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**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 of the
European Parliament and of the Council, as regards simplification of certain
requirements and procedures for chemical products**

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A. INTRODUCTION

The chemical sector holds a critical position in the European Union's economic architecture, forming the backbone of numerous industrial ecosystems and playing a pivotal role in innovation, employment, and sustainable growth. In the context of Europe's twin transition towards climate neutrality and digital transformation, maintaining a robust and competitive chemicals industry is essential for safeguarding the EU's strategic autonomy and global economic standing.

Regulatory burdens are one of the two top problems named by businesses operating in the EU when it comes to the investment climate. The analysis provided by the high-level reports of Enrico Letta¹ and Mario Draghi put 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 flagging regulatory obstacles and the administrative burden as their greatest challenge².

The European Commission's Better regulation agenda³ seeks to enhance the competitiveness of EU businesses by ensuring that legislation achieves its goals efficiently, without placing undue burdens on stakeholders.

President von der Leyen in her political guidelines for the European Commission's 2024–2029 mandate⁴ outlined a vision focused on driving sustainable prosperity and strengthening competitiveness across Europe, emphasising the need to make business easier and faster. Central to this vision are efforts to streamline business operations and further integrate the Single Market. To that end, each Commissioner is tasked with focusing on reducing administrative burdens and simplifying implementation and to stress-test the EU acquis. This is operationalised in the mission letters to all Members of the College, asking them to ensure that existing rules are fit-for-purpose and to focus on reducing administrative burdens and simplifying legislation.

The political commitment to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU is further reaffirmed in the Competitiveness Compass for the EU⁵. The Compass identifies the policy changes that are needed for the EU to step up to the new realities and develop novel ways of working together to increase the speed and quality of decision-making. A pivotal point to achieve this will be the simplification of the regulatory environment and the reduction of burden. The Compass, therefore, sets the target

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

² M. Draghi, The future of European competitiveness, 2024, available at: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059, p. 18.

³ 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>.

⁴ Political Guidelines for the next European Commission 2024-2029, available at: https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en.

⁵ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM (2025) 30 final: A Competitiveness Compass for the EU, available at https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass_en.

of cutting administrative burden by at least 25% for all companies and at least 35% for small and medium-sized enterprises (SMEs) without undermining the respective policy goals.

The Single Market Strategy further reiterated the commitment for more simplification and readiness for immediate actions to reduce red tape and make things simple. The Strategy highlighted the aim for simplification leading to lower costs, higher productivity, and a better functioning of the Single Market, while maintaining the ambition on the climate and sustainability, and social responsibilities. It also underlined the need to ensure that rules on labelling balance the need to be clearly understood by consumers with the need to reduce market barriers and burden for industry⁶.

Following those commitments, this initiative aims at simplifying and streamlining certain requirements and procedures under Regulation (EC) No 1272/2008⁷ on classification, labelling and packaging of substances and mixtures, Regulation (EC) No 1223/2009 on cosmetic products and Regulation (EU) 2019/1009⁸ laying down rules on the making available on the market of EU fertilising products, which were identified as particularly burdensome by industry and authorities. These provisions would benefit from regulatory streamlining and modernisation, that will improve the effectiveness of chemical legislation, while at the same time increasing the cost-effectiveness and overall competitiveness of the EU chemicals industry and related sectors.

A more predictable and less burdensome regulatory landscape is indispensable for enhancing the chemicals sector's competitiveness and facilitating its green transition. A smarter approach to regulation – one that removes redundant requirements, avoids duplication, and ensures consistency – will help unlock the full potential of the chemical industry as a driver of sustainable European prosperity.

B. THE EU CHEMICAL LEGISLATION

The EU has a comprehensive legal framework on chemical substances, on their own and in mixtures, as well as on products containing chemical substances and mixtures. Together, these rules aim to ensure the safety of EU citizens and the protection of the environment, while enabling the free movement of chemical substances and products on the internal market. The pieces of chemical legislation targeted by this initiative are briefly presented in this chapter.

⁶ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM (2025) 500 final: The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, available at: https://single-market-economy.ec.europa.eu/publications/single-market-our-european-home-market-uncertain-world_en.

⁷ 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.

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

1. Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Hazardous Chemicals (CLP)

The objective of Regulation (EC) No 1272/2008 (the CLP regulation) is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and certain articles. The CLP regulation implements in the EU the United Nations' Globally Harmonised System (GHS) and establishes legally binding hazard identification and classification rules. It also contains detailed labelling and packaging rules. Together with other EU legislation, it sets up rules to ensure that hazardous chemicals are safe when placed on the market.

The CLP regulation requires economic operators to classify, label and package their hazardous chemicals appropriately before placing them on the market, and contains rules in this regard. A classification can be harmonised and applied across the EU to all duty holders. Such classification is adopted at EU level according to a regulatory procedure. Where harmonised classification does not exist, economic operators have to assess and classify their hazardous chemicals according to available data ('self-classification'). The hazard classification determines, amongst others, the appropriate labelling and packaging of the chemicals in the supply chain, in particular to protect workers, consumers and the environment.

In addition, the CLP regulation lays down notification requirements for economic operators. It requires manufacturers and importers to submit classification and labelling information for the hazardous substances they are placing on the market to the Classification and Labelling Inventory managed by European Chemicals Agency (ECHA), which then publishes certain information submitted to the inventory. Furthermore, CLP regulation lays down harmonised requirements for submission of the information related to emergency health response and preventative measures, that duty holders placing hazardous mixtures on the market should submit to the appointed bodies in the Member States (so-called 'Poison centres notifications').

The CLP regulation was recently amended by Regulation (EU) 2024/2865⁹, which introduced numerous legislative changes aiming at improving communication of hazard-related information to users of chemicals, ensuring adequate classification rules as well as addressing identified legal gaps and uncertainties.

2. Regulation (EC) No 1223/2009 on cosmetic products (CPR)

The CPR, adopted by the European Parliament and the Council on 30 November 2009, replaced the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

The CPR applies to all cosmetic products made available on the EU market either manufactured in the EU or entering the EU market from third countries. It comprehensively harmonises the human health protection rules in the Union to achieve an internal market for cosmetic products.

⁹ 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: <http://data.europa.eu/eli/reg/2024/2865/oj>.

The CPR impacts manufacturers, importers, distributors, and consumers by ensuring that all cosmetic products in the EU are safe for use and that the rules for selling them are consistent across countries. The key aspects of the CPR include:

- Upholding the unconditional free movement in the EU of cosmetic products complying with the CPR by requiring the member states not to refuse, prohibit or restrict the making such cosmetic products available on the EU market.
- The almost automatic prohibition of the ingredient or substance from the use in cosmetic products where such an ingredient/substance had received a harmonised classification as a carcinogenic, mutagenic and reprotoxic (CMR) substance unless the request for derogation was introduced, and the substances was assessed and found safe and meets all the other derogation criteria.
- The obligation to pre-notify cosmetic products containing nanomaterials in the CPNP before such products are placed on the EU market.
- An authorisation of substances used as colorants, preservatives or UV filters.
- The obligation to notify the EU's cosmetics database, the CPNP, for each cosmetic product placed on the market.
- The introduction of a harmonized system for the safety assessment of cosmetic products, which must be carried out by a qualified person and consider the product's formula, packaging, and labelling.
- The ban on animal testing for finished cosmetic products and ingredients.
- The requirement for a Responsible Person (RP) based in the EU to oversee the compliance of cosmetic products.
- The need for a Product Information File (PIF) for each cosmetic product, which must contain information about the product's safety, efficacy, and quality, as well as the results of the safety assessment.
- The requirement for labelling and packaging compliance, including the list of ingredients, instructions for use, and any necessary warnings or precautions.

From 2013 (when the CPR started to apply in its entirety) until 2025, more than 50 amendments¹⁰ of the Annexes (I-VI) to the Regulation have taken place to ensure consumer safety, harmonise market rules and promote a level playing field within the cosmetics sector. In particular, Annexes II through VI of the CPR establish lists of substances that are regulated for use in cosmetic products within the European Union¹¹.

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20240424>

¹¹ Annex II (prohibited substances) contains a list of substances that are strictly prohibited in cosmetic products. These are materials identified as hazardous to human health and should not be used in any cosmetic formulations. Annex III (restricted substances) includes substances that are permitted in cosmetics under specific conditions or restrictions. It defines maximum allowable concentrations, limitations on product types, or specific labelling requirements, etc. Annex IV (permitted colorants) lists colorants that are approved for use in cosmetic products, specifying the types of products in which they may be used and any associated restrictions or conditions. Annex V (permitted preservatives) details preservatives that can be used in cosmetics to ensure product stability and safety by preventing microbial growth. Conditions for their use, including concentrations and product types, are specified. Annex VI (permitted UV filters) provides a list of UV filters approved for use in sunscreen and other cosmetics. It specifies the allowable concentrations and the conditions under which these filters may be safely included in products. These annexes serve to ensure that cosmetic products marketed in the EU meet strict safety standards and do not pose risks to consumer health.

3. Regulation (EU) 2019/1009 on EU Fertilising Products (FPR)

The Fertilising Products Regulation was adopted by the European Parliament and the Council in June 2019 and entered into application in July 2022. The general objective of the measure was to incentivise large scale fertilising products production in the EU from domestic organic or secondary raw materials by creating a regulatory framework granting such fertilisers access to the internal market and to address the well-recognised issue of soil contamination by contaminants present in fertilising products. In addition, it fundamentally changed the rules for plant biostimulants, which were until then regulated under the Plant Protection Products Regulation¹², by defining them based on their function rather than their ingredients.

Following in the tradition of its predecessor, the FPR does not fully harmonise fertilising products on the EU market, but leaves it to the manufacturer to choose if to follow the EU rules (and have the free movement in the internal market guaranteed) or to follow national rules (and rely on mutual recognition in case of sales in other Member States). This flexible framework allows Member States to maintain national rules adapted to their specific situation, applicable to non-harmonised/national fertilising products.

The FPR sets out harmonisation rules for seven categories of EU fertilising products (fertilisers, liming materials, soil improvers, growing media, inhibitors, plant biostimulants and fertilising product blends). It also defines the component materials which may be used in the production of EU fertilising products, the labelling requirements and conformity assessment procedures applicable. The FPR is based on the New Legislative Framework¹³ (NLF).

The Commission is empowered to adopt delegated acts to amend Annexes I-IV to the Regulation, in order to adapt them to technical and scientific progress, to facilitate internal market access and free movement for EU fertilising products and to add certain additional materials. Since the adoption of the FPR in 2019, the Commission adopted several delegated acts adding new component material categories or amending the existing ones, to further build the circular economy in the fertilising product sector¹⁴.

C. MAIN ISSUES AT STAKE AND THE WAYS TO ADDRESS THEM

High product standards in the EU are crucial for the protection of the EU citizens and the environment and a fair and sustainable economy. However, as also underlined in the Draghi report¹⁵, the increasing number and complexity of rules risks limiting EU businesses' room of

¹² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; OJ L 309, 24.11.2009, p. 1; ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

¹³ [New legislative framework - European Commission](#)

¹⁴ See current [consolidated version](#).

¹⁵ M. Draghi, The future of European competitiveness, 2024, available at: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059.

manoeuvre, preventing them from flourishing and from remaining competitive, especially in light of fundamental transitions, economic instability and geopolitical tensions.

This balancing act between ensuring the safety of products and allowing businesses to thrive is also a reality for the EU's chemical sector and related sectors which are characterised by proactive and innovative businesses but also by a challenging regulatory and economic environment.

Against this background, the Commission has organised Reality Checks in May 2025 to identify the most significant burdens and administrative obstacles under Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and (EU) 2019/1009 and explore the potential for simplification and burden reduction. In addition, the European Commission received a significant number of letters and detailed analyses from all types of stakeholders (from companies, consumer and business associations, Non-Governmental Organisations, chambers of commerce, Member States' national administrations).

The following sub-sections outline the main issues identified and provide an overview of the proposed amendments to the legal texts to address these issues and to streamline and ease compliance with the three pieces of EU chemical legislation. These sub-sections also present associated estimated cost savings for companies.

1. Issues and proposed amendments to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Hazardous Chemicals (CLP)

The Commission received various suggestions to simplify, clarify certain provisions introduced into the CLP by the Regulation (EU) 2024/2865 to remove the excessive administrative burden stemming from these provisions. These have been detailed in stakeholders' proposals for simplification of European chemical legislation¹⁶, from the Reality Check on the possible simplification of chemicals legislation, that took place on 16 May 2025 and numerous position papers received before and after the event. The Reality Check aimed at collecting the experiences of stakeholders (businesses, practitioners applying EU law, consumer and business associations as well as competent authorities) on the impact the CLP rules have on their activities, identifying any unintended consequences of the newly introduced rules, and exploring possibilities for simplification, cost-savings and reduction of the administrative burdens. 577 participants in total attended the event, and over 150 position papers with additional information were received as a follow-up. Overall, the Commission received information from industry, both from large companies and SMEs, from some non-governmental organisations and from some competent authorities of Member States. The Commission has analysed the wealth of additional data and compared to data received during the CLP revision between 2020 and 2023, bearing in mind the

¹⁶ For example: Cefic, Towards a simpler, faster and more supportive legislative framework to help restore Europe's competitiveness, p. 2, available at <https://cefic.org/resources/cefic-views-towards-a-simpler-faster-and-more-supportive-legislative-framework-to-help-restore-europes-competitiveness/>; VCI, Omnibus proposal, p. 4, available at <https://www.vci.de/ergaenzende-downloads/vci-sectorial-omnibus-chemical-industry.pdf>; Business Europe, Reducing regulatory burden to restore EU's competitive edge, p. 12, available at: https://www.buressurope.eu/wp-content/uploads/2025/02/2025-01-22_buressurope_mapping_of_regulatory_burden-d55-1.pdf.

objectives of the CLP to ensure a high level of protection of human health and the environment on one hand and the free movement of substances and mixtures on another hand.

a. Mandatory formatting requirements, including minimum font sizes and line spacing for the labelling of hazardous chemicals introduced by the Regulation 2024/2865

Regulation (EU) 2024/2865 laid down minimum requirements for the label formatting, as follows, in addition to existing rules for minimum label and pictogram sizes:

Minimum dimensions of labels and pictograms and minimum font size¹⁷

<i>Capacity of the package</i>	<i>Dimensions of the label (in millimetres) for the information required by Article 17</i>	<i>Dimensions of each pictogram (in millimetres)</i>	<i>Minimum font size (x-height in millimetres)</i>
<i>Not exceeding 0,5 litres</i>	<i>If possible, at least 52×74</i>	<i>Not smaller than 10×10 If possible, at least 16×16</i>	<i>1,2</i>
<i>Greater than 0,5 litres but not exceeding 3 litres</i>			<i>1,4</i>
<i>Greater than 3 litres but not exceeding 50 litres</i>	<i>At least 74×105</i>	<i>At least 23×23</i>	<i>1,8</i>
<i>Greater than 50 litres but not exceeding 500 litres</i>	<i>At least 105×148</i>	<i>At least 32×32</i>	<i>2,0</i>
<i>Greater than 500 litres</i>	<i>At least 148×210</i>	<i>At least 46×46</i>	<i>2,0</i>

In addition, section 1.2.1.5 in Annex I to the CLP regulation provides that:

‘The text on the label shall have the following characteristics:

- (a) printed in black on a white background;*
- (b) the distance between two lines shall be at least 120 % of the font size;*
- (c) a single font that is easily legible and without serifs shall be used;*
- (d) the letter spacing shall be appropriate for the selected font to be easily legible.*

¹⁷ See table 1.3 in section 1.2.1.4 in Annex I to the Regulation (EC) No 1272/2008 as amended by Regulation 2024/2865.

For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains easily legible, where it is deemed important to place the most critical statement, such as a hazard statement or EUH statement, and where the outer packaging meets the requirements of Article 17.'

These changes followed up from the Fitness Check¹⁸ which identified labelling of hazardous substances and mixtures as an issue. The Fitness Check noted that labels for those substances and mixtures were overcrowded and difficult to read. 'Labelling space on chemical products is usually limited, while at the same time many pieces of legislation in addition to the CLP require different labelling elements'. The requirements are so extensive that 'labels can become overloaded with information e.g. too much text, too long and not meaningful chemical names to non-professional users making it difficult for downstream users and consumers to focus on the essential hazard information, thus reducing the effectiveness of hazard communication. Too much text included on labels, especially when this is required to appear in multiple languages, thus restricting the understandability of the information'¹⁹. Too much text is included on labels, especially when this is required to appear in multiple languages (in countries with more than one official language), thus restricting the understandability of the information. The Fitness Check suggested that (partially) digitalised labels could improve the situation: 'There are inefficiencies in relation to consumer labelling under the CLP regulation [...] in terms of proportionality of costs for companies to change some aspects of labelling and the effectiveness of the communication. In addition, the length and amount of hazard and precautionary statements that need to be printed on some labels lead some consumers to become inured to the hazards that mixtures (mainly) pose, reducing the ability of the hazard communication to deliver its intended benefits. The existing provisions and requirements do not take into account opportunities offered by digitalisation which could help reaching consumers more effectively, increase the amount of available information e.g. via printing Q-R codes to be scanned with a mobile phone, and at the same time reduce costs related to labelling'²⁰.

The CLP regulation, before its amendment by Regulation (EU) 2024/2865, required label elements to 'stand out clearly from the background and they shall be of such a size and be spaced in such a way as to be easily read'. In its Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, ECHA recommends in section 5.2 a minimum font size of 1.2mm ('*x-height*') as a reference. It further states that 'a supplier may decide whether to increase the letter size with the overall volume of the packaging and dimensions of the label, or [...] a supplier may decide whether to have larger letter sizes for certain label elements while others are presented in smaller

¹⁸ Commission Staff Working Document - Fitness check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Accompanying the document Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses, SWD(2019) 199 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52019SC0199>.

¹⁹ See Commission SWD Fitness Check p. 53.

²⁰ See Commission SWD Fitness Check p. 280.

letters'²¹. ECHA's guidance gives flexibility on the minimum font size, depending on the label elements, the volume of the packaging, the size of the label.

The Impact Assessment Report²² for the targeted revision of the CLP Regulation identified the need to improve communication of hazard-related information, including the legibility and readability of CLP labels. It noted 'that consumers and workers are often faced with unattractive labels with too much text in too small font size, in particular in relation to multilingual labels restricts the comprehensibility of the information displayed'²³. Moreover 'the unspecific rules also hamper enforcement efforts as different interpretations are possible e.g. of what "size and spacing as to be easily read" actually means. Despite the existing guidance, the problem persists, as the guidance is not legally binding. Without further action, the problem will persist or even increase'²⁴.

The Impact Assessment analysed 'the possibility to amend Section 1.2 Annex I to introduce general provisions for a minimum font size and other provisions to improve the readability of the label, based on current ECHA guidance'²⁵ in conjunction with additional flexibility to use fold-out labels. The SWD noted that formatting requirements would come together with allowing a wider use of fold-out labels. However, they would also apply to standard labels'²⁶.

The Impact Assessment acknowledged that 'adjusting to a new labelling format would incur initial conduct of business cost but the changes are not a stand-alone measure and costs would occur anyway as a result of other changes. Potential cost could also be compensated by taking advantage of the wider possibilities to use fold-out labels. It is not likely that [minimum font requirements] would have an impact on the market size.'

The intelligence collected and evaluated during the Impact assessment did not identify significant issue with setting minimum font requirements based on the recommendations of ECHA's guidance and in the absence of specific requirements to analyse. One can infer from the report that most hazardous substances and mixtures are correctly labelled in accordance with ECHA's guidance, using 1.2mm as a reference for minimum size of letters. The Impact assessment further noted that 'SMEs did not express a particular opinion on [minimum typographic requirements] and concluded that prices of consumer goods are unlikely to be significantly influenced by [these changes]'

²¹ Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, p. 45. https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65.

²² Commission Staff Working Document Impact Assessment Report Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, SWD(2022) 435 final, available at: https://environment.ec.europa.eu/publications/proposal-clp-revision_en.

²³ Impact Assessment for the Revision of CLP, p. 347.

²⁴ Impact Assessment for the Revision of CLP, p. 347.

²⁵ Impact Assessment for the Revision of CLP, p. 348.

²⁶ Impact Assessment for the Revision of CLP, p. 348.

As a whole, it concluded that the few negative impacts (e.g. fold-out labels being more expensive than regular 2D ones and their design more difficult) were offset by recurrent savings from labelling simplification (€ 59 million).

Overall costs and benefits for changes to the CLP communication of hazards estimated in Impact Assessment Report 2022

Description of changes	Costs (recurrent or one-off ones) [target]	Benefits (recurrent or one-off ones) [target]
Non-labelling of fuel and small items (e.g., pens)	€ 8.61 million (recurrent) [indirect for consumers]	€ 9.91 million (recurrent) [direct for industry]
Flexibility for fold-out labels		€ 39.50 million (recurrent) [direct for industry]

Regulation (EU) 2024/2865 introduced new formatting requirements, including minimum font sizes for different sizes of packaging, minimum distance between lines and colour of the text of the labels. The new rules also introduced a possibility to use fold-out labels as regular label²⁷, providing more flexibility to stakeholders to choose the type of labels. Existing derogations for very small packaging (below 10mL) were further extended, but still limited in terms of eligible hazardous substances or mixtures. Furthermore, the labelling requirements of fuels at service stations was softened. Other derogations for small packaging (less than 125mL) remained untouched.

Stakeholder views

A large majority of the commenting stakeholders from industry raised strong concerns about costs and administrative burden triggered by the new rules of label formatting laid down in Regulation (EU) 2024/2865 as the rules lack flexibility. The stakeholders highlighted that the future formatting requirements have long-lasting consequences impacting the majority of their portfolio, such as a forced move to fold-out labels or a multiplication of stock-keeping units due to a change to monolingual 2D-labels, because of fewer languages fitting on a 2D label²⁸. They called first for a pause in implementing the future formatting rules, followed by a revision of these rules. The former would give enough certainty and an early signal to industry to also pause their investments in updating their labels, processes and production or logistic lines. Moreover, industry called for flexibility in ensuring that labels are readable, considering the diversity of products, audience and business models. According to the majority of input from industry, the last column of table 1.3 in section 1.2.1.4 and section 1.2.1.5 in Annex I to the CLP regulation should be deleted. Provisions in Article 31 should be complemented by more detailed guidance than the current guidelines, to be developed by ECHA, in order to remediate to the issue identified in the Fitness Check. Some

²⁷ Previously fold-out labels could be used by derogation only, in exceptional cases.

²⁸ Some companies even flagged that fewer languages would fit on the type of fold-out labels they currently use, leading as well to an increase number of SKUs.

companies indicated that they would alternatively welcome an alignment with the Food Information to Consumers (FIC) Regulation²⁹, where the font size is 1.2 mm with a possibility to use 0.9 mm for smaller labels and packaging. Some Member States showed flexibility to softening the future rules on label formatting without reducing the level of protection of human health and of the environment. Other MSs, joined by NGOs, called for sticking to the agreed rolling-out of the provisions of the Regulation (EU) 2024/2865 as industry still has time to adjust and the current requirements would still be the best option to ensure legible labels.

As a starting point, stakeholders from industry, including SMEs, commented that they have more labels than identified in the Impact Assessment Report (up to 1000 or more, some already multilingual ones for paint or detergent SME manufacturers compared to between 200 and 300 monolingual labels for detergent SMEs and between 2250 and 3750 ones for large companies in the CLP IA³⁰). Those labels already contain multiple languages in order to place products in multilingual countries such as Belgium or Finland, which request more than one language on CLP labels, but also because of cost-saving synergies in the single market and outside the EU/EEA (up to 31 languages per label for some large lubricant companies). The latter minimises the need of stock-keeping units (SKU), streamlining label design and production, labelling, logistic, market supply across MS and limiting waste (see table below). The choice of grouping or not languages on labels belongs to industry as long as it stays within the framework provided by the CLP regulation.

Companies that described their on-going processes or strategies to align with the future labelling rules confirmed that the large majority of their labels³¹ need to be redesigned (between 13% to 100%, with an estimated average between 80 and 95%), as identified by the CLP IA. However, they stressed out that the number of languages fitting on a label will be negatively impacted, forcing them to move to fold-out labels, or to reduce the number of languages per label and increasing the number of SKUs. In some extreme cases, companies highlighted technical difficulties to develop fold-out labels big enough (i.e. with 7 to 11 pages) to contain their SKU number unchanged. This contrasts with the evidence reported in the CLP IA, where more flexibility on fold-out labels will only provide an option to use them. ‘The use of a fold-out label versus a standard label would be a voluntary business choice of the relevant supplier. It is likely that suppliers will only opt for a fold-out label where it actually is economically beneficial for them’³².

²⁹ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18.

³⁰ CLP IA, table 98 p. 342. Savings were identified for the detergent industry, considering a range of 40-60 products and up to 5 languages per SME and 150-250 products and up to 15 languages for large companies.

³¹ Many companies reported that 100% of their labels have to be redesigned. Some national sector organisations reported 95% of the labels would undergo the redesign process. The lowest rate reported was 13% for an SME manufacturing lubricants.

³² CLP IA, p 340

The input from industry also highlighted that such decisions on labelling strategies are strongly connected to other costs (logistics, in-house/outsourcing of labels, storage capacities, SKU, labelling robots/printers and price difference between labels) and *in fine* to the business model of companies. In addition, some of the costs incurred would be recurrent. The CLP IA considered in 2022, based on the input received at that time, that font requirements and flexibility to use fold-out labels would only bear ‘initial conduct of business costs’.

	Impact Assessment Report	Reality Check
Consumers	Increased legibility/readability (+)	Increased legibility/readability (+) Prominence of CLP label elements, instead of instructions for use (-)
Industry	Fold-out labels as regular labels; More languages on fold-out labels, simplifying the supply of the single market (+); Redesigning labels (-); Relabelling product (-); (Increased costs of fold-out labels ³³)	Increased space for CLP labelling at the expense of other compulsory label elements, marketing elements (-); In some cases, increased packaging size in contradiction to the Packaging and Packaging Waste Regulation (-); Increased material for communication (leaflet for other label elements than CLP ones) (-); Fold-out labels as most frequent labels (-). Same number of languages on fold-out labels but increased number of pages and technical practicalities (-); Alternatively single-language labels (-); Redesigning labels (-); Relabelling product (-); Fold-out labels are thicker, impacting packaging size and labelling/production lines (-); Fold-out labels are not applied as 2D labels: new equipment, additional production/labelling lines where fold-out and 2D labels, additional space (-); Increased number of pre-printed labels negatively impact production

³³ The higher cost of fold-out labels compared to 2D labels is acknowledged in the Impact Assessment Report. However, it is not factored into the recurring costs.

		<p>time (setting lines between two labels) (-);</p> <p>Increasing the number of SKU (-);</p> <p>Increased needed space for stock (-);</p> <p>Increased complexity for logistics (-);</p> <p>Reduction of market size where SKUs no longer break even (-);</p> <p>Outsourcing fold-out labels: additional label stocks (minimum order for labels), potential increase waste for out-dated labels (-);</p> <p>Packaging with fold-out labels are more difficult to recycle (costs where extended producer responsibilities are in place). Possible impact on eco-design;</p> <p>For business-to-business trade, an SDS is required, providing more granular hazard communication than CLP labels.</p>
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Regarding simple 2D labels, both SMEs and larger companies reported that almost all labels should be redesigned to comply with the new rules, especially with the minimum font sizes and line spacing. According to evidence submitted by a large company, the decrease in space on the label left to other elements than CLP ones would reach up to 60% for products larger than 1L. This decrease would leave almost no space on the label for other label elements than CLP ones on the back of a product, if all other parameters remain unchanged (e.g., the number of languages). Some companies mentioned that they would need to label the front and the back of the product to comply to the future CLP requirements, notwithstanding the additional labelling requirements from other pieces of legislation.

Following new formatting requirements, the number of languages per label would be reduced by a factor of 2 or 3, according to some stakeholders, both SMEs or larger companies. Many companies highlighted the extreme but possibly frequent case of 2D labels where only one language can fit in the future. As a first consequence, companies consider switching from 2D labels to fold-out labels in Member States which request more than one official language on the label. In that case, the number of different labels would not increase but setting a labelling line for fold-out label bears both one-off and recurrent costs (see below for subsequent consequences). As an alternative consequence, companies could also be forced to develop single-language 2D labels in order to avoid fold-out labels, thus undermining the single market for chemical products. In both cases, this would increase the number of labels or printed packaging, of stock-keeping units (SKU) and logistics space needed, as well as the cost of any future label changes due to multiplication of labels. Companies mentioned an increase of SKUs, which requires more storage capacities and logistic operations on a recurrent basis. Some companies mentioned up to € 40 million investment required for storage and logistic capacities. Because of those additional costs, some companies

even state that they no longer have a business case for their products if they need to label them with monolingual labels. An increased number of SKUs indeed implies reduced turn-over per SKUs, to the point that some SKUs make not break even and would be terminated. Companies would stop placing those products in these smaller markets, disrupting the single market and challenging a fair competition in those markets.

The Impact Assessment Report accompanying the proposal for an amending regulation concluded that fold-out labels represents an alternative solution to 2D labels, offering enough space for all label elements, including those requested by the CLP. However, according to industry, fold-out labels are up to 4 times more expensive than 2D labels (printed in-house) (according to concurring sources for a recurring cost). Moreover, labelling lines for fold-out labels are not compatible with labelling machines fed by rolls of (pre-printed) labels, triggering one-off investment costs. The production of fold-out labels is outsourced, increasing the SKUs, as well as the length of the supply chain and the cost of future label changes. To these recurrent costs, industry also identify one-off costs in switching their 2D-labelling lines to printers and labelling machines for fold-out labels. Some SMEs reported investments of between € 0.5 million and € 1.5 million to adapt their production line to printers/labelling machines handling fold-out labels.

Finally, some companies which already use fold-out labels also shared concerns about the impact of the new rules on font sizes and label formatting. Some indicated that keeping the same number of languages would be a technical challenge as the fold-out label would expand from 3 or 4 pages to up to 11 pages.

Regarding environmental impact, industry highlights that the ultimate option of increasing the size of the packaging to fit all elements of the CLP in sufficient space would be incompatible with the limitation of packaging size (and packaging waste) requested by the Packaging and Packaging Waste Regulation and in the end to the environment. Possible negative effects are also reported as a consequence of increased SKUs, such as more space needed, more products stored (and not in the supply chain), resulting in more CO₂ emitted and more raw material used. For future changes of labels, this could also create more waste, as fold-out labels and packaging bearing them are more difficult to recycle than for 2D ones.

The changes could increase the need of workers in the labelling industry or in the chemical industry (updating 5000 labels is equal to 1 full-time equivalent for a year). This would lead to the increase of costs of chemical products, including of many consumer products, as most companies stated that the extra costs will raise the price of these products.

Many companies called for a clear and swift “stop-the-clock” in addition to an amendment of the formatting rules. Many of them have developed multi-annual strategies to adapt to the new rules ahead of the end of the deferred application period, and decision to implement those strategies are in many cases about to be made.

Non-governmental organisations shared their concerns about a possible amendment of the rules on CLP label formatting, which would jeopardise the future and improved protection of human health and of the environment offered by Regulation (EU) 2024/2865. They recalled that the Fitness Check concluded that consumers are not well informed because labels of chemicals

products are overcrowded and too obscure, making them difficult to understand and read by consumers. They referred to the positive outcome identified in the impact assessment for the CLP revision, where costs stemming from formatting rules for labels are counterbalanced by more flexibility on the types of allowed labels.

The Member State feedback reflects a broad consensus on the importance of ensuring label readability to protect health and environmental safety. Furthermore, Member States raise significant concern about the proportionality, feasibility, and timing of the possible simplification measures, that would come just after the adoption of Regulation (EU) 2024/2865, creating uncertainties and potential additional administrative costs for both for national authorities and for industry players.

There is a common consensus among the Member States that provided feedback that improved readability of labels serves an essential purpose – protecting human health and the environment by clearly communicating information about the hazards. Several Member States insisted that the minimum font size of 1.2 mm x-height should not be lowered, as this would compromise label legibility. They, however, showed openness to the alignment of the font size rules to those laid down in Food Information to Consumers (FIC) Regulation³⁴, where the font size is 1.2 mm with a possibility to use 0.9 mm for smaller packaging. Such alignment is viewed to reduce manufacturing complexity and promote cross-sector efficiency.

One Member State suggested focusing on more prominent formatting for consumer products, while potentially exempting professional and industrial products – considering that professional and industrial users are protected by Occupational Safety and Health legislation and have access to hazard information via the safety data sheets.

A number of Member States advocated for embracing digital labelling to alleviate label space constraints and improve legibility. They suggest expanding the scope of information to be provided on a digital label beyond what is currently allowed under the CLP regulation. However, concerns are also raised by other Member States about digital divide issues and the practicality of accessing digital information during emergencies.

Proposed amendments and next steps

In light of the proposed simplification agenda and in order to reduce disproportionate costs identified by stakeholder feedback, the Commission proposes to remove mandatory label formatting rules introduced by the Regulation (EU) 2024/2865. The proposed amendments would reintroduce the requirements for labels to stand out clearly from the background and to be of such a size and be spaced in such a way as to be easily read, thus focusing on keeping labels clear and readable rather than enforcing rigid formatting rules. The proposed amendments are guided by the

³⁴ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18.

key objectives of administrative burden reduction, regulatory simplification and enhancing European competitiveness, as well as ensuring cost-effective delivery of the policy objectives of the European Green Deal.

Estimated cost savings

Based on the input from stakeholders into the Reality check, the conclusions of the impact assessment performed for the CLP revision need to be updated and further refined.

For the detergent industry, the Impact Assessment Report accompanying the proposal for an amending regulation concluded that a broader use of fold-out labels would generate annual savings of between € 24 million and € 55 million (see table 98). The data received for the Reality Check highlights the following shortcomings:

- Significant recurring increased cost per label, from moving from in-house printing or pre-printed labels to fold-out labels or for designing fold-out labels with fewer languages: between 22 % and 200%;
- Significant one-off investment costs to set up a labelling line and associated storage for fold-out labels, which are usually stack labels, compared to 2D labels, which come in rolls: the cost of new printers or labelling machine: €4000 to €40000 per label printing equipment and €170000 to €250000 per labelling robots (one for each impacted production line and between 2 and 4 production lines per site);
- Indirect recurrent costs of a longer supply chain, because of outsourced production of (fold-out) labels or few languages per label and more labels, resulting in an increase of SKUs: between 22% to 400% (for 3000 products, from 15000 SKU to 40000 SKU in a large company);
- Future more complex amendments of labels because of classification update: increased time and resource for designing more labels and/or fold-out ones, as well as destruction of unused fold-out labels;

From table 98 in the Impact Assessment Report, savings were calculated to reach between €618.750 and €1.406.250 per large detergent companies and between €55.000 and €112.500 for SMEs manufacturing detergents, considering an average of 15 labels per products for a large company and 5 for an SME.

These assumptions do not fit with the feedback received from stakeholders, where current 2D labels bear more than one-language, some companies already use multi-language fold-out labels and the price difference between 2D labels and fold-out ones is not considered in the relabelling cost in the IA.

Two extreme scenarios are analysed in greater details in the Annex II: companies using 2D labels which have to develop monolingual labels for all their products and companies using 2D multilingual moving to fold-out labels containing the same amount of information because of the future formatting rules. The real situation may be more complex, with some companies using a mix of 2D and fold-out labels, some labels being already compliant with new rules.

For an SME manufacturing detergents which considered splitting their 800 existing multilingual 2D labels in around 2.200 CLP compliant 2D ones (x2.5), the one-off cost investment in additional printers is estimated between €20.000 and €60.000. The cost of any update of the labelling of a product would increase by 175% up to €1.306 per mixture.

Table 1.1: Possible costs for detergent manufacturers going only for monolingual labels (increased number of labels and of SKUs and unchanged price per label, in addition to 100% relabelling to comply with Regulation (EU) 2024/2865).

Type of companies	No of companies	No of consumer products per company	Average of (partially multilingual) labels (current situation)	Average of monolingual labels (future situation)	One-off costs of relabelling according to Reg. (EU) 2024/2865	Recurrent costs following Reg. (EU) 2024/2865 ³⁵
Large	50	150-250 sold in all MS	15	22 ³⁶	€20.370.000 - €33.950.000	€1.995.000 - €3.325.000
SME	600-650	40-60 sold in 5 MS	2	5	€34.200.000 - €61.750.000	€2.736.000 - €4.446.000
Total	650-700	31.500-51.500			€54.570.000 - €101.700.000	

Table 1.2: Possible costs for detergent manufacturers going only for fold-out labels (unchanged number of labels and increased price per label, in addition to 100% relabelling to comply with Regulation (EU) 2024/2865).

Entreprise type	No of companies	No of consumer products per company	Average of (partially multilingual) labels (current situation)	Average of multilingual fold-out labels (future situation)	One-off costs of relabelling according to Reg. (EU) 2024/2865	Recurrent costs following Reg. (EU) 2024/2865 ³⁷
Large	50	150-250	15	15	€112.500.000 - €187.500.000	€1.875.000 - €4.414.000

³⁵ This is based on ECHA's understanding that 1% of notifications of classification of substances are updated every year. Considering a mixture contains on average 8 substances, 8% of CLP labels for mixture would be updated per year. SME reported printing around 250.000 labels per year for 40 to 60 products, which was extrapolated to larger companies printing between 937.500 and 1.562.500 labels per year. In addition, data shows the cost of an additional SKU is between €4.400 and €6.700 par additional SKU (average €5.400). Reported costs add yearly cost of relabelling part of the products and of increased SKUs for additional labels due to splitting to monolingual labels.

³⁶ Industry reported between 20 and 400% increase of SKUs (median: 57%, average: 153%). It is understood that labelling in Irish or Maltese would occur only together with English. It was also considered for simplification that those labels would not fit for MS requesting multiple languages on CLP labels.

³⁷ This is based on ECHA's understanding that 1% of notifications of classification of substances are updated every year. Considering a mixture contains on average 8 substances, 8% of CLP labels for mixture would be updated per year. SME reported printing around 250.000 labels per year for 40 to 60 products, which was extrapolated to larger companies printing between 937.500 and 1.562.500 labels per year. In addition, data shows the cost of an additional SKU is between €4.400 and €6.700 par additional SKU (average €5.400). Reported costs add yearly cost of relabelling part of the products and of increased SKUs for additional labels due to splitting to monolingual labels.

SME	600-650	40-60	2	2	€48.000.000 - €78.000.000	€6.000.000 - €13.772.000
Total	650-700	31.500- 51.500			€160.500.000 - €265.500.000	

The lubricant manufacturers reported an already existent extensive use of fold-out labels for small packaging, with up to 31 languages per label, some of them addressing non-EU markets. In the sector, the share of products sold to industry or professionals is significant, up to 90% for some large companies. The new formatting rules would force those manufacturers to increase the number of pages from 5 to 11, making it a technical challenge. Alternatively, companies could cluster, with more fold-out labels covering fewer Member States or countries. For larger packaging, companies need to switch to fold-out labels, which can be a technical challenge for products travelling by sea or stored outdoor. In most of the cases, large companies representing about 50 % of the European market for lubricant identified one-off relabelling cost of between €2.000.000 and about €10.000.000 to comply with Regulation (EU) 2024/2865, with a possible total for the whole sector of €49.000.000. Moreover, those companies also reported a recurrent cost of future increased number of SKUs between €7.000.000 and €80.000.000 per year per large company and around €3.000.000 for SMEs. For the sector, these recurrent costs could amount, by extrapolation, to €400.000.000 per year, let alone routine relabelling costs.

Finally, paint and ink manufacturers reported higher number of articles than in other chemical sectors, usually in smaller packaging and sometimes tailored made. Companies also reported increased costs for fold-out labels (between €0.15 to €1.50 per label), which could trigger a one-off relabelling cost of between €4.500.000 and 18.000.000 per large company, considering an average number of 3000 different (fold-out) labels and 1.000.000 products labelled per year. The total one-off relabelling cost for the paint and ink sector could be extrapolated to between €225.000.000 and €900.000.000, according to information received. The price increase for fold-out labels will increase the recurrent cost of routine updates of CLP labels. Moreover, companies would need to invest in new labelling machines for fold-out labels, the price of which is between €200.000 and €500.000 per production line, depending on the company.

With the proposal to revert back to CLP provisions before their amendment by Regulation (EU) 2024/2865, almost of the costs for the sectors listed above and for other sectors not mentioned here would disappear. Unfortunately, costs engaged by front-runners may not be fully recovered.

As the new rules would be deleted, any impact on human health or on the environment, whether positive or negative, would be annulled. Companies which have industrial or professional customers highlighted that their customers always have access to safety data sheets, as required by the REACH regulation.

b. Rules on advertisements

Article 48 of CLP regulation as currently applicable³⁸ requires the advertisements for a hazardous substance to mention the hazard class concerned. For mixtures, Article 48 lays down obligations to mention the type of hazards only for the advertisements that allow a member of the general public to conclude a contract for purchase without first having sight of the label. This was to protect the recipients of hazardous mixtures, including consumers, who would not be able to see the label information before the purchase.

Regulation (EU) 2024/2865 introduced Article 48a requiring all distance offers to indicate full CLP labelling information, thus ensuring that the final user is always informed about the hazards concerned and is always able to see (or be informed about) all label elements, including hazard pictograms, signal words, hazard and precautionary statements before buying a product. At the same time, Regulation (EU) 2024/2865 amended Article 48 and introduced new rules on advertisements that require any advertisement (including on radio, on social media, in promotional leaflets etc.) to indicate all hazard information, i.e. hazard pictogram, hazard statement and EUH statement, together with invitation to always follow the label information. These rules were highlighted by stakeholders as disproportionate and going far beyond what is required of other industries, such as for pharmaceuticals, biocidal and plant protection products.

Stakeholder views

A large majority of the stakeholders from industry which provided input raised strong concerns on the proportionality and the excessive cost of the extended requirements in new Article 48 for promotional communications. They reminded that advertisements do not constitute purchase offers and do not necessarily lead to a purchase. They also emphasised that new rules will expand the application of Article 48 to all advertisements, including supermarket leaflets, TV and radio commercials and social media advertisements, including advertisements as short as 3 seconds – while most of them were not covered by the previous requirements.

It was pointed out that a primary way of informing users about associated hazards is (and should remain such) the CLP label on the product – which users are always able to consult without buying a product, – and not the advertisements. As Regulation (EU) 2024/2865 introduced requirements for distance sales, full labelling information will be always presented to a user in the online offer.

A recurring concern highlighted by stakeholders is the impracticality of implementing the new requirements across all advertisement formats. Many stakeholders point out that certain media formats – particularly radio, short-form digital content, and printed materials – are incompatible with the volume of information required by the new Article 48. In the case of audio-only formats like radio, it is nearly impossible to convey complex hazard information in the time available. Similarly, social media advertisements, often designed for small screens and quick engagement, lack the necessary space for full hazard details. Furthermore, for online sales the provision on advertisements is in most cases redundant, as the advertisement is taking place in the environment of the sales offer and the consumer has direct access to the necessary hazard information through the product offer page, which is a click away. Printed formats, such as leaflets and promotional

³⁸ New provisions on advertisements introduced by Regulation (EU) 2024/2865 will enter into application as of 1 July 2026.

catalogues, widely used in retail sectors, not only face space constraints but also run the risk of becoming outdated, potentially leading to discrepancies between advertising and product labelling.

Another prominent concern is that the comprehensive inclusion of CLP hazard information in advertisements could overwhelm and confuse consumers. Too much emphasis at the stage of advertisements would deter consumers. Several stakeholders argue that too much technical data can lead to disengagement, thereby reducing rather than enhancing consumer safety. A commonly proposed alternative favoured by majority of stakeholders is to include a simplified, uniform phrase such as “Always read the label and product information before use”. This approach mirrors practices in other EU legislation and is seen as more effective in directing consumers to the label where complete information is available.

Stakeholders also draw attention to inconsistencies between new provisions of Article 48 and requirements for advertisements laid down in other sectoral legislation, such as in the Biocidal Products Regulation³⁹ and the Directive on Medicinal Products⁴⁰. These legislative acts require a simple invitation to consult the label, rather than reproducing detailed hazard elements in advertisements. Harmonizing requirements across regulatory frameworks is a common recommendation, to avoid confusion and redundant obligations.

According to the input received from companies, the implementation of the revised Article 48 is expected to introduce substantial administrative complexity and cost. Businesses will need to revise existing contracts, marketing materials, and workflows to ensure compliance with new requirements. In addition to resource demands, stakeholders also highlight the need to produce EU-specific versions of global advertising content, increasing fragmentation. The challenge is particularly acute for B2B communications, where audiences already rely on Safety Data Sheets (SDS) and are not expected to benefit from advertising-based hazard disclosures.

Concerns were also raised about the potential chilling effect of Article 48 on innovation and sustainability. The detergents and home care sector emphasised to have a well-established safe use record and low incident rates, all of which do not suggest that intensified hazard communication is needed. Furthermore, concentrated detergents may have more severe CLP classifications due to their concentration. When these products must carry prominent hazard warnings in advertising, consumers may be deterred from purchasing them and would instead choose diluted and less effective alternatives, bearing milder hazard classes, thereby undermining sustainability goals. In this regard, stakeholders also raised the consistency between the CLP regulation and the Packaging and Packaging Waste Regulation⁴¹ (PPWR). While the future rules of the CLP will deter consumers to buy concentrated (and thus more hazardous) consumer products instead choosing larger volumes of diluted hence less hazardous ones, this goes against the objectives of PPWR to foster the

³⁹ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.

⁴⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

⁴¹ Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, OJ L, 2025/40, 22.1.2025, ELI: <http://data.europa.eu/eli/reg/2025/40/oj>.

reduction of packaging and packaging waste. But the PPWR fails to provide an incentive in advertising concentrated products in smaller packaging and it is not clear whether this would be allowed by the Green Claims Directive⁴².

In addition, stakeholders expressed their concerns that the new rules will discriminate chemical product categories being regulated under CLP (such as detergents, adhesives, paints) against non-CLP regulated categories (such as cosmetics), because the quantity of hazard-related information would make these products less attractive, for instance on supermarket leaflets.

Finally, a major concern for stakeholders is the lack of clarity in the definition of ‘advertisement’ under the CLP Regulation. Stakeholders highlight confusion over whether the requirements apply to various promotional materials, including online banners, leaflets, and social media content. To ensure consistent application and enforcement, stakeholders call for a precise and harmonised definition to be included in the legislation or in the supporting guidance.

In addition to the qualitative feedback provided by companies and member states, the findings of a stakeholder poll held during Reality Check workshop further substantiate the concerns raised. The results illustrate strong opposition to the advertisement requirements introduced in the revised Article 48 and reinforce the call for simplification and alignment with other EU regulatory frameworks.

A clear majority (59%) of respondents believe the new advertisement rules impose unjustified and disproportionate burdens on businesses. Only 3% consider the rules fully appropriate, while 20% regard them as moderately burdensome. This underscores the perception that the obligations are excessive relative to the intended safety benefits.

The usefulness of hazard information in advertisements was also questioned. A majority (55%) do not believe that including this information in advertisements helps consumers make better-informed decisions. Only 35% believe it does. Instead, 87% of participants expressed confidence that current product labels already provide adequate hazard information, supporting the argument that duplicating this data in advertisements is unnecessary.

There is substantial support (80%) for simplifying the advertisement provisions to reduce regulatory burdens. When asked about preferred simplification measures, 57% favored retaining only the invitation to read the product label or Safety Data Sheet (SDS), 28% supported removing requirements solely for B2B advertisements, and 21% supported removing the requirement for all advertisements.

Open-ended feedback from the poll included the excessive burden for B2B advertisements where SDS communication is already mandatory, inconsistency with the requirements laid down in other EU regulations such as the Biocidal Products Regulation, and the need for clearer definitions of ‘advertisement’ in the CLP context. Many also warned of potential consumer confusion and information overload if full hazard data is required in all advertisements formats.

⁴² Proposal for a Directive of the European Parliament and of the Council on substantiation and communication of explicit environmental claims (Green Claims Directive), COM/2023/166 final.

Some Member States showed flexibility to softening the rules on advertisements, narrowing the amount of required elements in advertisements to hazard pictogram, possibly supported by a signal word, together with the invitation to read product information on the label, or to the statement indicating hazardous properties of the product, such as “*This product contains chemical substances that are harmful to human health and/or the environment*”. They expressed the opinion that advertisements requirements would contribute to strengthening consumer and worker safety through earlier risk warnings and will empower market surveillance authorities to tackle online sales more effectively. Others called for sticking to the agreed rolling-out of the provisions of Regulation (EU) 2024/2865, as they were adopted with the aim of ensuring a high level of protection of human health and the environment. Overall, Member States called for a cautious approach when reopening the provisions that were recently agreed by co-legislators, calling for a thorough assessment supporting any legislative changes.

NGOs shared their concerns about the revision of the advertisement rules, indicating that advertisement is by its nature intended to influence consumer choices. They consider it is therefore essential that consumers have access to all important information related to an advertised products as part of the advertisement and not only at the time of purchase when a decision may already have been made. They welcomed the new clearer rules on advertisement insofar that they will support informed consumer choice including by preventing product presentations that could mislead consumers e.g. by downplaying or omitting an advertised product’s hazardous properties. The new rules would also support Member States in their CLP enforcement activities.

Proposed amendments and next steps

In light of the proposed simplification agenda and in order to reduce disproportionate costs identified by stakeholder feedback, the Commission proposes to simplify information requirement in advertisements for general public. This would result in the requirement for advertisements of chemicals to encourage customers to read the label and product information before use (i.e. by adding a sentence “*Always read the label and product information before use*”) without the requirement to duplicate the hazard information from product labels. Furthermore, advertisements provisions would be amended to limit their scope to chemicals sold to the general public. Hazardous substances and mixtures traded between professionals already have information requirements under Regulation (EC) No 1907/2006, so additional rules would not be proportionate.

Estimated cost savings

Stakeholders provided a range of qualitative and quantitative estimates highlighting the significant financial and operational burdens of implementing the revised Article 48 requirements. These costs stem from increased complexity in adapting existing advertisement formats to include the full suite of CLP hazard elements, alongside necessary updates to supporting systems, staff, and procedures.

In accordance with provided estimates, due to the obligation to display hazard elements within the limited space of TV advertisements, at least two seconds of valuable consumer engagement time would be lost in a standard 20-second advertisement. This was projected to result in an annual loss of €30 million in advertising value for just one product category. This estimate underscores the commercial significance of even small changes in advertisement content requirements.

For adhesives and sealants industry, according to the feedback received, the identified average cost of new requirements on advertisements is €21.470 per company. This is optimistic estimation that is not considering the cost of market loss when retailers would choose not to advertise at all or reduce advertisements for chemical products due to additional requirements.

A mid-sized company estimated €200.000 annually in additional staff costs alone, driven by the need to expand marketing, compliance, and regulatory staff. Another stakeholder reported needing 10 new full-time employees (FTEs) solely for managing one advertising channel. Assuming €50.000 per FTE per year, this equals €500.000, which results in €700.000 per year in total.

Increased requirements for catalogues and printed advertisements would lead to greater production and distribution expenses. One example cited a €50.000 increase due to added pages, with others referencing similar impacts.

Costs related to revising contracts, updating documents, adapting compliance processes, and implementing new software solutions were commonly cited. In one Member State these costs were estimated in approximately €30.000 per year. Across EU stakeholders, these burdens likely total several hundred thousand euros annually.

International companies noted that they would need to split marketing campaigns into separate EU and non-EU formats, introducing design duplication and added production costs. While not fully quantified, this was projected to cost several million euros annually.

c. Other areas where stakeholders called for simplification

Stakeholder views

In addition to topics outlined above, stakeholders raised a broad range of additional simplification opportunities. Most of the issues were highlighted during Reality Check workshop and later confirmed and further illustrated by stakeholder's written contributions.

“Stop-the-clock”:

Many stakeholders called for freezing the transition period to the application of the new rules on label formatting laid down by Regulation 2024/2865. As many companies started their investments to comply with the new labelling rules, a strong political signal is needed that the revision of the formatting rules is seriously considered.

It was noted that some organisations also called for a postponement of the implementation deadlines of the new hazard classes introduced by the Regulation 2023/707, and rules on classification of mixtures containing more than one constituent substances (MOCS), in order to prepare better, gain more experience and develop additional guidance. It was highlighted that unified application deadlines resulting from various CLP requirements would provide the opportunity to implement all required changes simultaneously, which will constitute a real simplification to industry and authorities.

Placing vs. making available on the market:

Calls were made to align CLP regulation with other NLF product legislation by distinguishing the concepts of ‘placing on the market’ and ‘making available on the market’, to reduce unnecessary stock reclassification.

It was highlighted that CLP regulation does not differentiate between the terms “placing on the market” (the first making available on the market) and “making available on the market” (the subsequent making available on the market), unlike products legislation covered by the New Legislative Framework. It means that all changes introduced to CLP, including new harmonised classifications, apply to all chemical products already in the supply chain. This causes a disproportionate cost as the foreseen deferred applicability period does not allow the sell off of the substances and mixtures that are already in the supply chain.

However, several Member States highlighted that the concept of placing on the market in CLP is mirroring the same concept and logic of REACH regulation – both being framework chemical legislations, that should stay aligned with each other.

Differentiation between consumer products and B2B:

Significant number of stakeholders pointed to the fact that industrial and professional users (workers) normally rely on Safety Data Sheets (SDS) for safe use conditions and, in industrial settings, on Standard Operating Procedures (SOP) and other documentation, rather than just labels. They also pointed out to additional obligations from Occupational Safety and Health (OSH) legislation that requires the employer to determine and assess the risks of hazardous chemicals, and to provide information and training for the workers in this regard. It was indicated that labels are insufficient to convey all necessary safe use information in industrial and professional use settings. Workers must receive use instructions prior to starting to work with a chemical in question (i.e. before being able to physically inspect the label content).

The stakeholders therefore considered certain requirements, particularly mandatory formatting rules, advertisements and online sales, being disproportionate and unnecessary in B2B context, with a questionable contribution to the increase of safety of workers and called for simplification and reduction of the requirements in this regard. It was also suggested by some stakeholders to allow broader use of digital labelling in industrial sector, allowing for a possibility to use English only on a physical label while providing the information in other languages on a digital label.

Self-classification labelling deadlines:

Strong support emerged for aligning the six-month deadline for self-classified substances with the 18-month timeline used for harmonised classifications. A number of stakeholders noted that such short timeline is extremely challenging, considering the time required for label production, which includes document preparation, graphic creation, procurement of new labels, and printing. Furthermore, such tight deadline could lead to product and label waste, undermining the Green Deal and packaging legislation.

Companies highlighted that the increased outsourcing of label printing will further extend the supply chain for labels by 2 to 3 months on average, which makes compliance with updating labels within 6 months of self-classification a piece of challenge.

Furthermore, it was highlighted that often certain label elements are pre-printed on the packaging. In case of a label change, the packaging must be re-designed, ordered, manufactured and supplied to the manufacturer of the substance or mixture in question. This process alone may take more than 6 months. In addition, the 6-month period to update the label also makes it very difficult to consume the existing stock of pre-printed packaging and of the already packaged material that normally cannot be repackaged or re-labelled. Consequently, upon the expiration of the 6-month period to update the label, the unused pre-printed packaging and unsold materials in the old packaging will have to be disposed of.

At the same time several Member States expressed strong believe that 6 months should be enough for every actor in a supply chain and that the deadline is driven by the need to inform users about changes in the classifications as soon as possible.

Poison Centre Notifications (PCN):

Numerous stakeholders described the current poison centres notification system as burdensome and fragmented, with inconsistent national requirements and high associated costs, especially for small production batches or tailored-made products. The fees requested by some Member States make the placing on the market of chemical mixtures in those Member States not viable economically for products placed on these markets in very low tonnage. The need for the prohibition to impose national fees for PCNs was therefore highlighted by a number of stakeholders.

Strong support emerged for centralisation of PCN submissions via ECHA. Stakeholders highlighted that having ECHA PCN tool as the only tool for notifications, that would also allow for submission of PCN information only once, would simplify and eliminate additional administrative and economic burden for industry to submit notifications to different portals and having discrepancy among the information/fees to be provided. Furthermore, several stakeholders suggested the PCN submission only in English, highlighting that this would remove excessive administrative burden and associated costs.

Numerous stakeholders voiced the need of a comprehensive review of the current PCN system, to identify its drawbacks and potentials for simplification.

Unique Formula Identifier (UFI) for fuels:

Multiple actors requested flexibility in UFI requirements for fuels, where the diversity and mixing of supplies makes practical implementation extremely difficult. They also highlighted that since UFI can be printed directly on the packaging, outside the CLP labelling space, the formatting rules (especially black on white requirement and font sizes) should not apply to them.

Stakeholders also strongly advocating for removing the requirement to provide UFI on fuelling pumps, highlighting that according to various poison centres, a UFI is not required when advising on emergencies and accidents involving standardised fuels and combustibles. They indicated that it is sufficient to provide to poison centres information on the type of fuel (e.g. diesel, gasoline, heating oil) to receive an adequate health response. Furthermore, it was indicated that the additive content is so low that it has no influence on the emergency advice and measures.

Digital labelling:

Many stakeholders advocated expanding the possibilities of digital labelling, especially for professional and industrial chemical products, to complement or partially replace on-pack information. According to these stakeholders, extended digitalisation of CLP labels would alleviate part of the administrative burden triggered by the formatting rules laid down in Regulation (EU) 2024/2865. In stakeholders' view, use of digital label would reduce the use of physical materials and remove excessive information from physical labels on one hand and would simplify the management, update and distribution of information on the other hand, thus contributing to sustainability and competitiveness of European industry.

Among the information that could be moved to the digital label, stakeholders highlighted precautionary statements, that, in industry view, are disregarded or not understood by the majority of consumers, and EUH statements, especially for non-hazardous mixtures. This could be complemented by the statement "more hazard information available online" to inform the users about the need to check digital label.

At the same time, concerns were also raised by member states and NGOs about digital divide issues and the practicality of accessing digital information during emergencies.

Harmonised Classification and Labelling (CLH):

Industry and NGO representatives highlighted the need to streamline the CLH process. Proposals included allowing better use of new data and clarifying exposure routes, while NGOs suggested an automatic updating of Annex VI based on scientific opinions.

Industries called for a stronger dialogue at the early stages of the CLH process, to ensure that industries commitments to tests are fully included in the CLH assessment process. This would ensure that all relevant scientific data is considered upfront. Early engagement would enable industry to contribute to CLH assessment process constructively, especially in cases of lack of relevant data, that could have been avoided if REACH tests had been completed, which could consequently help mitigating significant downstream impacts.

Some NGO representatives further suggested to delete the need to justify the need of a CLH dossier for hazard classes other than those listed in Article 36(1) or (2). According to them, such a change would increase the number of CLH dossiers targeting environmental classification.

Several Member States reiterated that CLP Regulation already foresees possibilities for route-specific classifications, if it can be conclusively proved that no other route of exposure exhibits the hazard.

Mixture classification and expert judgment:

Stakeholders of certain chemical sectors highlighted that the recent revision of Article 9(4) of the CLP regulation significantly restricts the use of expert judgment in the classification of chemical mixtures, limiting it solely to the selection of reference mixtures for bridging principles. While this may streamline enforcement, it imposes disproportionate costs and operational burdens on industry, particularly in sectors where formulations change frequently. Stakeholders warned that

limitations on the use of expert judgment and weight-of-evidence approaches could lead to disproportionate and misleading classifications. One leading company identified an additional cost of more than € 2.7 million in additional testing needed to derive appropriate classification.

Stakeholders therefore voiced the need to reinstate the ability to apply expert judgment in mixture classification, thus ensuring a balanced approach that supports enforcement, scientific integrity, innovation and consumer protection.

Additional derogation for ink cartridges:

Manufacturers of ink cartridges called for additional labelling derogations as these cartridges usually do not offer enough space of inner packaging for the limited label elements required, especially in the context of new font sizes. These cartridges, being inserted in the printing devices, also cannot accommodate fold-out labels. It was highlighted that currently applicable derogations for 125 and 10 ml are mostly not applicable to such type of chemical products, especially the ones that are not classified but bear EUH statements.

Derogations for on-site formulated mixtures:

SME representatives flagged the difficulties related to PCN notifications for mixtures prepared as individual fragrance compositions for aromatherapy and similar uses. It was indicated that due to the high variety of constituents and concentrations (the usual set of basic fragrances is 150 to 200 substances, all being essential oils from plants) the poison centre notifications for such tailor-made mixtures become highly burdensome and almost impossible. In this regard, a call for a specific derogation (like the one currently foreseen for bespoke paints) from PCN notification requirements for on-site formulated mixtures in small containers less than 10 ml was made.

At the same time, one Member State highlighted that essential oils are highly concentrated substances and can be very hazardous. In accordance with the data from Poison centre in that Member State, 820 incidents (462 concerning children) with essential oils were registered in 2023. There were symptoms in 576 cases, including 30 cases of serious or prolonged symptoms and 2 cases of severe or life-threatening symptoms. It is therefore essential to ensure that CLP labelling and PCN notifications requirements are being followed. It was highlighted that new exemptions have been introduced by Regulation (EU) 2024/2865 for small packaging, that could facilitate the aromatherapy sector.

Proposed amendments and next steps

In light of the proposed simplification agenda and in order to remove administrative burden and disproportionate requirements identified by stakeholder feedback, the Commission proposes to clarify and simplify the following requirements:

Limiting rules on distance offers to public

Similarly to the approach proposed for rules on advertisements, it is suggested to limit the provisions on distance sales offers to those offers aiming at general public only. This will bring more flexibility to B2B sector without, however, compromising health and safety of workers, as

B2B customers usually receive a copy of the SDS even prior to any purchasing decision, as part of the material assessment and qualification process.

Flexibility on labelling deadlines

It is suggested to remove fixed deadline for the obligation to update the label, as it appeared to be not feasible to comply with due to the complexity of supply chains. In order to create flexibility for suppliers and create equal conditions for SMEs who often outsource label printing services, and taking into account the fact that preparation and production of fold-out labels is significantly longer than that of standard 2D labels, the provision would require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.

Derogations for smaller packages

It is suggested to clarify provisions allowing for derogations from labelling requirements for small packaging, especially for very small containers under 10 ml. The amendments would allow economic operators to reduce information required to be provided on the label for packaging containing smaller quantities of chemical substances or mixtures without the need to prove that this packaging is either in such a shape or form or is so small that it is impossible to meet full labelling requirements. In addition, derogations from labelling requirements for 10 ml packaging, introduced by Regulation 2024/2865 would be further clarified and simplified, especially for the substances and mixtures bearing milder hazards.

Use of digital labels

It is suggested to broaden the use of digital labelling introduced by Regulation (EU) 2024/2865. Suppliers would be able to include extra contact information on digital labels instead of the physical label, saving space on physical labels and making it easier to manage and update product details using digital technology, without, however, compromising health and safety of users.

Labelling of fuelling stations

It is suggested to simplify the labelling requirements for fuelling stations. Some label elements, such as nominal quantity and UFI, would not be required on fuel pumps, helping fuel suppliers meet the requirements without lowering safety standards.

2. Issues and proposed amendments to Regulation (EC) No 1223/2009 on cosmetic products (CPR)

To collect a first-hand experience from the stakeholders, a Reality Check on the CPR took place on 16 May 2025⁴³. The following issues and potential solutions were discussed.

- a. Lack of clear and comprehensive procedure for the addition of colorants, preservatives, and UV filters to Annexes IV–VI of the CPR**

⁴³ The minutes of the Reality Check, are in Annex III to this document.

A substance can be used in cosmetic products as a colorant, preservative or UV filter only if it is listed in respective Annexes IV, V and VI to the CPR.

Currently, the procedure laid down in Article 31(2) of the CPR is used to add colorants, preservatives and UV filters to Annexes IV, V and VI, respectively. However, specific provisions laying down the procedure for adding new colorants, preservatives or UV filters in the Annexes to the CPR upon request from the cosmetics industry, would enhance clarity and legal certainty and support innovation and competitiveness of the EU cosmetics sector.

Stakeholder views

Most participants of the Reality Check agreed that the current situation is unsatisfactory as Article 14 of the CPR prohibits the use in cosmetic products of substances as colorants, preservatives or UV filters which are not listed in the relevant Annexes to the CPR, but it does not set out any procedure according to which those substances could be included into these Annexes. The establishing of a clear and specific procedure for the inclusion of colorants, preservatives and UV filters in Annexes IV, V, and VI of the CPR, respectively, would be highly beneficial for stakeholders (economic operators and market surveillance authorities), as it would enhance transparency, ensure consistent safety assessments and streamline the authorisation process overall. In particular, according to Slido responses⁴⁴, 67% of participants supported introducing such a procedure, citing improvements in clarity and regulatory certainty. Nearly 20% were also in favour but noted that certain aspects would still require further clarification.

Proposed amendments and next steps

To address the current lack of legal clarity and certainty, it is proposed to add an article outlining the procedural steps involved, the role of the European Commission, and reaffirming the responsibility of the SCCS in assessing the safety of any substance which will be proposed for inclusion in the list of colorant, preservative or UV filter.

b. Article 15: CMR substances – procedure for prohibition and requesting derogation from the ban

Article 15 of CPR establishes that substances which have been classified as carcinogenic, mutagenic or reprotoxic (CMR) in Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging of chemical substances and mixtures (CLP Regulation) are prohibited for use in cosmetic products, unless an exemption has been granted. More specifically,

- Pursuant to Article 15(1) of the CPR, the use of a CMR substance of category 2, listed in Part 3 of Annex VI to the CLP Regulation, is prohibited in cosmetic products unless it has been evaluated by the SCCS and found safe for use in cosmetics.
- Article 15(2) provides that the use of substances classified as CMR substances of category 1A or 1B, listed in Part 3 of Annex VI to the CLP Regulation is prohibited in cosmetics, except when the following criteria are cumulatively fulfilled:
 - d) *the substance complies with the food safety requirements*

⁴⁴ 197 participants answered the question via Slido

- d) *there are no suitable alternatives*
- d) *the application has been made for a particular use of the product category with a known exposure, and*
- d) *the substance has been evaluated and found safe by the SCCS considering the cumulative exposure from other sources outside cosmetics.*

As regards the deadline for the implementation of the exemption procedure for CMR 1A/1B substances, fourth subparagraph of Article 15(2) of the CPR provides that the Commission shall amend the relevant Annexes to this Regulation within 15 months of the “*inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008*”.

Recent experience has revealed several challenges and limitations within the current system, suggesting that the process for prohibiting or restricting substances -following the exemption procedure- is not operating as effectively or efficiently of as intended.

Growing number of cosmetic ingredients receiving harmonised classification as CMRs

In 2025, The Committee for Risk Assessment⁴⁵ adopted opinions for 110 substances, including several for which CMR 1B classification was proposed. Many of these substances are widely used in cosmetic products. For example, Piperonal is a key ingredient in fine fragrances and signature perfumes, p-cymene is a component found in more than 360 essential oils, and Tea Tree Oil is used in numerous cosmetic formulations. This trend is expected to continue as an increasing number of non-industrial chemicals are being proposed for harmonised classification as CMR substances. Moreover, the grouping approach recently introduced will further accelerate the pace at which substances are subject to harmonised classification including as CMR, intensifying the regulatory impact with significant negative effects on the cosmetics sector considering the current outdated provisions of Article 15.

Lack of legal certainty: Absence of clear timelines for a derogation requests and transitional periods

Businesses argue that the absence of clear regulatory rules, well-defined timelines, and justified transitional periods creates significant legal uncertainty. This undermines investment decisions, often forcing companies to make assumptions about whether a substance will receive a CMR classification and subsequently be banned from use in cosmetic products. Moreover, businesses highlighted that this regulatory ambiguity/uncertainty hinders their ability to plan and to scale operations effectively – an issue that disproportionately affects SMEs, for whom strategic planning and resource allocation are particularly critical.

⁴⁵

<https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>

Insufficient timeframe for submission of derogation request

The **submission by industry** to the Commission services of a complete **file for a possible exemption currently relies solely** on the RAC opinion, which proposes a potential classification under the CLP. However, such opinion is not legally binding and may differ from the final classification adopted under the CLP Regulation. The lack of legal certainty regarding the possible classification hinders economic operators from a timely submission of an exemption request and jeopardise the process when a dossier submission may be based on a different classification. Moreover, according to the current Guidelines on Article 15, the deadline for industry to submit a complete exemption file -set at no later than six months following the publication of the RAC opinion- has proven to be excessively short. This timeframe is insufficient for the preparation of a comprehensive dossier and for conducting a thorough safety assessment by the Scientific Committee on Consumer Safety (SCCS)).

Lack of transitional periods

The current **lack of transitional periods** for the implementation of Article 15 provisions, demonstrates that it is practically impossible to withdraw cosmetic products from the market in an effective and efficient manner.

For **CMR Category 1 substances**, **Article 15(2)** of the CPR stipulates a clear and binding timeline. The Commission is required to amend the Annexes to the CPR within **15 months of the inclusion of the substances in Part 3 of Annex VI of the CLP Regulation (Regulation (EC) No 1272/2008)**. This amendment process follows the **regulatory procedure with scrutiny**, as described in **Article 32(3) of the CPR**. This strict timeline ensures timely regulatory action for substances that present the **highest potential risk** for human health⁴⁶.

In contrast, for **CMR Category 2 substances**, **Article 15(1)** of the CPR does **not** specify a precise timeline for regulatory action. It states: *‘The use in cosmetic products of substances classified as CMR substances of Category 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in Category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends, the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation.’* [emphasis added]

The reference to **‘these ends’**, use of plural in the English version of the CPR covers **two distinct measures**:

1. The **prohibition** of CMR Category 2 substances in cosmetics, and

⁴⁶ CMR Category 1 substances include both proven and presumed carcinogens, mutagens, or reproductive toxicants. More specifically, category 1A includes substances known to have CMR effects in humans based on strong evidence (proven), while category 1B includes substances presumed to have CMR effects based on animal studies or other relevant evidence (presumed).

2. The **exemption process** that allows the use of a Category 2 substance if the **SCCS** has evaluated it and found it safe for use in cosmetics.

Despite the legal distinction between Category 1 and 2 substances in the CPR, the Commission has been preparing an **Omnibus Acts on CMRs** within **15-month timeline** as provided in Article 15(2) for amending the Annexes of the CPR, regardless of the classification category. According to the current practice which follows the interpretation of Article 15 of the CPR, the Omnibus Act on CMR enters into application at the same day as the relevant delegated act **under** the CLP Regulation. While this approach ensures a degree of consistency, it introduces a **discrepancy between the timeframes** given to economic operators for compliance with the CLP and CPR:

- Under the **CLP Regulation**, the date of entry into force of the delegated act **informs** economic operators that they have 18 months to prepare, while **compliance is required** from the **date of application** of the respective ATP.
- Under the **CPR**, the Omnibus Acts amend the Annexes to the CPR the legislation does **not** provide any timeframe for economic operators to **prepare** for its application. It should be also noted that the economic operators for cosmetic products are further downstream of the economic operators affected by CLP (i.e., raw material providers, manufacturers, etc.) and depend on the latter to acquire updated information on the materials they use in cosmetic products prior to making any changes in their products. **This creates a misalignment that leads to legal uncertainty and operational challenges for stakeholders.**

The table below demonstrates non-existence of the transitional period for businesses.

CMR Omnibus	Title and main substances impacted	Date of entry into force	Date of application	Period between the entry into force and application
I	Regulation 2019/831	12/06/2019	12/06/2019	0 months
II	Regulation 2019/1966	18/12/2019	11/06/2019 and 1/05/2020	-6 and 6,5
III	Regulation 2021/850	17/06/2021	01/10/2021	3,5 months
IV	Regulation 2021/1902	23/11/2021	01/03/2022	3,5 months
V	Regulation 2022/1531	06/10/2022	17/12/2022	2,5 months
VI	Regulation 2023/1490	09/08/2023	1/12/2023	3,8 months
VII	Regulation 2025/877	02/06/2025	1/09/2025	3 months

Simplifying derogation criteria for substances classified as CMR 1 A or 1B

Article 15(2) provides that the use of substances classified as CMR substances of category 1A or 1B, listed in Part 3 of Annex VI to the CLP Regulation is prohibited in cosmetics, **except** when the following criteria are **cumulatively** fulfilled:

- a) the substance complies with the food safety requirements
- b) there are no suitable alternatives
- c) the application has been made for a particular use of the product category with a known exposure, and
- d) the substance has been evaluated and found safe by the SCCS considering the cumulative exposure from other sources outside cosmetics.

Cosmetics and food products are mutually excluding categories. They have different exposure and, therefore, the derogation criterion regarding the compliance with food-safety requirements is not relevant and does not contribute meaningfully to consumer safety. Industry stakeholders have reported that the interpretation of this criterion has caused considerable confusion. In particular, the cases of formaldehyde and zinc Pyrithione illustrate how this misalignment has led to unnecessary regulatory burden and additional costs for businesses, without a corresponding benefit to consumer protection.

Criterion ‘c’ refers to the requirement that any request for derogation must specify the intended use within a defined product category, along with a clear understanding of how consumers will be exposed to the substance (important for the assessment of criterion ‘d’).

The ‘particular use’ implies that the derogation request must be specific about the intended cosmetic use (i.e., function or application) of the substance within a cosmetic product. The use should be clearly defined, such as whether the substance will be used for example in a face cream, shampoo, deodorant, lipstick, or sunscreen, etc. Broad, non-specific applications like ‘for all cosmetic products’ would not meet this criterion.

The ‘product category’ of cosmetic products must be identified for which the substance will be used. This is important since product categories in cosmetics have different levels of exposure based on the type and (e.g., rinse-off, leave-on products, etc.).

The ‘known exposure’ indicates that there must be a clear understanding and quantification of how and to what extent consumers will be exposed to the substance. This includes factors such as:

- the frequency and duration of use (e.g., daily, occasional)
- the concentration of the substance in the product
- the amount of product applied (typical quantity per application)
- the route of exposure (dermal, oral, inhalation), and
- the target population (general population, vulnerable groups like children or pregnant women, etc.)

In practice, this criterion ensures that the safety assessment and the derogation decision are based on realistic, specific and defined use scenarios, rather than hypothetical or generalized uses. In addition, this information enables the Scientific Committee on Consumer Safety (SCCS) to conduct a focused safety evaluation that considers the actual exposure risk for consumers. It helps avoid unnecessary risks by ensuring that the substance's safety is carefully considered by the SCCS in the specific context of its intended use.

This derogation criterion has been viewed as confusing, since it reflects standard industry practice when submitting dossiers to the SCCS. A clearly defined scope of application -particularly with regards to product categories- is already a prerequisite for any meaningful safety evaluation by the SCCS. As such, maintaining this requirement as a separate, self-standing criterion appears redundant and could be removed without adverse impact on consumer safety.

Clarifying the regulatory approach to natural complex substances containing CMR Cat. 1 or 2 constituents

In May 2023 the European Chemicals Agency (ECHA) received a proposal for harmonised classification and labelling of several substances, including 'p-cymene; 1-isopropyl-4-methylbenzene' ('p-cymene'). This substance is currently listed in Annex VI to the Regulation (EC) No 1272/2008 ('CLP Regulation') with the following hazard classification: 'Flammable Liquid Category 3, Acutely Toxic Category 3, Aspiration Toxicity Category 1, Hazardous to the aquatic environment - Chronic Hazard, Category 2'. In May 2023 submission it was proposed to add 'Reproductive Toxicity Category 1B (H360FD)' to the existing classification.

P-cymene can be synthetically produced (manufactured) but it is also naturally present as a constituent in around 350 plant extracts at different concentrations, for example in Thyme oil: 20%, Cumin oil: 9,7%, Lemon oil: 0,5%, Neroli (bigarade) oil: 0,3%, as well as in Lavender, Bergamot, Mint, Rosemary and Eucalyptus oils. P-cymene is also present in food like carrots, oranges, grapefruits, tangerines, raspberries and many others.

Ingredients of plant origin (i.e. plant extracts) are widely used in cosmetic formulations – not only in 'natural' or 'organic' products, but also in the vast majority of cosmetic products containing fragrance concentrates. Beyond their use in perfumes, the cosmetics industry reports that plant-based compounds represent approximately 32% of all ingredients used across the entire range of cosmetic products.

The CLP Regulation differentiates between a 'substance' and a 'mixture'. A substance can be 'mono-constituent' or can contain more than one constituent (so called a 'complex substance'). Plant extracts that are not chemically modified form a distinct subcategory within complex substances.

Article 15 of the CPR establishes a direct link between the harmonised classification of a substance as a carcinogenic, mutagenic, or reprotoxic (CMR) substance in categories 1A, 1B, or 2 and the prohibition or restriction of its use in cosmetic products. However, the CPR although it includes and defines the terms 'substance' and a 'mixture', it does not include the term 'complex substance'.

Consequently, it could be concluded that if a substance with harmonised classification as a CMR 1A, 1B, or 2 is present as a constituent in a natural complex substance, the prohibition established under Article 15 of the CPR applies specifically to the substance itself, and not to the natural complex substance in which it is contained. Currently, decisions regarding the regulatory treatment of such multi-constituent natural complex substances ultimately rely on the interpretation of the CPR, leading to a lack of legal certainty for both regulators and industry stakeholders. To address this ambiguity, it is proposed to add a paragraph to Article 15 clarifying that the harmonised classification of a constituent does not lead to a ban on natural complex substances containing a CMR substances as its constituent. However, to protect human health, the Commission will be required to request the SCCS opinion on the safety of such natural complex substances containing a constituent classified as a CMR and to take the regulatory measures following this scientific opinion.

When the cosmetic industry representatives participating in the “reality check” workshop were asked to point to one out of five solutions which have the biggest impact, 25% of them chose that clarifying the approach to natural complex substances would simplify business operations and reduce their burden. Only the suggestion to introduce transitional periods received equally high score.

Establishing a Ban Triggered by CMR Classification Solely on the Basis of Dermal Exposure

Article 15 of the CPR prohibits substances based on the harmonised classification as a CMR category 1A, 1B or 2. However, it does not take account of the route of exposure this classification may have. It could be that a substance has CMR properties only if it is inhaled or digested, but not if it comes into contact with the human skin (i.e., dermal exposure).

Stakeholder views

During the Reality Check stakeholders broadly supported the changes to Article 15 of the CPR. Some participants emphasised the need for reassurance that any simplification initiative in the area of cosmetics should not compromise the core policy objectives of the CPR. Specifically, participants underlined that the harmonised classification of a substance as a CMR must continue to trigger a ban for its use in cosmetics, and that derogations from this ban should only be granted in exceptional cases. Others stressed that the CPR must continue protecting consumers from the harmful chemicals and cautioned against excessively long transitional periods, warning that they could prolong consumers exposure to hazardous substances.

Responses to Slido questions indicated that, among five simplification measures, the top three - introducing transitional periods, clarifying the approach to natural complex substances, and simplifying the criteria for derogations - were seen as the most impactful in reducing regulatory and administrative burdens on the cosmetics industry. Specifically, 48% of respondents believed that all five proposals were to significantly streamline business operations, while 31% considered the benefit to be as moderate. Only 6% felt the impact would be marginal or negligible

Proposed amendments and next steps

Several changes could be made in Article 15 of the CPR to simplify it and reduce the burden on businesses without affecting the high level of protection of human health, meaning that the harmonised classification of a substance as CMR category 1 or 2 would continue to trigger its prohibition in cosmetic products, unless a derogation request is submitted, and the derogation criteria are met.

i. Establishing a fixed period for submission of derogation requests

The current CPR does not foresee a timeline for businesses to submit a derogation request. According to the so called ‘CMR Guidelines’⁴⁷, a submission should be made within six months after the publication of the RAC Opinion. To provide greater legal certainty, the CPR should explicitly set the deadline for the submission of derogation request which should amount to nine months following the publication of the RAC Opinion, as the current 6 months has been proved insufficient.

ii. Introducing transitional periods for compliance with new bans or restrictions

To enhance legal certainty and enable businesses to take appropriate measures, the CPR should introduce more realistic adaptation timelines – such as 12 months for products placed on the market and 24 months for products available on the market – following the entry into application of amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substances concerned as CMR category 1A, 1B or 2. These timelines could be extended to 36 months in cases where a derogation request has been submitted and the SCCS opinion has been sought.

iii. Simplifying derogation criteria under Article 15(2)

Among the derogation criteria of Article 15(2), two criteria could be revisited:

- a) the compliance with the food safety requirements and
- b) the application which must be made for a particular use of the product category with a known exposure.

Several stakeholders consider that the food safety criterion becomes a barrier to the use of substances that are not present in food but are demonstrably safe when applied on the external parts of the human body.

As regards the second criterion, it should be merged with criterion (d) ‘the substance has been evaluated and found safe by the SCCS considering the cumulative exposure from other sources outside cosmetics.

iv. Clarifying the regulatory approach to natural complex substances containing CMR Cat. 1 or 2 constituents

For the purpose of legal clarity and certainty, the CPR should provide that when a constituent of a multi-constituent substance has been classified as a CMR substance of categories 1A, 1B and 2,

⁴⁷ <https://ec.europa.eu/docsroom/documents/39989>

the prohibition from Article 15 would not apply to such a substance if it was extracted from plants or plant parts and which are not chemically modified.

v. *Establishing a Ban Triggered by CMR Classification Solely on the Basis of Dermal Exposure*

The link between the route of exposure, the harmonised classification as a CMR category 1A, 1B or 2 and the ban in cosmetics will be established so that the harmonised classification of a substance as a CMR will trigger the ban under Article 15 of the CPR only if the scientific evidence on which the classification is based shows that the CMR properties are due to a dermal exposure. Consequently, if a substance is hazardous and shows CMR properties only if it is ingested or inhaled, it does not create a hazard for human health and such harmonisation should not trigger a ban.

c. Prenotification requirements for products containing nanomaterials (Article 16)

According to the CPR, products containing nanomaterials (other than colorants, UV-filters, preservatives or nanomaterials in conformity with the requirements in its Annex III) must be notified to the Commission six months prior to being placed on the market, unless they have already been placed on the market by the same responsible person before 11 January 2013. This obligation is in addition to the notification obligation that applies to all cosmetic products under Article 13 CPR.

Table: number of products notified to the CPNP containing nanomaterials under Article 16 of the CPR and number of all notifications based on Article 13 of the CPR

Year/number of notifications to the CPNP	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Art. 13 notifications of cosmetics with nanos	3925	3476	3573	3731	3632	4034	3265	3824	2755	2465	XX
Art. 16 pre-notification	144	74	265	131	200	175	137	222	57	76	XX

This double notification of products containing nanomaterials seems no longer justified as the cosmetic products containing nanomaterials should not be considered less safe than other cosmetic products as they are subject to the appropriate safety assessment under the responsibility of the responsible person. Furthermore, the current specific provision which enables the Commission to request the opinion of the SCCS on the safety of nanomaterial in case of safety concerns will not be affected by the amendments nor the requirement that the responsible person must provide any necessary data to the Commission on its request.

This approach is aligned with the conclusions of the Commission report on the use of nanomaterials in cosmetics⁴⁸

Stakeholder views

This pre-notification requirement for cosmetic products containing nanomaterials has been considered burdensome. Suggestions for improvement included simplifying the notification processes by relying on Article 13 of the CPR to reduce industry costs without compromising product safety.

According to Slido results, approximately 61% of respondents agreed that the pre-notification requirements impose significant and disproportionate burdens and costs on the cosmetic industry. Meanwhile, 14% considered the burden to be manageable, and 3.2% believed the current process is appropriate and does not result in unnecessary costs.

Proposed amendments and next steps

The prenotification obligation laid down in Article 16 of the CPR could be therefore removed to reduce unnecessary burden. In order to ensure the same level of consumer safety and appropriate enforcement, the requirements related to the provision of the relevant pieces of information will be transferred to Annex I to the CPR so that the cosmetic product safety report contains the adequate description of the nanomaterials used in a given cosmetic product.

d. Publication of the glossary of cosmetic ingredients in the Official Journal of the EU

Article 33 of the CPR provides that for the purpose of labelling cosmetic products placed on the EU market, the Commission must compile and update a glossary of common ingredient names, via a Commission Decision, taking into account of internationally recognised nomenclature including INCI names.

To date, such glossaries have been published in the Official Journal of the EU in 2019 and 2022. However, the current approach to updating the glossary has become suboptimal for the following reasons:

- **Slow pace of updates:** the majority of common ingredient names used in cosmetics are based on the International Nomenclature of Cosmetic Ingredients (INCI), developed by the Personal Care Products Council (PCPC). Although new INCIs are regularly introduced or revised by the PCPC, updates to the EU glossary occur only approximately every three years. This delay hinders timely adaptation to technical and scientific developments within the sector.
- **additional burden and duplication of effort for competent authorities and business:** Given the legal status of the Commission Decision establishing the list of common ingredients names, both the market surveillance authorities and business operators are

⁴⁸ Report from the Commission to the European Parliament and the Council on the use of nanomaterials in cosmetics and on the review of Regulation (EC) No 1223/2009 on cosmetic products as regards nanomaterials; COM(2021) 403 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0403>

required to ensure that ingredient names used on product labels align precisely with those listed in the Decision. To facilitate and streamline this process, stakeholders often refer to the CosIng to identify the appropriate INCI name, which must then be cross-checked against the official entry in the Commission Decision -resulting in redundant administrative effort.

The current approach leads to additional work and unnecessary burden while the internationally recognised nomenclature of common ingredient names is publicly available and regularly updated on the website of the Personal Care Products Council (PCPC).

Stakeholder views

The Commission sought stakeholders' views on the continued relevance of the glossary of common ingredient names, proposing that it could be replaced by a reference in the CPR to the internationally recognised cosmetic ingredient nomenclature. During the discussion, many participants expressed a preference for retaining the glossary as a legally binding source of ingredient names. However, they recommended that it be made available in an electronic format – integrated into the CosIng database – to enable more frequent updates and significantly enhance user experience.

Some stakeholders, however, argued that the glossary is either no longer necessary or would require substantial improvements to maintain its usefulness. These diverging views were reflected in the Slido poll results: 50.2% of respondents considered the glossary to be of limited value and believed it could be discontinued without major consequences. Conversely, 41% supported retaining the glossary or acknowledged its usefulness, but emphasised the need for improvements in accuracy, format and the frequency of updates.

Proposed amendments and next steps

A solution could be to remove the obligation to compile the glossary and enable businesses and competent authorities to rely on the internationally recognised nomenclature and relevant information provided electronically in a Commission database⁴⁹.

e. Reporting on market surveillance actions (Article 22)

According to Article 22 of the CPR, Member States must perform appropriate checks of cosmetic products and periodically review and assess the functioning of their surveillance activities. Such reviews should be carried out at least every four years and the results should be communicated to the other Member States and the Commission.

Over the years different networks and tools have been created to inform about and coordinate the market surveillance activities by the competent authorities:

- the EU Product Compliance Network (EUPCN) has been established to structure the coordination and cooperation between market surveillance authorities in EU countries,

⁴⁹ Existing Cosmetic Ingredients database (CosIng) provides information on cosmetic substances and ingredients including frequently updated common ingredients names.

- PEMSAC group facilitates the exchange of information among the market surveillance authorities responsible for cosmetics,
- The ICSMS (Information and Communication System for Market Surveillance)⁵⁰ functions as the comprehensive communication platform for market surveillance on non-food products and for mutual recognition for goods.

The ICSMS allows information on investigated products (test results, product identification data, economic operator information, accident information, information on measures taken by surveillance authorities etc.) to be quickly and efficiently shared between authorities. It supports market surveillance activities, by providing a register for their documentation, the identification of the products inspected and the results of the tests/checks.

Stakeholder views

Some participants cautioned against introducing measures that could weaken EU-level oversight of national market surveillance activities. This cautious stance was reflected in responses to the Slido question: ‘Do you consider that the deletion of the reporting obligations would reduce burden on competent authorities?’ Most respondents did not express a clear opinion. However, among those who did respond, half believed that removing the obligation would result in significant or moderate reduction in administrative burden.

Proposed amendments and next steps

With the introduction of ICSMS, the reporting obligation introduced in Article 22 of the CPR has become redundant and therefore, it should be removed.

f. Outdated or obsolete reporting obligations

Several reporting obligations could be eliminated, as they have become obsolete due to the expiry of transitional periods or the implementation of the digital tools that now facilitate exchange of information:

- A **catalogue of all nanomaterials** was to be established by 11 January 2014 and regularly updated. In addition, Article 16(10) of the CPR requires the Commission to prepare an **annual status report on the use of nanomaterials in cosmetic products**. This obligation has become redundant as more detailed information on nanomaterials can be easily obtained from other sources. For instance, the European Union Observatory on Nanomaterials manages the publicly available data base on nanomaterials, which also indicates their use in various products including cosmetics.
- Article 18(2) of the CPR establishes the transitional period for phasing out the use of tests on animals for the purposes of manufacturing cosmetic products, which ended on 11 July 2013.

⁵⁰

<https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance>

- Article 20 of the CPR requires the Commission to submit a **report regarding the use of claims in relation to cosmetic products** by 11 July 2016. This obligation has been fulfilled with the adoption by the Commission of the required report in September 2016, and therefore, this provision has become obsolete and could be deleted.
- Article 35 of the CPR requires the Commission to **report on animal testing**, in particular on the development, validation and legal acceptance of alternative methods to animal testing and on progress in complying with the phasing out of animal testing. Following the end of the transitional period for animal testing for cosmetic products and the total ban on animal testing, this Article has become devoid of its purpose and could be deleted.

Proposed amendments and next steps

The reporting obligations indicated above could be deleted as they are no longer relevant. They create unnecessary compliance burden for the Commission and, indirectly, on competent authorities and businesses as the reports would have to rely on information provided by those stakeholders.

Estimated cost savings

Business stakeholders have long expressed concerns that the current legislative framework for cosmetics - in particular Article 15 of the CPR- is not adequate in addressing the growing number of harmonised classifications of substances as CMR category 1A, 1B or 2, many of which are commonly used in cosmetic products.

They claim that the derogation procedure for CMR substances in category 1A and 1B is practically non-functional. Industry requests for derogations have been consistently rejected, even in cases where the substances were assessed by the SCCS and deemed safe for use in cosmetic products, due to the difficulty to prove that the other criteria (compliance with food safety and lack of suitable alternatives) have been met. Hence, the strong calls for the exemption procedures to be made more transparent, timely, and workable for economic operators especially SMEs.

The cosmetic industry is increasingly concerned about its future due to the following reasons:

- The growing number and accelerated pace of chemical classifications under the CLP require reformulations. In many cases, this leads to discontinuation of products -including iconic ones- that cannot be reformulated or would suffer significant compromises in performance;
- Reformulations triggered by Article 15 prohibitions (i.e., forced reformulations) are often atypical and highly complex, as they involve key ingredients central to the function and identity of cosmetic products. These reformulations require lengthy innovation processes, diverting both financial and human resources away from genuine innovation and towards regulatory compliance;
- One-to-one ingredient substitution is rarely feasible, as it is highly technically complex, resource-demanding and has yielded only limited success to date;

- The unique combination of performance, safety, sensory experience and regulatory requirements in cosmetics makes the identification of suitable alternatives extremely challenging in the short term.;
- Reformulation of products is an inherent part of the cosmetic industry's continuous innovation cycle. It follows established timelines and milestones aligned to product' lifecycles and business models. 'Forced reformulations' interfere and disrupt these processes, causing delays and resource reallocation that hinder innovation.
- SMEs are disproportionately affected, lacking the capacity to develop complex alternatives. Larger companies, meanwhile, face significant challenges due to the scale of their operations and complexity of global supply chains.

Industry stakeholders stress that adequate transition periods are essential. These would enable regulatory-driven reformulations to be integrated into industry's natural innovation/reformulation cycles. Transitional periods would also provide the necessary time to reformulate, relabel and adequately manage existing stocks -thereby preventing market withdrawals and the destruction of safe, unsold products.

Example 1: Lilial (BMHCA)

Lilial is a widely used ingredient in the cosmetic sector. After its classification as a CMR substance, it was banned from the use in cosmetic products via the Omnibus Act IV which amended Annex II to the CPR. The ban applied 3,5 months after the publication of this Regulation.

Data provided by several cosmetics companies indicate that the prohibition of Lilial under Article 15 of the CPR resulted in substantial direct costs – including reformulation, product withdrawal, and administrative burden such as reporting. For large international companies, these costs ranged from **EUR 5.32 to 53.5 million** (one-off cost per company). Large national companies reported reformulation costs between **EUR 2 and EUR 23 million**, while medium-sized companies estimated costs between EUR 0.6 and EUR 0.8 million.

Apart from the reformulation costs, companies also conducted 'Product-in-Use' (PIU) tests to ensure consumer acceptance and maintain product 'likeability'. With average PIU test costs of approximately EUR 80.000 per product, one large national company estimated the **total cost of the Lilial phase-out to be around EUR 30 million.**

Example 2: Zinc Pyrithione (ZnPt)

Zinc Pyrithione, a widely used anti-dandruff ingredient, had a long-standing history of safe use in cosmetic products prior to its classification as CMR category 1B substance. Following its classification, industry submitted a derogation request under Article 15(2) of the CPR, providing

data to demonstrate its safety in cosmetic products, its compliance with food safety legislation, and the lack of suitable alternatives on the market.

The SCCS subsequently confirmed the safety of ZnPt when used in shampoos and its compliance with food safety legislation was acknowledged by the CPWG. However, the European Commission and Member States concluded that alternatives were available, citing the presence of antidandruff shampoos on the market using alternative ingredients.

Industry argued that, at the time, these alternatives were not available in sufficient quantities. Scaling up product required significant investment and adaptation of manufacturing sites, due to the physical hazards -such as explosiveness-associated with the alternative substance. As such, industry requested a temporary exemption, or a ban accompanied by an adequate transition period to allow sufficient availability of the alternative. However, this flexibility was not permissible under Art. 15(2).

The consequences of the ban were significant. One large international company reported that the impact represented **18% of its yearly turnover** (one-off cost) generated from cosmetic products. A large national company estimated a **5-6% reduction in its annual turnover**.

Both international and national companies stressed that the ban severely affected their competitiveness. Particularly compared to non-EU companies that continue to use Zinc Pyrithione in their products available outside the EU.

Currently, approximately 10 fragrance ingredients are undergoing harmonised classification and labelling (CLH) evaluation, with proposals or conclusions identifying them as CMR category 1B substances. Once officially classified, these ingredients would trigger the need to reformulate around 85% of the 500,000 cosmetic products currently on the market within the next 2-3 years. The estimated average cost of reformulating a single cosmetic product is approximately EUR 15,000 covering the costs of laboratory testing, machinery adjustments/equipment and quality control. Based on this estimate, the reclassification of just these 10 fragrance ingredients would require the reformulation of approximately 425,000 products, resulting in a total cost of **EUR 6.75 billion for the cosmetics industry**.

The average cost of re-labelling and re-packaging follow the reformulation as the change in ingredients must be reflected on the package. For medium companies, the **packaging cost varies from 1% to 3% of the total company turnover**. A medium size company reported that the estimated impact of recent regulatory changes requiring allergen labelling would reach **between EUR 2 and 5 million** (one-off cost for one company). These costs include the recruitment of personnel managing the relabelling (equivalent to 5 FTEs), changes in production nomenclatures, revision of ingredient list, production and distribution of products with new labels and withdrawal of products with old, non-compliant labels.

The costs of product withdrawals and destruction ranges from 0.5 % to 3 % of a company's annual turnover.

3. Issues and proposed amendments to Regulation (EU) 2019/1009 on EU Fertilising Products (FPR)

A Reality Check for the Fertilising Products Regulation took place on 8 May 2025. The following issues and potential solutions were discussed.

a. REACH registration of substances in EU fertilising products

Chemical substances, on their own or in mixtures, if manufactured or imported in quantities above one tonne per company per year, need to be registered in accordance with Regulation (EC) No 1907/2006 of the Parliament and of the Council³ (REACH). Information requirements increase with the volume in which the substance is manufactured or imported per year, with the following ranges: 1-10 tonnes per year, 10-100 tonnes per year, 100-1000 tonnes per year and 1000 tonnes or more per year. Substances manufactured or imported below one tonne per year do not need to be registered. A chemical safety report (CSR) is only required for substances manufactured or imported above 10 tonnes per year and not for substances present in a preparation in very low concentrations (below 0.1%). For substances meeting the criteria for classification as hazardous in accordance with the CLP Regulation or that are assessed to be persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, the CSR has to include an exposure assessment.

For substances⁵¹ used in EU fertilising products, on their own or in mixtures, the FPR does not apply the gradations of information requirements under REACH, but requires more extensive information. It requires that those substances, regardless of their concentration in the EU fertilising products and of volume in which they are manufactured or imported in the EU, have been registered, as a minimum:

- with the information requirements set out by Regulation (EC) No 1907/2006 for substances manufactured or imported in quantities of 10 to 100 tonnes per company per year or higher; and
- a CSR covering their use in a fertilising product, in accordance with Article 14 of that Regulation.

Moreover, not all exemptions from the registration requirement that exist under REACH apply under the FPR⁵².

Stakeholder views

As confirmed by stakeholders in the Reality Check, this requirement poses significant obstacles for manufacturers of EU fertilising products in using certain substances. Stakeholders explained that most substances used in EU fertilising products below 10 tonnes per year are manufactured by upstream suppliers. Therefore, the registration obligation first applies to these upstream

⁵¹ Virgin substances under Component Material Category 1 and additives under other Component Material Categories.

⁵² Only the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, 9 or 10 (only for magnesia) of Annex V to that Regulation apply to substances used in EU fertilising products.

suppliers. Manufacturers of EU fertilising products often do not know whether a substance that they would like to use is registered in accordance with the FPR requirements. Where they know that this is not the case, they have little leverage to persuade their supplier to upgrade the registration, unless the use in EU-fertilising products represents the majority of the market. Moreover, to protect confidential business information, suppliers are often unwilling to disclose data to the manufacturers of EU fertilising products, preventing those from upgrading the REACH registration themselves. Finally, according to business associations, some producers or importers of substances produced in low quantities, especially small and medium enterprises (SMEs), can simply not afford REACH registration in accordance with the FPR.

As consequences, manufacturers cannot use certain substances in EU fertilising products. They alternatively market their products under national rules for national fertilising products instead or stop supplying the EU market and turn to other markets, such as the US. Some also replace the substance in question by already registered but underperforming substances. Such reformulation, as explained by a company, implies costly reformulation tests, stability tests and greenhouse tests.

The problem was reported to be particularly relevant for technical additives, like dyes, which are mostly used in very small quantities and are difficult to substitute as performance varies a lot from one additive to another. But also, some primary components are produced and used in small amounts and therefore affected by this extended REACH registration requirement.

Several stakeholders considered that the more extensive REACH registration should be maintained, at least for certain substances, such as very hazardous substances, like persistent, bioaccumulative and toxic ones, and/or for certain unknown, bio-active substances, also considering the specific use pattern of fertilising products, namely their direct, continued and often large-scale application in the environment.

Proposed amendments and next steps

Taking into account the concerns described above, and in light of the extensive safety and information requirements under REACH for all substances manufactured and used in the EU and the safety requirements under the FPR, the extended REACH registration requirement under the FPR seems to pose a disproportionate burden.

Therefore, it is proposed to delete the requirement to register substances in EU fertilising products in accordance with the requirements outlined above from the FPR. In absence of any specific requirements under the FPR, the general REACH provisions, including the relevant gradations depending on volume, would apply to substances used in EU fertilising products.

The amendment concerns Annex II, Part II, CMC 1, point 2, CMC 3, point 1(d), CMC 4, point 1(b) and 3d, CMC 5, point 1(d) and 3d, CMC 6, point 2, CMC 8, point 1, CMC 10, point 1.3, CMC 11, point 2, CMC 12, point 13, CMC 13, point 8, CMC 14, point 7, and CMC 15, point 10.

Estimated cost savings

When considering the cost saving from applying standard REACH registration requirements to substances used in EU fertilising products, costs for different actors in the supply chain need to be

considered: the manufacturer/importer of the substance, the manufacturer of the EU fertilising product and the user of the EU fertilising product.

For substances below 1t/y, the extended REACH registration requirement in the FPR creates substantial new costs compared to the absence of a registration obligation under REACH, while for substances between 1t and 10t/y, as explained by a company, the registration costs are about 65% higher for substances used in EU fertilising products.

Companies registering a substance under REACH are required to pay a fee to the European Chemicals Agency (ECHA). For substances in the range 10 to 100 tonnes, the currently applicable fee is € 4,674 for individual submission for new registrations. For SMEs reduced fees apply ranging from € 234 for micro enterprises to € 3,038 for medium enterprises. The standard fee for updating a registration dossier from the 1-10 tonnes range to the 10-100 tonnes range, for individual submissions, amount to €2,935, for SMEs fees range from € 147 to € 1,908⁵³.

In a study carried out for the Commission in 2021⁵⁴, based on results from a survey among industry, the average overall costs per registration, per company, for 10-100 t/y substances, including fees, dossier preparation and testing, was estimated at around €101,000 per registrant and €280,000 per substance, although, depending on the testing required for the substance concerned, costs may be much higher. The costs of preparing a registration dossier (including drafting, finalising a technical registration dossier and submitting it, including administrative data and producing summaries for REACH annexes) at this tonnage band was estimated at €39,000. The average costs for physicochemical, toxicological and ecotoxicological tests for 10-100t/y substances was estimated at € 144,329.⁵⁵ In addition, the costs for a chemical assessment/report were on average € 14,801. The average costs for updates of registration dossiers were not assessed.⁵⁶

In the context of the Reality Check, stakeholders reported costs for complying with the extended REACH registration requirement of **up to €500,000 per substance**. An industry association shared results from a survey carried out among their members asking about the burden of the extended REACH registration requirement under the FPR. Depending on the tonnage band and extent of data required, the costs reported in the survey for upgrading a registration dossier in accordance with the FPR vary **between €10,000 to €500,000 per substance**. **€180,000** was found as the typical investment needed to **upgrade a registration dossier from 1-10t/y to the 10-100t/y requirements**. A company contributing to the Reality Check reported costs in a similar range. For the six substances that the company registered in accordance with the extended requirements under the FPR, it spent between **€100,000 and €500,000**, including the costs for data generation, consultancy, dossier preparation and the fees paid to ECHA. It explained that, for substances below

⁵³ Commission (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 107, 17.4.2008, p. 6, ELI: <http://data.europa.eu/eli/reg/2008/340/oj>.

⁵⁴ Wood, Study on the impacts of the 2018 REACH registration deadline. [Final Report](#), 2021.

⁵⁵ Physicochemical requirement study costs: €13,125, toxicological requirement study costs: €104,911, ecotoxicological requirement study costs €26,293.

⁵⁶ Wood, Study on the impacts of the 2018 REACH registration deadline. [Final Report](#), 2021, pp. 53, 122, 123.

1t/y, the FPR creates new costs compared to the absence of a registration obligation under REACH, while for substances between 1t and 10t/y the registration costs would be 65% higher for substances used in EU fertilising products. In the same vein, an industry association estimated that costs for upgrading a registration from the 1-10 tonnes to 10-100 tonnes band, excluding the fees, can result in costs of **up to € 400,000**, and another industry association reported that, depending on the substance and its registration status (upgrading from the 1–10 t/year band to 10–100 t/year or registering an exempt substance in the >10 t/year band), costs range between **€150,000 and €240,000**. Costs in this range were also confirmed by a Member State authority, estimating total registration costs of **€270,000** for a substance produced below one tonne per year.

On this basis, it is estimated that **a one-off cost of between €1.540.000 and €52.500.000** (see Annex IV) would occur to update REACH dossiers for all substances registered with possible value in fertilising products and a tonnage band of less than 10t/y, let alone the substances not registered under REACH because they are currently placed on the market in volumes below 1t/y.

Although **SMEs** benefit from reduced registration fees, they also incur costs for proving SME status, as explained by a company. Moreover, the fees represent less than 5% of total registration costs, whereas the bulk of costs, i.e. for the preparation of the dossier and testing, is the same for large companies and SMEs.

According to a position paper signed by several industry associations, the costs for the extended REACH registration eventually leads to **increased costs for manufacturers of EU fertilising products and materialises in increased prices for users**. Using several examples, they calculated that the cost of the extended REACH registration, if spread over a period of five years, would lead to an **increase of the cost of the substance by 40%-540%**, depending on the volume in which it is manufactured or imported and the concentration in which it is used in the fertilising product. This was confirmed in position papers of another industry association and a competent authority. The price of the end product would then also have to be increased. For an EU fertilising product using a substance below in the <1t range, the estimated price increase would be by **26%**.

By removing the extended REACH registration requirement from the FPR, normal REACH requirements would apply to substances used in EU fertilising products, even if manufactured in low quantities. This would allow more substances to be used in EU fertilising products, as many of them might be exempt from the registration requirement or already registered for the 1-10 t/y band. It would thereby avoid the costs of (updating) registration in the 10-100 t/y band for substances used in low quantities that are difficult to substitute, thereby reducing the cost of reformulation. This would remove a technical barrier and increase the added value of EU fertilising products compared to national ones, which are already subject to the ‘standard’ REACH provisions only.

Manufacturers which would CE-mark their products to place them on the single market, would no longer face multiple fees for national registrations (between €0 and €50.000 per product per MS) and costs to adapt their products, labels or packaging to meet different rules between two or more

national rules (reported adaptation costs between two sets of national rules between €15.000 and €43.000).⁵⁷

b. Assessment of microorganisms in plant biostimulants

Micro-organisms are an important area for innovation in fertilising products. They can be used in plant biostimulants which stimulate plant nutrition processes and, thereby, allow for a reduced use of fertilisers. However, currently, only four groups of micro-organisms may be used as component material (CMC 7) in EU fertilising products: *Azotobacter* spp., mycorrhizal fungi, *Rhizobium* spp. and *Azospirillum* spp. The Commission is empowered to add new strains of micro-organisms after having assessed their safety and agronomic efficiency. For such assessment, the Commission depends on the support of external contractors and is constraint by the available budget that can be spent on such external studies.

Stakeholder views

Microbial biostimulants, based on a variety of micro-organisms, bring **several benefits for farmers and the environment**. According to stakeholders participating in the Reality Check, those include:

- Enhancement of Nutrition Use Efficiency (NUE) and function as nitrogen-fixing, phosphorus-solubilizing, and potassium-mobilizing agents;
- Increasing the crops' tolerance to abiotic stress;
- Improvement of water absorption (mycorrhizal fungi);
- Reduction of water contamination by nutrients and greenhouse gas emissions;
- Minimisation of soil degradation, promotion of microbial biodiversity in agricultural soils, and contribution to CO₂ capture from the atmosphere.

The mechanism for allowing the use of additional strains of micro-organisms in EU fertilising products under the FPR, presupposing a one-by-one strain-level assessment by the Commission, has been criticised by stakeholders as being **incompatible with the need and the pace of development of the growing plant biostimulant sector**. It is considered to slow down market access for microbial plant biostimulants, discourage innovation and investments, and delay the availability of these products to farmers.

Industry associations underlined that, as a consequence of not being able to market their biostimulants under EU rules, manufacturers market their product **under national rules** of the Member States. This is a **significant burden, especially for SMEs**, due to the large variations of Member States' rules, the need to seek approval in different jurisdictions and the well-known issue with mutual recognition of authorisations for fertilising products. Moreover, EU manufacturers might seek **alternative markets outside the EU**. Finally, given the unfavourable conditions in the EU, **innovation and investment of such products might take place in third countries**.

In a survey carried out by an industry association in the plant biostimulant sector among 65 members, **88% of participants said that they were not able to place their microbial plant**

⁵⁷ Impact Assessment accompanying the Proposal for a Fertilising Product Regulation, SWD(2016) 64 final.

biostimulant on the EU market because the micro-organism used it was not yet on the positive list. Most respondents placed microbial plant biostimulants on the market via national rules, with approval times ranging from 6 months to 3 years and costs between €5,000 to €30,000. **59% of respondents are currently exporting microbial plant biostimulants to third countries**, incl. the United States, Argentina, Mexico and Brazil, which means that their products manufactured in the EU, and often developed using EU research funding, are not provided to EU farmers. 72% of respondents said that they have several products which would be ready to go through the FPR's conformity assessment within two years, if the micro-organisms used therein would be allowed under CMC 7.

A study carried out for the Commission to support it in the assessment of additional strains of micro-organisms for potential inclusion under CMC 7 is currently assessing a set of 34 strains which were submitted for assessment in 2022.⁵⁸ Since then, the Commission has received several requests to assess additional strains. This shows the great number of micro-organisms that could potentially be used in EU microbial plant biostimulants. An industry association shared in the Reality Check that, in Spain alone, sales of micro-organism-based fertilising product from associated companies exceed €30 million, underlining the potential of these products also for the internal market.

The study is developing a methodology and general criteria for the assessment which could be used as a basis for a future amendment of CMC 7 in exercise of the Commission's new empowerment. Many stakeholders participating in the Reality Check were in favour of the criteria-based approach and of using the methodology developed in that study as basis for the amendment to CMC 7. Some written contributions pointed to certain weaknesses of the current draft methodology. A few stakeholders underlined the importance of a thorough safety assessment and of providing for the possibility of a reassessment on the basis of new information, and some suggested that the assessment should not be left to manufacturers and notified bodies but be carried out by an independent body, like the European Food Safety Agency (EFSA). One stakeholder emphasised the importance of ensuring the protection of confidential business information within the new criteria-based mechanism.

Proposed amendments and next steps

Based on the feedback received, it is proposed to provide the Commission with a new empowerment in Article 42 FPR to amend Annex II, Part II, CMC 7, to set out general safety and efficiency criteria for micro-organisms and a methodology which manufacturers and notified bodies should use to assess and demonstrate compliance with those criteria.

The criteria and methodology developed in the ongoing study could be used as a basis for a future amendment of CMC 7 in exercise of the Commission's new empowerment.

The current empowerment for the addition of strains of micro-organisms to the positive list would be maintained. This would allow the Commission to include the strains currently being assessed

⁵⁸ Study ongoing at the time of adoption of the proposal.

and, potentially, further strains in the future. Manufacturers and notified bodies would not need to assess those strains against the general criteria which are included in the positive list.

Estimated cost savings

The amendment of the empowerment as such will not entail any cost savings. However, once the Commission has made use of the empowerment, economic benefits are expected for various actors:

- **Manufacturers of plant biostimulants:** Although manufacturers and importers of EU plant biostimulants might incur some additional cost in the conformity assessment of their product to cover the assessment of the micro-organism, these costs are expected to be negligible compared to the **economic benefit of having free access to the internal market**⁵⁹. Costs currently incurred for familiarising and complying with the different national rules for microbial plant biostimulants could be avoided by complying with the harmonised rules under the FPR. It is estimated that **regulatory cost to access the single market instead of 5 national markets would be reduced by 50%**⁶⁰. Allowing industry and notified bodies to perform the safety and efficiency assessments would also **speed up the access to the market**, considering that national authorisations can take more than 18 months.
- **Farmers:** It is expected that the new mechanism for the assessment of micro-organisms would increase the availability of microbial plant biostimulants on the EU market. Farmers would benefit from a larger choice of products they can use to improve the plant nutrition processes of their crop. As a result, they might be able to reduce the volume of fertilisers used. Studies have shown that **by applying certain microbial plant biostimulants, the fertilisation could be reduced between 33% and 80%**, depending on the product and the overall treatment of the crop, without any negative effect on the yield.⁶¹ In consequence, external costs can be reduced and the autonomy of the EU for fertilising products be reduced.
- **Notified bodies:** Notified bodies will need to update their accreditation and notification to cover the assessment of micro-organisms in accordance with the criteria and methodology set out by the Commission. However, they will likely benefit from an increased number of applications for conformity assessment for microbial plant biostimulants.

⁵⁹ In the context of the Reality Check, no costs were brought forward as an argument against this proposed amendment.

⁶⁰ As explained in the context of the extended REACH registration requirement, manufacturers which would CE-mark their products to place them on the single market, would no longer face multiple fees for national registrations (between €0 and €50.000 per product per MS) and costs to adapt their products, labels or packaging to meet different rules between two or more national rules (reported adaptation costs between two sets of national rules between €15.000 and €43.000).

⁶¹ Gazoulis *et al.*, A Preliminary Assessment of the Combined Effects of a Novel Microbial Biostimulant Product, Fertilizers, and Herbicides on the Growth and Yield of Field Crops in Greece, *Agronomy* 14:8, 2024; Rossini et al, Combining nitrogen fertilization and biostimulant application in durum wheat: Effects on morphophysiological traits, grain production, and quality, *Italian Journal of Agronomy* 20:1, 2025.

- **European Commission:** The cost for the assessment of micro-organisms would, in the future, be born by industry. In consequence, costs for external studies, which are in the lower 6-digit range per study, would be saved and could be invested elsewhere.⁶²

c. Inclusion of derived products outside the scope of Regulation (EC) No 1069/2009

Under the Fertilising Products Regulation, the Commission is empowered to include derived products within the meaning of Regulation (EC) No 1069/2009 (Animal By-Products Regulation, ABPR) as component materials in EU fertilising products where an end point in the manufacturing chain has been determined in accordance with that Regulation. From that point in the manufacturing chain, derived products in scope of the ABPR are considered to no longer pose any significant risk to human, animal or plant health, to safety or to the environment and are therefore no longer subject to the requirements of that Regulation, including veterinary controls. Certain derived products within the meaning of Regulation (EC) No 1069/2009 are excluded from the scope of that Regulation in accordance with Article 2(2) of the Regulation. Such products can currently not be included in CMC 10 under the FPR, because an end point cannot be determined in accordance with the ABPR.

Stakeholder views

Stakeholders in the Reality Check confirmed the high interest in the inclusion of additional derived products under the FPR. For many stakeholders, the inclusion of derived products *within the scope* of the ABPR – for which an endpoint has already been determined or which are currently assessed in a study carried out for the Commission – is a priority. Nevertheless, the initiative of allowing for the inclusion of materials that are *outside the scope of the ABPR* was appreciated as the exclusion from the ABPR’s scope is understood as indication that those materials do not pose a risk. The following materials were mentioned as particularly interesting⁶³:

- shells from shellfish with the soft tissue and flesh removed;
- fish sludge (i.e. faeces from farmed fish together with uneaten feed from land aquaculture in freshwater and from aquaculture in open sea cages (saltwater) and land- or semi land-based facilities with saltwater);
- mineralised guano;
- plant-based soiled cat litter.

Industry associations pointed to the benefits that the use of those materials would mean for fostering a circular economy, organic agriculture and bioeconomy.

Proposed amendments and next steps

It is proposed to amend the empowerment in Article 42(5) to allow the Commission to add derived products *within the meaning but outside the scope* of the ABPR in the component material categories of the FPR, after an assessment concluding that the derived product does not present a

⁶² To note that there is no recurrent budget for such studies. While one study is ongoing, it is unclear if and when the next study could be launched.

⁶³ Some other materials were mentioned by stakeholders which are, however, in the scope of the ABPR and therefore not relevant for this initiative.

risk to human, animal or plant health, to safety or to the environment, and ensures agronomic efficiency. The empowerment for adding derived products within the scope of the ABPR would remain the same, i.e. an end point first has to be determined.

Estimated cost savings

The amendment of the empowerment would as such neither entail nor save any costs. Moreover, no quantitative data is available in relation to the economic implications of the inclusion of those derived products on the basis of the new empowerment. However, an industry association emphasised that not being allowed to use certain derived products in EU fertilising products results in higher raw material costs for manufacturers as they are compelled to use other more expensive material. Moreover, it would create barriers to circular business models and slow down progress on soil health and organic matter restoration, which might indirectly impact the yields and resilience of crops. Another stakeholder pointed out that the use of such materials would not only entail economic benefits for manufacturers of EU fertilising products but also recover valuable materials which otherwise would be treated as waste. Specifically on fish sludge, a stakeholder pointed to the material's potential to become an important phosphorus source in the circular economy and to replace some of the use of mined phosphorus in fertilisers. As regards shells, a competent authority explained that the disposal of shells is a challenge for small companies that produce canned mussels and are important for the economy of coastal villages. An industry association pointed to the high amount of crustaceans consumed by EU citizens and the corresponding shells available for further use. Concerning plant-based cat litter, a stakeholder explained that the reuse in EU fertilising products would not only reduce the volume of municipal solid waste but also ensure that the plant-based component of the soil and the cat excrements are introduced into soil, providing nutrients and increasing soil organic matter.

d. Digitalisation

Under the FPR, certain provisions seem to not fully enable the use of new technologies and digitalisation of procedures. Due to the FPR's specificities, including the rules on voluntary digital labelling, it was not included in the Proposal for a Regulation of the European Parliament and of the Council amending Regulations [...] as regards digitalisation and common specifications (Omnibus IV)⁶⁴.

One example is the contact information that economic operators are required to provide on the product. Currently, the name, trade name or trademark and postal address need to be indicated, while the indication of a digital contact, such as an e-mail address, is only voluntary. Moreover, economic operators are required to provide competent authorities, upon request, with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product. This can be done either in electronic or in paper form. As it is not specified whether documents drawn up in the context of the conformity assessment, either by notified bodies or by manufacturers, should be in paper or electronic format, some might currently only be available in paper. The EU declaration of conformity, currently, does not need to accompany the EU fertilising

⁶⁴ [COM\(2025\)504](#).

products, but must be made available to the relevant authorities or economic operators upon request. The format in which it shall be provided is not further specified.

As outlined in the Staff Working Document accompanying Omnibus IV, Member States and their various market surveillance authorities have divergent views and practices, some requiring documents in paper format while others accept digital transmission of documents.⁶⁵ Overall, the existing provisions might lead to a situation where manufacturers, despite the flexibility provided by the FPR, draw up documents in paper format, in order to be sure that the documents will be accepted by authorities and notified bodies.

Stakeholder views

In the targeted consultations for the evaluation of the NLF⁶⁶, 74.5% of the respondents thought that the efficiency of the conformity assessment procedure would largely improve (35 responses) due to digitalisation of the declaration of conformity / technical product information / technical file, without hindering market surveillance activities, while a further 12.8% (six responses) thought it would improve to a moderate extent. The NLF evaluation also found (on p.49) that “[i]ndustry respondents were in favour of moving towards digital only CE marking, product compliance and user information as soon as possible. This was seen as potentially reducing costs, but only if hard copy versions were no longer required. However, none of the national competent authorities shared this view.”

Moreover, in the context of the preparations of the Omnibus IV, the Commission organised an outreach event aiming at gathering the opinions and feedback of the stakeholders on the simplification exercise. In parallel, the Commission reached out directly to stakeholders representing sectorial industries in order to gather data on potential cost savings that a ‘digital by default’ policy could create. In addition, on 14 April 2025, the Commission consulted the members of Task Force 1 of the Industrial Forum and other stakeholders, including representatives of consumer organizations to gather their opinions on the digitalisation of the DoC, digital instructions for use and on the introduction of the DPP and its use as a tool for making compliance related information accessible. Feedback received in the context of these consultation activities showed broad support for the digitalisation initiative from stakeholders⁶⁷.

In the context of the Reality Check carried out in preparation of this proposal, several stakeholders, including industry and authorities, underlined that the digitalisation of information requirements can reduce the administrative burden for companies and authorities as electronic management can facilitate the exchange, storage and access to information, reduce errors associated with manual process, and minimise paper usage and the costs linked to the handling of paper documents.

Some concerns were expressed in relation to cyber security, availability and interoperability of digital infrastructure, costs for acquiring necessary technology and, in relation to exports, paper-

⁶⁵ [SWD\(2025\) 130 final](#), p. 4.

⁶⁶ [SWD\(2022\)364 final/2](#), p. 34

⁶⁷ [SWD\(2025\) 130 final](#), pp. 13f.

based systems in third countries. Several stakeholders pointed out that industry and authorities would need 2-3 years to adjust to the new digital requirements, while one suggested 1-2 years.

Proposed amendments and next steps

Aligning the FPR, where appropriate, to the Omnibus IV, this proposal includes amendments to Article 2, Articles 6-9, Article 15, Article 16 and Article 41, as well as to Annex I, Part II, and Annex IV, Part II, which would implement the following changes to information and reporting obligations:

- Specifying that the EU declaration of conformity must be drawn up in electronic form and made accessible through an internet address or data carrier;
- The addition of a ‘digital contact’ as information to be indicated by economic operators on the products which are placed on the market in order to facilitate communication between economic operators and national authorities. Once the European Business Wallet is available, the digital address it provides to economic operators could constitute the “digital contact”;
- The amendment of reporting obligations to national authorities that require a ‘paper or electronic format’ to ‘electronic form’ only;
- Specifying that documents and exchanges between the economic operators and notified bodies related to conformity assessments shall be in electronic form;
- An obligation that, if a digital label is used, the same data carrier providing access to the digital label should also provide access to the EU declaration of conformity;
- An obligation to provide the information contained in the EU declaration of conformity and, if applicable, digital labelling on the digital product passport when the product is subject to other Union legislation that requires the use of such a digital product passport.

In line with the Omnibus IV and the suggestions from stakeholders, the entry into application of these amendments should be deferred by 24 months.

Estimated cost savings

In the context of the Reality Check, stakeholders confirmed that the further digitalisation would entail cost savings but were unable to quantify these savings. In the Staff Working Document accompanying the Omnibus IV, it was concluded that the digitalisation of reporting obligations would imply the following costs or cost savings:

- **For businesses:** The digitalisation of economic operators’ obligations would facilitate and speed up the transmission of documents to authorities. The simplified document management, i.e. no handling of paper copies and no update costs of existing documents, would result in cost savings, which, however, could not be quantified. In addition, it was estimated that companies can save costs related to paper, printing and postage of about €4 per year, assuming they are asked to provide these documents to authorities in paper once a year. For businesses that are already providing all relevant information in electronic format the amendments would not bring any cost savings. At the same time, companies would incur no or only negligible additional costs, related to the upload of the relevant information to a digital storage.

- **Public administrations:** Costs and cost savings for public authorities could not be quantified. It was acknowledged that they may incur some additional costs for the training of staff in working with electronic files and the relevant IT systems. However, they could save costs related to the handling of paper documents (opening letters, registering the document, filing/storing the physical document) and it was expected that, in the medium- to long-term, the digitalisation of reporting obligations will increase public authorities' efficiency.
- **Environmental costs and cost savings:** Some environmental benefits will be achieved by reducing the use of paper. It is estimated that roughly one ton of CO₂ emissions are associated to the production of one ton of paper⁶⁸, with lower values for recycled paper and higher values for virgin paper. Although, on the other hand, there will be some negative environmental impacts linked to the creation and use of additional digital infrastructure, it was expected that “the environmental balance in the medium to long run is favourable for replacing paper with digital technology”⁶⁹.

e. Removal of the ‘unbundling clause’

The FPR empowers the Commission not only to add additional strains of micro-organisms to CMC 7 or derived products to CMC 10, but also to make other amendments to the component material categories in Annex II to the Regulation, in order to adapt those Annexes to technical progress or to new scientific evidence and to facilitate internal market access and free movement for EU fertilising products. However, according to Article 43 FPR, the Commission shall adopt a separate delegated act in respect of each component material category. In view of the many amendments still to come for the addition of new materials, which will foster the circular economy, or for making other adjustments, this ‘unbundling clause’ is a source of significant inefficiencies. From the legal drafting, via the consultation of experts and the public, until the adoption procedure – the entire procedure for adopting delegated acts is multiplied, even if the same or similar amendments are made to all component materials.

Stakeholder views

Stakeholders were not directly consulted on this provision as it mainly concerns Commission procedures. However, stakeholders frequently complain about the slow pace of the adoption of delegated acts under the FPR, which is causing delays in the use of certain materials. Moreover, the experts in the Commission Expert Group are consulted on every delegated act and the higher the number of delegated acts proposed, the more time they need to spend on familiarisation with the proposal and providing feedback. Any amendment which might speed-up the process is therefore expected to be welcomed also by stakeholders.

⁶⁸ <https://bioresources.cnr.ncsu.edu/resources/life-cycle-carbon-footprint-analysis-of-pulp-and-paper-grades-in-the-united-states-using-production-line-based-data-and-integration>

⁶⁹ [SWD\(2025\) 130 final](#), pp. 18-21.

Proposed amendments and next steps

It is therefore proposed to delete Article 43 FPR, in order to enable the Commission to make amendments to several component material categories in one delegated act.

Estimated cost savings

This amendment would not directly save costs for industry or authorities, but it would streamline the procedure for the adoption of delegated acts, thereby freeing resources and speeding up the inclusion of additional materials or other changes in the component material categories.

f. Other areas where stakeholders called for simplification

In the context of the Reality Check, stakeholders made several other suggestions for simplification which were not taken on board in this targeted simplification exercise.

• Clarifications in the legal text

An industry association suggested making several clarifications, currently addressed in the Commission's FAQ document⁷⁰, in the legal text. As the amendments proposed concern exclusively the Annexes to the Regulation, they can be made via delegated act and the Commission will consider them independently from this proposal.

• Moving to a criteria-based approach for derived products from animal by-products or for all component material categories

Several industry stakeholders advocated for moving away from an individual assessment of materials to be added to the different component material categories (CMCs) to a criteria-based approach for all CMCs, or at least for derived products from animal by-products (CMC 10). As this would be a substantial departure from the current functioning of the FPR, the Commission considers that whether there are shortcomings or inefficiencies in the existing system should first be assessed in the ongoing evaluation of the Regulation

• Changes to the digital labelling rules

Some industry stakeholders suggested changes to the rules on digital labelling introduced in 2024, including alignment with CLP and extension of information which can be provided in the digital label only, without duplication on a physical label.⁷¹ The labelling rules will be applicable from 1 May 2027. The Commission considers that there is currently no reason to amend the rules agreed upon by the co-legislators in 2024. The Commission will carry out an evaluation of the digital labelling rules 21 October 2031 and, if appropriate, develop a legislative proposal to adjust the provisions.⁷²

⁷⁰ <https://ec.europa.eu/docsroom/documents/63434>.

⁷¹ Regulation (EU) 2024/2516 of the European Parliament and of the Council of 18 September 2024 amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products, OJ L, 2024/2516, 30.9.2024, ELI: <http://data.europa.eu/eli/reg/2024/2516/oj>.

⁷² See Article 49a of Regulation (EU) 2019/1009.

- **Improving coherence with other relevant legislation**

Some industry stakeholders pointed to unclarities or coherence issues between the FPR and other relevant legislation, notable the ABPR, REACH and the Waste Framework Directive (Directive 2008/98/EC).⁷³ As the FPR is assessed for external coherence under the ongoing evaluation, any measures in this regard would be premature.

- **Clarification in relation to impurities**

Several industry stakeholders asked the Commission to clarify that component materials may contain detectable traces of impurities and unintended substances which are not considered component materials. The Commission considers that, with the envisaged removal of the extended REACH registration requirement, such clarification is no longer relevant. Impurities and unintended substances fall within the definition of ‘substance’ under Regulation (EC) 1907/2006 and within CMC 1 under the FPR. They can therefore be used in EU fertilising products and, following the envisaged amendment, will be only subject to REACH registration if manufactured or imported above 1 ton per year.

- **Negative list of prohibited compounds**

A Member State authority proposed to establish a negative list of compounds not to be used in fertilising products similar to the list in Annex III to Regulation (EC) No 1107/2009 on plant protection products⁷⁴. The Commission considers that consideration of that kind should only be made once the results of the ongoing evaluation of the FPR are available. The evaluation is assessing whether the FPR’s current provisions are appropriate to ensure a high level of safety and environmental protection.

- **Revision of the Information and Communication System on Market Surveillance (ICSMS)**

A Member State authority suggested the revision of the Information and Communication System on Market Surveillance (ICSMS) to better account for the specificities of the fertilising products sector. The establishment and use of ICSMS as a horizontal market surveillance tool is mandated by Regulation (EC) No 765/2008.⁷⁵ While it is not specifically tailored to fertilising products, the Commission considers that its general outline allows its use also for those products. A task force within the Administrative Cooperation Group for EU fertilising products is currently working on a guidance document to support authorities with the use of ICSMS for fertilising products.

⁷³ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3, ELI: <http://data.europa.eu/eli/dir/2008/98/oj>.

⁷⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁷⁵ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30, ELI: <http://data.europa.eu/eli/reg/2008/765/oj>.

- **Sludge**

Some stakeholders called for allowing more types of sludge to be used as input for component materials. The Commission considers that such an amendment is not related to simplification and would require a specific scientific assessment.

- **Removing the HAS assessment of harmonised standards**

A representative from a European Standardisation Organisation (ESO) suggested removing the step of an assessment by a consultant ('HAS assessment') after the publication of the European standard by the ESO and before the citation in the *Official Journal*. The Commission notes that the procedure for the assessment of harmonised standards is not set out in the FPR but is applied across legislation. It is therefore outside the scope of this targeted simplification exercise.

D. OVERALL CONCLUSIONS

The measures proposed in this initiative would simplify requirements and streamline procedures under Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and Regulation (EU) 2019/1009, with the aim and expectation of reducing costs and administrative burden for industry and authorities, while maintaining a high level of protection of human health and the environment.

As regards **classification, labelling and packaging of chemicals**, the proposed measures will simplify and allow more flexibility for the formatting rules removing the excessive costs for industries. The saving from the proposed changes to the font size requirements and related typographic rules for the EU chemicals sector could amount to at least **€226.200.000** (from **€31.000.000 to €2.469.000.000**). In addition, it will also alleviate the burden to businesses and improve the free circulation of substances and mixtures in the internal market lightening obligations for advertisements of hazardous substances and mixtures, and narrowing the scope of obligations to advertisements for the general public, saving EU chemicals sector on average from **€20.000 up to €30.000.000** annually.

As regards cosmetics, the proposed measures will relieve the cosmetics manufacturers, especially SMEs, from the unnecessary compliance and administrative burden allowing them to shift the financial and human resources from compliance and administrative tasks **to R&D and innovation**. The changes will not only ensure that consumers and professionals will continue receiving safe cosmetic products, but ultimately products which meet their needs or expectations. The changes will allow the EU cosmetic businesses (of which 98% are SMEs) to scale up and be more competitive on the EU and global arena.

As regards **EU fertilising products**, the amendments are expected to foster the manufacturing and marketing of innovative and high-performing EU fertilising products, with increased use of secondary raw materials and safe and efficient micro-organisms. More concretely, the obstacle of the costs for complying with the extended REACH registration requirements (**up to €500,000**) for substances in EU fertilising products would be removed. Manufacturers of fertilising products will likely have a greater choice of (affordable) substances that can be used in EU fertilising products, which may encourage them to market their products under FPR rules in the Single Market. Like

this, they can save fees for national registrations (**up to €50.000** per product per MS) and adaptation costs (at an estimated range of **€15.000 to €43.000**).

The amendments also pave the way for the use of a larger variety of micro-organisms in EU fertilising products which will create economic opportunities in the EU and might reduce farmers' use of fertilisers. The streamlined assessment of those micro-organisms will also free up resources in the Commission which can be invested elsewhere. By enabling the inclusion of additional animal by-products, the amendments support a more circular economy, reducing costs alternatively spent on primary raw materials and waste treatment.

Moreover, the removal of the 'unbundling clause' would streamline the adoption of delegated acts, thereby freeing resources of stakeholders and the Commission and speeding up the inclusion of additional materials and the adoption of other necessary amendments to the component material categories.

Finally, the digitalisation of reporting requirements can reduce the administrative burden for companies and authorities linked to the handling of paper documents.

ANNEX I

REALITY CHECK ON THE POSSIBLE SIMPLIFICATION OF CHEMICALS LEGISLATION – CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES SYNOPSIS REPORT

Meeting date: 16 May 2025, 9.00-12.30;

Location: Online (Webex);

Organised by: European Commission – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Unit F2;

Participants: businesses, practitioners applying EU law, consumer and business associations, competent authorities;

Number of registrants: 711;

Number of participants who attended: 577.

I. Welcoming Remarks and Introduction to the Commission Simplification Initiatives

The event opened with an introduction to the Commission’s policy on simplification and its new technical-level consultation tool, the “Reality Check.” The objective was to collect feedback of stakeholders (businesses, practitioners applying EU law, consumer and business associations as well as competent authorities) on potential simplification of the Classification, Labelling and Packaging Regulation (CLP) following its revision via Regulation (EU) 2024/2865, with the aim for cost-savings and reduction of the administrative burdens. The context was the Commission’s broader simplification strategy to enhance EU competitiveness through streamlined legislation.

II. Mandatory Formatting Requirements

A significant majority of participants expressed concern about the mandatory formatting requirements, especially minimum font sizes, line spacing, and black-on-white text obligations. Stakeholders highlighted the disproportionate economic burden these rules place on businesses, particularly in multilingual markets, and raised concerns about increased packaging waste, limited label space, and the high cost of fold-out labels. Numerous participants supported the use of digital tools (e.g. QR codes) as a supplementary or alternative means of conveying information. Others noted that the one-size-fits-all approach did not account for the diverse professional contexts (e.g. B2B transactions) where hazard communication is already ensured through Safety Data Sheets (SDS). There was strong and repeated support for “stopping the clock” on the new formatting requirements to allow for further analysis and adaptation. At the same time the concerns about the need to protect consumers and workers and ensure legibility of labels and provide clear and comprehensive hazard information were also raised.

III. Rules on Advertisements

Many participants criticised the broadened requirements for advertisements introduced in the revised CLP, particularly the obligation to include detailed hazard information (e.g. pictograms, signal words and hazard statements) in all promotional material. Stakeholders considered this approach disproportionate, especially in comparison to advertising rules in sectors like pharmaceuticals. Concerns were raised about practical feasibility in modern digital formats (e.g. online banners, small-space media) and the risk of overwhelming consumers with excessive detail, thereby reducing the clarity of key safety messages. The majority supported replacing the new requirements with a simplified standard message such as “Always follow the information on the product label.” Several participants advocated exempting B2B advertisements from these requirements entirely, citing the adequacy of SDS for professional users.

IV. Other Areas for Simplification in CLP Regulation

Stakeholders raised a broad range of additional simplification opportunities. Key topics included:

- **Placing vs. making available on the market:** Calls were made to align CLP with other NLF product legislation by distinguishing these concepts, to reduce unnecessary stock reclassification.
- **Poison Centre Notifications (PCN):** Numerous participants described the current system as burdensome and fragmented, with inconsistent national requirements and high associated costs. Centralisation via ECHA was proposed.
- **Unique Formula Identifier (UFI):** Several actors requested flexibility in UFI requirements, particularly for fuels, where the diversity and mixing of supplies makes practical implementation extremely difficult.
- **Self-classification labelling deadlines:** Strong support emerged for aligning the six-month deadline for self-classified substances with the 18-month timeline used for harmonised classifications.
- **Digitalisation:** Many stakeholders advocated expanding the legal basis for digital labelling, especially in B2B and multilingual contexts, to complement or partially replace on-pack information.
- **Harmonised Classification and Labelling (CLH):** Industry and NGO representatives agreed on the need to streamline the CLH process. Proposals included allowing better use of new data, clarifying exposure routes, and automatically updating Annex VI based on scientific opinions.
- **Mixture classification and expert judgment:** Particularly for detergents, stakeholders warned that limitations on the use of expert judgment and weight-of-evidence approaches could lead to disproportionate and misleading classifications.
- **Label updates and stock management:** Several stakeholders noted that short implementation timelines could lead to product and label waste, undermining the Green Deal and packaging legislation.
- **Terminology clarity:** Calls were made to better define “advertisement” and “distance sales” in the CLP to avoid compliance ambiguities.

V. Conclusions

- The new formatting requirements, particularly font sizes and line spacing, were considered excessively burdensome by a wide range of stakeholders. Many called for a pause in their implementation and proposed a more flexible, digitally enabled approach.
- The revised rules on advertisements were widely criticised for being disproportionate and lacking clarity. A simplified approach focusing on referencing the product label was strongly supported.
- Multiple suggestions were made for further simplification of the CLP Regulation, including aligning timelines, clarifying key definitions, streamlining the CLH and PCN processes, and enhancing digitalisation.
- Stakeholders were invited to submit written contributions by 31 May 2025 (or 1 June at the latest), particularly with quantifiable evidence to support simplification proposals.
- The Commission will prepare a report to inform political decision-making.

VI. Summary of poll results

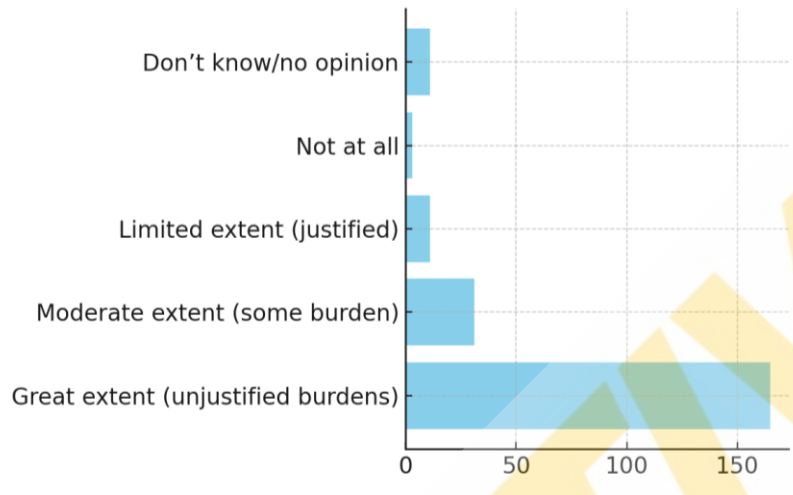
a. Mandatory formatting requirements

First poll focused on mandatory formatting requirements and consisted of six questions, including one open-ended question. 222 participants in total provided their replies, while open question gathered 55 qualitative responses. The objective of this poll was to evaluate the stakeholders' perception of the new rules on formatting introduced by the Regulation 2024/2865, identify key concerns, and propose actionable next steps.

Question 1. Perceived Burden of CLP Formatting Requirements:

- 75% of respondents believe the new formatting rules impose significant and unjustified burdens.
- Only 6% think the requirements are justified or not burdensome.

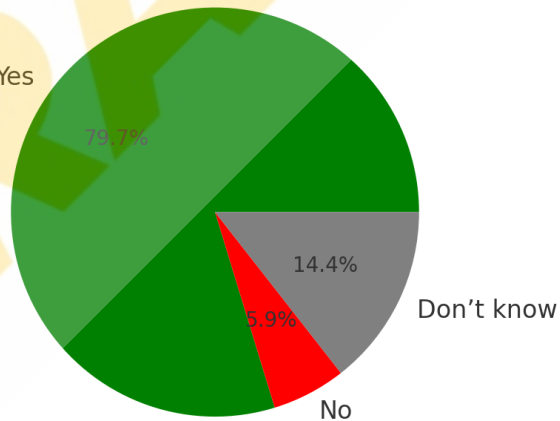
Figure 1: Perceived Burden of CLP Formatting Requirements



Question 2. Need for Simplification:

- 80% see potential for simplification and burden reduction.
- Only 6% see no need for change.

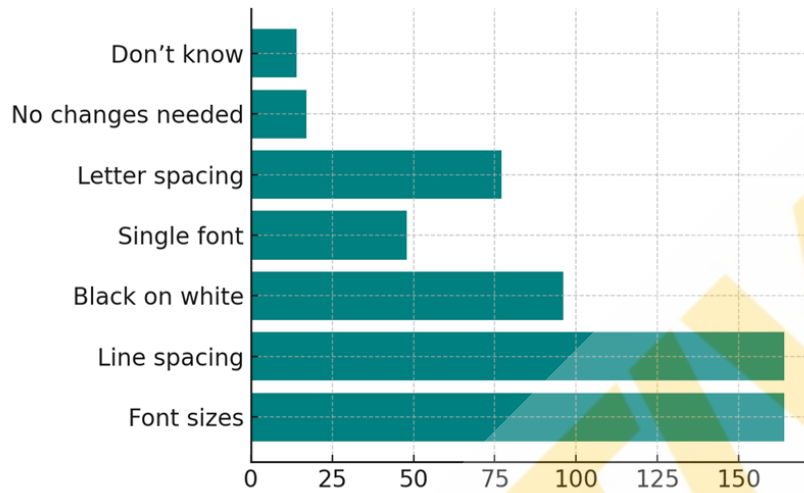
Figure 2: Potential for Simplification of Formatting Requirements



Question 3. Elements That Could Be Simplified:

- Font sizes and line spacing (75% each) are top concerns.
- Black-on-white requirement (44%) and letter spacing (35%) also notable.

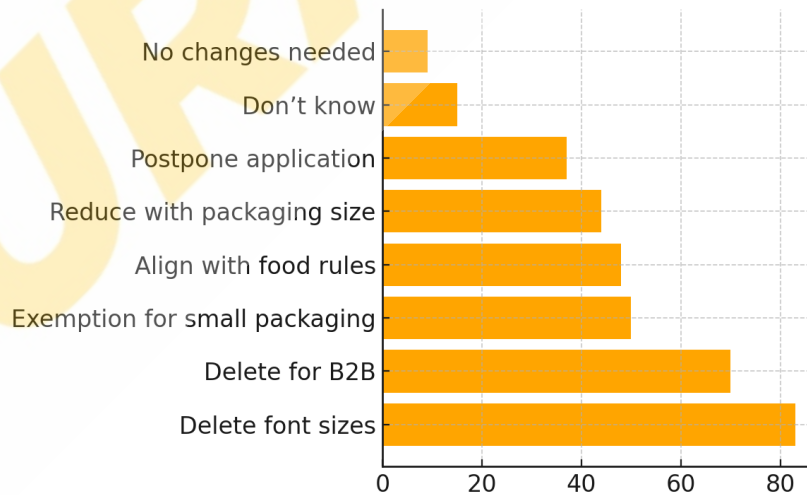
Figure 3: Elements of Formatting Requirements That Could Be Simplified



Question 4. Font Size Simplification Options:

- 38% of respondents indicated their preferences for mandatory font sizes to be deleted entirely.
- 32% support deletion of mandatory font sizes for B2B use.
- 23% favor exemptions when space is insufficient.

Figure 4: Proposed Options Regarding Font Sizes

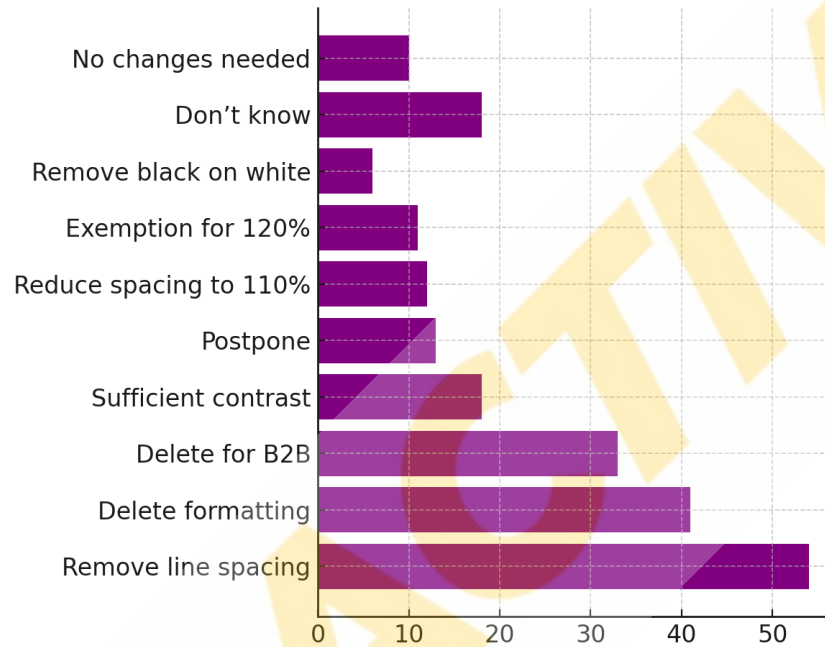


Question 5. Formatting Requirement Changes:

- 25% of respondents indicated their preferences for mandatory line spacing obligations to be removed.
- 19% advocate for deletion of all formatting requirements.

- 15% support B2B exemptions.
- 8% suggest replacing “*black on white*” with “*sufficient contrast*”.

Figure 5: Proposed Options Regarding Formatting Requirements



Question 6: Other solutions. Insights from 55 open responses:

- **“Stop the Clock”:** Widespread support for pausing implementation until impact assessment is complete.
- **Flexibility by Packaging and Use Type:** Requests for exemptions based on packaging size, product type, or distribution channel.
- **Remove or Ease Formatting Requirements:** Suggestions to remove font size, line spacing, and other prescriptive formatting rules.
- **Embrace Digital Labelling:** Many propose QR codes and digital options to declutter physical labels.
- **Revert or Align with Past Rules:** Support for returning to previous CLP rules or to align font sizes with food sector rules.
- **Criticism of Policy Process:** Calls for formal consultation and data-driven policy rather than workshop-based polling.

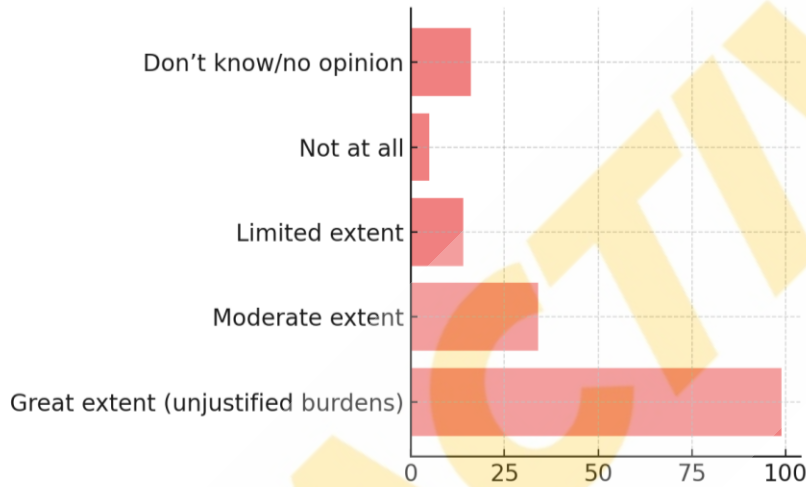
b. Rules on advertisements

Second poll on rules on advertisements collected quantitative feedback from 168–171 participants, and 22 qualitative replies to an open question. The poll explored perceived burdens, adequacy of new requirements on advertisements introduced by Regulation 2024/2865, stakeholders’ views on simplification potential, and open-ended proposals for improvement.

Question 1. Perceived Burden of Advertisement Requirements:

- 59% believe the new rules impose significant and unjustified burdens and costs.
- 20% consider them moderately burdensome.
- Only 3% believe the rules are fully appropriate.

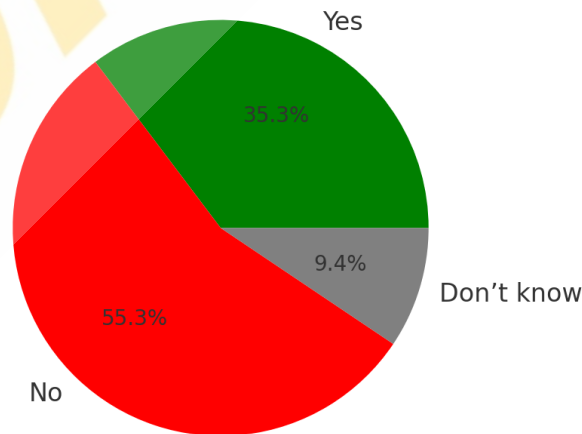
Figure 6: Perceived Burden of Advertisement Requirements



Question 2. Usefulness of Hazard Info in Advertisements:

- 55% believe that providing hazard information in advertisements does not help end-users make more informed choices.
- Only 35% believe it does.

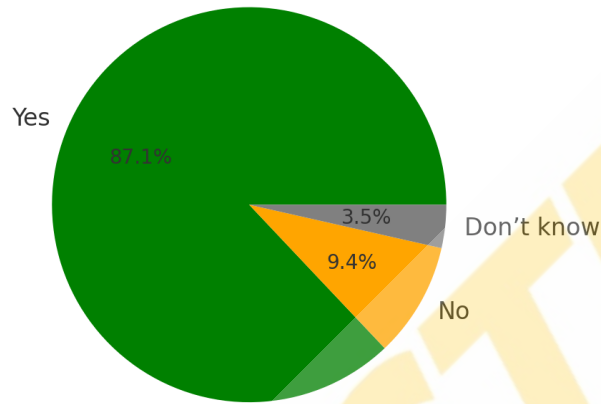
Figure 7: Does hazard information in advertisements helps making informed decisions



Question 3. Adequacy of Hazard Info on the Product Label:

- 87% believe the product label already provides adequate hazard information.
- Only 9% disagree.

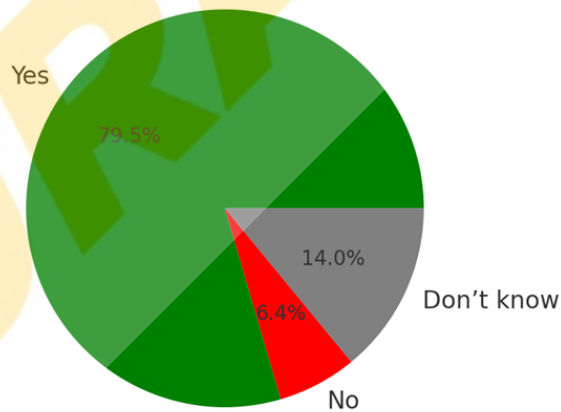
Figure 8: Adequacy of Hazard Information on the Product Label



Question 4. Potential for Simplification of Advertisement Provisions:

- 80% see potential for simplification and burden reduction.
- Only 6% say no changes are needed.

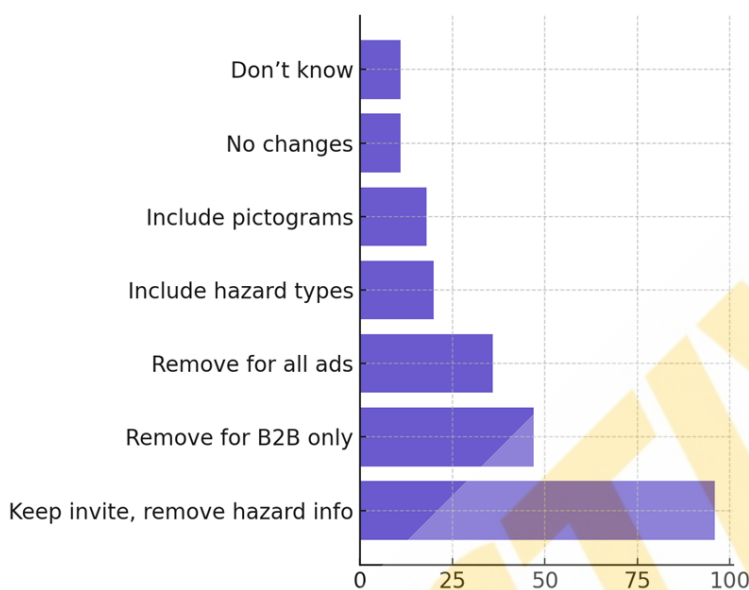
Figure 9: Potential for Simplification of Advertisement Provisions



Question 5. Specific Simplification Proposals:

- 57% prefer removing hazard information requirements but keeping the invitation to read the label.
- 28% prefer removing requirements for B2B advertisements.
- 21% support removing the requirement across all advertisements.

Figure 10: Preferred Simplification Measures



Question 6. Other solutions. Insights from 22 open responses:

- **Excess Burden for B2B:** Many believe that advertisements targeting B2B audiences should be exempt since SDS is already provided.
- **Comparison with Other Legislation:** Participants cite excessive requirements in comparison with other EU regulations, such as pharmaceuticals, biocidal products and plant protection products.
- **Need for Clearer Definitions:** Calls for clarification on what constitutes ‘advertising’ and better guidance on digital media usage.
- **Risk of Confusion or Information Overload:** Some warn that excessive hazard info on advertisements may confuse users and reduce label engagement.
- **Suggestions for Simplification:** Limit advertisements content to symbols or general references to product information; redirect users to the label or SDS.

c. Other burdensome provisions

Third poll consisted of two open questions suggesting participants to indicate other CLP provisions that are too burdensome and costly and to propose measures for simplification of these provisions. These two questions yielded 49 and 48 qualitative responses respectively.

Question 1. Indication of other burdensome CLP provisions. Insights from 49 open responses:

- **Short Timelines & Implementation Pressure** - Multiple stakeholders stressed that 6-month deadlines for implementing classification changes, labelling updates, PCN

notifications, and MOCS were unrealistic. The 18-month timeline was repeatedly cited as a more workable standard.

- **C&L Inventory and PCN Notification Burden** - Respondents flagged the duplication and inefficiency of CLP notification processes – particularly PCN requirements. Inconsistent national procedures and the lack of a central system were noted as major issues.
- **UFI On Fuelling Stations** - The requirement to display UFI at fuel pumps was highlighted as excessive and non-beneficial from a safety perspective.
- **MOCS Rules** - The classification burden for MOCS was seen as excessive and non-beneficial from a safety perspective. Several proposed a removal of these rules entirely.
- **Hazard Classification & Label Content Overload** - Numerous comments criticized the complexity of label content, citing too many hazard (H) and precautionary (P) statements, oversized pictograms, and over-specified EUH text.
- **Digitalisation** - There was strong support for more use of digital labels and QR codes. Respondents recommended removing non-essential content from labels.
- **Centralisation of PCNs** - Stakeholders emphasised creating a single, centralised PCN system managed by ECHA to reduce redundancy and streamline compliance.
- **Misalignment with Other Regulations** - Many noted conflicts between CLP and REACH, GHS, and downstream legislation such as on detergents and cosmetics.
- **Ambiguity & Interpretation Issues** - Several comments emphasized the lack of clarity around terminology such as ‘placing on the market’ or ‘product identifier’, which leads to differing interpretations and regulatory uncertainty.

Question 2: Simplification proposals. Summary of 48 replies:

- Extend relabelling deadlines from 6 to 18 months.
- Centralize PCN submission through ECHA.
- Exempt from UFI requirements to certain mixtures.
- Remove MOCS rules.
- Move non-critical content to digital labels.
- Discontinue or limit C&L Inventory requirements.
- Clarify ambiguous legal terms and processes.
- Harmonize CLP obligations with GHS and downstream legislation.
- Align multiple application deadlines coming from different CLP amendments.

ANNEX II

DETAILS ON THE COSTS AND SAVINGS ANALYSIS FOR THE CHANGES TO FONT SIZE REQUIREMENTS

In this section, we develop the analysis of costs, savings and benefits from the proposed provisions on font size requirements and other label formatting rules.

To the extent possible, the analysis was performed in accordance with the Better Regulation principles, using available data, from previous impact assessment analysis, together with input gathered via the reality check.

A. ANALYSIS FOR THE DETERGENT SECTOR

Baseline: the future provisions apply as laid down in Regulation (EU) 2024/2685. This means companies have to analyse the design of their current labels, compare them to the future rules and select the most cost-effective solution(s) to comply with the upcoming rules on 1 January 2027. This means they would be considering at the time this Staff Working Document is developed investing in new equipment, selecting new label providers and relabelling on the short term their products to comply with the rules on time.

Option analysed: the Commission simplification omnibus on chemicals proposes to remove the detailed label formatting rules (minimum font sizes, minimum line spacing and background colour) while keeping the overall obligation of easy-to-read labels, completed by ECHA guidance.

An evaluation of two extreme scenarios was performed, depending on the adaptive choice(s) of companies to comply with Regulation (EU) 2024/2865: either to set monolingual 2D labels for all products or just update their labels, regardless of whether they are 2D ones or fold-out ones or to turn all their labels into fold-out ones. From the input received, it is not possible to quantify the proportion between the three scenarios. Stakeholders reported difficulties in some cases with fitting a monolingual label on existing packaging. Others reported difficulties to extend the number of pages of existing fold-out labels to comply with the label requirements. A significant share of stakeholders reported higher labelling costs because of switching to fold-out labels.

To the extent possible, the analysis was performed using three hypotheses, minimum, medium or higher impacts, to give an idea of its sensibility.

Period considered: 20 years, from 2025. It is assumed that design updates and relabelling of products would happen ahead of the end of the transition period laid down in Regulation (EU) 2024/2685.

Parameters used:

- *Ratio of labels of hazardous mixtures to be updated:* depending on feedback received, a range between 70% to 100% was used.

- *Costs to redesign labels:* according to the Impact Assessment accompanying the proposal for a targeted revision of CLP (reference), the cost to redesign a 2D label for a hazardous mixture was €475 in 2022. The cost for the (re)design of a fold-out label was considered higher, between €500 and €1.000.
- *Cost of a label:* from the input received in the reality check the price of 2D/simple labels is considered as €0.03 (€0.01 – €0.05) and for a fold-out label as €0.10 (€0.03 – €0.5). Stakeholders reported an increase cost ranging from +70% to +900%, with a median/average of +200%, which was applied in this analysis.
- *Future relabelling rate:* it is understood that labels need repeated updates, to mirror the changes in classification of the mixture or its components. ECHA estimates that 1% per year of substance classification are updated in the classification and labelling inventory (see IA CLP). Considering that a substance would be in 11 mixtures or 25 mixtures (see IA CLP), the rate of label updates for mixtures taken into account in this analysis is 11% per year (5% - 25%). There is significant uncertainty about the exact number of mixture classification update per year, hence of label updates; mixtures contain multiple substances by definition, the concentration of these substances reclassified may vary, triggering or not a change of classification of the mixture. But it is reasonable to assume that mixtures would be reclassified at least once in 9 years (every 4th year to every 20th year).
- *Current number of labels per products:* the CLP IA identifies that for detergent companies (reference), that SMEs would place their products in 5 MS and larger companies in 15 MS. The Impact Assessment accompanying the proposal for a targeted revision of the CLP Regulation is unclear whether currently companies, regardless of their sizes, have monolingual or multilingual labels. From the feedback received in the Reality Check, it seems that across sectors, both SMEs and large companies already have multilingual labels. There are two main reasons for this: first there are multiple MS or countries in the EEA or with significant trade with MS where various languages on the CLP label are required (e.g. Belgium with 3 languages, Finland with 2, Switzerland with 3); second businesses have developed products for groups of MS, most probably with a combination of required languages, in order to save costs and break even for specific SKUs. The point at which an SKU breaks even depends on many factors which are specific to companies, products, the size of required CLP label elements and markets. In order to test the variability and sensitivity of this analysis, the following combination were tested.
- *Number of companies:* the evaluation of the Detergent Regulation⁷⁶ reported about 700 companies in the sector of detergents in the EU, with 85% of SMEs (about 595 companies). The CLP IA used 50 large companies and 600 to 650 SMEs (medium: 625). In order to allow some comparisons, figures from the CLP IA were used.

⁷⁶

Commission Staff Working Document – Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
<https://ec.europa.eu/docsroom/documents/36289>.

- *Number of products per company*: figures from the CLP IA (reference) were reused (200 products per large companies – from 150 to 250 – and 50 products per SME – from 40 to 60).
- *Number of labels per year* were estimated from the limited input received. ‘Future label number’ reflects the situation where Regulation (EU) 2024/2865 is fully implemented. ‘Current label number’ refers to the situation before Regulation (EU) 2024/2865 was not published, and where no companies have taken steps to adapt the labels and labelling processes to that regulation.
- *One-off costs* were calculated as follows: $\text{Cost} = \% \text{labels to be updated} * (\text{number of products per company} * \text{number of future labels per product} * \text{cost for label update} * \text{number of products} + \text{cost of a label} * \text{number of labels})$
- *Recurring costs* are the costs borne by companies when updating labels because of future classification update. The costs are born only for the adapted labels in line with Regulation (EU) 2024/2865 and to the extent of mixtures which classification is amended. It calculated as follows: $\text{recurring cost} = \% \text{labels to be updated} * \text{relabelling rate per year} * (\text{cost of a label} * \text{number of labels per year} + \text{number of future labels per product} * \text{number of products per company} * \text{cost redesign difference})$.

Results are displayed in Table A. From the various estimates and despite the great uncertainty, significant total annualised costs to comply with Regulation (EU) 2024/2865 are identified, for both SMEs and larger companies, with the largest range between about €1.300.000 and €103.700.000 for the scenario of fold-out labels. It is worth noting that the middle estimate of annual costs (annualised one-off costs and recurrent costs) of all three scenarios is around €9.500.000.

In reality, companies may combine the three different scenarios and apply different solutions within their portfolios. The similar order of the magnitude of these labelling costs may not lead companies to favour one scenario over the other two. However associated costs may play in greater role in that sense, as the scenarios imply different evolutions of the number of SKUs per company and the need or not to invest in new labelling equipment or storage facilities, as depicted in Table X below.

TABLE A: COST AND BENEFIT ESTIMATES FOR DETERGENT COMPANIES

	Only reformatting the label			Only monolingualistic 2D labels			Only fold-out labels			
	Min	Middle	Max	Min	Middle	Max	Min	Middle	Max	
Ratio of labels to redesign	70%	90%	100%	70%	90%	100%	70%	90%	100%	
Cost to redesign labels	1,000	750	475	475	475	475	500	750	1,000	
Current cost of a label	0.05	0.03	0.01	0.01	0.01	0.01	0.30	0.10	0.01	
Future cost of label	0.50	0.10	0.03	0.03	0.03	0.05	0.50	0.50	0.50	
Relabelling rate	0.05	0.11	0.25	0.05	0.11	0.25	0.05	0.11	0.25	
Large companies	Current label numbers	3	7	15	15	7	3	3	7	15
	Number of languages covered	15	15	15	15	15	15	15	15	15
	Future label number	3	7	15	15	15	15	3	3	3
	Number of products	150	200	250	150	200	250	150	200	250
	Number of companies	50	50	50	50	50	50	50	50	50
	Number of labels printed per year per company	500,000	2,500,000	10,000,000	500,000	2,500,000	10,000,000	500,000	2,500,000	10,000,000
	One-off cost per company	332,500	1,001,250	1,881,250	751,625	1,305,000	1,881,250	262,500	630,000	850,000
	Recurring labelling cost per company	7,875	18,563	50,000	350	6,390	103,000	3,500	98,280	1,222,000

	Total one-off cost	16,625,000	50,062,500	94,062,500	37,581,250	65,250,000	94,062,500	13,125,000	31,500,000	42,500,000
	Total recurring cost	393,750	928,125	2,500,000	17,500	319,500	5,150,000	175,000	4,914,000	61,100,000
SMEs	Current label numbers	1	3	5	5	3	1	1	3	5
	Number of languages covered	5	5	5	5	5	5	5	5	5
	Future label number	1	3	5	5	5	5	1	1	1
	Number of products	40	50	60	40	50	60	40	50	60
	Number of companies	600	625	650	600	625	650	600	625	650
	Number of labels printed per year per company	30,000	100,000	500,000	30,000	100,000	500,000	30,000	100,000	500,000
	One-off cost per company	29,050	103,500	147,500	66,500	106,875	142,500	4,200	10,125	3,000
	Recurring cost per company	473	743	2,500	21	288	5,240	210	3,870	61,010
	Total one-off cost	17,430,000	64,687,500	95,875,000	39,900,000	66,796,875	92,625,000	2,520,000	6,328,125	1,950,000
	Total recurring cost	283,500	464,063	1,625,000	12,600	180,000	3,406,000	126,000	2,418,750	39,656,500
Whole sector	Total one-off cost	34,055,000	114,750,000	189,937,500	77,481,250	132,046,875	186,687,500	15,645,000	37,828,125	44,450,000
	Total annualised one-off cost	2,289,031	7,713,002	12,766,783	5,207,957	8,875,624	12,548,332	1,051,590	2,542,644	2,987,738
	Total recurring cost	677,250	1,392,188	4,125,000	30,100	499,500	8,556,000	301,000	7,332,750	100,756,500
Super total per year		2,966,281	9,105,190	16,891,783	5,238,057	9,375,124	21,104,332	1,352,590	9,875,394	103,744,238

B. LUBRICANTS

Some large to very large manufacturers of lubricant and an SME share granular details about the impact of Regulation (EU) 2024/2865 on their portfolio. They gave details about the restructuring of their SKU, the additional cost of labels compliant with that Regulation, without confirmed differentiation that future labels would all be fold-out ones. Interestingly, depending on the company, the product type or size, the impacts ranged from nothing to very significant costs.

Table B gives an overview of the aggregation of the data received.

TABLE B: COST ESTIMATES FOR LUBRICANT COMPANIES

	Total (€)	Number of companies	Minimum reported	Maximum reported
Rate of SKU impacted	N/A		27%	100%
Increased of SKU	48834	7	€550	€25000
Price for additional SKU	46,500,000	3	€2,000,000	€34,500,000
Increase of labelling costs (1st relabelling)	26,807,100	6	€2,000,000	€6,900,000
Investment in new equipment	6,927,585.00	5	€80,000	€3,200,000
Recurrent relabelling	2,885,378	6	€27,000	€1,725,000
Annualised total one-off costs	2,360,629	(6)		
Total recurrent costs	55,385,378			
Total annual costs for lubricant manufacturers	115,492,015			

In order to compare with other sectors, one-off costs and recurrent costs were calculated in table C, as well as annualised on-off costs, using the following approximations:

C. OVERALL DISCUSSION FOR THE EUROPEAN CHEMICAL SECTOR

According to the estimates developed for detergents and facts reported for the sectors of lubricants, there is concurring evidence showing that there are both one-off costs and recurrent consequences stemming from Regulation (EU) 2024/2865, which were not highlighted in the CLP IA.

From the analysis performed for the detergent sector and the account of this sector (4.2% in 2018) in the production value of the total chemicals sector in the EU, the saving from the proposed changes to the font size requirements and related typographic rules for the EU chemicals sector could amount to at least €226.200.000 (from €31.000.000 to €2.469.000.000).

The possible costs to the whole EU chemical industry were extrapolated from estimates calculated for the detergent and lubricant sectors. Some stakeholders also reported total one-off costs for a national sector or national chemical industry. Table D illustrates the order of magnitude derived from these extrapolations.

TABLE C: EXTRAPOLATION OF COSTS ESTIMATED FOR SECTORS OF DETERGENTS OR LUBRICANTS OR FROM SOME MEMBER STATES OR NATIONAL SECTOR ORGANISATIONS

Source	Annual cost (€)	One-off cost (€)	Share of EU chemicals production value ⁷⁷	Extrapolation to EU chemicals industry	Type of cost
Detergent sector (calculated)	9,500,000		4.2%	226,200,000	Annual overall cost
Lubricant companies (calculated)	115,492,015		1.2%	9,919,200,000	Annual overall cost
National paint and ink sector (reported)		60,000,000	0.1%	68,356,200,000	One-off ⁷⁸
Member State (reported)		50,000,000	1.3%	3,780,300,000	One-off ⁷⁸
National chemicals sector (reported)		583,000,000	11.2%	5,194,900,000	One-off ⁷⁸

The proposed change should hence limit indirect and adjustment costs estimated above. While those estimated bear significant uncertainty, table D looks at the plausibility and likelihood of such impacts to materialise and to what extent.

TABLE D: ESTIMATED PLAUSIBILITY OF VARIOUS IMPACTS IDENTIFIED FOR DETERGENTS AND LUBRICANTS

Scenario	Only reformatting labels	Only monolingual 2D labels	Only fold-out labels
Increased SKU	Neutral	Certain	Possible if the space increase needed does not fit in a fold-out label (some stakeholders reported issues with bigger packaging or labels with more than 10 pages).
Increased price of labels, including cases where other label elements than CLP ones on another medium	Likely as reported in some cases by stakeholders (increased number of pages in a fold-out label, increased size of labels)	Neutral, unless label size has to be increased, as pointed out by some stakeholders.	Certain, all stakeholders reported fold-out labels being more
Change of labelling equipment	Possible as reported in some cases (linked	Neutral, unless label size has to be increased, as pointed	Certain for many companies not using fold-out labels yet and

⁷⁷ The production value of the EU industry is €499 billion in 2022

⁷⁸ This cost is a total, non-annualised one-off cost

	to increased price of labels)	out by some stakeholders.	reporting they would be forced to move to fold-out labels
Change of packaging	Possible (outer packaging mainly) as indicated by some stakeholders.	Unlikely but plausible in specific situations where limited space would be available and no derogation possible.	No
Placing other label elements than CLP ones on another medium	Likely, unless existing labels are fold-out ones.	Possible	Unlikely
Loss of (smaller) market	Neutral	Highly liCertain	

EURACTIV

ANNEX III

REALITY CHECK ON THE POSSIBLE SIMPLIFICATION OF CHEMICALS LEGISLATION – COSMETIC PRODUCTS REGULATION SYNOPSIS REPORT

Meeting date: Friday , 16 May 2025, 14:00-17:30

Location: Webex;

Organised by: European Commission – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Unit F2

Participants: Representatives from the Commission, Member States authorities, industry associations, and NGOs

Number of registrants: 268

Number of participants who attended: 226

1. Welcoming Remarks and Introduction to the Commission Simplification Initiatives

The Commission outlined the general context and political priorities of the current mandate, with particular focus on simplifying and streamlining EU rules to boost EU competitiveness. The Commission presented the Reality Checks as new technical-level consultation tools designed to support the Commission’s simplification agenda. The objective of this specific Reality Check event was to identify opportunities to simplify the Cosmetic Products Regulation⁷⁹ and reduce administrative and compliance burdens, while maintaining high standards of consumer safety and industry compliance.

Participants were invited to share their views through oral interventions, contributions in the chat, and responses to questions posted via Slido⁸⁰.

2. Cosmetic Products Regulation - potential areas for simplification and burden reduction

⁷⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209, ELI: <http://data.europa.eu/eli/reg/2009/1223/oj>.

⁸⁰ Slido is the audience interaction platform. It helps users to get the most out of meetings and events by crowdsourcing top questions and engaging participants with live polls and quizzes. More information on <https://www.slido.com/>

a. Reducing administrative and compliance burden related to CMR classified ingredients (Article 15)

Based on earlier input from stakeholders, the Commission services compiled a list of issues relating to the implementation of Article 15 of the CPR, which have created interpretation challenges and which, according to industry, imposed a significant burden on the cosmetic industry. Several participants agreed that changes to Article 15 would be essential, notably stressing the importance of realistic transitional periods, which they felt should be explicitly provided in the CPR. Additionally, several participants expressed that the prohibitions under Article 15(1) and (2) should not apply to the natural complex substances, even if one of their constituents has received a harmonised classification as a CMR substance.

Stakeholders broadly welcomed the proposed amendments, including the suggestion to link the ban in Article 15 to actual dermal exposure to the CMR substance.

Some participants emphasised the need for reassurance that any simplification initiative in the area of cosmetics should not compromise the core policy objectives of the CPR. Specifically, they underlined that the harmonised classification of a substance as a CMR must continue to trigger a ban on its use in cosmetics, and that derogations from this ban should only be granted in exceptional cases. Others stressed that the CPR must continue protecting consumers from the harmful chemicals and cautioned against excessively long transitional periods, warning that they could prolong consumers exposure to hazardous substances.

One stakeholder also raised a question about how this simplification initiative relates to other ongoing workstreams, including the full-fledged evaluation of the CPR and the activities of the Working Group on Cosmetic Products regarding the revised CMR Guidelines.

Responses to Slido questions indicated that, among five simplification measures, the top three - introducing transitional periods, clarifying the approach to natural complex substances, and simplifying the criteria for derogations - were seen as the most impactful in reducing regulatory and administrative burdens on the cosmetics industry. Specifically, 48% of respondents believed that all five proposals were to significantly streamline business operations, while 31% considered the benefit to be as moderate. Only 6% felt the impact would be marginal or negligible (see Slido results).

b. Facilitating the addition of colorants, preservatives, and UV filters to Annexes IV–VI

Most participants agreed that establishing a specific procedure for introducing colorant, preservatives and UV-filters in Annexes IV – VI of the CPR, respectively, would be beneficial. A stakeholder suggested that, as part of this procedure, the SCCS should be tasked with reviewing the safety of all substances in the positive lists every 10 years, like the review process under REACH authorisations.

According to Slido responses, 67% of participants supported introducing such a procedure, citing improvements in clarity and regulatory certainty. Nearly 20% were also in favour but noted that certain aspects would still require further clarification (see Slido results in the Annex).

c. Streamlining requirements under Article 33 on the glossary of cosmetic ingredients

The Commission sought stakeholders' views on the relevance of the glossary of common ingredient names, suggesting it could be replaced by a reference in the CPR to the internationally recognised cosmetic ingredient nomenclature. During the discussion, many participants expressed a preference for retaining the glossary as a source of legally binding ingredient names but recommended that it be made in an electronic format – integrated into CosIng – to allow more frequent updates and provide significantly improved user experience.

Some stakeholders, however, argued that the glossary is either no longer necessary or would require substantial improvements to remain useful. These diverging views were reflected in the Slido results: 50.2% of respondents considered the glossary to be of limited value and believed it could be discontinued without major impact. Conversely, 41% felt that the glossary should be maintained or found it useful but noted that improvements were needed in terms of accuracy, format and the frequency of updates (see Slido results in the Annex).

3. Reducing notification and reporting obligations

a. Prenotification requirements for products containing nanomaterials (Article 16)

Article 13 of the Cosmetic Products Regulation requires businesses to notify to the Commission all cosmetic products before they are placed on the market. In addition, if those products contain nanomaterials, they have to comply with additional notification requirements, as information about such products including detailed data on nanomaterials, must be transmitted to the Commission six months before placing them on the market (Article 16 of the CPR). This pre-notification requirement for cosmetic products containing nanomaterials has been considered burdensome. Suggestions for improvement included simplifying the notification processes by relying on Article 13 of the CPR to reduce industry costs without compromising product safety.

According to Slido results, approximately 61% of respondents agreed that the pre-notification requirements impose significant and disproportionate burdens and costs on the cosmetic industry. Meanwhile, 14% considered the burden to be manageable, and 3.2% believed the current process is appropriate and does not result in unnecessary costs (see Slido results in the Annex).

b. Market surveillance reporting obligations (Article 22)

Article 22 of the Cosmetic Products Regulation requires Member States to periodically review and assess the functioning of their surveillance activities and communicate the results of such review to the other Member States and the Commission and made them available to the public. This obligation places an unnecessary burden on competent authorities as existing tools, such as ICSMS, are already used for reporting and sharing information on market surveillance measures among EU competent authorities. Additionally, PEMSAC – the platform for market surveillance bodies for cosmetics, supports a coherent approach to enforcing the Cosmetic Products Regulation.

Some participants cautioned against introducing measures that could weaken EU-level oversight of national market surveillance activities. This cautious stance was reflected in responses to the

Slido question: ‘Do you consider that the deletion of the reporting obligations would reduce burden on competent authorities?’ Most respondents did not express a clear opinion. However, among those who did respond, half believed that removing the obligation would result in significant or moderate reduction in administrative burden (see Slido results in the Annex).

4. Other Areas for Simplification in Cosmetic Products Regulation

Stakeholders raised a broad range of additional topics that could be included in the simplification process, including:

- **Animal testing and microplastics (under REACH):** these were identified as areas where reducing reporting obligations could significantly benefit businesses.
- **Transition periods for placing new products on the market:** Several participants called for harmonised transition periods in Commission decisions concerning ingredients whose safety has been confirmed. Some suggested that the changes to the CPR should be adopted once per year on a fixed date, with aligned transposition deadlines to facilitate planning and implementation.
- **Labelling of cosmetic products:** suggestions included improving labelling accuracy, adding CPNP numbers and expiration or validity dates to product packaging. Stakeholders highlighted the potential of voluntary digital labelling -particularly for the list of ingredients- to reduce burdens and improve consumer access to information. Some participants proposed that labelling information should be available only in English, arguing that translation requirements are unnecessary.
- **Online sales rules** – participants called for the CPR to include specific provisions for cosmetics sold online, including requirements for label information to be displayed on the websites and online marketplaces offering products to EU consumers.
- **Harmonisation of the nano definition:** Stakeholders urged alignment of the CPR definition with the Commission’s 2022 Recommendation on nanomaterials.
- **Removal of absolute animal testing reporting obligations:** as animal testing is banned under the CPR, stakeholders advocated for removing related data submission requirements, which they viewed as outdated.
- **Alignment across relevant EU legislation:** There was a strong call to improve coherence between the CPR and other EU acts such as CLP, REACH, and POP to enhance clarity and legal certainty. For example, it was suggested that the annexes to the CPR could be updated to reflect REACH restrictions on substances used in cosmetic products.
- **Improving CosIng:** Stakeholders proposed that the CosIng database should also indicate substances banned in cosmetics under the REACH or due to environmental concerns.

5. Conclusions

- Most stakeholders agreed that the proposed changes would offer meaningful benefits in terms of simplification and burden reduction. However, they emphasized that any modifications must be carefully implemented to avoid compromising consumer safety or the credibility of the CPR as a benchmark for cosmetic product safety.

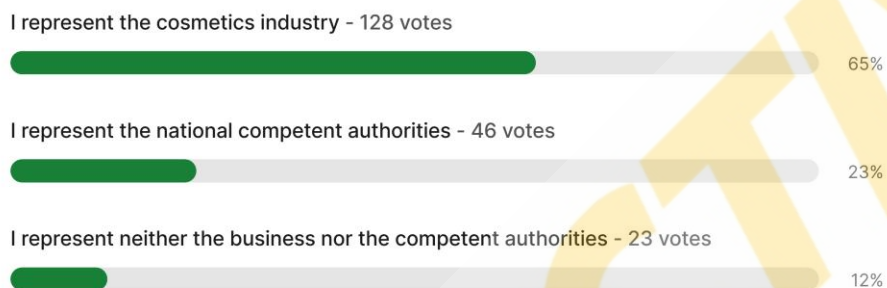
- Numerous additional suggestions for simplifying the CPR were put forward. These included: digitalising labelling requirements, establishing rules for online sales, streamlining the implementation of bans or restrictions on cosmetic substances, removing reporting obligations related to on animal testing data, and strongly supported – enhancing alignment between the CPR and, other key legislation, particularly, CLP and REACH.
- Stakeholders were invited to submit written contributions by 31 May 2025 (or 1 June at the latest), especially including quantifiable evidence to support proposed simplification measures.
- The Commission will prepare a report based on the input received to support political decision-making.

EURACTIV

Opinions of the participants of the Reality Check on cosmetics collected via slido




Point I of the agenda

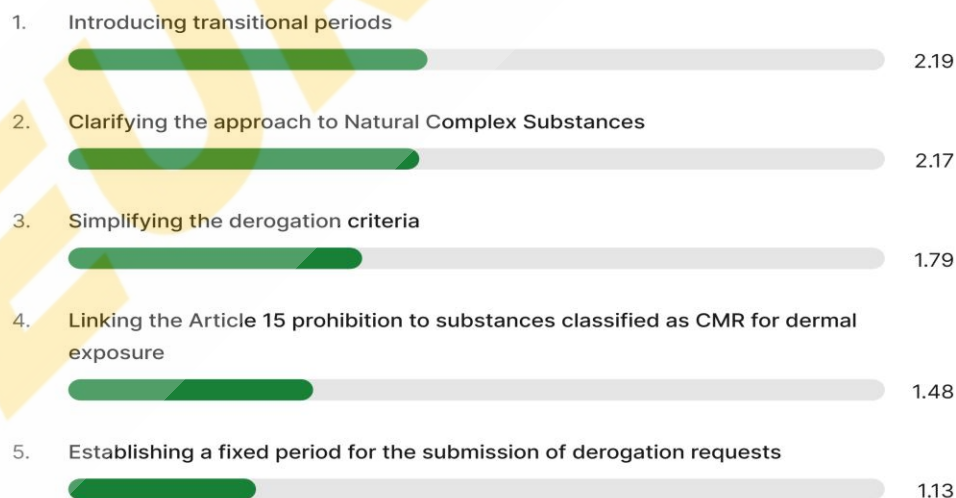
 **Let's introduce ourselves**
Multiple Choice Poll  197 votes  197 participants



slido

Point II (a) of the agenda

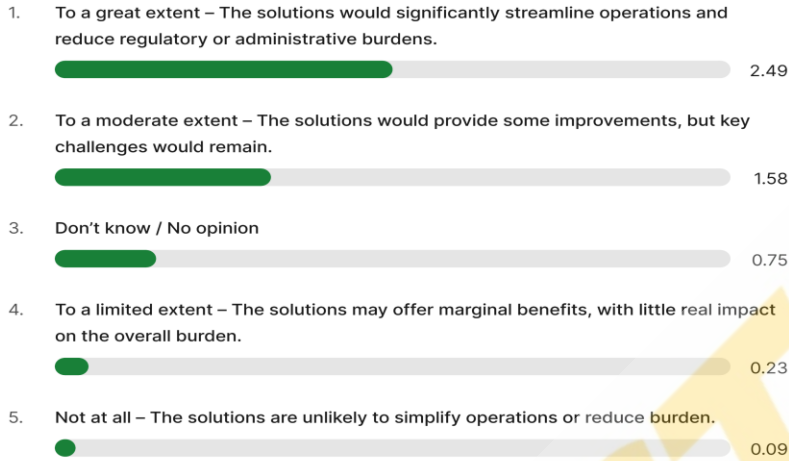
 **To what extent do you consider that the suggested solutions could simplify business operations and reduce burden on the cosmetic industry?**
Ranking Poll  165 votes  165 participants



slido

📊 To what extent do you consider that the suggested solutions could simplify business operations and reduce burden on the cosmetic industry?

Ranking Poll 151 votes 151 participants

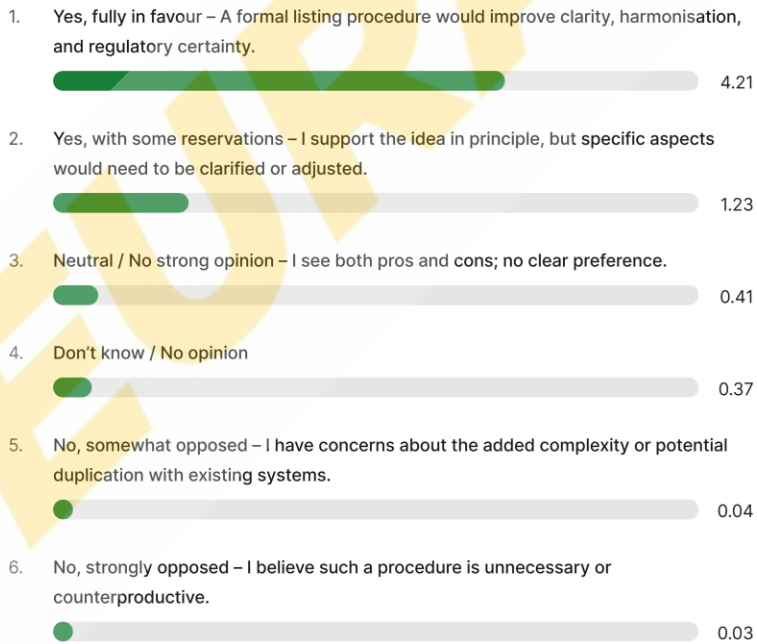


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Point II (b) of the agenda

📊 Would you be in favour of adding a procedure to list colorants, preservatives and UV filters to CPR Annexes?

Ranking Poll 134 votes 134 participants



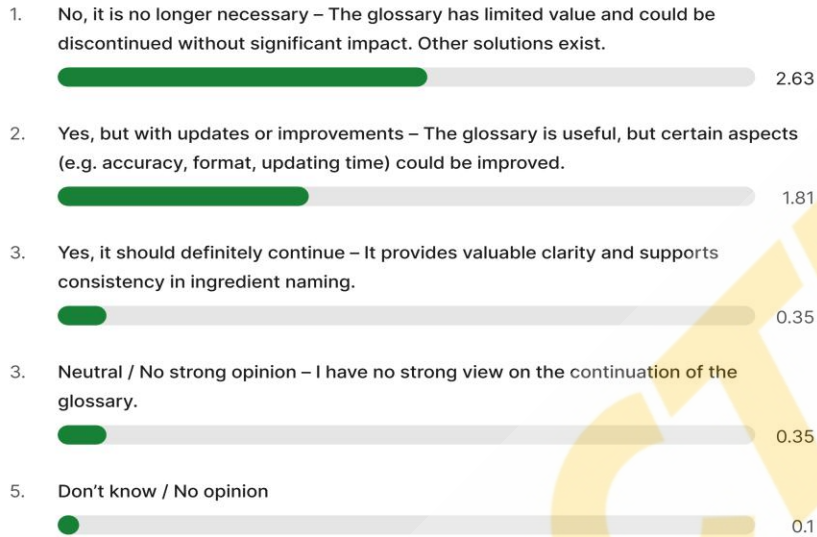
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Point II (c) of the agenda



Do you consider that the glossary of cosmetic ingredients should continue?

Ranking Poll 130 votes 130 participants



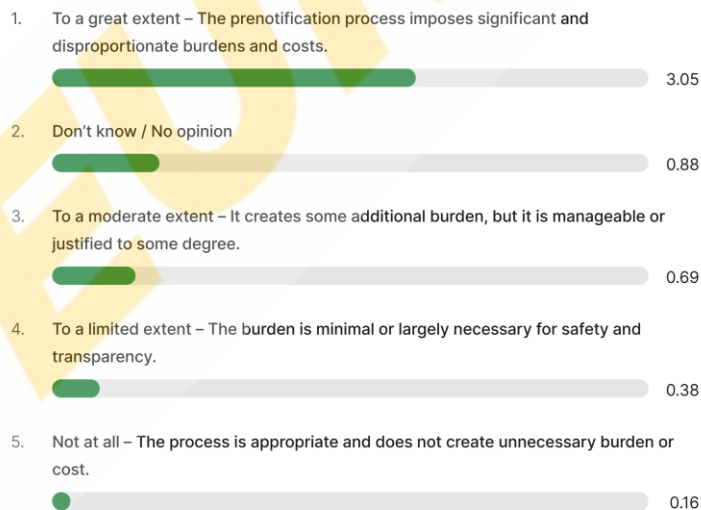
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Point III of the agenda



To what extent do you consider that prenotification of cosmetic products containing nanomaterial (Article 16) creates unnecessary burden and costs on the cosmetics industry?

Ranking Poll 121 votes 121 participants



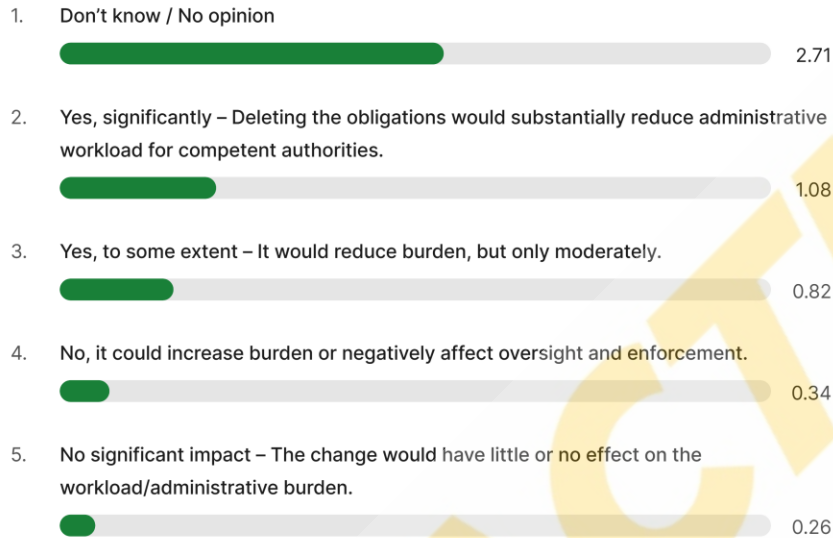
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Point IV of the agenda



Do you consider that the deletion of the reporting obligations would reduce burden on competent authorities?

Ranking Poll 88 votes 88 participants



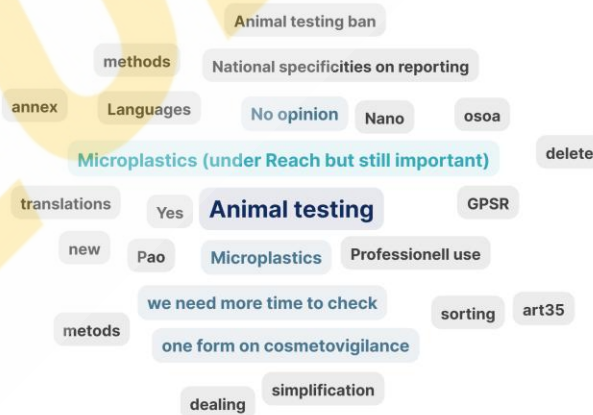
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Point V of the agenda



Are there other reporting obligations which could be deleted?

Wordcloud Poll 105 responses 67 participants



slido

ANNEX IV

REALITY CHECK ON THE POSSIBLE SIMPLIFICATION OF CHEMICALS LEGISLATION – FERTILISING PRODUCTS REGULATION SYNOPSIS REPORT

Meeting date: Wednesday, 7 May 2025, 15:30-17:30

Location: Centre Albert Borschette, Brussels and online (Microsoft Teams);

Organised by: European Commission – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Unit F2

Participants: Representatives from the Commission, Member States authorities, industry associations, and NGOs

Number of registrants: approx. 135

Number of participants who attended: approx. 95

1. Context and purpose of the Reality Check

The Reality Check took place in the context of the Commission's broader simplification strategy to enhance EU competitiveness through streamlined legislation and, more specifically, in preparation of a proposal for a Regulation amending certain requirements and procedures for chemical products. The objective was to collect feedback of stakeholders (industry, Member States authorities, NGOs) on potential simplification of Regulation (EU) 2019/1009 ('Fertilising Products Regulation', 'FPR').

The Reality Check was held as part of the Commission Expert Group meeting on fertilising products, taking place on 7 and 8 May 2025. Approx. 135 stakeholders registered for the meeting and about 95 eventually attended. By 13 June 2025, written feedback was received from 27 stakeholders.

The Commission had uploaded a Concept Note⁸¹ ahead of the meeting, presenting some preliminary ideas for simplification and a set of questions to stakeholders. The feedback received at the meeting and in writing is summarised below.

2. REACH registration of substances in EU fertilising products

Most stakeholders confirmed that the requirement to register substances in EU fertilising products, regardless of their tonnage, as a minimum with the information requirements for substances manufactured or imported in quantities of 10 to 100 tonnes per company per year and a chemical safety report covering the use in a fertilising product poses significant challenges for manufacturers

⁸¹ <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/65de137e-4755-48b0-9c63-13baab43018c/details>

of EU fertilising products. Stakeholders explained that most substances used in EU fertilising products below 10 tonnes per year are manufactured by upstream suppliers. Therefore, the registration obligation is, in the first place, incumbent on these upstream suppliers. Whether a substance is registered in accordance with the FPR requirements is often not easy to find out for manufacturers of EU fertilising products who would like to use a certain substance. And even if they know that it is not, they possess limited influence to convince their suppliers to enhance the registration unless the EU fertilising product use constitutes the majority of the market. Moreover, for considerations of confidential business information, suppliers are often reluctant to share data with the manufacturers of EU fertilising products, preventing those from upgrading the REACH registration themselves. Finally, according to business associations, some producers or importers of substances produced in low quantities, especially small and medium enterprises (SMEs), can simply not afford REACH registration in accordance with the FPR.

As consequences, certain substances are not used in EU fertilising products. Manufacturers alternatively market their products under national rules or in third countries, such as the US. Some also replace the substance in question by already registered but less effective substances. Such reformulation, as explained by a company, implies costly reformulation tests, stability tests and greenhouse tests.

According to stakeholders, the issue is particularly pertinent for technical additives, like dyes, which are mostly used in very low volumes and are difficult to substitute as the performance of different additives varies significantly. But also, some primary components are produced and used in small amounts and therefore affected by this extended REACH registration requirement.

Several stakeholders also submitted data on the costs related to the extend REACH registration requirement after the workshop. An industry association shared results from a survey carried out among their members asking about the burden of the extended REACH registration requirement under the FPR. Depending on tonnage band and extent of data required, the costs reported in the survey for updating a registration dossier in accordance with the extended REACH registration requirement vary between €10,000 to €500,000 per substance. €180,000 was found as the typical investment needed to upgrade a registration dossier from 1-10t/y to the 10-100t/y requirements. A company contributing to the Reality Check reported costs in a similar range. For the six substances that the company registered in accordance with the extended requirements under the FPR, it spent between €100,000 and €500,000, including the costs for data generation, consultancy, dossier preparation and the fees paid to ECHA. It explained that, for substances below 1t/y, the FPR creates new costs compared to the absence of a registration obligation under REACH, while for substances between 1t and 10t/y the registration costs would be 65% higher for substances used in EU fertilising products. In the same vein, an industry association estimated that costs for upgrading a registration from the 1-10 tonnes to 10-100 tonnes band, excluding the fees, can result in costs of up to € 400,000, and another industry association reported that, depending on the substance and its registration status (upgrading from the 1–10 t/year band to 10–100 t/year or registering an exempt substance in the >10 t/year band), costs range between €150,000 and €240,000. Costs in this range were also confirmed by a Member State authority, estimating a total registration cost of €270,000 for a substance produced below one tonne per year.

A company explained that the burden of registration is almost the same for large companies and SMEs, despite the more limited financial resources of SMEs. It explained that, although SMEs are entitled to a reduced registration fee, the effort for proving SME status would largely offset this reduction. Moreover, the fees represent less than 5% of total registration costs, whereas the preparation of the dossier and testing, which does not depend on the size of the company, represents the bulk of registration costs.

According to a position paper signed by several industry associations, the costs for the extended REACH registration eventually leads to increased costs for manufacturers of EU fertilising products and materialises in increased prices for users. Using several examples, they calculated that, by complying with the extended REACH registration requirement, the cost of a substance, depending on the volume in which it is manufactured and imported and the concentration in which it is used in the fertilising product, increases by 40%-540%, which was confirmed in a position paper of another industry association and a competent authority. In one of the examples, the end product price would have to be increased by 26%.

Most stakeholder were in favour of relieving the burden of extended REACH registration under the FPR, by applying normal REACH, including the gradations according to tonnage, to all or most substances in EU fertilising products. Several stakeholders considered that for very hazardous substances, like persistent, bioaccumulative and toxic ones, and for certain unknown, bio-active substances, and for inhibiting compounds more extensive REACH registration might still be warranted, also considering the distinct use pattern of fertilising products, i.e. repeated application over large areas with direct emissions to the environment.

3. Assessment of micro-organisms in plant biostimulants

The majority of stakeholders welcomed the Commission's considerations on simplifying the procedure for the assessment of micro-organisms (Component Material Category 7) used in plant biostimulants.

Many stakeholders view the current mechanism for permitting additional strains of micro-organisms in EU fertilising products under the FPR as inconsistent with the demands and rapid development pace of the burgeoning plant biostimulant sector. Several stakeholders highlighted that this process impedes market access for microbial plant biostimulants, discouraging innovation and investment, and delaying the availability of these products to farmers.

According to stakeholders participating in the Reality Check, the development and availability of microbial plant biostimulants in the EU is crucial, not least because of the various benefits they bring to farmers and the environment:

- Enhancement of Nutrition Use Efficiency (NUE) and function as nitrogen-fixing, phosphorus-solubilizing, and potassium-mobilizing agents;
- Increasing the crops' tolerance to abiotic stress;
- Improvement of water absorption (mycorrhizal fungi);
- Reduction of water contamination by nutrients and greenhouse gas emissions;

- Minimisation of soil degradation, promotion of microbial biodiversity in agricultural soils, and contribution to CO₂ capture from the atmosphere.

An industry association in the plant biostimulant sector shared the results of a survey carried out among 65 of their members. 88% of participants said that they were not able to place their micro-organism on the EU market because it was not yet on the positive list. When asked if they would apply for the FPR conformity assessment if their micro-organism was on the list, 69% responded affirmatively. 59% of respondents are currently exporting microbial biostimulants to third countries, incl. the United States, Argentina, Mexico and Brazil, which means that their products produced in the EU are not provided to EU farmers.

Industry associations highlighted that the inability to market their biostimulants under EU regulations compels manufacturers to market their products under the national regulations of Member States. This poses a significant burden, particularly for SMEs, due to the considerable variation in Member State regulations, the requirement to obtain approvals in different jurisdictions, and the persistent issue of mutual recognition of authorisations for fertilising products. Furthermore, EU manufacturers may turn to alternative markets outside the EU. Ultimately, due to the unfavourable conditions in the EU, innovation and investment in such products might be redirected to third countries.

Many stakeholders participating in the Reality Check were generally in favour of the criteria-based approach and of using the methodology developed in that study as basis for the amendment to CMC 7. Some stakeholders pointed to certain weaknesses in the current version of the methodology. More generally, one stakeholder emphasised the importance of ensuring the protection of confidential business information within this new criteria-based mechanism. Moreover, several stakeholders emphasised the importance of an independent assessment of micro-organism, such as the European Food Safety Agency (EFSA). Two Member State authorities shared their concerns about the proposal to let notified bodies assess the micro-organisms in accordance with the general criteria and methodology.

4. Inclusion of derived outside the scope of Regulation (EC) No 1069/2009

Stakeholders in the Reality Check confirmed the interest in the inclusion of additional derived products from animal by-products under the FPR. Many stakeholders called for the prioritisation of the inclusion of derived products within the scope of the ABPR – for which an endpoint has already been determined or which are currently assessed in a study carried out for the Commission. Nevertheless, the initiative of allowing for the inclusion of materials that are outside the scope of the ABPR was appreciated as the exclusion from the ABPR's scope is understood as indication that those materials do not pose a risk. The following materials were mentioned as particularly interesting:

- shells from shellfish with the soft tissue and flesh removed;

- fish sludge (i.e. faeces from farmed fish together with uneaten feed from land aquaculture in freshwater and from aquaculture in open sea cages (saltwater) and land- or semi land-based facilities with saltwater);
- mineralised guano;
- plant-based soiled cat litter (i.e. waste from ‘cat toilets’).

Stakeholders did not share any cost data in relation to this proposed amendment. However, an industry association emphasised that as a consequence of not being allowed to use certain derived products in EU fertilising products manufacturers are forced to use other more expensive material. In addition, circular business models and progress on soil health and organic matter restoration would be hampered, which might indirectly impact the yields and resilience of crops. Another stakeholder pointed out that the use of such materials would not only entail economic benefits for manufacturers of EU fertilising products but also enable the recovery of valuable materials that would otherwise be classified as waste. Concretely regarding fish sludge, a stakeholder noted the material's potential to become a significant phosphorus source within a circular economy, potentially substituting some mined phosphorus in fertilisers. Regarding shells, a competent authority clarified that their disposal poses a challenge for small companies producing canned mussels, which are economically vital to coastal villages. Concerning cat litter, a stakeholder explained that the reuse in EU fertilising products would not only reduce the volume of municipal solid waste, but also ensure that the plant-based component of the soil and the cat excrements are introduced into soil, providing nutrients and increasing soil organic matter.

5. Digitalisation

Although digitalisation of reporting requirements under the FPR did not seem to be the most relevant concern of stakeholders at the Reality Check, several stakeholders, including industry and authorities, underlined in their written submissions that the digitalisation of information requirements can reduce the administrative burden for companies and authorities as electronic management can facilitate the exchange, storage and access to information, reduce errors associated with manual process, and minimise paper usage and the costs linked to the handling of paper documents.

Some concerns were expressed in relation to cyber security, availability and interoperability of digital infrastructure, costs for acquiring necessary technology and, in relation to exports, paper-based systems in third countries. Several stakeholders pointed out that industry and authorities would need 2-3 years to adjust to the new digital requirements, while one suggested 1-2 years.

6. Other ideas for simplification

Stakeholders had many additional ideas for simplification, which they submitted after the workshop, including:

- An industry association suggested making several **clarifications**, currently addressed in the Commission’s FAQ document⁸², **in the legal text**.
- Several industry stakeholders advocated for moving away from an individual assessment of materials to be added to the different component material categories (CMCs) to a **criteria-based approach for all CMCs**, or at least for derived products from animal by-products (CMC 10).
- Some industry stakeholders suggested **changes to the rules on digital labelling** introduced in 2024⁸³, including alignment with CLP and extension of information which can be provided in the digital label only, without duplication on a physical label.
- Some industry stakeholders pointed to **unclarities or coherence issues between the FPR and other relevant legislation**, notable the ABPR, REACH and the Waste Framework Directive (Directive 2008/98/EC)⁸⁴.
- Several industry stakeholders asked the Commission to clarify that component materials may contain **detectable traces of impurities and unintended substances** which are not considered component materials.
- A Member State authority proposed to establish a **negative list of compounds not to be used in fertilising products** similar to the list in Annex III to Regulation (EC) No 1107/2009 on plant protection products⁸⁵.
- **Revision of the Information and Communication System on Market Surveillance (ICSMS)**
A Member State authority suggested the revision of the Information and Communication System on Market Surveillance (ICSMS) to better account for the specificities of the fertilising products sector.
- **Sludge**
Some stakeholders called for allowing more types of sludge to be used as input for component materials.
- **Removing the HAS assessment of harmonised standards**
A representative from a European Standardisation Organisation (ESO) suggested removing the step of an assessment by a consultant (‘HAS assessment’) after the publication of the European standard by the ESO and before the citation in the *Official Journal*.

7. Conclusions

- Applying ‘standard’ REACH registration requirements to substances in EU fertilising products would remove an important obstacle for the EU fertilising products industry in

⁸² <https://ec.europa.eu/docsroom/documents/63434>.

⁸³ Regulation (EU) 2024/2516 of the European Parliament and of the Council of 18 September 2024 amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products, OJ L, 2024/2516, 30.9.2024, ELI: <http://data.europa.eu/eli/reg/2024/2516/oj>.

⁸⁴ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3, ELI: <http://data.europa.eu/eli/dir/2008/98/oj>.

⁸⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

using certain substances, thereby reducing costs for reformulation, ensuring the use of the most suitable substances, and encourage manufacturers to obtain the CE marking.

- A simplified procedure for the assessment for micro-organisms is needed to ensure innovation and investments in microbial plant biostimulants in the EU and ensure the availability of these products to EU farmers. An assessment by manufacturers and notified bodies in accordance with general safety and efficiency criteria and a methodology, which could be based on the methodology developed in the ongoing study, seems to be a viable solution.
- Amendments to the empowerment for the inclusion of animal by-products outside the scope of the Animal By-Product Regulation and for the digitalisation of reporting obligations would be welcome but are less pressing for stakeholders than the other two proposed amendments.
- Multiple suggestions were made for further simplification of the FPR, some of them going beyond this very targeted simplification exercise. Some aspects could be further investigated in the context of the ongoing FPR evaluation. Other suggestions could also be implemented, independently from the envisaged legislative proposal, via a delegated act.
- Any legislative proposal will be subject to standard co-legislative procedures, including Council and Parliament review.

ANNEX V

DETAILS ON THE COSTS AND SAVINGS ANALYSIS FOR THE CHANGES TO EXTENDED REACH REGISTRATION REQUIREMENTS FOR FPR

Baseline:

1. Substances falling under the Component Material Category 1 – Virgin substances and mixtures and substances and additives used under other Component Material Categories must have been registered with a REACH registration dossier in line with, at a minimum, the requirements set in Annexes VI to VIII (tonnage band 10-100t per year) and containing a chemical safety report demonstrating safe use in a fertilising product.
2. Manufacturers of fertilising products, or manufacturers of substances used in a fertilising product (at the request of manufacturers of fertilising products) currently need to prepare or update a REACH registration dossier to comply with the FPR's requirement, if they want a substance to be used in an EU fertilising products. This implies the generation of more data and the development or update of the chemical safety assessment showing safe use in a fertilising product. In addition, they have to pay a fee to ECHA for the new registration or the update.
3. The high costs related to complying with the extended REACH registration requirement may discourage manufacturers of fertilising products from placing their product on the market as an EU fertilising product under the FPR. Instead they can place their products on national markets, where they would face costs for registration in various MS, subject to various sets of rules and the complexity of mutual recognition⁸⁶.

Cost analysis on compliance with the extended REACH registration requirement

Based on survey data provided by an industry association in the context of the Reality Check, depending on tonnage band and extent of data required, the costs for updating a registration dossier in accordance with the extended REACH registration requirement under the FPR vary between €10,000 to €500,000 per substance. €180,000 was found as the typical investment needed to upgrade a registration dossier from 1-10t/y to the 10-100t/y requirements. Data from the public database of the European Chemicals Agency (ECHA) on the substances currently registered for the use in a fertilising product, but not in accordance with the FPR's extended REACH registration requirement, illustrates to what extent this requirement poses an obstacle for the Single Market access of fertilising products.

REACH registration dossiers of substances contain information about the uses and the sectors of uses. On that basis, the following numbers were extracted from ECHA's public database to provide an indication on the number of substances registered for use in a fertilising product. However, the quality, including comprehensiveness, could not be ascertained, especially because, while some substances are direct component materials of fertilising products, other are used as raw materials to product component materials for fertilising products. Therefore, substances either with described use as a fertiliser (product category 12 – PC12) or with described sector of use in agriculture, forestry and fishing (sector of use 1 – SU1) were included.¹

Table 1: Number of substances relevant as potential component materials for CE-marked fertilising products but not yet registered in line with FPR requirements

	Substances registered with uses as fertilisers (PC12)	Substances registered with uses as fertilisers (PC12) and in the sector of agriculture, forestry and fishing (SU1)	Substances registered with uses in the sector of agriculture, forestry and fishing (SU1)	Total substances of potential interest (PC2 U SU1)
Substances registered to the range 0 to 10t per year	30 (15)*	17 (12)	26 (17)	39 (20)
Substances registered to the range 1 to 10t per year	83 (25)	44 (14)	76 (19)	115 (30)
Total	113 (40)	61 (26)	102 (36)	154 (50)

*Figures between brackets report the number of substances for which a chemical safety assessment is available, indicating that much testing has already been undertaken and possibly more data is already available. Accordingly, a lower cost for update may be possible.

Table 2: Costs incurred for REACH registration if substance were to be used in an EU fertilising product

	Lower	Medium	High
Reported cost per registration update from 1 to 10T per year ¹	€10.000	€180.000	€500.000
Number of substances of potential interest	154, out of which 50 already have a CSA		
One-off costs from updating existing REACH registration dossiers for all substances of potential interest	€1.540.000 ¹	Between €19.220.000 ¹ and €27.700.000 ^{Error!} Bookmark not defined.	Between €52.500.000 ^{Error!} Bookmark not defined. and €77.000.000 ^{Error!} Bookmark not defined.

3. As a consequence of the current difficulty to ensure that all substances used in the fertilising products are registered in accordance with the FPR, some fertilising products may be placed on national markets according to national rules. For placing the product on the market in other Member States, manufacturers need to ensure compliance with that State's legislation or rely on mutual recognition. In the Impact Assessment accompanying Commission's proposal for

FPR, costs for national registrations up to €50.000 per product per Member State were reported. Moreover, two cases studies showed adaptation costs for manufacturers seeking mutual recognition, incl. adaptation of their products, labels and/or packaging, of € 15.000 and €47.000⁸⁷.

Scenario following the envisaged amendment:

1. The FPR no longer requires an extended REACH registration. Manufacturers could place their products on the EU market as CE-marked fertilising products, relying on the current registration without any update (assuming that there would be no increase in the volume of the substance placed on the market in the EU, or a limited one, with no jump to a higher tonnage band).
2. Manufacturers which would CE-mark their products to place them on the Single Market, would no longer face multiple fees for national registrations and save adaptation. Assuming that they place their product on the market in five Member States and costs for registration and adaptation in accordance with national rules at the higher end, this can result in cost savings of up to €500.000.

⁸⁷ Impact Assessment accompanying the Proposal for a Fertilising Product Regulation, SWD(2016) 64 final.