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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 July 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
Subject:	COMMISSION STAFF WORKING DOCUMENT Accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products and the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions

Delegations will find attached document SWD(2025) 531 final.

EUROPEAN
COMMISSION

Strasbourg, 8.7.2025
SWD(2025) 531 final

COMMISSION STAFF WORKING DOCUMENT
Accompanying the documents

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions

{COM(2025) 531 final} - {COM(2025) 526 final}

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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 Letta[1] 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 challenge[2].

The European Commission's Better regulation agenda[3] 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 mandate[4] 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 EU[5]. 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

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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 industry[6].

Following those commitments, this initiative aims at simplifying and streamlining certain requirements and procedures under Regulation (EC) No 1272/2008[7] on classification, labelling and packaging of substances and mixtures, Regulation (EC) No 1223/2009 on cosmetic products and Regulation (EU) 2019/1009[8] 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, without compromising on the level of protection of human health and the environment.

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.

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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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

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 the European Chemicals Agency (ECHA), which then publishes certain information submitted to the inventory. Furthermore, the 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) 2024/2865[9], 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.

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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 substance was assessed and found safe, while meeting the other derogation criteria.
- The obligation to pre-notify cosmetic products containing nanomaterials in the EU's cosmetics database (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 to the Commission, through the EU's CPNP, each cosmetic product placed on the market.
- The introduction of a harmonised 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 amendments[10] of Annexes I to 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 Union[11].

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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

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 fertilising products easier 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 Regulation[12], 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 harmonised 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 Framework[13] (NLF). In 2024, the FPR was amended to allow for voluntary digital labelling. Those rules will apply form 1 May 2027[14].

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 sector[15].

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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.

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 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).

15 See current consolidated version.

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 report[16], the increasing number and complexity of rules risks limiting EU businesses' room of 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.

Over the past years, burdens, inefficiencies and obstacles in relation to the implementation of Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 have been raised by stakeholders, which are considered to cause disproportionate costs or prevent market access. Against this background, the Commission has organised Reality Checks in May 2025 to identify the most significant burdens and administrative obstacles under the three pieces of legislation and to explore the potential for simplification and burden reduction. In addition, the Commission received a significant number of letters and detailed analyses from all types of stakeholders (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 acts 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 legislation[17], 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

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

17 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.businesseurope.eu/wp-content/uploads/2025/02/2025-01-22_businesseurope_mapping_of_regulatory_burden-d55-1.pdf.

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 non-governmental organisations and from national competent authorities. 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 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 the other 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 Table 1, in addition to existing rules for minimum label and pictogram sizes:

Table 1: Minimum dimensions of labels and pictograms and minimum font size

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

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.

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 Check[18] 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

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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 (Commission SWD Fitness Check), 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.

(EC) No 1272/2008[21], 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 letters'[22]. 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 Report[23] 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'[24]. 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 [which illustrates example of what can be considered to be easily read], the problem persists, as the guidance is not legally binding. Without further action, the problem will persist or even increase'[25].

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'[26] in conjunction with additional flexibility to use fold-out labels. The Impact Assessment further noted that formatting requirements would come together with allowing a wider use of fold-out labels, noting that 'it is likely that suppliers will only opt for a fold-out label where it actually is economically beneficial for them'[27]. However, they would also apply to standard labels[28].

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.' [29] In other words, the Impact Assessment assumed that companies voluntary moving to fold-out labels would identify savings larger than the one-off

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21 Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008, rev. 4.2 March 2021, https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65.

22 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.

23 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.

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

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

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

27 Impact Assessment for the Revision of CLP, p. 340. See measures #12 and #15.

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

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

relabelling costs. As this would be a company choice, the report did not consider those costs. The report further noted that '[such a change] is not likely that [minimum font requirements] would have an impact on the market size.' Companies would not gain or loose market share because of their choice of label types.

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]'.

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 (€49 million, see Table 2), under the assumption that suppliers would make a voluntary choice to move to fold-out labels, where they identify economic benefits.

Table 2: Overall costs and benefits for changes to the CLP communication of hazards estimated in Impact Assessment Report 2022[30]

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]

Aside to the new provisions on label formatting, Regulation (EU) 2024/2865 introduced other changes related to labelling of hazardous substances and mixtures. It is now possible to use fold-out labels as regular label[31], 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

Overview of comments received

30 See table 98, Impact Assessment for the Revision of CLP, p. 348.

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

A large majority of the commenting stakeholders from industry raised, during the Reality Check, 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. This followed from some earlier and more isolated comments around the adoption of the CLP Revision. The stakeholders highlighted that the future formatting requirements have long-lasting consequences impacting the majority of their portfolio, such as a loss of flexibility for labelling resulting in 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 label[32] (see below). 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. Some stakeholders also referred to the existing rules laid down in Food Information to Consumers (FIC) Regulation[33], more specifically for products sold to consumers. A limited number of companies hence indicated that an alignment with the FIC Regulation could be possible, where the minimum font size is 1.2 mm with a possibility to use 0.9 mm for smaller labels and packaging. There may also be a need to develop a holistic analysis of labels for chemicals. Some companies indicated that they would alternatively welcome an alignment with the Food Information to Consumers (FIC) Regulation[34], where the font size is 1.2 mm with a possibility to use 0.9 mm for smaller labels and packaging. Some other companies noted that for trade between companies, REACH requires the communication of a safety data sheet, which communicate hazard to a greater extent than a CLP label does, which is used by recipients as the primary source of information. They suggested to exempt chemicals traded to industrial or professional users from the rules provided in Regulation (EU) 2024/2865 and revert back to current generic CLP rules.

Some Member States showed understanding about the reintroduction of flexibility in 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.

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32 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.

33 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, ELI: http://data.europa.eu/eli/reg/2011/1169/oj).

Detailed description of evidence received

As a starting point, stakeholders from industry, including SMEs, commented that they have more labels than initially identified (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 IA[35]). Those labels may already contain multiple languages in order to place products in multi-lingual 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). Multilingual labels for combinations of national markets currently 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). Industry highlighted that the choice of grouping or not languages on labels should belong to companies, depending on their business model as long as it stays within the framework provided by the CLP regulation and other pieces of legislation.

Companies that described their on-going processes or strategies to align with the future labelling rules confirmed that they no longer find any flexibility left with the requirements for minimum font size, minimum line-spacing and black font on white background. Most of the repliers indicated that they are forced to move fold-out labels and that the large majority of their labels[36] 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 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 extend their current fold-out labels to allow enough space as required by Regulation (EU) 2024/20865 (i.e. with 7 to 11 pages) to keep their SKU number unchanged. Initially, it was estimated that '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'[37]. According to new evidence received, it turns out that in most cases industry will be forced to use fold-out labels. 'The use of a fold-out label versus a standard label would be a voluntary business choice of the relevant supplier.

The input from industry also highlighted that contrary to the initial assessment, such decisions on labelling strategies are strongly connected to other increased costs (e.g., relating to logistics, in-house/outsourcing of labels, storage capacities, SKU, labelling robots/printers and price difference between labels) and finally to the business model of companies. In addition, some of the costs incurred would be recurrent. A qualitative summary of the evidence is provided in Table 3.

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35 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.

36 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, which seems to be a singleton.

37 Impact Assessment for the Revision of CLP, p. 340.

Table 3: Overview of impacts and their qualitive assessments (+: positive, -: negative, o: neutral)

	Initial Assessment	Reality Check	
Consumers	Increased legibility/readability (+)	Increased legibility/readability (+) Prominence of CLP label elements, instead of instructions for use (-)	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[38]) Impact on market size (o) and price of consumer goods (o) Impact on raw materials and generated waste (o-) Impact on the single market and competition (+)	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[39] (PPWR) (-); 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 or packaging negatively impact production time (setting lines between two labels) (-); Increasing the number of SKU (-) or reduction of market size where SKUs no longer break even (-); Increased needed space for stock (-); Increased complexity for logistics (-);	

[38] The higher cost of fold-out labels compared to 2D labels is acknowledged in Impact Assessment for the Revision of CLP. However, it is not factored into the recurring costs.

[39] 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).

		Outsourcing fold-out labels: additional label stocks (minimum order for labels), potential increase waste for out-dated labels (-); Packaging with fold-out labels are more difficult to recycle (costs where extended producer responsibilities are in place). Possible impact on eco-design; For business-to-business trade, an SDS is required, providing more granular hazard communication than CLP labels.
Environment	Neutral impact (o) apart from redesigning current labels and some moves to fold-out labels	Lower level of recyclability (-), including additional fees in MS when extended producer responsibility schemes are in place (-); Additional copies of labels needed and possibly discarded when labels are updated (when label printing is outsourced) (-); Additional (immobilised) materials and products where additional SKUs are needed (-); More complex logistic management (o).

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, such as the Detergents regulation[40] or the PPWR.

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 and larger companies. Many companies highlighted the extreme but possibly frequent case of 2D labels where only one language would fit. As a first consequence, companies are forced to consider switching from 2D labels to fold-out labels in the 3 Member States which request more than one official language on the label[41]. In this case, the number of different labels would not increase but a forced move to fold-out label bears both one-off (setting a labelling line and redesigning labels) and recurrent costs[42] (higher costs of labels, higher redesign costs and outsourcing labels) - see below section *estimated savings* 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 in the market of smaller Member States, if they need to label them with monolinguistic labels. According to those companies, 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 represent an alternative solution to 2D labels, offering enough space for all label elements, including those requested by the CLP. As discussed above, such changes should be

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40 Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/648/oj).

41 See Guidance document on labelling and packaging in accordance with Regulation (EC) No 1272/2008, rev. 4.2, footnote 7, p. 15 and Document 'Languages required for labels and safety data sheets', https://echa.europa.eu/documents/10162/17217/languages_required_for_labels_and_sds_en.pdf/735e95d2-1b84-4f6a-a196-fb65a756300f.

42 The concerned companies still have the flexibility to switch all their labels to fold-out ones or only those for which available space is no longer sufficient. In the former case, they would probably have to out-source all label production, whereas in the latter, they would have to set up a different labelling line for fold-out labels or improve their existing one to accept both roll labels and stack ones.

decided by companies, where there are economic benefits. According to industry, as also reported above, the formatting requirements remove the flexibility foreseen in the CLP IA. Industry informed that 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 (stack) 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.

Some companies which already use fold-out labels also shared concerns about the impact of the new rules on font sizes and label formatting. They 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, the Impact Assessment Report did not identify positive or negative impacts. However, industry highlights that possible negative effects are reported as a consequence of increased SKUs, such as more space needed, more products stored (and not yet 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. Moreover, industry stated that, where fold-out labels are not an option, the ultimate option of increasing the size of the packaging to fit all require elements 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.

Regarding social impacts, the changes could increase the need of workers in the labelling industry or in the chemical industry (according to some companies, updating 5 000 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 be transferred to the price of their products.

Regarding protection of human health and of the environment for consumers and other users of chemicals, non-governmental organisations shared their concerns about a possible amendment of the rules on CLP label formatting, which would jeopardise the increased 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 overall a broad consensus on the importance of ensuring label readability to protect health and environmental safety. Furthermore, some Member States raise

significant concern about the proportionality of the possible simplification measures suggested by industry, their feasibility including the timing of a legislative proposal. Such changes would come just after the adoption of Regulation (EU) 2024/2865, before its full application. This could create uncertainties and potential additional administrative costs for both national authorities and industry players.

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) Regulation, 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.

Regarding impacts on human health and of the environment, the Fitness Check noted that labels not only difficult to read but also overcrowded and difficult to read. The CLP Regulation requires labelling of hazardous substances and mixtures to inform about their hazard properties. Via the precautionary statements selected according to the hazardous properties, the CLP part of label informs about good handling in a generic way. According to the Eurobarometer, consumers note a chemical is hazardous thanks to the presence of pictograms and in turn read the use instructions to understand how to safely use such a product. There should be sufficient space left for other pieces of information which are critical to use and dispose of a chemical product in a safe way, like detailed dosage, use instructions or sorting instructions for disposal. Space dedicated to those pieces of information should enable an easy reading.

Moreover, consumers may not always understand long and complex chemical names when provided as required by the CLP Regulation, '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'[43]. Regulation (EU) 2024/2865 only look at one component of the problem identified in the Fitness Check and the solutions it offers may not flexibility to fix the other components to make labels of chemicals easy to understand to consumers and other users of chemicals. Regulation (EU) 2024/2865 does not

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43 See Commission SWD Fitness Check p. 53.

differentiate between consumers and professional or industrial users, where the latter would have a better understanding of labels or other ways to access information on hazards and on how to safely use hazardous chemicals.

Proposed amendments and next steps

The Commission takes note that the future rules laid down in Regulation (EU) 2024/2865 leave no flexibility for businesses. The future situation would possibly create large negative impacts on the chemical industry, such as increased costs, a more fragmented single market for chemicals leading to a reduced competitiveness of the European chemical industry. The Commission suggests bringing back sufficient flexibility in label formatting requirements. This would allow companies, depending on their business model and the types of products in their portfolio, to make the most responsible decision on appropriate and informative enough CLP labels for their customer responsibly.

The Commission proposes to replace specific mandatory label formatting rules introduced by the Regulation (EU) 2024/2865 to set up generic obligations. The proposed amendments would require 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 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.

Provisions in Article 31 would have to be complemented by more detailed guidance than the current guidelines. Such guidelines would be developed by ECHA, in order to provide more clarity to this issue. They could be inspired by what is available for Food Information to Consumers and on consumer behaviour.

The proposed amendments and complementing guidance are guided by the 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, while keep a high level of protection of human health and of the environment.

Estimated cost savings

Based on the input from stakeholders ahead and during the Reality Check, the savings of the proposed amendments are estimated.

Possible savings estimated for the detergent industry

For the detergent industry, the Impact Assessment Report accompanying the proposal for an amending regulation concluded[44] that a broader use of fold-out labels would generate annual savings of between €24 million and €55 million (see table 98 in that report). From the initial assessment[45], savings from a voluntary use of fold-out labels instead of monolingual 2D ones were estimated as 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.

The semi-quantitative data received since the publication of the Impact Assessment for the Revision of CLP highlights the following shortcomings[46]:

- 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: €4 000 to €40 000 per label printing equipment and €170 000 to €250 000 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 3 000 products, from 15 000 SKU to 40 000 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 these new pieces of evidence, it seems that current 2D labels may often 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, as fold-out labels were expected to be voluntary. Furthermore, the initial assessment did not identify an impact on the price of chemical products, at least for SME companies.

Three theoretical scenarios are analysed in greater details in the Annex II: (i) companies using a mix of 2D labels and fold-out ones, which can keep their labels but face more complex and slightly more expensive labelling costs (see Table 4), (ii) companies using 2D labels which have to develop monolingual labels for all their products[47] (see Table 5) and (iii) companies using 2D multilingual moving to fold-out labels containing the same amount of information because of the future

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44 Stakeholders from the industry did not negatively comment on measure #12 in conjunction to measure #15 during the development of the Impact Assessment for the Revision of CLP. However, concerns were received once the adopted Commission Proposal became available.

45 Impact Assessment for the Revision of CLP, p. 342

46 See Table 3 for a comprehensive qualitative overview of reported impacts.

47 This estimate does not cover the case highlighted by some stakeholders that they would have to develop a new packaging (addition of an additional secondary packaging or larger primary packaging).

formatting rules (see Table 6). 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.

Table 4: Possible costs for detergent manufacturers with a mix of 2D and fold-out labels (unchanged number of labels and slightly increased price per label, in addition to 100% relabelling to comply with Regulation (EU) 2024/2865).

Size of company	Average number of labels		Average relabelling costs from Reg. (EU) 2024/2865		
	Current	Future	One-off costs	Recurrent costs	Total annualised costs
Large	7	7	€50 100 000	€300 000	€6 200 000
SME	3	3	€64 700 000	€200 000	€7 700 000
Total			€114 800 000	€500 000	€14 000 000

Table 5: 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).

Size of company	Average number of labels		Average relabelling costs from Reg. (EU) 2024/2865		
	Current	Future	One-off costs	Recurrent costs	Total annualised costs
Large	7	15	€65 300 000	€300 000	€8 000 000
SME	3	5	€66 800 000	€200 000	€8 000 000
Total			€132 000 000	€500 000	€15 500 000

Table 6: 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).

Size of company	Average number of labels		Average relabelling costs from Reg. (EU) 2024/2865		
	Current	Future	One-off costs	Recurrent costs	Total annualised costs
Large	7	7	€58 500 000	€5 000 000	€11 800 000
SME	3	1	€6 300 000	€2 400 000	€3 200 000
Total			€64 800 000	€7 400 000	€15 000 000

Possible savings estimated for the lubricant industry

The lubricant manufacturers reported an already existent extensive use of fold-out labels for small packaging, with up to 31 languages per label covering both EU and non-EU markets[48]. In the sector, products sold to industry or professionals represent the majority of the market, with up to 90% for some large companies. The new formatting rules would force those manufacturers to increase the number of pages of current fold-out labels, from 5 pages to 11, making it a technical challenge. Alternatively, companies could cluster, with more fold-out labels covering fewer

[48] For the purpose of this analysis, only EU MS markets will be considered. It should however be acknowledged some companies may save costs from further rationalisation of labels beyond the European languages .

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.

Few large companies, representing about 50 % of the European market for lubricant, reported during the Reality Check one-off relabelling cost of between €2 000 000 and €6 900 000 to comply with Regulation (EU) 2024/2865. Based on the market value of the sector, impacts for the whole sector is estimated to about €53 600 000 (one-off costs). 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 an SME. For the sector, these recurrent costs could amount, by similar extrapolation as for one-off costs, to €111 000 000 per year, let alone routine relabelling costs. Finally the impact for the lubricant sector could be estimated to about €119 000 000 in a conservative way.

Possible savings estimated for the paint and ink industry

Finally, paint and ink manufacturers reported higher number of articles than in other chemical sectors, usually in smaller packaging and sometimes tailor-made. Companies also reported additional costs for fold-out labels compared to 2D labels (between €0.15 to €1.50 per label). Similarly to detergents where 2D labels are all redesigned into fold-out ones (similarly to the 3rd scenario for detergents), one-off relabelling costs could be estimated between €3 150 000 and 4 500 000 per large company, considering an average number of 3 000 different (fold-out) labels and 1 000 000 products labelled per year. The price increase for fold-out labels will increase the recurrent cost of routine updates of CLP labels which however could not be estimated, due to the limited amount of evidence available and the increased diversity of products in this sector. Moreover, companies would need to invest in new labelling machines for fold-out labels, the reported price of which is between €200 000 and €500 000 per production line, depending on the company. However, due to limited evidence from this sector, a more detailed and comprehensive analysis of the impacts to the paint and ink sector is not possible.

Extrapolation to the European chemical industry

In order to further estimate the overall costs of the future rules laid down in Regulation (EU) 2024/2865 for the European chemical sectors, estimated or reported sectorial/national impacts were extrapolated to the whole EU chemical industry (see Table 7 and calculation explanation in Annex II).

Table 7: Possible costs for the EU chemical industry to comply with Regulation (EU) 2024/2865.

Source	Share of EU chemicals production value	Annual cost (€ million)	One-off cost (€ million)	Extrapolation to EU chemicals industry (€ million)	Type of costs
Detergent sector (calculated)	4.20%	14.0		333.0	Annual overall cost
Lubricant companies (calculated)	1.16%	119.0		9 956.0	Annual overall cost
National paint and ink sector (reported)	0.09%		60.0	4 481.0	Annualised one-off cost

Member State (reported)	1.32%		50.0	255.0	Annualised one-off cost
National chemicals sector (reported)	11.22%		583.0	349.0	Annualised one-off cost

Conclusion

The proposed reversal of CLP requirements to CLP provisions before their amendment by Regulation (EU) 2024/2865 will save industry from costly adaption to the recent revision of CLP. Those costs have not yet fully materialised, as only some front-runners may have initiated some changes, the cost of which may not be fully recovered. However, the estimates, even if theoretical and subject to many uncertainties, should be considered as savings, as they will materialise if Regulation (EU) 2024/2865 fully applies.

The estimates derived for the detergent industry are identified as the most robust ones amongst those reported in Table 7 above. Notably, they have partially based on cross-checked figures from existing Impact Assessments. These estimates are of the same order of magnitude as other reported costs when extrapolated to the whole EU chemical sector. As the Impact Assessment for the CLP Revision developed a specific focus on the implications of some measures on that sector, a comparison is also easier. For these reasons, the yearly savings estimated to about €333 million based on the extrapolation from the impact to the detergent industry will be used for the semi-quantitative assessment of the proposed rules on label formatting.

As the new rules from Regulation (EU) 2024/2865 would be reverted to the current situation where they do not apply yet, any impact on human health, on the environment or on the European society, whether positive or negative, would be also lifted. As suggested above, clearer guidance on labelling and especially what is considered legible and readable will secure some improvement for the protection of human health and of the environment compared to the current situation where Regulation (EU) 2024/2865 does not apply yet. The reinstated flexibility for suppliers of hazardous chemicals to design their CLP labels in a way that is easy to read will also be useful to leave enough space and prominence to other parts of the label, such as the use instructions, where needed and required by other legislation, to inform users on how to safely use a chemical product.

b. Rules on advertisements

Article 48 of CLP regulation as currently applicable[49] 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

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

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 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.

The introduction of extended rules on advertisement follows the identification in the initial assessment that 'non-compliance with the provisions of CLP on online advertisement is very frequent, especially for chemicals sold online, both by EU and non-EU actors. […] As online offers and advertisements often do not display hazardous information, consumers may not be able to make informed choices, or correctly use, store or dispose of mislabelled chemicals such as detergents or paints, leading to risks for their health and/or the environment'[50]. The initial assessment looked at options to '[ensure] that CLP labelling is shown in online offers and online advertising'[51] and fix the '[ambiguities] in the CLP Regulation about online offers, online advertisements, the obligation to display labelling information in online offers and to mention certain hazard information'[52].

While measure #17 of the initial Impact Assessment looked at 'Amend CLP provisions to make them explicitly apply to online offerings and online advertising and to clarify that labels need to be provided also for online sales', Regulation (EU) 2024/2865 laid down extended rules targeting any kind of advertisement, including offline ones that constitute promotional messages without direct invitation to buy a product.

Stakeholder views

These introduced 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. 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 would 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.

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50 Impact Assessment for the Revision of CLP, p. 14.
51 Impact Assessment for the Revision of CLP, p. 21.
52 Impact Assessment for the Revision of CLP, p. 17.

It was pointed out that a primary way of informing users of hazardous chemicals about associated hazards is (and should remain such) the CLP label on the product – which consumers and professional 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 pointed 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 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 argued 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 would mirror practices in other EU legislation and is seen as more effective in directing consumers to the label where complete information is available.

Stakeholders from industry also drew 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 Regulation[53] and the Directive on Medicinal Products[54]. These legislative acts require a simple invitation to consult the label, rather than reproducing detailed hazard elements in advertisements. Stakeholders suggested harmonising requirements across regulatory frameworks, which 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 highlighted the need to produce

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53 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, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

54 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, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

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 they can report well-established safe use records and low incident rates, all of which do not suggest that intensified hazard communication is needed. Furthermore, they highlighted that concentrated detergents may have more severe CLP classifications due to their concentration. If these products would have to 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 Regulation. 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 reduction of packaging and packaging waste. The detergents and home care sector noted that 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 Directive[55].

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, stakeholders highlighted 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 called for a precise and harmonised definition of advertisement 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 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

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55 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.

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% favoured 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.

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, as laid down in Regulation (EU) 2024/2865, 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.

A large company reported that 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. They projected this would result in an annual loss of €30 million in advertising value for just one product category.

For adhesives and sealants industry, according to the feedback received, the identified average cost of new requirements on advertisements would raise to €21 470 per company. This is not considering the cost of market loss when retailers would choose not to advertise at all or reduce advertisements for hazardous 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.

Increased requirements for catalogues and printed advertisements would lead to greater production and distribution expenses. One example cited a €50 000 increase, with others reported 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, hence larger, companies noted that in the case they have joint marketing campaign covering EU and non-EU countries, they would need to split those campaigns into separate EU and non-EU formats, introducing design duplication and added production cost. While not fully quantified, they projected it could cost several million euros annually.

c. Other areas where stakeholders called for simplification which are addressed in the Commission proposal

Stakeholder views

In addition to topics outlined above, stakeholders raised a broad range of additional opportunities to simplify the CLP Regulation, which are listed below in this section. Most of the issues were highlighted during Reality Check and later confirmed and further illustrated by stakeholder's written contributions.

"Stop-the-clock" for font size and other related requirements

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, they claimed that a strong political signal is needed that the revision of the formatting rules is seriously considered.

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 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.

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.

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 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.

Postponing the entry into application of formatting requirements and other related provisions

From the legal perspective it is not possible to freeze the implementation deadlines laid down by the Regulation 2024/2865. However, a proposal to postpone the entry into application of the provisions on mandatory formatting requirements, relabelling, advertisements and distance sales offers and labelling of fuel stations until 1 January 2028 was put forward by the Commission[56] in

[56] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions.

order to ensure legal clarity for businesses while these provisions are being discussed by co-legislators.

d. Other areas where stakeholders called for simplification which were not addressed by the Commission proposal

In addition to topics outlined above, other proposals to simplify the CLP Regulation were emphasised by the stakeholders. Most of these issues were highlighted during Reality Check workshop and later confirmed and further illustrated by stakeholder's written contributions.

These additional suggestions were not taken on board in the Commission proposals for which this Staff Working Document is developed. While some suggestions may not be in line with the objective of regulatory simplification without reduced protection of human health and of the environment, other proposed measures would not fit in a legislative proposal and could be better addressed outside legislative changes. For some suggestions too limited information was available to either identify the issue or to conclude that the options submitted would actually address the issue raised in a satisfactory way.

Additional work, of various nature, would be needed for all those options not reflected in the Commission proposal.

"Stop the clock" for all regulatory changes to the CLP Regulation

In addition to the call to stop-the-clock for the application of label formatting rules, some organisations representing industry 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 national 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.

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.

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.

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

Since the entry into application of the Cosmetics Products Regulation in July 2013, cosmetic manufacturers have increasingly raised concerns about the absence of transitional periods. These concerns became more prominent following the European Commission's rejection of derogation requests for substances such as Zinc Pyrithione (ZnPt) and butylphenyl methylpropional (Lilial) - commonly used ingredients in cosmetics – which were subsequently banned as of March 2022 with only a three-month transitional period. This decision prompted the industry to regularly highlight difficulties in the practical application of the derogation criteria, as well as the challenges caused by the lack of sufficient transition time to adapt product formulations.

Since 2023, concerns have grown further with the proposal to classify various natural oils and constituents of natural complex substances as CMR substances. These include ingredients such as Tea Tree Oil, hydroxycitronellal (HCA), L-carvone, spearmint oil, cuminic aldehyde, and p-cymene[57]. Given that over 70% of cosmetic products placed on the EU market contain fragrances – and more than 85% of those include ingredients potentially subject to such bans – the implications of these classifications are significant. The current lack of specific provisions addressing natural complex substances within the Cosmetic Products Regulation has therefore become a major source of concern for the EU fragrance industry.

These issues have been the subject of ongoing discussions between the cosmetics industry, Member States, and the European Commission, including in the context of the Working Group on Cosmetic Products[58] as well as through bilateral meetings. The Commission has received numerous letters, position papers, and reports from industry stakeholders, all underscoring the growing regulatory burden. Frequent changes in regulatory classifications necessitate repeated reformulations and adjustments to company portfolios, leading to rising operational and compliance costs. These pressures disproportionately affect small and medium-sized enterprises (SMEs) and risk undermining the competitiveness and innovation capacity of the EU cosmetics sector as a whole.

To collect a first-hand experience from the stakeholders, a Reality Check on the CPR took place on 16 May 2025[59]. 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

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.

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57 The Committee for Risk Assessment adopted its opinion on Cuminic Aldehyde and p-cymene in 2024, opinion published on 9 January 2025.

58 https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=1302

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

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. A clear, fair, and efficient procedure for adding new colorants, preservatives, and UV filters to the Annexes of the Cosmetics Regulation would reduce regulatory uncertainty and lower the risks associated with innovation. When the path to approval is predictable, companies are more likely to invest in research and development, knowing they have a realistic opportunity to bring new substances to market and generate returns on their investment. Faster and more transparent procedures also support the development of safer, more effective, and more sustainable ingredients that align with consumer demands and EU policy goals. Ultimately, strengthening the EU regulatory framework in this way helps retain innovation within Europe, making the internal market more attractive for global investment and competitiveness.

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, based on the Slido responses[60], 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 colorants, preservatives or UV filters.

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 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.

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60 197 participants answered the question via Slido

- 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.

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 2024, The Committee for Risk Assessment (RAC)[61] adopted/published several opinions for which CMR 1B classification was proposed. Some of these substances are widely used in cosmetic products. For example, Piperonal[62] is a key ingredient in fine fragrances and signature perfumes, p-cymene[63] is a component found in more than 360 essential oils, and Tea Tree Oil[64] 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

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

62 Also known as Heliotropine, RAC opinion was adopted on 6 June 2024; https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e187205ab2

63 RAC adopted its opinion on 18 November 2024; https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e188d24acd

64 Also known as Melaleuca alternifolia. RAC opinion was published on 10 September 2024.

operations effectively – an issue that disproportionately affects SMEs, for whom strategic planning and resource allocation are particularly critical.

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 Regulation. However, such opinion is not legally binding and may differ from the final classification adopted under the CLP Regulation[65]. 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**. 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 health[66].

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].

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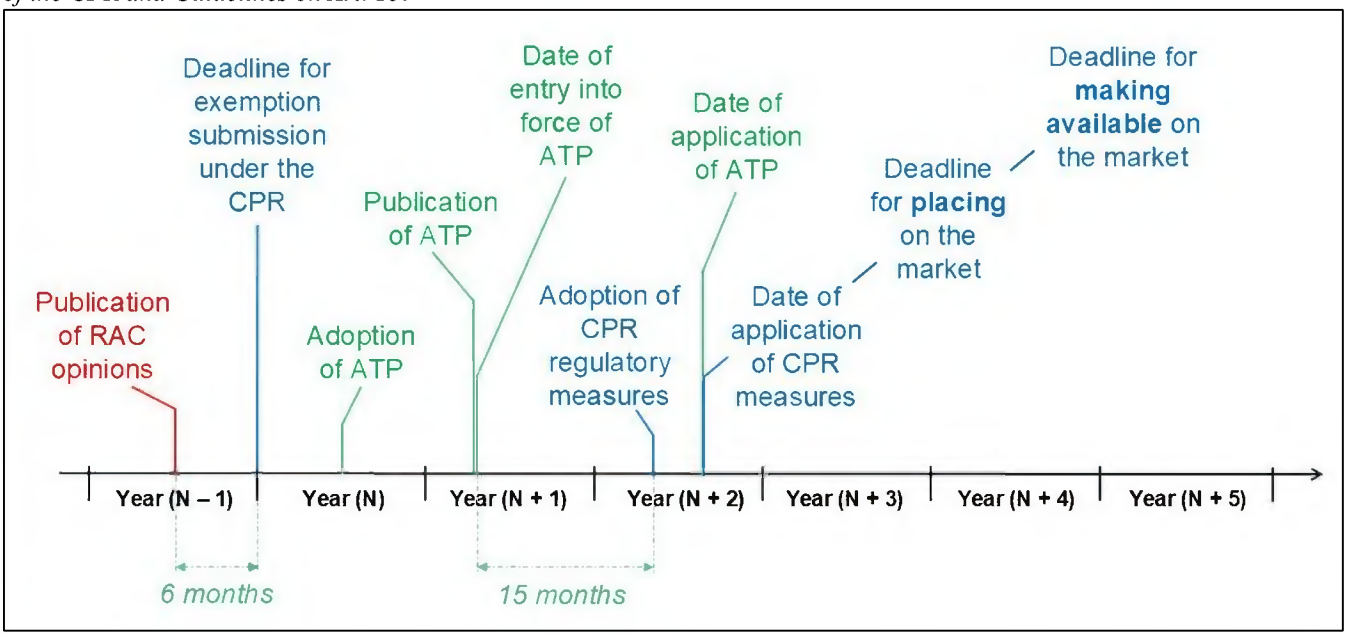
65 Such divergences, though not frequent, do occur, as the Commission may take into account additional policy, legal, or socio-economic considerations when deciding on the final harmonised classification

66 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).

Figure 1: Timeline of adoption and entry into application of a ban/restriction on CMR substances under Article 15(2) of the CPR and Guidelines on Art. 15.



ATP (Adaptation to Technical Progress) corresponds to the Commission delegated Regulation amending Part 3 of Annex VI to the CLP Regulation.

Despite the legal distinction between Category 1 and 2 substances in the CPR, the Commission has been preparing regulations amending Annexes to the CPR banning or restricting the CMR substances from use in cosmetics (also referred to as 'CMR Omnibus Acts') within **15-month timeline** as provided in Article 15(2) for amending the Annexes of the CPR, regardless of the classification category (see figure 1). According to the current practice which follows the interpretation of Article 15 of the CPR, the CMR Omnibus Act on CMR enters into application at the same day as the relevant delegated act under the CLP Regulation (as shown in figure 1). 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 Adaptation to Technical Progress (ATP).
- Under the **CPR**, the Commission regulations (CMR Omnibus Acts) amend the Annexes to the CPR, but **not** provide any timeframe for economic operators to **prepare** for their application. It should be also noted that economic operators for cosmetic products are further downstream users 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 the lack of transitional periods for businesses to adapt to regulatory measures.

Regulation amending Annexes to the CPR	**Date of entry into force**	**Date of application**	**Period between the entry into force and application**
Regulation 2019/831	12/06/2019	12/06/2019	0 months
Regulation 2019/1966	18/12/2019	11/06/2019 and 1/05/2020	-6 and 6,5
Regulation 2021/850	17/06/2021	01/10/2021	3,5 months
Regulation 2021/1902	23/11/2021	01/03/2022	3,5 months
Regulation 2022/1531	06/10/2022	17/12/2022	2,5 months
Regulation 2023/1490	09/08/2023	1/12/2023	3,8 months
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.

Criterion (a) requires that, for a CMR substance to be used in a cosmetic product despite its classification, it must also comply with food safety standards. The assumption used in this case is that if a substance is safe enough for ingestion, it should theoretically be safe for external, topical application, which typically involves lower systemic exposure. However, this requirement has proven problematic for several reasons:

Cosmetic and food products are fundamentally different in terms of route, frequency, and context of exposure. Cosmetics are applied externally, often in lower concentrations, whereas food involves ingestion and metabolic processing. This mismatch in exposure profiles means that compliance with food safety requirements does not necessarily correlate with safety in cosmetics or vice versa. In many cases, substances used in cosmetics are not intended to be ingested and may

never be assessed by the European Food Safety Authority (EFSA), the authority responsible for food safety evaluations. In particular, if a substance is not authorised or evaluated for use in food, it can be disqualified for derogation in cosmetics regardless of its actual safety profile for topical use.

In essence, this criterion creates a misalignment between regulatory frameworks and has been viewed by industry as scientifically inappropriate and legally rigid, especially when the substance has been deemed safe for topical use by the SCCS. Many stakeholders have therefore called for its removal or reformulation, arguing that it adds burden without improving consumer protection.

Criterion (b) requires the applicant to demonstrate that no technically and economically feasible alternatives exist that would perform the same function in the specific cosmetic application. The rationale is that derogations for CMR substances should only be granted as a last resort, where the substance is necessary for performance or stability and no safer options are available.

Nevertheless, the definition of "suitable" alternatives is unclear: It is not always specified whether alternatives must be equivalent in function, efficacy, cost, or compatibility with other formulation components. In addition, the assessment of alternatives is often subjective or context-specific, especially in high-performance products like sunscreens, hair dyes, or preservatives, where technical performance and formulation stability are crucial. Furthermore, the economic feasibility is rarely quantified, but in practice, industry may face significant reformulation costs or loss of product effectiveness if forced to switch to inferior or possibly costlier alternatives. Lastly, this requirement may also discourage innovation or delay access to market for products that rely on well-understood and previously authorised ingredients, even when they pose no real safety concern at the intended use level.

Therefore, while it is reasonable to encourage the use of safer alternatives, the current application of criterion (b) can be ambiguous and overly restrictive. Stakeholders have proposed that greater clarity be provided on how alternatives should be assessed, and that the criterion should focus more on whether the substance can be safely used in the specific context, rather than presuming that presence of any alternative is sufficient to justify prohibition.

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 is already considered (as such) in the SCCS safety assessment. 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 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 ensure the protection of 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 possible changes to Article 15 of the CPR relevant to the food criterion, particular use and assessment of suitable alternatives. 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 revised/updated derogation criteria are met.

i.Establishing a fixed period for submission of derogation requests

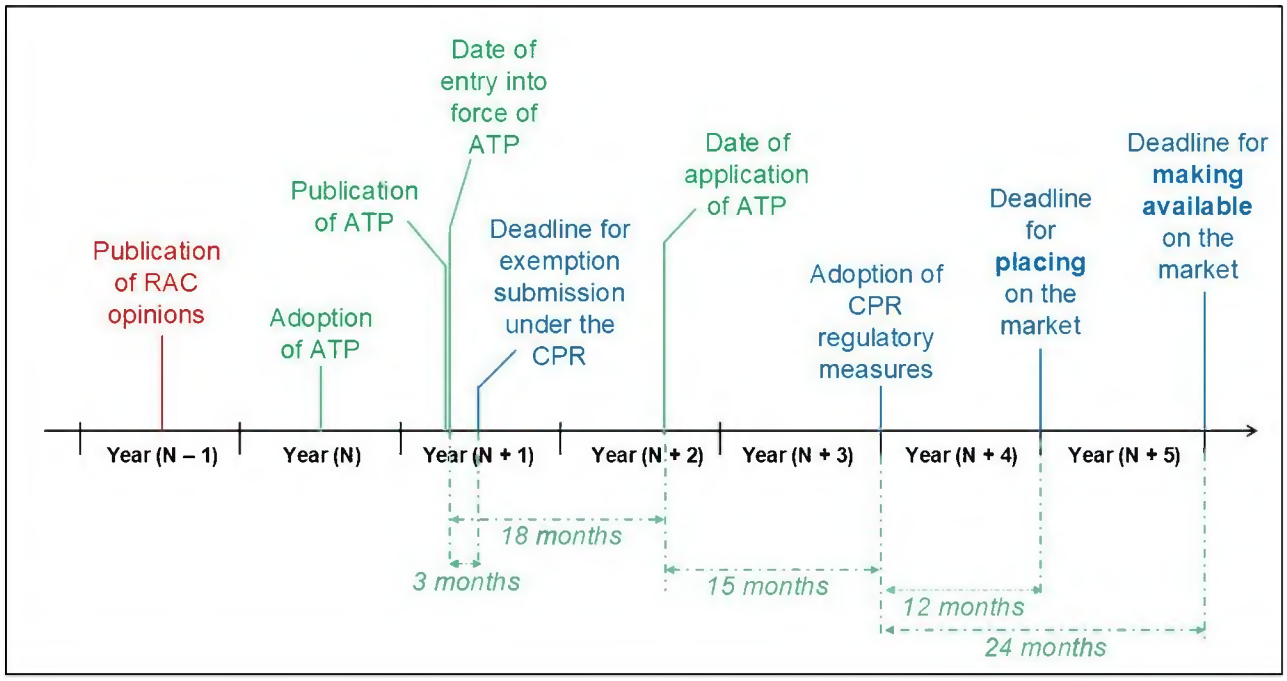
The current CPR does not foresee a timeline for businesses to submit a derogation request. According to the so called 'CMR Guidelines'[67], a submission should be made within six months after the publication of the RAC Opinion. To provide greater legal certainty, the CPR should explicitly set the deadline for the submission of derogation request which should not exceed three months after the entry into force of the changes to Part 3 of Annex VI of the CLP Regulation. It will allow business operators several months to prepare and collect data and evidence demonstrating compliance with the derogation criteria (see figure 2).

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 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 force of the amendments to the relevant Annexes to the CPR (see figure 2).

Figure 2: Planned timeline of adoption and entry into application of a ban/restriction on CMR substances under Article 15(2) of the CPR after amendments.

67 https://ec.europa.eu/docsroom/documents/39989



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, 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. However, to address possible safety concerns, the Commission should request the SCCS to provide its opinion on the safe presence of the constituent classified as CMR substance in the plant extract used in cosmetics.

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 requirement 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	2333
Art. 16 pre-notification	144	74	265	131	200	175	137	222	57	76	51

According to the cosmetics industry, the pre-notification process of one product takes 3 working days of 1 FTE. Therefore, in 2024, when the number of prenotifications was the lowest, the administrative costs for the industry amounted to €36 000[68] while in 2016, with the highest number of prenotifications, this amount was substantially higher and reached €187 000.[69] 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

[68] 51 notifications *24 hours= 1224 hours per year, 1224 * 29.40 = approximately €36 000 per year

[69] 265 notifications *24 hours= 6360 hours per year, 6360 * 29.40 = approximately €186 984 per year or 187, 000

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 cosmetics[70]

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

[70] 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

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 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 database[71].

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.

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

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,
- PEMSAC group facilitates the exchange of information among the market surveillance authorities responsible for cosmetics,
- The ICSMS (Information and Communication System for Market Surveillance)[72] 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.

Assuming that the collection of data is already performed, the analysis of such data and the preparation of the respective report would take 10 days for 1 FTE, the savings will amount to €129 360[73] yearly.

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.

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

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

73 55 authorities were taken into account for this calculation including state and provincial authorities in federal states. Calculation: 10 days x 8 hours = 80 hours x 55 competent authorities = 4.400 hours x 29.40 = €129 360

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 Regulation 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 **€5 320 000 to €53 500 000** (one-off cost per company). Large national companies reported reformulation costs between **€2 000 000 and €23 000 000,** while medium-sized companies estimated costs between € 600 000 and €8 000 000.

Apart from the reformulation costs, companies also have to conduct 'Product-in-Use' (PIU) tests to ensure consumer acceptance and maintain product 'likeability'. With average PIU test costs of approximately €80 000 per product, one large national company estimated the **total cost of the Lilial phase-out to be around €30 000 000.**

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 Cosmetic Products Working Group. 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 on the global market. 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 €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 **€6 750 000 000 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 €2 000 000 and 5 000 000** (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)

The Fertilising Products Regulation has been applicable since 2022 only. Nevertheless, stakeholders have identified several issues and shortcomings in the Regulation's implementation which they brought to the Commission's attention, in bilateral exchanges and in the Commission Expert Group for fertilising products. The responsible Commission services have also themselves experienced certain obstacles and inefficiencies in procedures mandated by the Regulation, which create bottlenecks for the use of certain materials in EU fertilising products. With a view to gather additional feedback on the identified issues and to give stakeholders the opportunity to make further suggestions for simplification of the FPR, a Reality Check for the Fertilising Products Regulation was held on 7 May 2025. The following issues and potential solutions were identified and discussed with stakeholders.

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 Council[3] (REACH). Information requirements increase with the quantity 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 mixture 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 substances[74] 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 the quantity 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 FPR[75].

As explained in recital 26 of the Regulation, the rationale for this extended REACH registration requirement was to ensure that the safety of the intended use of the EU fertilising product is demonstrated in a manner comparable to that achieved through other regulatory regimes for products intended for use on arable soil or crops, notably Member States' national fertiliser legislation and Regulation (EC) No 1107/2009 on plant protection products[76]. However, the Impact Assessment for the FPR did not assess this horizontal requirement for all substances in EU fertilising products[77]. Instead it analysed the impact of the extended REACH registration requirement for chemical plant biostimulants, as a counterbalance to their exclusion from Regulation (EC) No 1107/2009 on plant protection products, which provides for very extensive data requirements, to fall under the scope of FPR.

Stakeholder views

Already in 2022, an industry stakeholder approached the Commission to express its concerns about the extended REACH registration requirement under the FPR, pointing to the high costs of REACH registration under these conditions and related price increases for substances and end products, as well as to the lower requirements in competing markets. Market distortion and

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

75 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.

76 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).

77 SWD(2016) 64 final.

impeded innovation were cited as consequences. In 2023, the topic was discussed in a workshop organised by an industry organisation, where similar concerns were raised. Stakeholders in the Reality Check confirmed that this requirement poses significant obstacles for manufacturers of EU fertilising products in using certain substances.

Stakeholders generally 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 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 additional 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 additional FPR requirements.

As consequences, manufacturers cannot use certain substances in EU fertilising products. They alternatively market their products under national rules for national fertilising products or stop supplying the EU market and turn to other markets, such as the US. In the above-mentioned workshop in 2023, results from a survey among 18 members of the industry association showed that more than half of respondents were marketing their products under national rules because of the onerous registration requirements under the FPR. Some manufacturers also replace the substance in question by already registered but underperforming substances. Such reformulation, as explained by a company in the Reality Check, implies costly reformulation tests, stability tests and greenhouse tests. It can also result in lower product quality, for instance when removal of an anticaking agent leads to lumping of the product[78].

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. In the 2023 workshop, it was reported, based on the survey results, that 90% of manufacturers were using technical additives that were only registered at the 1-10 tonnes band, and hence not eligible for use in an EU fertilising product. Moreover, nearly all of the respondents said that most or some of their technical additives are mixtures with unknown composition, making it impossible for them to verify the different substances' registration status. But the problem does not only concern additives. Some primary components of fertilising products are also produced and used in small amounts and therefore affected by this extended REACH registration requirement.

Several stakeholders in the Reality Check 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

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78 Example presented at the 2023 workshop.

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 quantity, would apply to substances used in EU fertilising products. The safety of EU fertilising products would still be ensured for the following reasons:

a) under REACH, manufacturers, importers and downstream users are obliged to ensure that they only manufacture, place on the market or use substances that do not affect human health or the environment;
b) where Member States or the Commission have a concern about a certain substance used in fertilising products which should be addressed on an EU-wide basis, they should prepare a restriction dossier in accordance with Article 69 of REACH. If the concern is well-founded, the substance can be banned for the use in fertilising products, including EU fertilising products, under REACH. The Commission has initiated such assessment for calcium cyanamide[79];
c) it is expected that, without the extended REACH registration requirement, more companies will start to market their products as EU fertilising product. Having access to the Internal Market, they will likely go into larger-scale production. From that point on, the quantities of most substances used in EU fertilising products will trigger registration at the 10-100 tonnes band, i.e. the information currently required under the extended REACH registration requirement will in most cases be available also in the future;
d) under the FPR, manufacturers are obliged to carry out an analysis and assessment of risks and may not place on the market a product that presents a risk to human, animal or plant health, regardless of whether the risk results from no-compliance or aspects not covered by the FPR. The FPR's safety requirements can be amended by the Commission on the basis of new scientific evidence, such as new information about harmful substances or contaminants;
e) with more fertilising products being marketed as EU fertilising products, more fertilising products on the Internal Market will comply with the FPR rules, which are more stringent than many national rules;

[79] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1824484f8.

f) food safety is further ensured by other EU legislation, notably Regulation (EU) 2023/915 on maximum levels for certain contaminants in food[80] and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin[81].

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 €1 908 In case of joint submissions, the fee to be paid by each registrant is lower[82]. Currently, 154 substances are registered for agricultural use under REACH, but do not meet the FPR's extended requirements (see Annex V). Assuming a share of those substances between SMEs and large companies in the fertilising products sector as estimated in the Impact Assessment for the FPR[83], industry would have to pay fees of about €187 586 if those registration dossiers were to be updated to comply with the FPR via individual submissions.[84]

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80 Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 05/05/2023, p. 103, ELI: http://data.europa.eu/eli/reg/2023/915/oj).

81 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj).

82 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).

83 SWD(2016) 64 final.

84 As no data on the shares of medium, small and micro enterprises within the SME category was available, the figure was calculated assuming equal shares for each enterprise size.

Although **SMEs** benefit from reduced registration fees, they also incur costs for proving SME status, as explained by a company in the Reality Check. 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.

In a study carried out for the Commission in 2021[85], 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 cost for physicochemical, toxicological and ecotoxicological tests for 10-100t/y substances was estimated at €144 329 per substance.[86] 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.[87] In the Impact Assessment for the FPR, overall costs for industry to comply with the extended REACH registration requirement were not assessed. Only the costs for the registration of plant biostimulants were calculated, but only for the 1-10 tonnes band. The costs for compiling data and the fees together were initially estimated at €131 714 per substance[88].

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 the 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**. Across the evidence received, **€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. 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. All those figures from stakeholders and the cost estimates from the study mentioned above roughly concur. Overall, it can be assumed that costs for complying with the

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85 Wood, Study on the impacts of the 2018 REACH registration deadline. Final Report, 2021.

86 Physiochemical requirement study costs: €13 125, toxicological requirement study costs: €104 911, ecotoxicological requirement study costs €26 293.

87 Wood, Study on the impacts of the 2018 REACH registration deadline. Final Report, 2021, pp. 53, 122, 123.

88 SWD(2016) 64 final, see table 47.

extended REACH registration dossier range from €10 000 (for substances already registered, with little additional data to be generated for the upgrade) to €500 000 (for substances not yet registered or registered for 1-10t, with a significant amount of additional data to be generated). €180 000 can be considered the average cost for complying with the requirement.

On this basis, it is estimated that **a one-off cost of about** €19 220 000 (see Annex IV) would occur to update REACH dossiers (data generation, dossier preparation and fees to ECHA) 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.

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 at 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).[89]

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.

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

and *Azospirillum* spp. The Commission is empowered to add new micro-organisms or strains of micro-organisms to the positive list after having assessed the safety and agronomic efficiency of each strain. 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.

Since the entry into force of the FPR, no additional micro-organisms or strains of micro-organisms were added to the positive list. A study carried out for the Commission by the Austrian Institute for Technology is currently assessing 34 strains for potential inclusion. The study was launched end of 2023, and it will run for a period of 24 months. Based on the outcome of the study, the Commission will prepare a delegated act to add those strains that meet the safety and efficiency requirements of the FPR to the positive list. The adoption process will take at least six months.

In the meantime, new strains of micro-organisms for potential use in EU fertilising products, which are not covered by the study are discovered by industry. If and when those might be added to the positive list is uncertain. The current mechanism for adding new micro-organisms or strains of micro-organisms is thus creating a bottleneck for the placing on the market of plant biostimulants in the EU.

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-mobilising 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 CO□ capture from the atmosphere.

The mechanism for allowing the use of additional micro-organisms or 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**, and discussions about a potential simplification of the procedure started already in 2021[90]. The process 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 in the context of the Reality Check that, as a consequence of not being able to market their biostimulants under EU rules, manufacturers market their product **under**

[90] At the Expert Group meeting of 22-23 November 2021, several options were discussed. Stakeholders submitted position papers with their preferred solutions. The relevant documents are accessible on CIRCABC. At the Expert Group meeting of 26-27 November 2024, it was again on the agenda, based on a proposal by the Forum of Notified Bodies, see CIRCABC.

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 biostimulant on the EU market** because the micro-organism used 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 was allowed under CMC 7. 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 above-mentioned study is developing a methodology and general criteria for the assessment of strains of micro-organisms 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 agronomic efficiency criteria for micro-organisms and a methodology which manufacturers should use to assess and demonstrate compliance with those criteria and by notified bodies to confirm this assessment. This approach would be to some extent similar to what has been agreed by the co-legislators for the assessment of risks associated to the use of microbial detergents in the revised Regulation on detergents and surfactants[91]. It should be noted however, that, in the risk assessment

[91] Council and Parliament strike a deal to make detergents safer for the population and the environment - Consilium.

of microbial detergents, there is no involvement of notified bodies and manufacturers are self-certifying the safety of the products.

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 Commission will make sure that the criteria and methodology that will eventually be introduced allow for a thorough verification that a strain of a micro-organism does not present a risk to human, animal or plant health, to safety or to the environment, and that it ensures agronomic efficiency. Trusting that only qualified and reliable conformity assessment bodies are notified by Member States' notifying authorities, the new mechanism will provide an assessment of, at least, the same quality as under the current empowerment.

The current empowerment for the addition of new micro-organisms or strains of micro-organisms to the positive list would be maintained. This would allow the Commission to include the strains currently being assessed and, potentially, further strains in the future. Manufacturers and notified bodies would not need to assess those strains included in the positive list against the general criteria.

Estimated cost savings

The introduction of the new empowerment as such will not entail any cost savings. However, once the Commission has made use of the empowerment, economic benefits in terms of incentives for innovation, faster market access, enhanced competitiveness and increased availability of products 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 negligeable compared to the **economic benefit of having free access to the internal market**[92]. 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 multiple national markets would be significantly reduced**[93]. 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.

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

93 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 (up to €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 €47 000), see tables 13 and 14 in SWD(2016) 64 final. In order to place a fertilising product according to national rules in 5 Member States, a company could face administrative costs of at least €60 000. Assuming €3 900 for a certification by a notified body under module B+C for 10 years (see table 40 in SWD(2016)64 final).

- **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 that 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.[94] In consequence, fertilisation costs for farmers can be reduced and the autonomy of the EU for fertilising products be improved.
- **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.
- **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.[95]

c. 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)[96].

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 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.

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94 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.

95 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.

96 COM(2025)504.

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[97]. 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 NLF[98], 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 (see 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 stakeholders[99].

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 processes, 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.

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97 SWD(2025) 130 final, p. 4.
98 SWD(2022)364 final/2, p. 34
99 SWD(2025) 130 final, pp. 13f.

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"[100];
- 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. The Staff Working Document accompanying the Omnibus IV 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

[100] Building on the European digital identity framework, the EU Business Wallet will enable secure digital identification, data sharing and legally valid notifications across the EU. See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14663-European-Business-Wallet-digital-identity-secure-data-exchange-and-legal-notifications-for-simple-digital-business_en.

would incur no or only negligeable 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 tonne of CO_2 emissions are associated to the production of one tonne of paper[101], 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"[102].

d. Removal of the 'unbundling clause'

The FPR empowers the Commission not only to add additional micro-organisms or strains of micro-organisms to CMC 7, 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 and its proposed amendment 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 draft and providing feedback. Any amendment which might speed up the process is therefore expected to be welcomed also by stakeholders.

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101 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.

102 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.

e. 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.

- **Inclusion of derived products from animal by-products listed in Article 2(2) of Regulation (EU) 1069/2009**

Several stakeholders expressed interest in using derived products from animal by-products listed in Article 2(2) of Regulation (EU) 1069/2009 (Animal By-Products Regulation, ABPR) in EU fertilising products, in particular shells, fish sludge, mineralised guano and cat litter. In the light of the sensitivity of these materials, the Commission will further investigate the possibility and ways of adding those materials to the FPR.

- **Clarifications in the legal text**

An industry association suggested making several clarifications, currently addressed in the Commission's FAQ document[103], 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

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103 https://webgate.ec.europa.eu/circabc-ewpp/d/d/workspace/SpacesStore/148ac2da-00ae-4fa8-8ed0-270bce690efe/download.

label only, without duplication on a physical label[104]. 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 by 21 October 2031 and, if appropriate, develop a legislative proposal to adjust the provisions[105].

- **Improving coherence with other relevant legislation**

Some industry stakeholders pointed to unclarities or coherence issues between the FPR and other relevant legislation, notably the ABPR, REACH and the Waste Framework Directive (Directive 2008/98/EC)[106]. 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 such clarification is not needed as impurities and unintended substances are acknowledged in the definition of 'substance' under REACH, to which the FPR refers in its own definition of 'substance'. Impurities should not be considered as substances on their own, but should be dealt with in the context of the relevant substance they are part of in the REACH registration.

- **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 products[107]. The Commission considers that considerations 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

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104 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).

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

106 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).

107 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).

sector. The establishment and use of ICSMS as a horizontal market surveillance tool is mandated by Regulation (EC) No 765/2008[108]. 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.

- **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 savings from the proposed changes to the font size requirements and related typographic rules for the EU chemicals sector could amount **to at least €333 300 000 (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, it is challenging to quantify precisely the cost savings for businesses resulting from the proposed amendments to Article 15 of the CPR. While certain substances may be excluded from the ban, the obligation to conduct a safety assessment will remain where there are human health concerns—particularly in the case of substances classified as CMR (carcinogenic, mutagenic or toxic to reproduction). Accordingly, industry will continue to bear

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[108] 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).

some compliance costs. However, the proposed introduction of transitional periods is expected to yield tangible economic benefits. By allowing more time to adapt to regulatory changes, these transitional periods enable businesses to better plan, adapt product portfolios, and make informed decisions. This flexibility is likely to reduce the need for immediate product withdrawals and destruction, which can be especially costly when undertaken without prior notice. If, on average, the cost of sudden product withdrawal and destruction due to the absence of transitional periods is estimated at 1.75% of the sector's turnover (based on an assumed range between 0.5% and 3%), then the potential annual savings could reach approximately **€1 680 000 000**[109] (sector turnover: €96 000 000 000 × 1.75%). Furthermore, the deletion of the obligation to pre-notify cosmetic products containing nanomaterials is projected to generate additional annual savings **between €36 000 and €187 000** for industry. Similarly, the removal of reporting requirements for competent authorities is expected to save an estimated **€130 000 annually**.

Beyond direct cost savings, these regulatory adjustments are expected to **enhance operational efficiency**. In particular, the changes would enable companies to better integrate compliance tasks into their regular planning cycles, thus avoiding disruptive mid-year reallocations of resources. The added predictability provided by transitional periods can be strategically leveraged: businesses may choose to redirect resources previously devoted to administrative compliance toward research, innovation, and competitiveness-enhancing activities. Overall, the amendments support a more efficient regulatory environment, allowing industry to maintain compliance while fostering long-term resilience and innovation.

As regards **EU fertilising products**, the amendments are expected to foster the manufacturing and marketing of innovative and high-performing EU fertilising products. More concretely, the obstacle of the costs for complying with the extended REACH registration requirements (**at least €19 220 000** for the whole industry, of which **at least €187 586 for registration fees**) 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 Member State) and adaptation costs (at an estimated range of **€15 000 to €43 000** per product per Member State).

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.

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.

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[109] This estimate assumes that all companies would avoid this level of forced withdrawals thanks to the transitional periods. It might be worth noting that this is probably a worst-case scenario maximum and actual realised savings would depend on the number and type of substances affected.

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

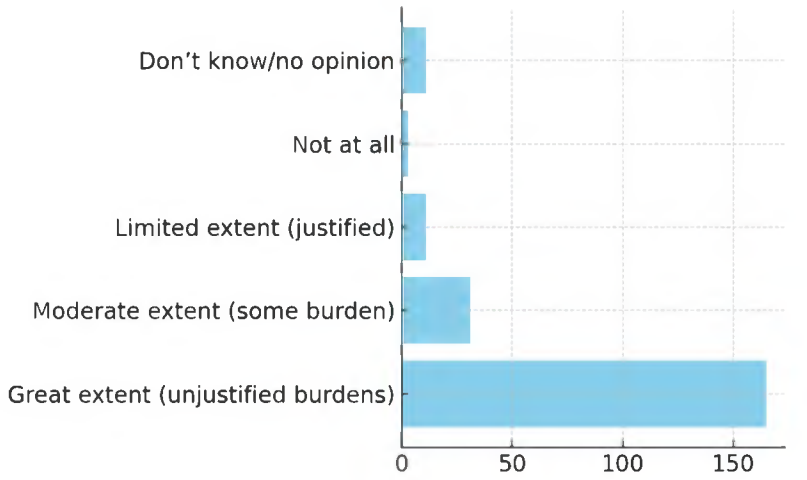
First poll focused on mandatory formatting requirements and consisted of six questions, including one open-ended question. 222 participants in total provided their replies, while open question gathered 55 qualitative responses. The objective of this poll was to evaluate the stakeholders' perception of 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

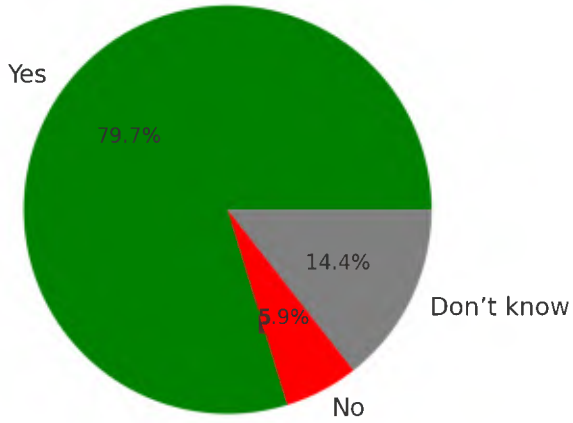


Question 2. Need for Simplification:

- 80% see potential for simplification and burden reduction.

- Only 6% see no need for change.

Figure 2: Potential for Simplification of Formatting Requirements

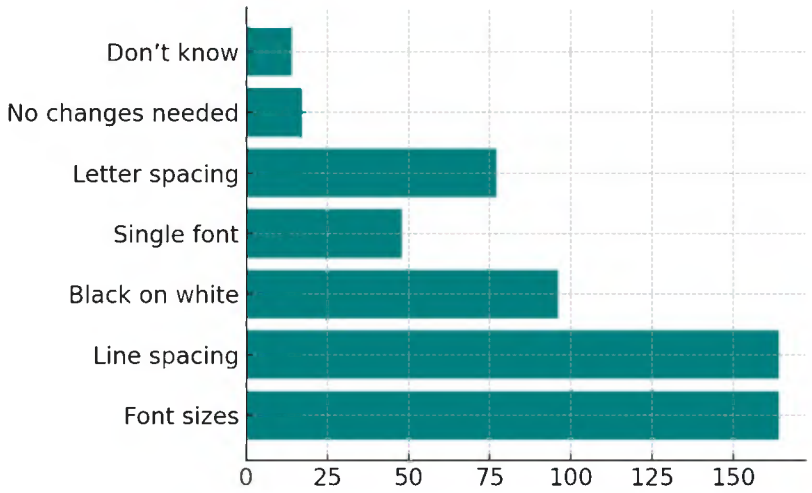


Question 3. Elements That Could Be Simplified:

- 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



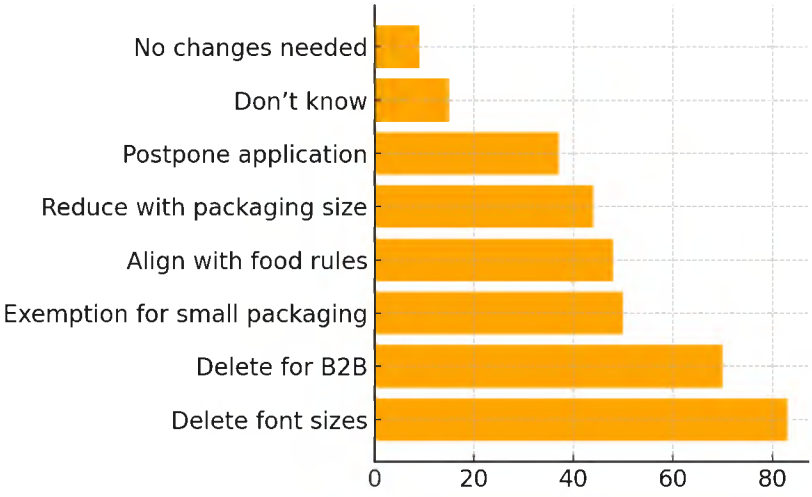
Question 4. Font Size Simplification Options:

- 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% favour exemptions when space is insufficient.

Figure 4: Proposed Options Regarding Font Sizes



Question 5. Formatting Requirement Changes:

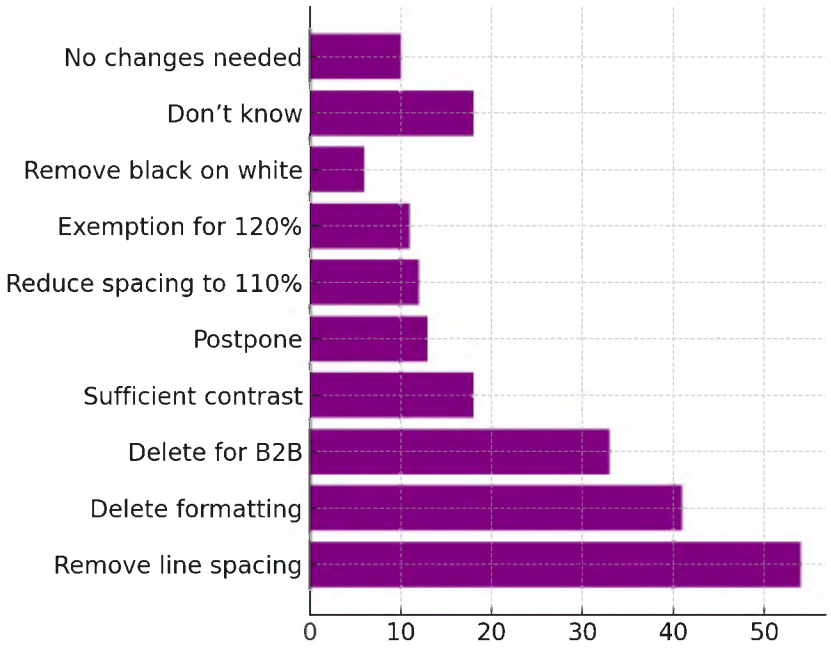
- 25% of respondents indicated their preferences for mandatory line spacing obligations to be removed.

- 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.

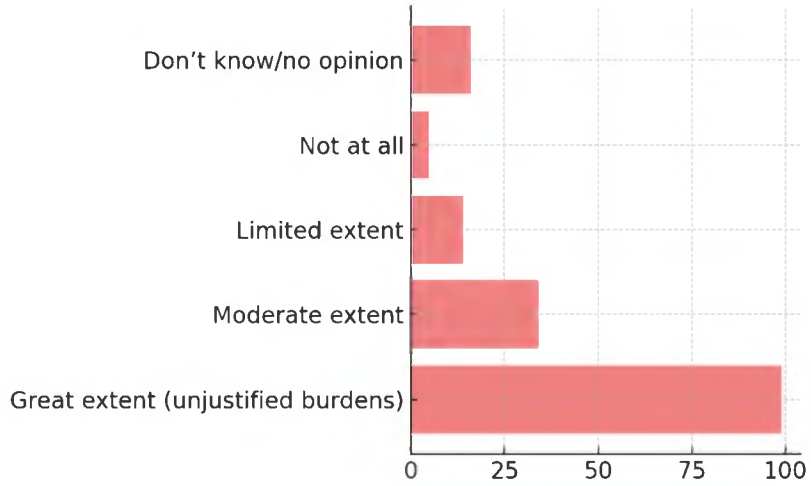
b. Rules on advertisements

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.

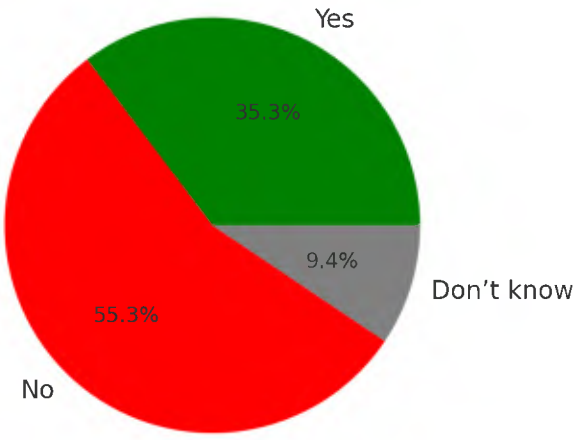
Figure 6: Perceived Burden of Advertisement Requirements



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.

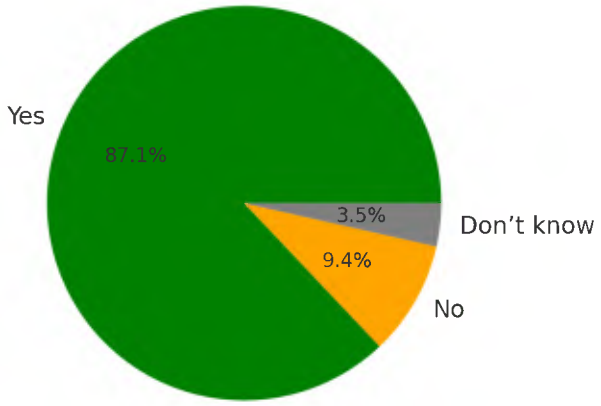
Figure 7: Does hazard information in advertisements helps making informed decisions



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

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

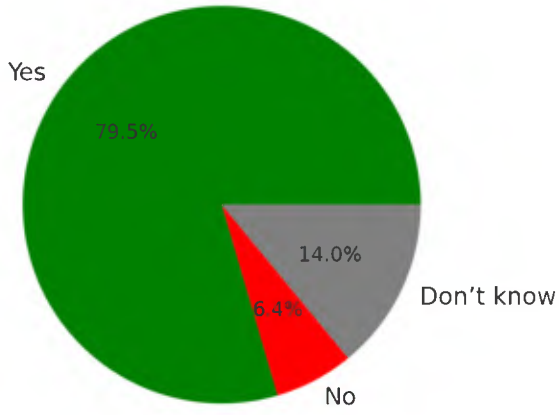
Figure 8: Adequacy of Hazard Information on the Product Label



Question 4. Potential for Simplification of Advertisement Provisions:

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

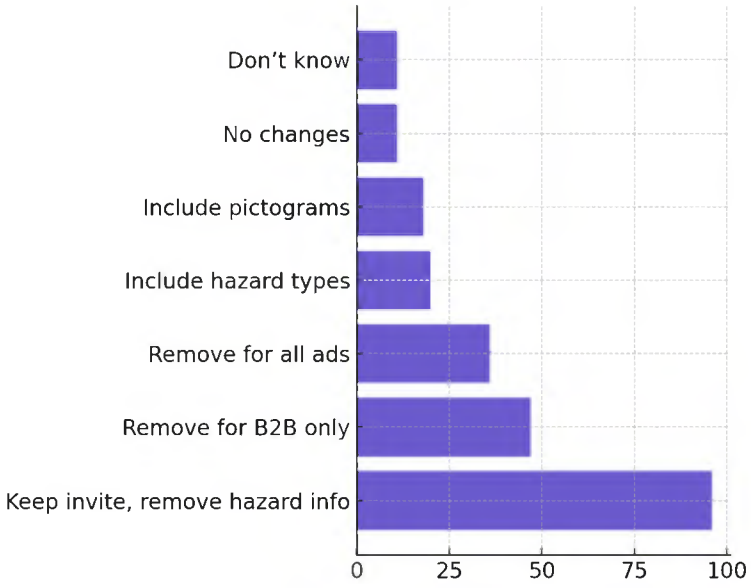
Figure 9: Potential for Simplification of Advertisement Provisions



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.
- Harmonise 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 extend 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 extend possible, the analysis was performed using three hypothesises, 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[110], 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[111].
- *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[112]. Considering that a substance would be in 11 mixtures or 25 mixtures[113], 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[114], 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 mean 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 Regulation[115] reported about 700 companies in the sector of detergents in the EU, with 85% of SMEs (about 595 companies).

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110 Impact Assessment for the Revision of CLP, p. 220.
111 Impact Assessment for the Revision of CLP, p. 341.
112 Impact Assessment for the Revision of CLP, p. 302.
113 Impact Assessment for the Revision of CLP, p. 197.
114 Impact Assessment for the Revision of CLP, p. 341.
115 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.

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.

- *Number of products per company:* figures from the CLP IA[116] 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: Cost = %labels to be updated * (number of products per company * number of future labels per product * cost for label update * number of products + cost of a label * 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: recurring cost = %labels to be updated * relabelling rate per year * (cost of a label * number of labels per year + number of future labels per product* number of products per company * cost redesign difference).

Results are displayed in Table 8. 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 €2 100 000 and €123 700 000 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 or slightly above €14 000 000.

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.

[116] Impact Assessment for the Revision of CLP, p. 341/

Table 8: Cost estimates for detergent sector

		Only reformatting the label			Only monolinguistic 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	0.05	0.05	0.10	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	7	15
	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	1 170 000	3 850 000

	Recurring labelling cost per company	0	6 188	225 000	350	6 390	103 000	3 500	99 080	1 225 000
	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	58 500 000	192 500 000
	Total recurring cost	0	309 375	11 250 000	17 500	319 500	5 150 000	175 000	4 950 000	61 250 000
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	0	248	11 250	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	0	154 688	7 312 500	12 600	180 000	3 406 000	126 000	2 418 750	39 656 500
Whole	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	64 828 125	44,450,000

	Total annualised one-off cost	3 992 285	13 452 201	22 266 469	9 083 166	15 479 922	21 885 470	1,051,590	2,542,644	2,987,738
	Total recurring cost	0	464 063	18 562 500	30 100	499 500	8 556 000	301 000	7 368 750	100 906 500
Super total per year		3 992 285	**13 916 263**	40 828 969	9 113 266	**15 979 422**	30 441 470	2 135 071	**14 968 584**	123 701 972

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 9 gives an overview of the aggregation of the data received.

Table 9: Cost estimates for lubricant sector

	Number of companies	**Minimum reported**	**Maximum reported**	**Total (€)**	
				Reporting companies	**Lubricant sector**
Rate of SKU impacted		27%	100%	N/A	-
Increased of SKU	7	€550	€25 000	48 834	-
Price for additional SKU	3	2 000 000	34 500 000	46 500 000	-
Increase of labelling costs (1st relabelling)	6	2 000 000	6 900 000	26 807 100	53 614 200
Investment in new equipment	5	80 000	3,200,000	6 927 585	13 855 170
Recurrent relabelling	6	27 000	1,725,000	2 885 378	5 770 756
Annualised total one-off costs	(6)			2 360 629	
		Total annual(ised) costs	59 502 537	**119 005 074**	

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 €333 300 000 (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 10 illustrates the order of magnitude derived from these extrapolations.

Table 10: Extrapolation of costs estimated for some sectors or national markets

Source	Share of EU chemicals production value	Annual cost	One-off cost	Extrapolation to EU chemicals industry	Type of cost[117]
Detergent sector (calculated)	4.20%	14 000 000		**333 000 000**	Annual overall cost
Lubricant companies (calculated)	1.16%	119 005 074		10 260 000 000	Annual overall cost
National paint and ink sector (reported)	0.09%		60 000 000	4 481 000 000	Annualised one-off cost
Member State (reported)	1.32%		50 000 000	255 000 000	Annualised one-off cost
National chemicals sector	11.22%		583 000 000	349 000 000	Annualised one-off cost

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 11: Estimated plausibility of various impacts identified for detergents and lubricants

Scenario	**Only reformatting labels**	**Only monolinguistic 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 to increased price of labels)	Neutral, unless label size has to be increased, as pointed out by some stakeholders.	Certain for many companies not using fold-out labels yet and 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 certain	

[117] The conversion to annualised present value is based on 3% discount rate and a period of 10 years.

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 Regulation[118] 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 Slido[119].

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

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118 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, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

119 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.

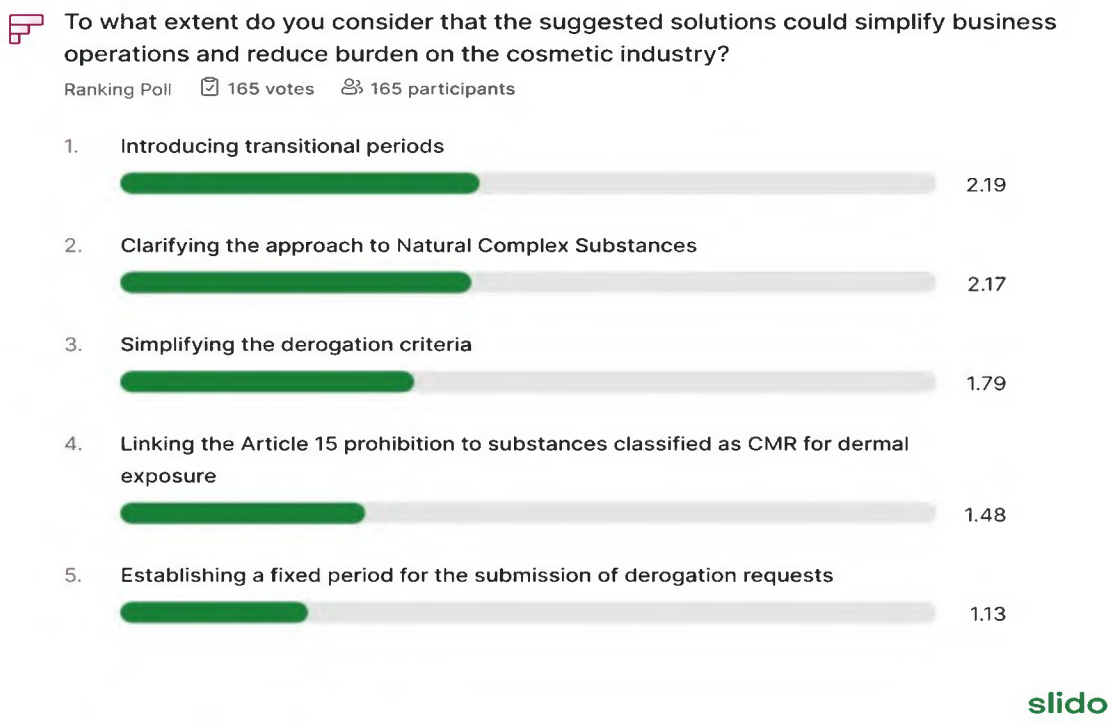
- Stakeholders were invited to submit written contributions by 31 May 2025 (or 1 June at the latest), especially including quantifiable evidence to support proposed simplification measures.

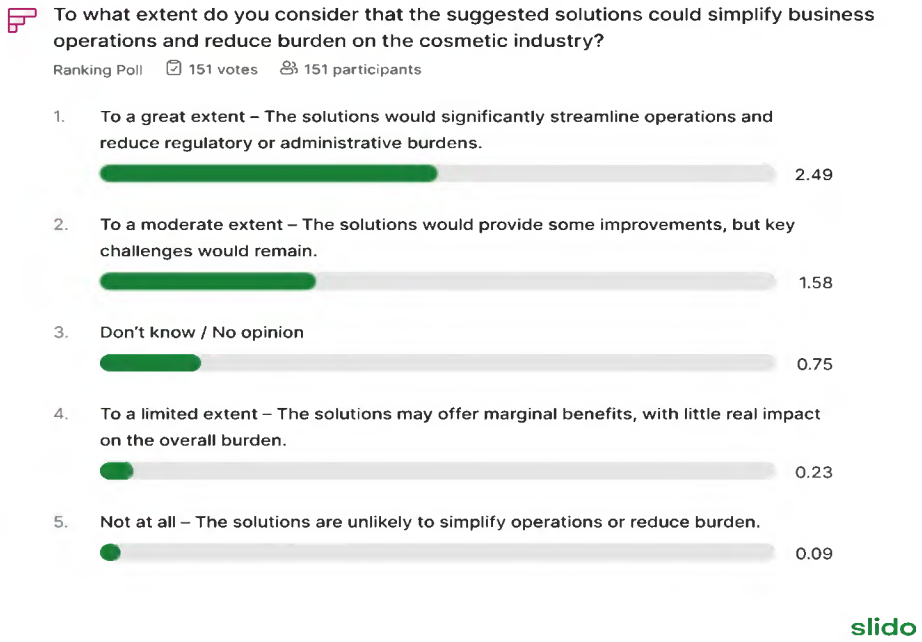
- The Commission will prepare a report based on the input received to support political decision-making.

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

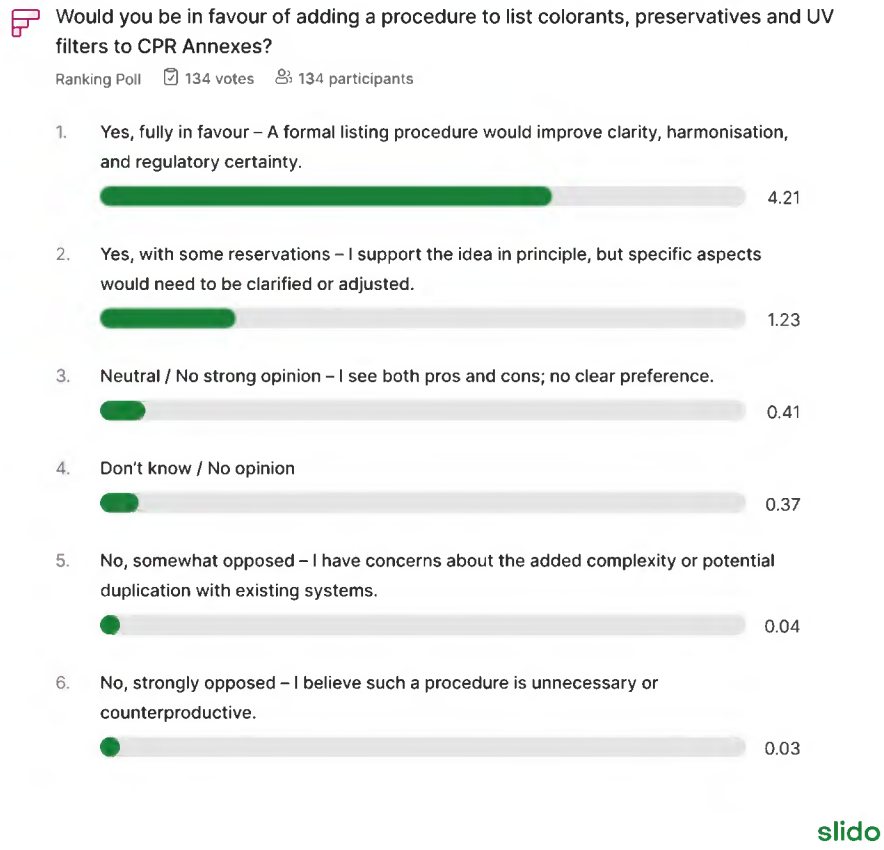
Point I of the agenda

Point II (a) of the agenda

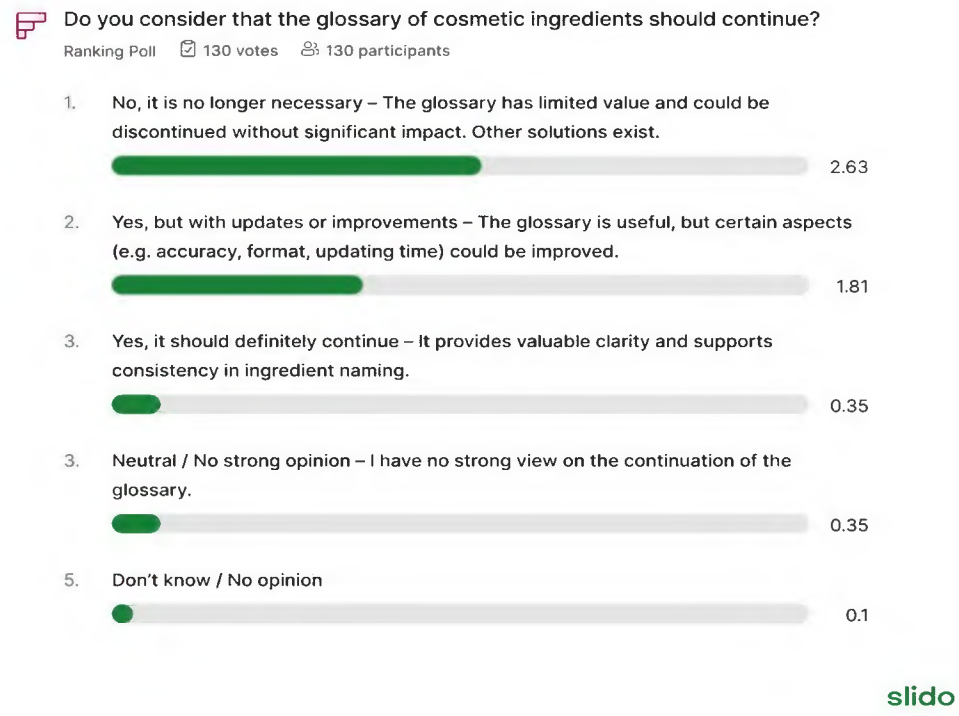




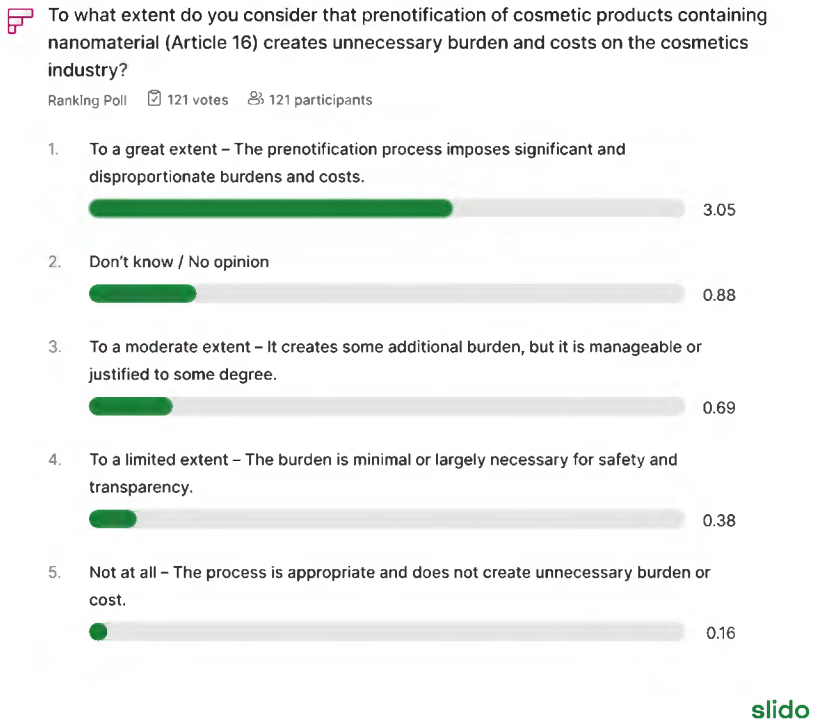
Point II (b) of the agenda



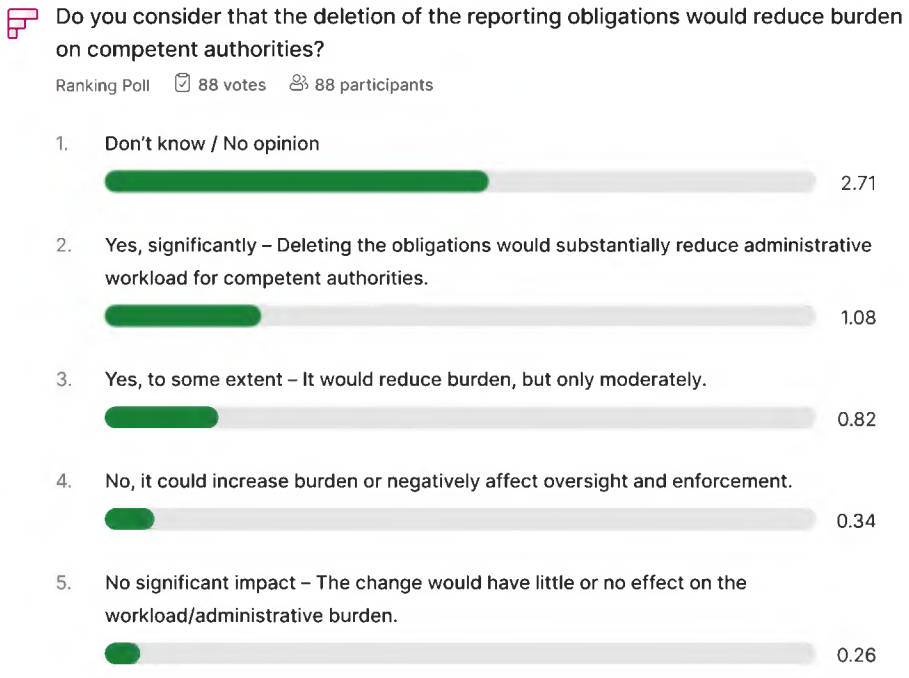
Point II (c) of the agenda



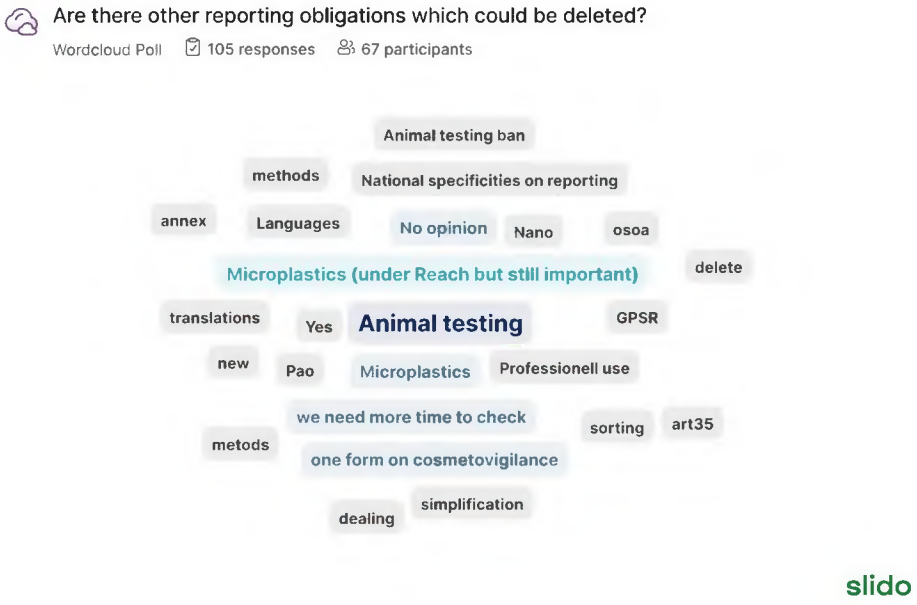
Point III of the agenda



Point IV of the agenda



Point V of the agenda



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: 91

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 91 eventually attended. By 13 June 2025, written feedback was received from 27 stakeholders.

The Commission had uploaded a Concept Note[120] 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 par company per year and a chemical

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

safety report covering the use in a fertilising product, poses significant challenges for manufacturers 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 upgrade 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 quantities 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 the 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 do not depend on the size of the company, represent 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 quantity 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 micro-organisms or 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-mobilising 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 CO□ 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 legislation 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 further derived products from animal by-products

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 for which an endpoint has already been determined or which are currently assessed in a study carried out for the Commission. Nevertheless, some stakeholders also expressed interest in using animal by-products listed in Article 2(2) of Regulation (EC) No 1069/2009. 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').

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 processes, 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 document[121]**, 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 2024[122], 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**, notably the ABPR, REACH and the Waste Framework Directive (Directive 2008/98/EC)[123].
- 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 EU fertilising products** similar to the list in Annex III to Regulation (EC) No 1107/2009 on plant protection products[124].
- 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.
- Some stakeholders called for allowing **more types of sludge** to be used as input for component materials.
- 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 using certain substances, thereby reducing costs for reformulation and ensuring the use of

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121 https://ec.europa.eu/docsroom/documents/63434.

122 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).

123 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).

124 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).

the most suitable substances, and would 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.
- 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 the European Chemicals Agency (ECHA) for the new registration or the update.
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 only on one or several 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 €47 000[125].

Evaluation of the proposed changes to revert to generic rules in REACH

1. The analysis of the reversal from the current extended REACH requirements under FPR to generic REACH requirements can be based on the evaluation of the additional costs of the substances registered under REACH or not, according to a tonnage band below or equal to 10-100 t/year, with or without a chemical safety report. The identified additional cost would be theoretical savings for companies using those substances as ingredients in their fertilising products.
2. Identification of the average update cost: Based on data provided by stakeholders in the context of the Reality Check, depending on tonnage band and the extent of data required, the costs for updating a registration dossier in accordance with the extended REACH

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125 SWD(2016) 64 final.

registration requirement under the FPR vary between €10 000 to €500 000 per substance. In a survey carried out by an industry association among their members, €180 000 was found as the typical investment needed to upgrade a registration dossier from 1-10t/y to the 10-100t/y requirements. This can be taken as a proxy for the average cost for compliance with the extended REACH registration requirement.

3. Identification of relevant substances for use as ingredients in fertilising products: Data from ECHA's public database on the substances currently registered for the use in a fertilising product, but not in accordance with FPR's extended REACH registration requirement, illustrates to what extent this requirement poses an obstacle for the Single Market access of fertilising products.
4. 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.

Table 12: 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 ∪ 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.*

5. Cost calculations: The update of the registration dossier of substances for which a chemical safety report is available would be cheaper (estimated at €10 000 per substance) than for a

full update in case no chemical safety report available (estimated between €10 000 and €500 000, average: €180 000).

Table 13: Costs incurred for REACH registration if substance were to be used in an EU fertilising product

	Lower	Average	High
Reported cost per registration update from 1 to 10T per year	€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 (50 * 10 000 + 104 * 10 000)	€19 220 000 (50 * 10 000 + 104 * 180 000)	€52 500 000 (50 * 10 000 + 104 * 500 000)
Annualised one-off costs[126]	€181 000	€1 292 000	€3 529 000

Estimated savings following the envisaged amendment:

1. The FPR would no longer require an extended REACH registration. Manufacturers could place their products on the EU market as CE-marked fertilising products, relying on the current registration without the creation or update of a registration dossier (assuming that there would be no increase in the quantity of the substance placed on the market in the EU, or a limited one, with no jump to a higher tonnage band). The 154 substances identified as potentially interesting for the use in EU fertilising products could be used without the one-off cost of about €19 220 000 (with a range between €1 540 000 and €52 500 000).
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 costs. 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 between €15 000 and €43 000 per product and national market. As no information is available on the number of concerned products, savings from moving to national rules and mutual recognition to the Single Market cannot be estimated.
3. Therefore, **the savings for the fertilising industry from reversing to generic REACH rules can be estimated in a conservative way to amount to €19 220 000 or €1 290 000 when annualised in present value**.

[126] The conversion to annualised present value is based on 3% discount rate and a period of 10 years.