex VIII, Part B, section 1 of Annex VIII, Part B, the third paragraph of section 3.1 of Annex VIII, Part B, section 3.6 of Annex VIII, Part B, the first row of Table 3 of section 3.7 of Annex VIII, Part B, the first paragraph of section 4.1 of Annex VIII, Part C, sections 1.2 and 1.4 of Annex VIII, and Part D, sections 1, 2 and 3 of Annex VIII to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may until 31 December 2026 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (1) and (9), Article 1, point (24)(b) and (d) of this Regulation and Annex IV to this Regulation.';

(6) the following paragraph is added:

'5a. By way of derogation from Article 30, Article 31(3), Article 48 of Regulation (EC) No 1272/2008, section 1.2.1 of Annex I and Part 5 of Annex II to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may

until 31 December 2027 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (14), (15)(c) and (26), points (2) and (3) of Annex I and point (2) of Annex II to this Regulation.'.

Article 2

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 all Member States. Done at Strasbourg,

For the European Parliament The President [...] For the Council The President [...]