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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	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 - MS comments

Delegations will find enclosed updated compilation with revised DE comments.

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Austria

Austrian comments regarding Omnibus VI–
Deadline 18-09-2025 cob

(EC) No. 1223/2009 (cosmetics)

In the context of the Omnibus VI package, Austria would like to emphasize that we take note with interest and appreciation that numerous Member States are also subjecting the proposed transition periods to critical scrutiny. In this regard, we would like to reiterate the proposal previously submitted by Austria to shorten the transition periods. This proposal foresees that, in cases where the shortened periods prove insufficient, an extension may be granted — provided that a supplementary risk based scientific assessment by the Scientific Committee on Consumer Safety (SCCS) is requested.

Czech Republic

Czech Republic's comments on Omnibus VI – answers to written questions

Omnibus VI – STC on CLP

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

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

Answer: Yes, the Czech Republic supports the Commission's "Stop-the-Clock" proposal, provided that the postponement does not weaken the protection of human health and the environment. The deferral will give companies, especially SMEs, time to prepare and avoid unnecessary double work.

Omnibus VI – Regulation on chemical products

CLP Regulation

Question 2: Can Member States support one of the above-mentioned options regarding formatting and readability? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).

Answer: Option (b) – The Czech Republic supports clarifying how "readability" should be understood, for example by setting minimum font size, sufficient colour contrast, and placement of key hazard information. This approach gives legal certainty for enforcement and ensures that consumers – including those with poorer eyesight – can actually see and understand the warnings, while still allowing flexibility for companies in the overall label design.

Question 3: Can you support one or more of the above-mentioned options regarding updating the labels for self-classified substances and mixtures?

Answer: Option (a) – The Czech Republic supports clarifying in a recital how "without undue delay" should be interpreted, for example by linking it to specific deadlines when new CMR or endocrine-disrupting hazards are identified. This ensures that workers and consumers receive timely warnings while avoiding unnecessary relabelling for minor updates.

Question 4a: Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

Answer: Yes – the Czech Republic supports restricting Article 48 to online advertisements for consumer products, since this is where consumers often buy without direct expert advice. Simplifying rules for other channels reduces administrative burden while still protecting the most vulnerable group – online buyers.

Question 4b: Which, if any, label elements can be removed from the rules on advertising in Article 48?

Answer: The Czech Republic supports limiting mandatory elements to the short prompt: "Always read the label and product information before use." This keeps the message simple and visible, while avoiding information overload that could confuse consumers.

Question 4c: Should the prompt also include a reference to (a) the presence of hazardous substances, and/or (b) the name and digital contact details of the responsible supplier?

Answer: The Czech Republic prefers keeping the wording simple. Details on hazards and supplier contacts are better placed on the label and in digital tools; adding them to adverts risks cluttering the message and reducing its effectiveness.

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

Answer: Yes – the Czech Republic supports restricting these rules to consumer products. Professionals have access to safety data sheets and training, while consumers need clear and direct warnings in online and distance sales.

Question 6: Do Member States have any objections to the PCY's proposed approach on digitalisation (digital contacts and digital labelling)?

Answer: The Czech Republic supports digitalisation, provided that essential hazard information (pictograms, signal words) always remains on the physical label. This guarantees access for all consumers, including those without smartphones or reliable internet.

Question 7: Can Member States support the Commission's proposal for exemptions from labelling and packaging requirements for packages containing less than 10 ml?

Answer: Yes, with caution – the Czech Republic supports exemptions only if key warnings remain accessible. Even very small packages can contain strong sensitisers or CMR substances, so safety information must not disappear entirely.

Cosmetic Products Regulation (CPR)

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

Answer: The Czech Republic supports the new timeline for submitting an application for derogation as suggested by the Commission because it is acceptable and technically feasible.

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

Answer: The Czech Republic supports the new timeline for the prohibition of CMR substances in cosmetic products under CPR. Suggested timeline is not of fundamental importance in terms of proportionality and the risk to public health from exposure to cosmetic products, taking into account the low dose and limited exposure of the organism through the skin from a cosmetic product.

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

Answer: The Czech Republic supports introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). The periods are proportionate and acceptable for the market to adapt and does not pose a risk to consumer health.

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

Answer: The Czech Republic supports the intention that criteria for derogation in an Article 15 para 2 are narrowed down, i.e. a) is deleted, i.e. meeting the requirement for the presence of a substance in food, because most of the newly classified CMR substances do not occur in food and the requirement is therefore not meaningful, and c) and d) are merged, i.e. that an application for an exemption and use of the substance in a certain product category is submitted and assessed by the SCCS (Scientific Committee for Consumer Safety), because this procedure is always ongoing together.

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

Answer: CZ supports the retention of all approaches listed under points a. to c. as this will facilitate a serious decision on a possible exceptional assessment of the necessity of using a substance classified as CMR in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

Answer: CZ supports points a. and b. in the sense that CMR (carcinogenic, mutagenic and reprotoxic) substances present in natural complex substances should generally be exempted from the prohibition in Article 15, but at the same time the SCCS should always evaluate their safety and presence in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Answer: CZ agrees to exclude CMR-substances from the generic ban under CPR if the CMR-substance classification is explicitly based on oral or inhalation route of exposure. However, an amendment requiring that the SCCS must always assess the safety of CMR-substances should be included to prove that their use is safe.

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

Answer: CZ agrees to abolish the requirement for pre-notification for nano-material ingredients in cosmetic products because new nanomaterials must be a subject of safety asessment by SCCS and become available in CosIng if assessed as safe.

Fertilising Products Regulation (FPR)

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

Answer: The Czech Republic has no objections to the empowerment in Article 43.

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

Answer: The Czech Republic is in favour of the rewording of recital 19.

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Answer: The Czech Republic has no objections to the PCY's proposed approach on digitalisation.

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

Answer: The Czech Republic considers that it would be appropriate to allow the inclusion in the list of positive components within the framework of the Regulation 2019/1009 of those microorganisms in microbial biostimulants that are traditionally approved and used at national levels, meaning those for which both the declared functions and potential risks are sufficiently known and verified. In these cases, we support a simplified approval process. For other micro-organisms, we can support the principle of approval of new microorganisms by an independent scientific body.

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

Answer: The Czech Republic is generally in favour of the standard REACH requirements for fertilizing products under Regulation 2019/1009. It is not clear which fertilizing products could potentially be included in the "positive list" exempted from REACH-registration, as announced by the COM. However, if fertilizing products were included in the aforementioned list on a similar principle to other substances in the current Annex IV of the REACH Regulation, which are exempted from the registration obligation under certain conditions (i.e. common substances verified in terms of safety), we can accept the creation of such a list.

Germany

Comments from Germany following the Antici Group meeting on 15 September 2025

Germany would like to thank the Presidency for the opportunity to make further comments. We reserve the right to make further comments in the course of further negotiations.

TOP “EU Fertiliser Products”

Discussions on Article 43

The discussions on the proposed deletion of Article 43 did not result in a unanimous opinion among the Member States.

In our view, a good compromise would be not to delete Article 43, but instead to reword the existing power in line with the Presidency's proposal. However, this would then have to be done in Article 43 itself. We do not consider a rewording of recital 29 to be sufficient and support the proposal put forward from EST at the meeting.

This would also make it possible to take appropriate account of the Commission's concerns when delegated shall be adopted separately.

In our view, the adoption of a "collective delegated act" would be acceptable if, for example, new scientific findings meant that regulations or parameters in several product function classes (PFC) or component material categories (CMC) had to be adjusted. In such a case, it would really make no sense for the Commission to adopt several delegated acts separately.

Proposal to include a positive list of substances to be exempted from REACH registration

We thank you for the proposal. After reviewing the information available to us on the proposal and based on the discussions held at the meeting on 15 September 2025, we do not see any advantages in terms of reducing bureaucracy and simplification if a positive list or exemption from REACH registration for substances that have always been used in the composition of fertilisers and do not pose a safety problem.

In our experience, it would be very difficult to draw up the necessary criteria and a corresponding list in the Expert Group on EU Fertilising Products, as many individual substances would have to be assessed and discussed – in some cases endlessly. In addition, the Commission

would then also have to adopt corresponding legal acts to make such a list legally binding. The time required would probably be too long.

Many "well-known substances" in the fertilising-products sector are likely to have already been registered under REACH, so there would be no advantage for such substances.

Overall, we consider the Commission's proposal to exempt certain substances from the REACH+ requirements to be more effective.

Topic: “Classification, Labelling and Packaging” (CLP)

Q2: Can member states support a) Retaining certain elements of the formatting rules introduced in 2024 or b) Further clarification in the text or the recitals on how readability should be understood? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarify (if option (b) is preferred).

Germany supports option (a); i.e. to retaining certain elements of the formatting rules introduced in 2024. Clear and unambiguous requirements on font formatting are essential for consumer protection, legal certainty, and enforceability. Without such minimum standards, certain consumers, particularly those with visual impairments, may be unable to access critical information. The current thresholds align with recognized regulatory and standardization benchmarks, including German DIN 1450, the European guideline on readability of medicinal product labelling, and Regulation (EU) No 1169/2011, which set minimum x-heights between 1.2 mm and 1.5 mm. These standards represent an established consensus on the minimum for legibility. The existing provisions are therefore consistent with other Union law ensuring that the provisions of Article 31(3) on readability are satisfied.

Nevertheless, the following simplifications of the current requirements could be accepted: Contrast requirement: Amendment of Section 1.2.1.5(a) by replacing the rigid “black on white” requirement with a functional requirement relating to a minimum contrast ratio, e.g., a Michelson contrast of at least 0.7 according to DIN 1450. Size-dependent thresholds for larger packaging: For example, reduction of the minimum x-height for packaging over three litres (over 3 litres up to a maximum of 50 litres, over 50 litres up to a maximum of 500 litres, and over 500 litres) to 1.5 mm.

Q3: Can Member States support one or more of the following options? a) Clarifying in a recital how the “Without undue delay” formulation should be understood? b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months? c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to “without undue delay” for other classifications?

DE supports option (b) if the fixed deadline for updating the labels for self-classified substances and mixtures is extended to 12 months. DE could also accept option (a) as “without undue delay is a common term also in other pieces of legislation Option (c), however, does not appear

necessary. The introduction of a specific rule for CMR and ED classifications would add unnecessary complexity while offering limited practical benefit. Changes in classification regarding CMR and ED substances are in most cases triggered by harmonised classification. For such cases, the transitional periods set out in Article 30(3) of the relevant delegated acts (normally 18 months) already apply. As a result, the added value of a separate special rule for CMR and ED classifications is considered low.

Q4: The PCY encourages member states to prepare answers to the following questions on advertisements:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels? b) Which, if any, label elements can be removed from the rules on advertising in article 48? c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

a) Could the Presidency clarify why a clarification of the term “advertisement” should be achieved specifically by limiting it to online advertising? Is the idea to have the proposed amendments to cover only online advertisement, while the original CLP proposals remain valid for all other forms of advertisement? What would be the rationale for treating online and other forms of advertising differently, in particular by applying different requirements to non-online advertising channels? b) All elements listed in Article 48(1) are dispensable, with the exception of the prescribed sentence “Always read the label and product information before use.” in the case of advertising

directed at consumers.

c) The current wording “Always read the label and product information before use.” is supported.

We do not consider it necessary to extend the statement with additional references.

Q5: Can you support restricting Article 48 on advertisements and Article 48a on

distance sales offers to only cover consumer products?

The restriction in Article 48 concerning advertising can be supported. However, we do not consider a distinction for distance selling offers to be appropriate. This is because the Commission’s assumption in the recitals - that these requirements for distance sales can be limited to products placed on the market for the general public because REACH already ensures adequate information flows - is incorrect. The information obligations under Regulation (EC) No 1907/2006 (REACH) begin at the time of supply and do not cover the point of purchase. Consequently, professional users would only be able to base their purchasing decisions on classification information if such an explicit provision existed.

Q6 Do member states have any objections to the PCY’s proposed approach on digitalisation?

We kindly ask the Presidency to clarify its current proposal regarding the inclusion of a “digital contact” on CLP labels. We would prefer if the relevant articles would refer to the “telephone number and/or digital contact”, as some small suppliers may only be reached via telephone and forcing them to create a digital means of contact would result in additional burden for them. Furthermore, could the Presidency clarify which stage of the Omnibus IV discussions this proposal refers to, as this is not clear from the information available to us. A general agreement to align the CLP Regulation with the outcome of the Omnibus IV discussions would be preferable, but not if this means that key information, such as the postal address of the supplier, would be absent from the label.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

DE still asks for further clarification concerning legal clarity and the protection of human health.

It is necessary for products that have skin-sensitizing properties or ingredients to maintain the labelling requirements in small packaging. The labelling of hazards is of central importance in this context, as, unlike other hazard properties, it can be relevant even when exposed to very small quantities. The proposed risk-based labelling exemption may be justified for hazard classes or hazard properties where the level of exposure in the event of an accident is limited due to the size of the packaging, meaning that no serious consequences for human health or the environment can be expected. Such an exemption would only be appropriate if experience or evidence showed that substances or mixtures classified in hazard classes not covered by section 1.5.2.4.1 do not pose a risk to human health or the environment in quantities below 10 ml, or that the risk is negligible in relation to the cost savings achieved by the labelling exemption.

Estonia

Cosmetic Products Regulation (CPR)- COM (2025)531

While our final national position is yet to be confirmed, please find following the responses I presented in the working group based on our initial positions.

New timeline for submitting an application for derogation for using CMR substances in cosmetic products

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

Estonia could support establishing a clear deadline for submitting applications for derogation, preferably in line with the COM proposal. A defined period would provide transparency and legal certainty for all stakeholders, including small and medium-sized enterprises, and would help to ensure a consistent and predictable process.

New timeline for amending the Annexes

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

Estonia could consider the Commission's proposed timeline for amending the Annexes as a reasonable approach. While the final national position has not yet been determined, Estonia sees value in providing a predictable timeframe that allows industry to adapt safely and ensures continued high protection of human health.

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

Estonia could consider the introduction of transitional periods as a practical measure to allow industry sufficient time to comply with restrictions on CMR substances. While the final duration would need further discussion, Estonia sees merit in a timeframe that balances timely market adaptation with the continued high level of protection for human health.

Amendments of criteria for derogation

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

Estonia could be open to the proposed simplification of the derogation criteria, including the deletion of criterion a) and the merging of criteria c) and d). We see potential value in clarifying that specifications for use are part of the safety evaluation by the SCCS, which could enhance legal certainty and streamline the assessment process.

Introduction of criteria for alternative assessment

Question 5: The PCY invites the Member States to participate in setting the direction:
a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?
b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?
c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

Estonia could be flexible regarding the approach to alternative assessment criteria. There are potential advantages in providing guidance rather than embedding all details in the Regulation, for example making updates operatively in line with scientific and technical developments. We could also be open to a broader understanding of what constitutes an alternative, potentially including alternative methods or combinations of alternatives, in order to ensure a practical and future-proof framework. As for environmental and economic aspects, Estonia would be open to consider including these elements in the Regulation with the primary focus remaining on the protection of human health.

Natural complex substances containing CMR-substances

Below are some indicative options identified by the PCY.

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

c. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

Estonia supports that SCCS would assess the safety of the classified components, providing legal certainty and a practical framework for industry and allowing flexibility for cases where exposure or risk is minimal. We prefer option (b).

Classifications based on ingestion or inhalation route of exposure

Below are some indicative options identified by the PCY.

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

Estonia supports SCCS to assess the safety of these substances when exemptions are considered, ensuring that human health protection remains the priority while maintaining a practical approach for the industry. We prefer option (b).

Abolishment of pre-notification of nano-material ingredients (Article 16)

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

Estonia could consider that, if the pre-notification requirement for nano-material ingredients is abolished, information on the presence of nanomaterials could still be made available in a flexible, practical manner, for example through the general product notification under Article 13. This approach could ensure transparency and support market surveillance, while avoiding unnecessary administrative burdens for the industry.

Abolishment of the glossary (Article 19 and 33)

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

Estonia considers that the use of a single internationally recognised nomenclature as the primary source for ingredient names could enhance legal clarity, provided that guidance or explanatory notes are made available to support consistent interpretation and application. Estonia could be flexible regarding the choice of the specific nomenclature, as long as it ensures transparency for regulators, industry, and consumers, and reduces ambiguity in the naming of ingredients. INCI sounds reasonable.

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

While our final national position is yet to be confirmed, please find following the responses I presented in the working group based on our initial positions.

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

PCY has identified the following indicative options regarding formatting and readability:

a) Retaining certain elements of the formatting rules introduced in 2024.

b) Further clarification in the text or the recitals on how readability should be understood.

Question 2: *Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).*

Estonia acknowledges the importance of maintaining a balance between simplification and consumer safety, and recognises the value of retaining certain formatting rules introduced in 2024, which ensure readability and legal clarity. However, we are open to consider more flexible approach and further clarify on how readability should be understood, as this would provide sufficient certainty for both suppliers and consumers.

Updating labels (Article 30(1))

PCY has identified the following indicative options on updating the labels and ensuring legal clarity:

a) Clarifying in a recital how the "without undue delay" formulation should be understood.

b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.

c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: *Can Member States support one or more of the above-mentioned options?*

Estonia recognises the need to balance flexibility for companies, particularly SMEs, with the importance of legal certainty, as well as consumer and worker protection. In order to reflect the realities of complex supply chains, Estonia could see merit in extending the current six-month deadline to a longer fixed period. At the same time, we admit the importance of ensuring timely updates for substances of the highest concern, such as CMRs and endocrine disruptors, and therefore suggest shorter timeline for these cases.

Advertising (Article 48) and distance sales offers (Article 48a)

Question 4:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

b) Which, if any, label elements can be removed from the rules on advertising in Article 48?

c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

Estonia could be open to clarifying the scope of “advertisement” in order to provide legal certainty and avoid disproportionate obligations. Estonia could see merit in a more proportionate approach, where a concise safety reminder is sufficient, especially in digital and audio advertising. This would help reduce unnecessary burdens for suppliers while still ensuring

that consumers are reminded of key safety aspects.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

The Commission proposes that CLP labels should include a "digital contact" instead of the current requirement for postal address and telephone number. A similar proposal is included in the Omnibus IV package (Digitalisation and Common Specifications).

Question 5: *Do Member States have any objections to the PCY's proposed approach on digitalisation?*

Estonia has no objections to the PCY's proposed approach on digitalisation. Estonia supports the alignment of Omnibus VI with the final outcome of Omnibus IV to ensure coherence and legal clarity. Estonia also considers the Commission's proposal to strike a reasonable balance between simplification and maintaining access to essential information, provided that consumers and market surveillance authorities can continue to access supplier contact details in a clear and reliable manner. Estonia could also support the possibility of including information on additional suppliers only on the digital label, as this would reduce administrative burden while ensuring that key contact details remain accessible on the physical label.

Fertilising Products Regulation (FPR) – COM(2025)531

The deletion of the "unbundling clause" attached to the adoption of delegated acts

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

Answer to questions 1 and 1a:

We support the state of view that the deletion of the "unbundling clause" leads to a situation where the delegated empowerment to the Commission becomes too wide. The limitation of empowerment was part of the wider package during the initial negotiations of FPR. We believe that, due to the specific nature of the delegated acts procedure, this proposal limits the possibilities for Member States to have a say in the process of making amendments. This applies in situations where a single draft act consolidates changes that are important to different stakeholders but may not be acceptable to all of them. In our opinion, the best approach to simplification is to clarify the existing rules, which currently require separate legal acts when changes are made to different component material categories. For example, if the same or similar changes affect all component material categories, it would be possible to consolidate the respective delegated acts into a single delegated act. As recitals have no legal power, the main text has to reflect it. Our wording proposal is as follows:

(10) Article 43 is amended as follows:

'When exercising its power to adopt delegated acts pursuant to Article 42, the Commission shall adopt a separate delegated act in respect of each component material category in Annex II. Those delegated acts shall include any amendments to Annexes I, III and IV which are necessary as a consequence of amendments to Annex II. Delegated acts of each component material category in Annex II may be merged into one if they concern the same amendment.'

The digitalisation of the EU-conformity assessment declaration

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

We do not have any objections to the proposed approach on digitalisation. The only point that still requires attention during the legislative process is to provide a sufficient transitional period for implementing the obligations and requirements arising from the Regulation.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

We can agree that the assessment of new microorganisms is confirmed by a notified body. Additionally, we would like to say, that we support innovation, but attention must be paid to the fact that the assessment process is too burdensome for micro-enterprises, which gives a significant advantage to microorganisms already on the positive list. To mitigate the negative impact on micro-enterprises, the European Commission should commission studies at regular intervals to supplement the positive list of microorganisms. Our wording proposal is as follows:

(9) Article 42 is amended as follows:

(a) in paragraph 4, the introductory statement is replaced by the following:

'The Commission shall adopt at least every 5 year delegated acts pursuant to paragraph 1 amending Annex II to add new micro-organisms or strains of micro-organisms, or additional processing methods to the component material category for such organisms after having verified which strains of the additional micro-organism fulfil the criteria in paragraph 1, point (b), on the basis of the following data:';

During market surveillance, a potential bottleneck may arise from the lack of information on microorganisms that have been assessed by manufacturers and notified bodies. Our wording proposal is as follows:

(9) Article 42 is amended as follows:

(b1) the following paragraph 4b is inserted:

'The Commission shall publish the list of micro-organisms which passed the conformity assessment of the EU fertilising product in accordance with that methodology and may be used as component material in EU fertilising products.'

Removal of the extended REACH-registration requirement for EU-fertilising products.

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

Since REACH is a horizontal piece of legislation and chemical substance registration is at its core, it is currently unclear how the positive list of fertiliser products will exempt them from registration under REACH. Please provide further clarification on the proposal.

Ireland

Responses to Discussion Note WK 11188 2025 INIT

1. **CLP**

"Stop-the-clock" – COM(2025)526

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

IE can accept the CION proposal

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

a) Retaining certain elements of the formatting rules introduced in 2024.

b) Further clarification in the text or the recitals on how readability should be understood.

Question 2: Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred)

IE sees merit in both a) and b), i.e. that we retain formatting rules and provide guidance in the recitals.

We have raised our concerns regarding the removal of the mandatory label formatting rules introduced by Regulation 2024/2865, due to the issues identified with labelling during the Fitness Check including overcrowding and difficultly in reading as well as enforcement experience which has shown that there are issues with enforcing 'easily read', as it is subject to interpretation. Therefore, IE suggests that consideration is afforded to including similar formatting requirements such as that in the Food Information to Consumers Regulation (Article 13 and Annex VI, presentation of mandatory particulars).

Additionally, our preference is that Annex I, section 1.2.1.5 is not deleted in its entirety and that the requirement for the text on the label to be printed in black on a white background is maintained. This will assist with legibility and ensure consistency across all hazardous products. We propose the following text for section 1.2.1.5: *The text on the label shall be printed in black on a white background.*

Updating labels (Article 30(1))

PRES has identified the following indicative options on updating the labels and ensuring legal clarity:

a) Clarifying in a recital how the "without undue delay" formulation should be understood.

b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.

c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: Can Member States support one or more of the above-mentioned options?

Firstly, we find the question a little confusing and unclear as (a) and (b) are deadlines with two separate classification processes – it would seem to be appropriate to ask MSs if they can agree to these three proposals.

In our opinion all three look like they are needed. A recital to explain and deadlines for legal clarity for enforceability purposes for both self classifications (b) and harmonised classifications (c).

Any self-classified substances and mixtures needs a deadline just the same as harmonised classifications. Therefore, in our opinion all three items above should be provided for in the text.

A recital to explain, a fixed deadline for self-classifications. In the context of b), we favour 9 months but can show flexibility to 12 months.

If we have misinterpreted c) and "all other classifications" is meant to cover both harmonised and self-classified, then it is not acceptable to have no deadline and revert to without undue delay.

Our preference is:

Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to extending it to 9 or 12 months for all other classifications both self classifications and all other harmonised classifications.

Additional Comments: IE wish to reiterate that our preference is not to return to 'without undue delay' for updating labels for self-classified substances and mixtures. We wish to have a fixed deadline retained in Article 30(1) and can agree to this deadline being extended from 6 months to 9 or 12 months. While IE sees merit in the suggestion to maintain the 6-month deadline for some hazard end-points such as CMRs and EDs, we envisage that suppliers would face the same challenges in meeting the 6-month deadline for substances or mixtures classified in those hazard classes as with any other hazard classes, and therefore we suggest one deadline only is put in place.

Advertising (Article 48) and distance sales offers (Article 48a)

Question 4:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

b) Which, if any, label elements can be removed from the rules on advertising in Article 48?

c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

The importance of consumer awareness is paramount when being exposed to advertisements. Therefore, IE can support CION's suggestion but would suggest the advertisement states:

'Warning – this product is hazardous to [with a reference to the relevant type of hazard present "harmful to human health" or "harmful to the environment] Always read the label and product information before use.'

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

IE's preference is that both cohorts are covered not just consumers.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

Question 6: Do Member States have any objections to the PCY's proposed approach on digitalisation?

IE is flexible to the proposed approach.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

Based on the feedback so far, our intention is to proceed with the proposal in its current form

IE agrees to the proposal as currently drafted.

2. Cosmetic Products Regulation

Amendments to Article 15

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

IE supports the proposed regulatory simplification in principle, although we stress that any procedural efficiency must not come at the expense of human health and consumer safety. The revised procedure would allow products containing newly classified CMR substances to remain on the market for up to 24 months after classification, compared to the current shorter transition periods. This extended timeframe raises concerns that consumers may be exposed to potentially harmful substances for longer durations, which could compromise public health protections. Therefore, support for the new timeline is conditional on the Commission providing robust safeguards, including:

- Clear scientific criteria for assessing derogation requests.
- Transparent risk assessments aligned with the latest toxicological data.
- Mechanisms to ensure timely market withdrawal of non-compliant products if derogations are not granted.

New timeline for amending the Annexes

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

As noted above, IE supports the proposed regulatory simplification in principle, but we consider that the suggested time period must be balanced against the need to protect human health and safety. With that in mind, IE proposes that the transitional periods should be no longer than 18 months.

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member

States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

Whilst the 12-month transition period for placing products on the market is considered acceptable, the timeframe for making available on the market proposal of 24-month is concerning as there is a potential for prolonged exposure to hazardous substances to consumers. The approach is intended to provide industry with sufficient time to reformulate products, update safety documentation, and ensure compliance with the Cosmetics Regulation and IE believes that a period of 12-18 months would be sufficient. The reduced timeframe would limit the potential for non-compliant products to remain accessible to consumers for longer periods, which would minimise risk to human health and safety.

Amendments of criteria for derogation

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

IE supports the proposal for the deletion of criteria (a) which previously allowed derogation based on the substance being authorised for use in food. The authorisation for use in food does not necessarily imply safety for dermal application in cosmetics, therefore, the proposed removal of these criteria would align with an approach based on exposure specifically and a more scientifically robust approach.

The proposal to merge criteria (c) and (d) supports and aligns further with the requirement for substance safety assessments to ensure that they are context specific and comprehensive enabling conclusive positions.

Introduction of criteria for alternative assessment

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

a. IE would be in favour of including the criteria for alternative assessments in the Regulation, to ensure legal clarity and enforceability. Whilst the provision of a guidance document detailing methodologies for alternative assessment would also allow for further granularity on methods and updates.

b. Yes, IE would be in favour of extending the criteria to foster innovation.

c. Both environmental and economic aspects fall outside the scope of the CPR, which is primarily focused on human health and consumer safety. Where relevant, these aspects should only be considered as a secondary criterion, ensuring that the overriding priority remains protection of human health and safety.

Natural complex substances containing CMR-substances

Below are some indicative options identified by the PCY.

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

c. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

Clarity relating to CMR classified components of natural complex substances is long awaited by member states. We understand that the SCCS continues to update their evaluation methodologies for the evaluation of complex mixtures, including botanicals and substances with multiple constituents remains a concern.

a. IE would not be in favour of creating an automatic exemption for natural complex substances as concentrations and overall exposure still needs to be considered.

b. This proposal would be supported by IE as the strongest option, ensuring that the SCCS always conduct the safety assessment regardless of the fact that the substances may be a component of a natural complex substance.

c. A case-by-case assessment would be more appropriate providing that safety assessments were conducted by SCCS and clear conclusions based on concentration & exposure levels. In the event where safety cannot be demonstrated then a ban would be appropriate.

<u>Classifications based on ingestion or inhalation route of exposure</u>

Below are some indicative options identified by the PCY.

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

Excluding CMR substances from the generic ban under the CPR if the CMR substance is explicitly based on oral or inhalation would exclude scenarios where unintentional exposure is present. For example, products which are presented in spray format or loose powder format may lead to inhalation, products that that are used in the oral cavities can result in unintentional ingestion and finally vulnerable consumers, especially children, may unintentionally ingest or inhale cosmetic products.

Exposure assessments are included in the criteria for SCCS assessments which include inhalation and oral ingestion.

a. IE would not be in favour of this proposed exemption as the decision for exemption would be implemented in the absence of a full safety assessment.

b. IE would support this option as clarity will be given for each substance through a full assessment conducted by the SCCS.

c. IE would not be in favour of this automatic ban as the ban would be implemented in the absence of a full safety assessment and consideration of all exposure aspects.

Abolishment of pre-notification of nano-material ingredients (Article 16)

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

Pre-notification requirements for products containing nanomaterials are proposed to be abolished. The article itself is purported to be outdated and results in unnecessary costs for industry to maintain compliance. Article 13 of the CPR outlines the notification process for all cosmetics to be placed on the market, with additional requirements detailed in Article 16 for those cosmetics containing nanomaterials. Safety aspects, such as the ability of the Commission to request the opinion of the SCCS on the safety of nanomaterials in case of safety concerns, and requirements for adequate descriptions of nanomaterials (where applicable) in cosmetic product safety reports are unaffected. The deletion is considered pragmatic and is supported by IE.

Access to nanomaterial data remains essential for consumer awareness, scientific research, and regulatory monitoring. This access can be facilitated with the continued requirement for toxicological profiles for each substance in the CPSR and the data could still be made accessible in CPNP to ensure visibility for member states. An electronic format would be preferable for ease of accessibility, monitoring and trending.

Abolishment of the glossary (Article 19 and 33)

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

This proposal is intended to simplify the accessibility of International Nomenclature of Cosmetic Ingredients (INCI) to ensure a more consistent and less burdensome industry approach. Member states will also benefit from having information available electronically to review ingredients of cosmetic formulations. This deletion from the CPR is considered pragmatic and is supported by IE.

In relation to proposals for how legal certainty can be ensured, IE would propose that INCI is formally designated as the primary source of ingredient nomenclature with a clear reference to its use in the CPR. In cases where an INCI name is not in existence, a specific approach should be defined and included for clarity.

The maintenance and regular update of the INCI database will be critical to ensure that the live data is accurate and to ensure that new inclusions or corrections are communicated within a reasonable timeframe.

3. Fertilising Products Regulation

The deletion of the “unbundling clause” attached to the adoption of delegated acts

Question 1: The empowerment laid down in Article 43 relates to the Commission’s right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission’s room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the

same additional materials to various CMCs should be implemented through a single delegated act?

Ireland considers that targeted changes to Recitals 19 and 29 could improve clarity, efficiency, and legal certainty.

For Recital 19, it would be beneficial to clarify the scope of the Commission's delegated powers, emphasise that safety and environmental assessments remain central, and highlight the need for coordinated introduction of new materials to avoid fragmentation.

For Recital 29, rewording to specify that the same additional materials across multiple CMCs should be implemented through a single delegated act would streamline procedures, reduce administrative burden, and avoid delays linked to "unbundling", while maintaining the existing obligations of economic operators.

Together, these adjustments would support timely adoption of delegated acts, support economic operators, and safeguard public and environmental safety. Ireland is open to this approach, provided it is clear that this constitutes a targeted amendment, since Recital 29 in the current proposal does not itself address delegated acts.

<u>The digitalisation of the EU-conformity assessment declaration</u>

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Ireland supports further digitalisation of fertilising product compliance, recognising the benefits for market efficiency, traceability, and data accuracy.

We note that the draft Omnibus VI does not currently specify conditions where paper-based documents may be appropriate.

Ireland considers it important to retain flexibility for limited use of analogue documentation in exceptional cases, and we therefore welcome aligning Omnibus VI with the Omnibus IV for consistency and when it is not practical to use digital documentation.

<u>A simpler assessment procedure for new micro-organisms in microbial biostimulants</u>

Question 3: In light of both the positive potential and the possible risks from new microorganisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

On the proposal for a simpler assessment procedure for new micro-organisms in microbial biostimulants, Ireland recognises the importance of facilitating innovation while maintaining high levels of safety for human health and the environment.

We consider that an independent scientific body, such as the European Food Safety Authority (or another competent body), should have a prominent role in the assessment process to ensure a scientific and impartial approach, and consistency across Member States. This would maintain trust in the system and provide greater legal certainty.

<u>Removal of the extended REACH-registration requirement for EU-fertilising products.</u>

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

Ireland notes the concerns raised about removing the extended REACH-registration requirement and acknowledges the intention behind a "positive list" of traditional fertilising products with a proven record of safe use.

While such a list could provide clarity and reduce administrative burden, it may create delays in drafting and updating the list, potentially slowing down not only the placing of new products on the market but also the timely adoption of the Omnibus package.

Ireland is therefore open to considering the approach, but stresses the need to avoid unintended barriers to innovation and to ensure procedures remain efficient and balanced.

Luxembourg

Omnibus VI – « Chemicals » (Proposal on « Cosmetics »)

- La réduction des critères de dérogation de 4 à 2 (dont 1 est supprimé et le 3e est réinséré dans un autre) est en effet tout à fait acceptable.

- Le délai de 3 mois pour soumettre une dérogation à partir de la date d'entrée en vigueur CLP est également tout à fait acceptable car cela clarifie les délais de soumissions des données.

- Cependant, les 15 mois nécessaires à la Commission pour effectuer les alignements d'interdiction des CMR dans COS et CLP ont été modifiés pour démarrer à partir de la date d'entrée en application CLP et plus à partir de la date d'entrée en vigueur comme actuellement. Ceci rallongerait la présence des CMR dans les COS déjà de 15 mois par rapport à la situation actuelle (nouveau subparagraph après le 4e subparagraph de l'article 15). A cela, s'ajouterait encore des délais de mise sur le marché (+ 12 mois proposition COM ?) et de mise à disposition (+24 mois proposition COM ?). Peut-on considérer 15 mois+ 6 ou12 mois + 9 ou 24 mois acceptable d'un point de vue protection de la santé ?

- COM indique que certaines substances classées comme CMR en tant que médicament ne sont pas classées comme substances à risque ». Dans la législation médicament, on parle d'une évaluation bénéfice/risque par rapport aux soins d'une maladie. Dans la législation cosmétique, un produit cosmétique mis à disposition sur le marché est sûr pour la santé humaine lorsqu'il est utilisé dans des conditions d'utilisation normale (article 3 du règlement 1223/2009).

- Concernant les critères d'alternative à des substances (new 3d subparagraph), une substance connue qui serait protégée par des droits exclusifs ne pourrait jamais être considérée comme alternative. Donc, si l'industrie protège les nouvelles substances « plus safe » avec des droits exclusifs, elles ne seront pas accessibles à tous les fabricants de COS en général (PME ?) et les substances CMR resteront dans les COS en général ? De plus, le

critère « techniquement faisable » est probablement toujours possible, mais le produit ne sera que similaire. Ces critères de solutions alternatives doivent être rediscutés, avant de savoir si cela doit être décrit au niveau du règlement ou d'une ligne directrice.

- Concernant les substances CMR comprises dans les substances naturelles complexes (NCS), le texte propose de ne pas les interdire et mentionne qu'uniquement la Commission consultera le SCCS en cas de « potential risk ». Pourquoi uniquement la Commission peut demander une évaluation SCCS, mais surtout comment est défini ce « potential risk » pour déclencher une évaluation par le SCCS alors qu'on parle de substances CMR ? Le SCCS devrait toujours être consulté.

- Comme pour le point précédent, dans son texte la Commission propose de ne pas interdire les substances CMR si leur classification dans CLP indique comme voie d'exposition 'oral or inhalation'. Les données concernant la voie dermatologique sont souvent manquantes pour être évaluées et les effets observés pour les voies orales et inhalations pourraient avoir les même effets CMR en voie dermatologique. Serait-il possible de savoir comment la Commissions définit le critère « potential risk » pour déclencher une évaluation par le SCCS ? Comment la Commission pourra-t-elle identifier qu'une substance CMR interdite sous CLP se retrouvera dans tel ou tel produit cosmétique (rouge à lèvre, spray solaire, bain de bouche, vernis, crème visage, shampoing) ? Le SCCS devrait toujours être consulté comme c'est le cas actuellement.

- Concernant la notification des nanomatériaux, le nouveau texte proposé par la Commission ne demande plus la notification dans CPNP des 2 points suivants : une estimation de la quantité de nanomatériau et le profil toxicologique du nanomatériau. De plus, les données sécurités seront selon la catégorie du produit COS et plus selon les conditions d'exposition raisonnablement prévisibles. Sachant toutes les erreurs de catégorie des produits cosmétiques encodés dans CPNP, tous les Etats membres sont-ils d'accord avec cela ?

La nomenclature internationale de référence des substances doit impérativement être définie (INCI ou autre) sinon le manque de clarté juridique entre les différentes législation (COS, REACH, POP,…) va se reproduire.

Luxembourg comments on "Simplification of certain requirements and procedures applicable to Regulation (EU) 2019/1009 establishing the rules on the making available on the market of EU fertilisers"

Luxembourg considers that the empowerment laid down in Article 43 relating to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories leads to a situation where the delegated empowerment to the Commission becomes too wide. We would prefer a more restrictive approach.

Luxembourg could be favorable to a rewording of recital 19 providing more flexibility to the Commission.

Luxembourg can accept a simpler assessment procedure for new micro-organisms in microbial biostimulants but would prefer to involve an independent scientific body in the approval procedure or the establishement of a European Reference laboratory (EURL) similar to the food and feed area.

The independent scientific body can be the European Food Safety Authority but might not be the only one to consider

Luxembourg supports creating a possible "positive list" of fertilising products exempted from REACH-registration.

Latvia

LATVIA_ Answers to PCY questions on Omnibus VI on simplification of certain requirements and procedures for chemical products

Fertilising Products Regulation (FPR) – COM(2025)531

1. The deletion of the "unbundling clause" attached to the adoption of delegated acts

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

Answer 1: Latvia **supports the removal of the 'unbundling clause'** (Article 43) and sees no concern that allowing the Commission to amend several categories of component materials with a single delegated act could make its powers too broad. **The most important thing is that the new powers should not lead to delays in the adoption of delegated acts.**

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

Answer 1a: **Latvia supports the current** wording of recital 19. Regarding recital 29, in our opinion, it sufficiently clearly sets out the changes envisaged by deleting Article 43 of the Fertilising Products Regulation.

2. The digitalisation of the EU-conformity assessment declaration

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Answer 2: **Latvia has no objections** to PCY's proposed approach on digitalisation.

3. A simpler assessment procedure for new micro-organisms in microbial biostimulants

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

Answer 3: Latvia **can support involvement of independent body**, if it contributes to simplification of micro-organism assessment **and does not lead to even more complicated and longer approval processes.**

4. Removal of the extended REACH-registration requirement for EU-fertilising products.

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

Answer 4: **Latvia does not support the "positive list".** Instead, Latvia supports the original COM proposal of removing extended REACH registration requirements and leaving normal REACH registration procedure without any additional lists. As compromise a "negative list" of potentially harmful ingredients, products of products groups requiring extended registration can be created.

Netherlands

NL Comments on Omnibus VI Chemicals

CLP

The NL believes the proposals to remove the deadline for updating the label, remove the label formatting requirements, and minimise the requirements for distance sales offers and advertisements should be reconsidered. The original CLP requirements contribute to the protection of human health and the environment; changing them as proposed in Omnibus VI would offset this protection level and create an increased burden for enforcement as proof of incompliance would become problematic. The NL was glad to see some alternative proposals within the Presidency Discussion Note, and believes discussing alternative proposals is the right way forward.

CPR

The NL would like to comments limit its comments to the proposed changes to article 15:

- *Derogation*

  It remains unclear how derogation decisions will be taken and what role Member States will have. The proposed criteria for assessing suitable alternatives are too weak and risk enabling derogations too easily. They should therefore be reconsidered.

- *Limiting scope CMR-ban*
  The Netherlands takes a critical stance on limiting the CMR ban's scope. CMR substances should remain prohibited in products that may be ingested or inhaled, such as loose powders or sprays. We are also critical of exempting natural complex substances (NCS), as natural and synthetic mixtures pose similar risks. Moreover, a Commission report on NCS is due by December 2029; decisions should await its outcome.
- *Transitional periods*
  NL opposes extending transitional periods. Longer availability of products with hazardous substances increases exposure for consumers and workers and undermines Europe's Beating Cancer Plan.

FPR

The NL supports the earlier shared written input by FRA and SPA that an independent scientific body recognized by the Member States should assess the risk and agronomic efficiency of micro-organisms for plant biostimulants (CMC7), and that this assessment should not be carried out by manufacturers or notifying bodies to prevent conflicts of interest.

Slovenia

Comments by Slovenia following the Antici Group on Simplification (AGS), Monday, 15 September 2025: Omnibus VI proposals on simplification of certain requirements and procedures for chemical products

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

We are inclined to support **option b**, with additional clarification provided in the recitals only. From our national experience, rigid label formatting requirements have not necessarily improved user safety and, in some cases, have created unintended challenges.

For example, when our national legislation mandated specific font sizes on labels during the transposition of the CLP directives, this provision proved difficult to enforce and burdensome for stakeholders, without delivering clear safety benefits.

In light of this experience, we believe that a more **flexible and pragmatic approach** to label formatting would be more effective, while still ensuring that the key objective of protecting users is fully preserved.

For these reasons, **we have a strong position that a more flexible and pragmatic approach to label formatting is preferable**.

Updating labels (Article 30(1))

Slovenia is inclined to support **option b**. In our view, suppliers – particularly SMEs – need sufficient time to update their labels in an orderly manner. At the same time, it is important that deadlines are clearly defined, especially for companies operating at the end of complex supply chains, so that legal certainty and smooth implementation can be ensured.

Advertising (Article 48) and distance sales offers (Article 48a)

On **point C**, we can support the Commission's proposal, as it would enhance information sharing and facilitate inspections. In our view, however, the prompt should also include:
a) a reference to the presence of hazardous substances, to further strengthen consumer awareness; and
b) the name and digital contact details of the responsible supplier, to ensure accountability and support effective market surveillance.

Regarding **Question 5**, we cannot support introducing such a restriction, as it would create significant practical challenges. In particular, it would be very difficult during inspections to demonstrate with certainty whether a chemical is intended for general or professional use, which could undermine both clarity and enforceability.

Cosmetic Products Regulation (CPR) – COM(2025)531

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

We have a **strong position** on this matter. We support the principle of introducing transitional periods, as we recognise the need to provide operators with legal certainty and sufficient time to adapt. However, we are concerned that the proposed timelines are disproportionately long and risk undermining the high level of consumer and worker protection that is the core objective of the regulation.

As a general principle, transitional periods should be kept as short as possible, with due regard to the protection of human health. From our perspective, a balanced approach would be to allow 3 months for placing products on the market and 6 months for making products available on the market. This would ensure both adequate time for operators to adjust and the timely withdrawal of products containing hazardous substances, thereby safeguarding consumer health.

Introduction of criteria for alternative assessment

Regarding **point a)**, we consider it important that the criteria for alternative assessment are specified directly in the Regulation, as this would provide greater legal clarity and ensure consistent implementation across Member States.

On **point c)**, in line with several other delegations, we believe that environmental criteria do not fall within the scope of the CPR and should therefore be deleted. Such aspects are already more appropriately and comprehensively addressed under other legislative frameworks, such as REACH or CLP. Including them here would risk unnecessary overlap and potential confusion without adding real value.

Natural complex substances containing CMR-substances

Slovenia could support **options a or b**, but not option c. In our view, a blanket ban on CMR constituents in natural ingredients would be impractical and disproportionate, as it would unnecessarily restrict the use of a wide range of substances of natural origin without providing additional safety benefits.

Classifications based on ingestion or inhalation route of exposure

Slovenia could support **options b or c**, but not option a. While this option concerns a very specific and limited hazardous property, we share the concerns raised by several Member States that consumers may still be exposed to cosmetics through inhalation (e.g. perfumes, deodorants, hairsprays) or via accidental ingestion. For this reason, we believe that a cautious and protective approach remains necessary.

Abolishment of pre-notification of nano-material ingredients (Article 16)

We are **strongly opposed** to the proposed amendments concerning nanomaterials and are firmly in favour of maintaining the current system. In our view, nanomaterials present unique properties and potential risks that require particular caution. They should therefore be subject to a **thorough safety assessment by the SCCS before being authorised** for use in cosmetic products, to ensure that a high level of protection of human health is fully preserved.

The proposed approach would not be sufficient. Such a system would weaken consumer protection, create legal uncertainty for operators, and could undermine public confidence in the safety of cosmetic products. For these reasons, we strongly advocate retaining the existing notification and assessment regime, which ensures that nanomaterials are scrutinised before they reach the market.

Slovakia

SK comments on Omnibus IV:

Review of the CLP Regulation:

"Stop-the-clock" – COM(2025)526
Question 1: SLOVAKIA supports the current “Stop-the-Clock” proposal as put forward by the Commission.

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

Question 2: SK supports option b) on further clarification in the text or the recitals on how readability should be understood.

Updating labels (Article 30(1))
Question 3: SLOVAKIA supports option a) on clarifying in a recital how the "without undue delay" formulation should be understood.

Advertising (Article 48) and distance sales offers (Article 48a)
Question 4a) We prefer to the wording on advertisement in Article 48 as proposed in document COM (2025)531 final
Question 4 b): We support the wording in document COM(2025)531 final.
Question 4 c): We support the wording in document COM(2025)531 : "Always read the label and product information before use."

Question 5: SK supports restricting Article 48 on advertisements and Article 48a on distance sales offers to cover only consumer products.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

Question 6: SLOVAKIA prefers the wording that also include digital contact and/or telephone number in Article 17(1) as well as in Annex I, section 1.6.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)
SK support the intention to proceed with the proposal in its current form.

<u>Fertilising Products Regulation (FPR) – COM(2025)531</u>

The deletion of the "unbundling clause" attached to the adoption of delegated acts

Question 1: In order to speed up the adoption of delegated acts, the Commission should be allowed to adopt several component material categories by a single delegated act. It is necessary to ensure that all new products made from those component materials do not present a risk to human, animal or plant health, to safety or to the environment.

Question 1a: Yes, by stressing the condition that all new products made from those component materials will not pose a risk to human, animal or plant health, to safety or to the environment.

The digitalisation of the EU-conformity assessment declaration

Question 2: We do not have any objections to the PCY's proposed approach on digitalisation, as the voluntary principle is maintained (as in the current wording of the Fertilising Products Regulation). The digitalisation of information requirements can reduce the administrative burden for companies and authorities, as electronic administration can facilitate the exchange, storage and access to information, reduce errors linked to the manual process and minimise the use of paper and the costs associated with the processing of paper documents.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

Question 3: We agree that an independent scientific body should have a prominent role in the approval process of new micro-organisms in microbial biostimulants because many new microorganisms are not sufficiently researched.

Removal of the extended REACH-registration requirement for EU-fertilising products.

Question 4: We support creating a possible "positive list" of safe and well-known fertilising products exempted from REACH-registration. This can significantly facilitate the marketing of some products. The extended registration under REACH should be maintained at least for certain very hazardous substances, such as persistent, bioaccumulative and toxic substances, and for certain unknown biologically active substances, also in view of the specific nature of the use of fertilising products, i.e. continuous and often extensive application to soil.

Cyprus

Presidency Discussion Note

Antici Group on Simplification (AGS)

Monday, 15 September 2025

Omnibus VI proposals on simplification of certain requirements and procedures for chemical products

Dear Colleagues,

Thank you for the written comments we have received concerning Omnibus VI on simplification of certain requirements and procedures for chemical products.

Based on previous discussions and the comments received, the PCY has noted support for the Commission proposal with the overall aim of reducing burdens to the chemical industry in Europe by simplifying certain rules in Regulation (EC) No 1272/2008 (CLP regulation), Regulation (EC) No 1223/2009 (Cosmetic Products Regulation) and Regulation (EC) 2019/1009 (Fertilising Products Regulation), while still maintaining high protection for the human health and the environment.

To guide the discussion, the PCY highlights below the main concerns raised in the written comments, and kindly asks the Member States to prepare their responses to the accompanying written questions. Together with the written comments already received, the responses will be used to draft a first compromise proposal.

"Stop-the-clock" – COM(2025)526

The targeted revision of the CLP in 2024 introduced new rules on label formatting, relabelling, distance sales, and fuelling station labelling, which will apply either from 1 July 2026 or 1 January 2027. To provide a short-term certainty for suppliers, the Commission proposes to postpone the date of application for these revisions until 1 January 2028. The more substantive changes to the CLP Regulation, revised in 2024, are addressed in the main Omnibus VI proposal.

The PCY intends to proceed swiftly with the "Stop-the-Clock"-proposal, and invites Member States to indicate their support for the Commission proposal in the first part of the Working Party meeting.

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

CY can support the current "Stop-the-Clock" proposal as put forward by the Commission.

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Member States are broadly supportive of the efforts to simplify the CLP Regulation, although several Member States stress the need to balance reduced administrative burdens with maintaining the Regulation's core objectives.

Key issues for debate concern the label formatting, the updating of labels for self-classified substances and mixtures, and certain distance sales rules on advertisements and online sales offers. The Member States also commented on digital contacts, digital labelling, and adjustments to the rules on packages under 10 ml.

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

Many Member States raised concerns on eliminating enforceable readability standards, underlining the need to balance simplification with consumer safety and legal clarity.

Based upon the Member States' responses, the PCY has identified the following indicative options regarding formatting and readability:

c) Retaining certain elements of the formatting rules introduced in 2024.
d) Further clarification in the text or the recitals on how readability should be understood.

Question 2: Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).

CY supports option (a) Retaining certain elements of the formatting rules introduced in 2024.

The 2024 formatting rules established a common framework that ensures labels are designed and presented in a consistent and uniform manner. Retaining key elements—such as minimum font size, structured headings and adequate spacing, ensures readability and avoids confusion across Member States. Option (a) provides continuity and minimizes the need for further guidance, whereas option (b) risks ongoing clarification and uneven application.

Updating labels (Article 30(1))

The Commission proposes repealing the six-month deadline for updating labels for self-classified substances and mixtures. The Member States recognise the cost implications for suppliers of updating the labels, particularly for SMEs. While some Member States welcomed a greater flexibility to reflect complex supply chains, many cautioned that returning to the formulation – "without undue delay" – creates legal uncertainty and puts consumers and workers at risk.

Based upon the Member States' responses, the PCY has identified the following indicative options on updating the labels and ensuring legal clarity:

d) Clarifying in a recital how the "without undue delay" formulation should be understood.
e) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.
f) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: Can Member States support one or more of the above-mentioned options?

CY supports option c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classification.

We consider option c) to be the most balanced and effective approach. Retaining the six-month deadline for CMR substances and endocrine disruptors ensures that the highest-risk categories are addressed urgently, thereby safeguarding public health and the environment. At the same time, reverting to the "without undue delay" option for other classifications introduces flexibility, avoiding disproportionate burdens on companies where risks are lower. This approach combines legal certainty with practicality: strict timelines are maintained for

the most hazardous substances, while Member States and industry retain the necessary adaptability for less critical updates.

Advertising (Article 48) and distance sales offers (Article 48a)

The 2024 CLP-revision adds additional requirements to the existing rules on which label elements/hazard information must be displayed in advertisements. The revision also introduced a new requirement on distance sales, including online sales, requiring that full label information is available at the point of sale. To reduce costs and avoid confusing consumers on the environmental performance of products, the Commission proposes to remove all requirements for displaying label elements/ hazard information in advertisements, replacing it with an amended prompt encouraging consumers to read the label before use. Furthermore, for both advertisement and distance sales offers, the Commission proposes waiving these rules for professional users, as professionals have access to safety data sheets.

While some Member States have backed the Commission's approach. Others highlight the need to deliver on the core purpose of the rules – early warning for users - and ensure a level playing field for online sales, particularly with regard to third country sellers, where the advertising rules in the CLP 2024 revision are adapted to the existing enforcement mechanisms under the DSA with regards to illegal online content.

Issues raised by delegates include defining what constitutes an "advertisement", balancing simplification with safety and advance warning of users, and linking obligations with other regulations for consistency. The Member States were also divided on whether the rules on advertisements and distance sales offers should apply to professional use.

Question 4: The PCY encourages Member States to prepare answers to the following questions on advertisements:

d) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?
CY supports restricting the rules in Article 48 to cover only online advertisements. This approach would provide greater clarity on the scope of the term "advertisement," ensuring that online marketing practices are clearly regulated without imposing unnecessary burdens on other traditional advertising channels, where existing rules are already well-established. Given that consumer exposure and risks are rapidly evolving in the online environment, this approach balances regulatory precision with practicality, enhancing legal certainty while avoiding overregulation.

e) Which, if any, label elements can be removed from the rules on advertising in Article 48?
None. CY believes that all labelling elements should be provided as shown on the label (Article 17 of the CLP Regulation). This approach is also easier to apply, as it allows advertisers to display clear and visible labelling elements—or a photo of the actual label—without the need to delete or modify any information.

f) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

CY supports the proposed wording: "Always read the label and product information before use."

Furthermore, CY agrees with the inclusion of the additional elements mentioned above, namely: (a) the presence of hazardous substances, which enhances consumer awareness; and (b) the name and digital contact details of the responsible supplier, as required under Article 4(11). These elements also assist market surveillance authorities in conducting automated monitoring of advertisements, thereby supporting compliance and enforcement.

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

CY supports limiting the scope of Article 48 on advertisements and Article 48a on distance sales offers to consumer products only. This targeted approach provides clarity for both regulators and industry, ensuring that consumer protection rules are applied where they are most needed. At the same time, CY emphasizes that products intended for professional use should be made available online exclusively to qualified professionals. The implementation of verification mechanisms and restricted access will prevent unauthorized sales, maintain high standards of consumer safety, and ensure that professional users can access the products they require.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

The Commission proposes that CLP labels should include a "digital contact" instead of the current requirement for postal address and telephone number. A similar proposal is included in the Omnibus IV package (Digitalisation and Common Specifications).

The PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position. The Commission also proposes the simplification of that supplier contact details by allowing information on additional suppliers to appear only on the digital label.

Member States expressed openness towards expanding the digital labelling. Based on the comments received, the PCY considers that the Commission's proposal strikes the right balance, albeit slight editorial amendments may be needed.

Question 5: Do Member States have any objections to the PCY's proposed approach on digitalisation?

CY has no objections to expanding digital labelling and supports the proposal to allow information on additional suppliers to appear solely on the digital label. This approach maintains clarity and accessibility for consumers while reducing the amount of dense information on physical labels.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

Member states are broadly supportive of the Commission's proposal on exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, some concerns remain on legal clarity and consumer protection for vulnerable groups.

Some have asked for slight editorial changes, alignment with other EU rules, and for clarification on the use of multilayer, booklet, or leaflet labels. The PCY will carefully examine the received editorial suggestions.

Based on the feedback so far, our intention is to proceed with the proposal in its current form.

CY agrees. Nevertheless, we would like to note that some concerns remain regarding legal clarity, particularly on how the exemption is to be applied consistently across different product categories. It is essential that these exemptions do not compromise consumer safety or create regulatory gaps.

Cosmetic Products Regulation (CPR) – COM(2025)531

Some Member States have questioned the Commission's assertion that the proposed amendments to the CPR will not affect consumer safety negatively, and particularly with regard to the presence of CMR substances in cosmetic products.

The PCY intends to raise this issue as central to the discussions.

Amendments to Article 15

Member States highlight that for the proposed amendments to Article 15 in particular, simplifications must not be made at the expense of human health and consumer safety. In the Staff Working Document (SWD (2025) 531), the Commission aims to explain the timelines.

New timeline for submitting an application for derogation for using CMR substances in cosmetic products

The Commission proposal suggest a new timeline for submitting an application for a derogation for using a CMR substance in cosmetic products. Some Member States express concern for the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

Yes, we can support the new timeline.

New timeline for amending the Annexes

In the Commission proposal, a new timeline is presented for the prohibition of CMR substances in cosmetic products under CPR. Some Member States express their concern about the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

Yes, we can support this approach and accept the time period

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

Yes, we can support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances.

However, shorter timelines than the ones suggested (e.g. 9 and 18 months) could be more acceptable in order to ensure a higher level of protection for human health.

Amendments of criteria for derogation

The Commission proposes that the criteria for derogation be narrowed down from four to two.

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

We can support the deletion of the criteria a) regarding food-safety compliance since this is not relevant for cosmetics and may lead to unnecessary use of resources by industry
Also criteria c) and d) can be merged

Introduction of criteria for alternative assessment

The Commission proposal introduces criteria for assessing whether alternatives are available when evaluating a derogation application for using a CMR substance in cosmetic products.

Some Member States are concerned that the criteria are too broad and will almost always result in the conclusion that no alternatives are available or that an alternative method or technical solution will not be recognised as a suitable alternative.

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?
Better to be specified in the Regulation to ensure legal clarity

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?
Yes, so as to be more clear

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?
These aspects may not be within the scope of the CPR as such, but they give a more complete view of what is considered a suitable alternative. Therefore we would like to keep the criteria.

Natural complex substances containing CMR-substances

The aim of the Commission proposal on natural complex substances is to create clarity when natural complex substances contain CMR-classified components. Some Member States express concern for the impact on the protection of human health.

Below are some indicative options identified by the PCY.

d. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

e. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

f. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

We better support option b

Classifications based on ingestion or inhalation route of exposure

The Commission proposes to exclude CMR-substances from the generic ban under CPR if the CMR-substance is explicitly based on oral or inhalation route of exposure.

Some Member States find that these substances still pose a risk, as many cosmetic products are used in the mouth area or are in a spray form, and are therefore concerned about the impact on the protection of human health.

Below are some indicative options identified by the PCY.

d. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

e. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

f. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

We better support option b

Abolishment of pre-notification of nano-material ingredients (Article 16)

The Commission proposes to abolish the requirement for pre-notification for nano-material ingredients in cosmetic products, suggesting that these products should be notified to the Commission when placed on the market like other cosmetic products.

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

If catalogue is abolished, Data on nano materials will still be available through the CPNP and CPSR

Abolishment of the glossary (Article 19 and 33)

While no Member State expressed opposition to the proposal regarding the suggested use of "internationally recognised nomenclature" instead of the current Glossary of common ingredient names, several member States call for greater legal certainty, and expressed a need for clear naming.

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

The internationally recognized nomenclature, supports international alignment, consumer understanding and market surveillance integrity.

Fertilising Products Regulation (FPR) – COM(2025)531

Based on previous AGS meetings and written comments, the following areas have been identified as the key issues for further discussions. The PCY invites Member States to prepare their replies to the accompanied questions.

The deletion of the "unbundling clause" attached to the adoption of delegated acts

Generally, a positive attitude to this part of the proposal. The PCY notes, nonetheless, that some Member States have expressed doubts on whether the proposal's scope is too wide. In other interventions, Member States queried whether the removal of the "unbundling clause" might even lead to delays in the process.

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?
we can be flexible, no objection.

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?
Cyprus supports a single delegated act as this could improve clarity.

The digitalisation of the EU-conformity assessment declaration

Similar to the Commission's Omnibus IV package, focusing on the digital transformation of product compliance, the PCY understands that the fertilising products market will also benefit from further digitalisation. Some Member States have indicated, that there might exist situations where the use of an analogue document may be appropriate.

In this regard, the PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position.

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?
Cyprus has no objection to the PCY's approach.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

The PCY recognises that the Member States generally agree that the long process for allowing new micro-organisms in microbial biostimulants constitutes an obstacle to European innovation. Hence, the Commission's proposal for a simpler approval procedure receives broad support among delegations. Nonetheless, the PCY notes that some Member States prefer to involve an independent body in the approval procedure.

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

Yes, in our opinion an independent scientific body should be involved and must have a prominent role in the approval process considering the fact that environmental safety and human health is not compromised.

Removal of the extended REACH-registration requirement for EU-fertilising products.

Member States generally support the removal of the extended REACH-registration requirement for the final EU-fertilising product and for the individual chemical substances of the fertiliser product. However, the PCY notes that some Member States express concerns when it comes to the ability of the national market surveillance authorities to supervise the market and avoid bringing public safety into jeopardy if certain products are exempted from the REACH-registration requirements.

In this regard, one Member State suggests that the Commission should draw up a "positive list" of safe, traditional and well known "historical" fertilising products that do not need to be REACH-registered (the list would in this case have to be developed).

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

Cyprus may support the creation of a "positive list", however, we should be caution with the creation of this list as issues regarding criteria and possible administration burden arise.

***

We are looking forward to seeing you on 15 September.

Kind regards

DK Presidency Team

Antici Group on Simplification

Lithuania

Presidency Discussion Note

Antici Group on Simplification (AGS)

Monday, 15 September 2025

Omnibus VI proposals on simplification of certain requirements and procedures for chemical products

Dear Colleagues,

Thank you for the written comments we have received concerning Omnibus VI on simplification of certain requirements and procedures for chemical products.

Based on previous discussions and the comments received, the PCY has noted support for the Commission proposal with the overall aim of reducing burdens to the chemical industry in Europe by simplifying certain rules in Regulation (EC) No 1272/2008 (CLP regulation), Regulation (EC) No 1223/2009 (Cosmetic Products Regulation) and Regulation (EC) 2019/1009 (Fertilising Products Regulation), while still maintaining high protection for the human health and the environment.

To guide the discussion, the PCY highlights below the main concerns raised in the written comments, and kindly asks the Member States to prepare their responses to the accompanying written questions. Together with the written comments already received, the responses will be used to draft a first compromise proposal.

"Stop-the-clock" – COM(2025)526

The targeted revision of the CLP in 2024 introduced new rules on label formatting, relabelling, distance sales, and fuelling station labelling, which will apply either from 1 July 2026 or 1 January 2027. To provide a short-term certainty for suppliers, the Commission proposes to postpone the date of application for these revisions until 1 January 2028. The more substantive changes to the CLP Regulation, revised in 2024, are addressed in the main Omnibus VI proposal.

The PCY intends to proceed swiftly with the "Stop-the-Clock"-proposal, and invites Member States to indicate their support for the Commission proposal in the first part of the Working Party meeting.

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

LT: Scrutiny reservation

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Member States are broadly supportive of the efforts to simplify the CLP Regulation, although several Member States stress the need to balance reduced administrative burdens with maintaining the Regulation's core objectives.

Key issues for debate concern the label formatting, the updating of labels for self-classified substances and mixtures, and certain distance sales rules on advertisements and online sales offers. The Member States also commented on digital contacts, digital labelling, and adjustments to the rules on packages under 10 ml.

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

Many Member States raised concerns on eliminating enforceable readability standards, underlining the need to balance simplification with consumer safety and legal clarity.

Based upon the Member States' responses, the PCY has identified the following indicative options regarding formatting and readability:

a) Retaining certain elements of the formatting rules introduced in 2024.
b) Further clarification in the text or the recitals on how readability should be understood.

Question 2: Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).

LT: The issue of clarity and readability of chemical labels was identified during the CLP review. Therefore, we are more supportive of option (b), which aims to clarify the new label formatting requirements to facilitate their implementation.

Regarding the labelling of small packages. The draft (replacing 2024/2865) provides for an exception only for 10 ml packages. Please note that, in implementing the lex generalis and lex specialis requirements, the information specified in the draft new regulation amending Commission Regulation 547/2011, including the colour scheme and information required by Commission Delegated Regulation (EU) 2023/707, and presented in the font and line spacing required by Regulation (EU) 2024/2865, does not fit on plant protection product packaging of 250 ml and below. The placing on the market of empty packaging for plant protection products is prohibited by 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. Article 10(1) (No later than January 1, 2030, the physical producer or importer shall ensure that packaging placed on the market is designed to minimize its weight and volume to the minimum necessary to ensure its functionality, taking into account its shape and the material from which it is made). Therefore, the implementation of these provisions in the field of plant protection is not possible.

Updating labels (Article 30(1))

The Commission proposes repealing the six-month deadline for updating labels for self-classified substances and mixtures. The Member States recognise the cost implications for suppliers of updating the labels, particularly for SMEs. While some Member States welcomed a greater

flexibility to reflect complex supply chains, many cautioned that returning to the formulation – "without undue delay" – creates legal uncertainty and puts consumers and workers at risk.

Based upon the Member States' responses, the PCY has identified the following indicative options on updating the labels and ensuring legal clarity:

a) Clarifying in a recital how the "without undue delay" formulation should be understood.
b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.
c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: Can Member States support one or more of the above-mentioned options?

Lithuania understands that a six-month deadline may be difficult to meet in complex supply chains; however, the absence of any concrete deadline complicates enforcement and may pose risks to human health and the environment. Therefore, we would support the introduction of a maximum deadline for this obligation. One possible approach could be to formulate it as "without undue delay, but no later than 9 or 12 months."

Additionally, we would like to emphasize the importance of an alignment with the changes foreseen in the proposal regarding Regulation 2011/547.

Advertising (Article 48) and distance sales offers (Article 48a)

The 2024 CLP-revision adds additional requirements to the existing rules on which label elements/hazard information must be displayed in advertisements. The revision also introduced a new requirement on distance sales, including online sales, requiring that full label information is available at the point of sale. To reduce costs and avoid confusing consumers on the environmental performance of products, the Commission proposes to remove all requirements for displaying label elements/ hazard information in advertisements, replacing it with an amended prompt encouraging consumers to read the label before use. Furthermore, for both advertisement and distance sales offers, the Commission proposes waiving these rules for professional users, as professionals have access to safety data sheets.

While some Member States have backed the Commission's approach. Others highlight the need to deliver on the core purpose of the rules – early warning for users - and ensure a level playing field for online sales, particularly with regard to third country sellers, where the advertising rules in the CLP 2024 revision are adapted to the existing enforcement mechanisms under the DSA with regards to illegal online content.

Issues raised by delegates include defining what constitutes an "advertisement", balancing simplification with safety and advance warning of users, and linking obligations with other regulations for consistency. The Member States were also divided on whether the rules on advertisements and distance sales offers should apply to professional use.

Question 4: The PCY encourages Member States to prepare answers to the following questions on advertisements:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

b) Which, if any, label elements can be removed from the rules on advertising in Article 48?
c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

LT: Regarding 4 a): if it is an online advertisement, it could also be an online sale, thus this should be regulated by Article 48a "Distance sales offers".

Awarenesses raising on hazardous substances or mixtures is crucial, and the use of prompt in advertisement is essential. We could also think about the prompt, which is in Regulation No 2024/2865: "Always follow the information on the product label." This prompt is more general and can refer to storage or waste requirements, not only to use. Also, there is no need to read the label/information before every time the product is used, but it is essential to follow what is written on the label/information. We could be flexible on which additional references could be included together with the prompt.

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

Lithuania notes that online sales are challenging to control and are exploited as a tool by illegal traders. It is therefore essential to ensure that online sales comply with the same product safety requirements as products sold in physical stores. Moreover, online sales must also ensure that a product intended solely for professional use can only be purchased by a buyer entitled to do so. Therefore, we believe that Article 48a on distance sales should cover all products.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

The Commission proposes that CLP labels should include a "digital contact" instead of the current requirement for postal address and telephone number. A similar proposal is included in the Omnibus IV package (Digitalisation and Common Specifications).

The PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position. The Commission also proposes the simplification of that supplier contact details by allowing information on additional suppliers to appear only on the digital label.

Member States expressed openness towards expanding the digital labelling. Based on the comments received, the PCY considers that the Commission's proposal strikes the right balance, albeit slight editorial amendments may be needed.

Question 5: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Lithuania agrees that Omnibus VI and Omnibus IV should be aligned regarding the "digital contact".

We can agree to the proposed extension of digital labelling, allowing additional suppliers to be listed digitally. However, we believe that additional information under Article 25(3) of the CLP Regulation that is related to consumer health (e.g., EUH 208 *Contains <name of sensitising substance>. May produce an allergic reaction*, EUH 380 *May cause endocrine disruption in humans*, EUH 441 *Accumulates in the environment and living organisms, including humans, to a high degree*, etc.) should not be provided exclusively in digital form. Similarly, we believe that digital provision of safety information and instructions for use should, for now, be only a supplementary measure. Safety information must be immediately visible to the user, without the need to search for it, as time, skills, or technical means may be lacking (e.g., no smartphone, no internet, poor connection, emergency situations).

For consistency and legal clarity, we suggest defining the digital form as "a data carrier" in line with the June draft amendment to Regulation (EU) No 547/2011.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

Member states are broadly supportive of the Commission's proposal on exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, some concerns remain on legal clarity and consumer protection for vulnerable groups.

Some have asked for slight editorial changes, alignment with other EU rules, and for clarification on the use of multilayer, booklet, or leaflet labels.

Lithuania has submitted written comments regarding the alignment of small package labelling requirements with the draft amendment to Commission Regulation (EU) No 547/2011. We look forward to the revised text.

We can agree to the simplification of labelling requirements for small packages and to revised derogations for very small packages (10 ml), however, we suggest aligning small package labelling requirements with the draft amendment to Commission Regulation (EU) No 547/2011 and setting them as foreseen in the June draft of that amendment:" In the case of small packages, information

required by point (k) to (r) of Annex I may be indicated on a separate leaflet accompanying the package. Such a leaflet shall be regarded as part of the physical label.

The PCY will carefully examine the received editorial suggestions.

Based on the feedback so far, our intention is to proceed with the proposal in its current form.

Cosmetic Products Regulation (CPR) – COM(2025)531

Some Member States have questioned the Commission's assertion that the proposed amendments to the CPR will not affect consumer safety negatively, and particularly with regard to the presence of CMR substances in cosmetic products.

The PCY intends to raise this issue as central to the discussions.

Amendments to Article 15

Member States highlight that for the proposed amendments to Article 15 in particular, simplifications must not be made at the expense of human health and consumer safety. In the Staff Working Document (SWD (2025) 531), the Commission aims to explain the timelines.

New timeline for submitting an application for derogation for using CMR substances in cosmetic products

The Commission proposal suggest a new timeline for submitting an application for a derogation for using a CMR substance in cosmetic products. Some Member States express concern for the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

LT: The proposed timeline extends the current one. In our view, the submission of application date may commence following the date of adoption of the RAC opinion.

By adhering to this principle, it would become evident at an earlier stage which substances are subject to the exemption procedure, whereas for others the automatic approval of the ban could be initiated.

The proposed timeline extends the current framework. We consider that applications should be submitted starting from the adoption date of the RAC opinion. This would provide earlier clarity on which CMR substances qualify for exemptions, while ensuring that the ban is automatically applied to all other CMR.

New timeline for amending the Annexes

In the Commission proposal, a new timeline is presented for the prohibition of CMR substances in cosmetic products under CPR. Some Member States express their concern about the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

LT: The newly proposed timelines extend the period during which consumers may use cosmetic products containing CMR substances whose safety has not been assessed as products containing CMR substances .

We would like to draw the attention – the wording of the provisions of paragraph 2, remained fourth and added new fifth subparagraphs, contradict each other concerning start date: " the date of the inclusion of the substances in Part 3 of Annex VI to Regulation (EC) No 1272/2008" mentioned in fourth subparagraph is not identical to "the date of entry into application of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008"

Current Regulation	Omnibus VI proposal
Article 15, paragraph 2, fourth subparagraph In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation ***within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.***	**Article 15, paragraph 2, new proposed fifth subparagraph** "The deadline laid down in the fourth subparagraph of this paragraph shall start **on the date of entry into application of the** relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of category 1A, or 1B.';

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

LT: Supports keeping the current principles of Regulation (EC) No 1223/2009. The prohibition on the use of CMR substances, unless an exemption has been requested and granted, should apply from the same application date of the harmonised classification of those substances under CLP.

Allowing cosmetic products containing CMR substances to remain on the market for 24 months appears disproportionate compared with other product categories that do not come into direct contact with the human body. Such an approach risks undermining the precautionary principle that forms the basis of Regulation (EC) No 1223/2009.

Amendments of criteria for derogation

The Commission proposes that the criteria for derogation be narrowed down from four to two.

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

LT: can demonstrate flexibility on this proposal. Article 15 shall apply in cases where the CMR classification is relevant to the dermal exposure route. For chemical substances classified as CMR and assessed by the SCCS, the safety assessment will be carried out under the intended conditions of use, including scenarios where incidental ingestion or inhalation exposure may give rise to concern.

Introduction of criteria for alternative assessment

The Commission proposal introduces criteria for assessing whether alternatives are available when evaluating a derogation application for using a CMR substance in cosmetic products.

Some Member States are concerned that the criteria are too broad and will almost always result in the conclusion that no alternatives are available or that an alternative method or technical solution will not be recognised as a suitable alternative.

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

LT: Additional guidance on the application of the new criteria would also be needed for their implementation.

For b) and c) criteria LT can be flexible.

Natural complex substances containing CMR-substances

The aim of the Commission proposal on natural complex substances is to create clarity when natural complex substances contain CMR-classified components. Some Member States express concern for the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

c. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

LT support option b: Risk-based evaluation of natural substance constituents in finished cosmetic products, as provided by the SCCS, with a focus on actual exposure levels and conditions of safe use.

Classifications based on ingestion or inhalation route of exposure

The Commission proposes to exclude CMR-substances from the generic ban under CPR if the CMR-substance is explicitly based on oral or inhalation route of exposure.

Some Member States find that these substances still pose a risk, as many cosmetic products are used in the mouth area or are in a spray form, and are therefore concerned about the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

LT support option b).

Abolishment of pre-notification of nano-material ingredients (Article 16)

The Commission proposes to abolish the requirement for pre-notification for nano-material ingredients in cosmetic products, suggesting that these products should be notified to the Commission when placed on the market like other cosmetic products.

LT maintains the position that all nanomaterials used in cosmetic products —not only colorants, preservatives, and UV filters — should continue t**o be subject to independent risk assessment by the SCCS.**

Valid paragraphs 4 and 5 of Article 16, allow the Commission to initiate evaluations when new nanomaterials are notified via the CPNP. However, the provisions do not clearly define the conditions under which the Commission would consider a nanomaterial to raise a safety concern. This lack of clarity creates legal uncertainty and risks inconsistent application across Member States.

Furthermore, delegating the responsibility for the safety assessment of nanomaterials in cosmetic products to Responsible Persons or national Competent Authorities would not guarantee a uniform and high level of consumer protection. Variations in the interpretation of Responsible Persons' obligations, differences in the qualifications of safety assessors, and disparities in the capacities of national authorities would inevitably lead to divergent practices and uneven safeguards for consumers across the Union.

LT stresses that the safety of nanomaterials should be explicitly aligned with the requirements set out in Article 14a, thereby ensuring regulatory consistency and maintaining the same level of risk assessment applied to other categories of ingredients, namely preservatives, UV filters, colorants and other restricted substances, included in Annex III of Regulation 1223/2009.

Some technical inaccuracy in article 16 paragraph 8: Paragraphs 3 and 7 proposed to be deleted;

Current Regulation	Omnibus VI proposal
Article 16, paragraph 8 8. The measures, referred to in paragraphs 6 and **7,** designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).	In Article 16, paragraphs 3 and 7 are deleted; But paragraph 8 is addressed to paragraph 7.

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

LT: The OMNIBUS VI proposal did not provide for the abolition of the nanomaterial catalogue by way of an amendment to paragraph 10, in which reference to that catalogue is made.

Current Regulation	Omnibus VI proposal
Article 16, paragraph 10 10. The following information shall be made available by the Commission: (a) By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available.	The proposal does not provide for any changes to paragraph 10, point (a) of which mentions the nano-materials catalogue.

Abolishment of the glossary (Article 19 and 33)

While no Member State expressed opposition to the proposal regarding the suggested use of "internationally recognised nomenclature" instead of the current Glossary of common ingredient names, several member States call for greater legal certainty, and expressed a need for clear naming.

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

LT: Legal certainty could be ensured by using INCI – The International Nomenclature of Cosmetic Ingredients (which has been the basis for the Glossary names), CosIng database.

Additional comment Lithuania's Position on Distance Selling of Cosmetic Products

Lithuania wishes to underline that it has submitted an additional proposal to incorporate specific requirements for distance selling into the draft legislation currently under preparation.

Lithuania emphasizes the urgent need for clear and comprehensive provisions regarding information requirements for cosmetic products sold through distance sales channels.

Current Situation:

Regulation (EC) No 1223/2009 does not establish obligations concerning the availability of information in the context of online or distance sales;

The EU General Product Safety Regulation (Regulation (EU) 2023/988) sets out general safety requirements and specific obligations for economic operators, but does not address the provision of ingredient list.

Access to ingredient information is crucial for consumers, professional users, and market surveillance authorities. The implementation of Regulation No. 20225/877 (OMNIBUS VII) on the prohibition of Trimethylbenzoyl Diphenylphosphine oxide (TPO) from 01/09/2025 has demonstrated how information is manipulated in practice in online stores - by limiting itself to the statement "without TPO", „Free of TPO“ and not disclosing the list of ingredients.

In light of this, Lithuania considers it both appropriate and timely to supplement Regulation (EC) No 1223/2009 through the Omnibus VI package with provisions ensuring the availability of relevant information for cosmetic products sold via distance sales channels.

Fertilising Products Regulation (FPR) – COM(2025)531

Based on previous AGS meetings and written comments, the following areas have been identified as the key issues for further discussions. The PCY invites Member States to prepare their replies to the accompanied questions.

The deletion of the "unbundling clause" attached to the adoption of delegated acts

Generally, a positive attitude to this part of the proposal. The PCY notes, nonetheless, that some Member States have expressed doubts on whether the proposal's scope is too wide. In other interventions, Member States queried whether the removal of the "unbundling clause" might even lead to delays in the process.

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

Lithuania supports the simplification of the procedures for the adoption of delegated acts, as this would enhance legislative flexibility and allow for quicker responses to technological developments in the fertilising products sector.

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

LT: Rewording recital 19 would clarify the scope of the empowerment, while recital 29 could specify that the introduction of additional materials to multiple CMCs should be done through a single delegated act, reducing duplication and administrative burden.

The digitalisation of the EU-conformity assessment declaration

Similar to the Commission's Omnibus IV package, focusing on the digital transformation of product compliance, the PCY understands that the fertilising products market will also benefit from further digitalisation. Some Member States have indicated, that there might exist situations where the use of an analogue document may be appropriate.

In this regard, the PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position.

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Lithuania supports the PCYs proposed approach on digitalisation.

Additionally, we would like to underline that, in the transition to digital labelling, it is essential to ensure:

- adequate access to information for all consumers, including those without smart devices, elderly people, and farmers in regions with limited internet connectivity;
- cybersecurity safeguards and data protection;
- a transitional period (2–3 years) to allow both businesses and consumers to adapt.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

The PCY recognises that the Member States generally agree that the long process for allowing new micro-organisms in microbial biostimulants constitutes an obstacle to European innovation. Hence, the Commission's proposal for a simpler approval procedure receives broad support among delegations. Nonetheless, the PCY notes that some Member States prefer to involve an independent body in the approval procedure.

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

Lithuania considers that an independent scientific body, such as the European Food Safety Authority, should have a prominent role in the approval process of new micro-organisms in microbial biostimulants. An Independent or EFSA-supervised assessment is necessary to ensure impartiality and to avoid conflicts of interest. In addition, the evaluation should be based on a clear risk assessment methodology, covering, inter alia, soil ecosystems and potential impacts on biodiversity.

Removal of the extended REACH-registration requirement for EU-fertilising products.

Member States generally support the removal of the extended REACH-registration requirement for the final EU-fertilising product and for the individual chemical substances of the fertiliser product. However, the PCY notes that some Member States express concerns when it comes to the ability of the national market surveillance authorities to supervise the market and avoid bringing public safety into jeopardy if certain products are exempted from the REACH-registration requirements.

In this regard, one Member State suggests that the Commission should draw up a "positive list" of safe, traditional and well known "historical" fertilising products that do not need to be REACH-registered (the list would in this case have to be developed).

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

LT: We are supportive of the proposed "positive list" of safe, traditional, and well-known "historical" fertilising products that do not require REACH registration. This would be a great help to national market surveillance authorities.

Portugal

PT comments on the Omnibus VI
(cosmetics) 19.09.2025

1) Cosmetics Regulation

Question 1 (New timeline for submitting an application for derogation for using CMR substances in cosmetic products)

PT has reservations regarding the newly proposed timeline. In particular, the transitional periods for placing products on the market and for making products available on the market should be shortened. We share the concerns raised by other Member States regarding the potential impact on the protection of human health.

Question 2 (New timeline for amending the Annexes)

PT has reservations regarding the newly proposed timeline: the transitional periods for placing products on the market and for making products available on the market should be reduced.

Question 3 (Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances)

PT has reservations regarding the newly proposed timeline: the transitional periods for placing products on the market and for making products available on the market should be reduced: to 9 and 18 months respectively.

Question 4 (Amendments of criteria for derogation)

PT agrees with the proposal; however, the two criteria should be applied cumulatively. All available safety data should be taken into account when assessing an ingredient or mixture. If the objective is to carry out a single assessment per ingredient, all relevant information must therefore be considered, including data on oral, dermal, systemic, and other types of exposure.

Question 5 (Introduction of criteria for alternative assessment)

The criteria adopted must apply to the ingredient rather than to the final product. These criteria should be specific, taking into account the chemical and physical properties of the substance under analysis.

Regarding the specific questions:

a) We believe it should be specified in the Regulation.
b) We believe the appropriate criteria should be selected.

c) Environmental criteria could be considered, but we have doubts regarding the economic criteria.

Question 6 (Natural complex substances containing CMR-substances)

PT agrees with this proposal. Regarding Natural Complex Substances (NCS), PT recognizes the importance of plant extracts for the cosmetics industry and the agricultural sector, as well as the complexity of this issue. This decision could have a major impact on these sectors. In this regard, we believe that if a 'problematic' ingredient (with potential toxicity) is present within an extract (NCS), the mixture obtained from the plant should not be immediately prohibited. Instead, the concentration of such a substance should be assessed by the SCCS. If authorised, a maximum limit in the finished product should then be established, according to the product category and intended use, in order to ensure consumer safety and public health. Therefore, PT only agrees with option b).

Question 7 (Classifications based on ingestion or inhalation route of exposure) PT agrees with options a) and b) only if applied cumulatively. If not, we can only accept the option b).

Question 8 (Abolishment of pre-notification of nano-material ingredients)

The information should be available in the Safety Assessment Report (article 10 of the CPR).

Question 9 (Abolishment of the glossary)

PT agrees with the proposal; however, the Commission must commit to the permanent updating of COSING, including a clear indication of prohibition in the entries relating to banned substances. The Commission should ensure that the COSING database is kept up to date, avoiding entries where prohibited ingredients are listed but not included in Annex II, or, alternatively, clearly indicating those ingredients that are prohibited. The COSING search engine should also be improved to allow for more intuitive searches, enabling general queries without the need to distinguish between different Union regulations or between substances and ingredients. Certain entries should be further detailed and, where appropriate, expanded, including, where relevant, by reference to data from the EMA, namely: entry 21 (sympathicomimetic amines acting on the central nervous system), entry 37 (substances with androgenic effect), entry 39 (antibiotics) and entry 323 (vaccines, toxins or serums defined as immunological medicinal products).

Belgium

Commission proposal	Drafting Suggestions	Justifications
General Comments		
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		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national Parliaments,		

Commission proposal	Drafting Suggestions	Justifications
Having regard to the opinion of the European Economic and Social Committee[1],		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) High quality and safety requirements for products on the Single Market ensure a high level of protection of human health and the environment and contribute to a fair and sustainable economy. In international competition, the reputation of high-grade products manufactured in the Union can create an advantage for Union companies.		
(2) The findings of the 2024 Draghi report[2] indicated that the increasing number and complexity of rules risks limiting room for manoeuvre for Union businesses and preventing them from remaining competitive. Against this background, certain procedures and requirements laid down in Regulations (EC) No 1272/2008[3], (EC) No 1223/2009[4] and (EU)		

[1] OJ C [...], [...], p. [...].

[2] 2024 report by Mario Draghi on the future of European competitiveness: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059

[3] 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).

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

Commission proposal	Drafting Suggestions	Justifications
2019/1009[5] of the European Parliament and of the Council should be simplified and unnecessary regulatory burdens should be removed, while maintaining the same level of protection of human health and of the environment.		
(3) In line with the Commission's objective to promote the 'digital by default' principle to support digital transformations and in order to facilitate communication between economic operators and national authorities responsible for enforcement, the indication of a digital contact on the label of hazardous substances and mixtures is necessary to enhance the effectiveness of official controls and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008. Currently, suppliers are required to indicate their address and telephone number on the label of the packaging of hazardous substances or mixtures, but this is not always sufficient to ensure that authorities responsible for enforcement can establish rapid contact. It is therefore necessary to require suppliers to provide a digital contact, which could be any up-to-date and accessible online communication channel with the supplier.		
(4) Regulation (EC) No 1272/2008 laid down the exemptions from labelling and packaging requirements		

[5] 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).

Commission proposal	Drafting Suggestions	Justifications
for packaging of specific shapes, forms or sizes. Those exemptions can only be triggered if all required label elements do not fit on the outer packaging or on a tie-on tag. To simplify the use of those exemptions, it is appropriate to allow the existing exemptions to be applied to smaller packages without the need to prove the impossibility of using the outer packaging or tie-on tag.		
(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[6] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208. It is also necessary to clarify the requirements for inner and outer packaging in cases where the 10 ml derogation is applied.	(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[7] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, ~~further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208. It is also~~ **it is** necessary to clarify the requirements for inner and outer packaging in cases where the 10 ml derogation is applied.	BE: see justification in the provisions.
(6) In order to provide the flexibility for suppliers of substances and mixtures, to create equal conditions for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to remove a fixed six months	~~(6) In order to provide the flexibility for suppliers of substances and mixtures, to create equal conditions for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to remove a fixed six~~	BE: see justification in the provisions.

[6] 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).

[7] 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).

Commission proposal	Drafting Suggestions	Justifications
relabelling deadline and to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.	~~months relabelling deadline and to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.~~	
(7) Regulation (EU) 2024/2865 laid down rules on mandatory requirements for label formatting. New information[8] pointed to excessive administrative burden and costs, associated with these requirements. To balance the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[9], it is necessary to simplify the current formatting obligations without reducing the level of protection of human health and the environment. Economic operators and enforcement authorities must remain responsible for	New information[10] pointed to excessive administrative burden and costs, associated with these requirements. To balance the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[11], it is necessary to simplify the current formatting obligations without reducing the level of protection of human health and the environment. ~~Economic operators and enforcement authorities must remain responsible for ensuring that the labels are legible in accordance with the legal requirements.~~	BE: see justification in the provisions.

[8] Detailed analysis of costs associated with new formatting requirements is provided in the Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

[9] As outlined in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10, available at: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

[10] Detailed analysis of costs associated with new formatting requirements is provided in the Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

[11] As outlined in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10, available at: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

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ensuring that the labels are legible in accordance with the legal requirements.		
(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, requirements for advertisements and distance offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[12] already provides clear obligations on information flows in supply chains for substances and mixtures.	(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, requirements for advertisements and distance offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[13] already provides clear obligations on information flows in supply chains for substances and mixtures.	BE: see justification in the provisions.
(9) Before the amendments introduced by Regulation (EU) 2024/2865, Regulation (EC) No 1272/2008 required the advertisements for hazardous mixtures, for which a member of the general public is allowed to conclude a contract for purchase without first having sight of the label, to mention the type or types of hazards indicated on the label, and	(9) Before the amendments introduced by Regulation (EU) 2024/2865, Regulation (EC) No 1272/2008 required the advertisements for hazardous mixtures, for which a member of the general public is allowed to conclude a contract for purchase without first having sight of the label, to mention the type or types of hazards indicated on the	BE: see justification in the provisions.

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

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

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required advertisements for substances to mention the hazard classes or hazard categories concerned. Regulation (EU) 2024/2865 introduced a new requirement for all distance sales of hazardous substances and mixtures to include all labelling information in the offer, thus ensuring that the buyer is always informed about the hazards before buying the product. That Regulation also expanded requirements for advertisements, requiring them to indicate the hazard pictograms, signal words, hazard statements and supplemental statements and, in addition, to invite general public to follow the information on the product label. Advertisements are means of promoting the sale or use of chemical products, and at the moment of sale the label on the packaging of the substance or mixture or the label information in the distance offer provides full information about the hazards associated with that substance or mixture. It would therefore be appropriate to require advertisements to invite customers to read the label and product information before use, but not to duplicate the hazard information from the label.	label, and required advertisements for substances to mention the hazard classes or hazard categories concerned. Regulation (EU) 2024/2865 introduced a new requirement for all distance sales of hazardous substances and mixtures to include all labelling information in the offer, thus ensuring that the buyer is always informed about the hazards before buying the product. That Regulation also expanded requirements for advertisements, requiring them to indicate the hazard pictograms, signal words, hazard statements and supplemental statements and, in addition, to invite general public to follow the information on the product label. Advertisements are means of promoting the sale or use of chemical products, and at the moment of sale the label on the packaging of the substance or mixture or the label information in the distance offer provides full information about the hazards associated with that substance or mixture. It would therefore be appropriate to require advertisements to invite customers to read the label and product information before use, but not to duplicate **all** the hazard information from the label.	
(10) As Regulation (EC) No 1107/2009 of the European Parliament and of the Council[14] and Regulation (EU) No 528/2012 of the European		

[14] 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).

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Parliament and of the Council[15] require advertisements for authorised plant protection products and biocidal products to use the statement 'Always read the label and product information before use', it would be appropriate to use the same requirement for advertisements of hazardous substances and mixtures to ensure consistency, especially in cases where advertised hazardous substances and mixtures are also authorised plant protection products or biocidal products.		
(11) Regulation (EU) 2024/2865 introduced specific provisions for the labelling of fuels supplied at fuelling stations. To remove unnecessary burdens on businesses, without undermining the protection of human health and the environment, it is necessary to clarify in Annex II of Regulation (EC) No 1272/2008 which of the label elements required by Article 17(1) of that Regulation are not needed on the pump.		
(12) Regulation (EU) 2024/2865 introduced the possibility to include certain labelling elements in the digital label only. To ensure broader use of technology and to allow a simpler and more flexible approach to labelling, suppliers should be allowed to place contact details of any additional suppliers on the digital label only. Inclusion of the digital contact would also be		

[15] 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).

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appropriate where contact details of additional suppliers are provided in the digital label.		
(13) To ensure that suppliers of substances and mixtures have time to adapt to the new rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should not be required to be reclassified or relabelled in accordance with this Regulation, to avoid an additional burden on suppliers of substances and mixtures.		
(14) In line with the transitional provisions of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the new classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before the date of the deferred application of these provisions.		
(15) In accordance with Regulation (EC) No 1223/2009, colorants, preservatives and UV filters may only be used in cosmetic products if they are listed in Annexes IV to VI to that Regulation. To ensure legal certainty for economic operators, a procedure should be provided specifying the different steps in the process for a substance to be included into the respective Annex for the purposes of adapting the Annexes to technical and scientific progress in accordance with Article 31(2) of Regulation (EC) No 1223/2009.		

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(16) Regulation (EC) No 1223/2009 provides the possibility to use in cosmetic products substances classified as CMR substances of category 1A and 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 under certain conditions. A request for derogation should be submitted to the Commission at the latest three months after the entry into force of the respective changes to Part 3 of Annex VI to Regulation (EC) No 1272/2008. As the relevant opinion of the Committee for Risk Assessment proposing the substances for the harmonised classification is made publicly available several months before the Commission follows with the regulatory measure, such deadline is sufficient.		
(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.		
(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be specified. In particular, it should be provided that the		

Commission proposal	Drafting Suggestions	Justifications
use of alternative substance should result in reduced overall risk to human health and the environment and the substance should provide an equivalent or similar function in a cosmetic product, be available on the market in sufficient quantities, so that it can be technically feasible and economically viable for businesses and especially for SMEs. In addition, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives.		
(19) In addition, in order to streamline the derogation procedure, the condition that the derogation request is made for a particular use of a product category with a known exposure should become part of the SCCS assessment criterion. Currently, the scientific committee is already assessing the safety of the substance considering its hazard properties and exposure, (i.e., namely specific use in particular product category), therefore, a separate criterion is redundant.		
(20) Due account should be taken of the specific exposure of cosmetic products, which are mainly placed in contact with the external parts of human body (for example epidermis, hair system, nails, external genital organs) and that they are not ingested, inhaled, injected or implanted into the human body. The prohibition triggered by Article 15 of Regulation (EC) No 1223/2009		

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should cover the substances with CMR harmonised classification under the Regulation (EC) No 1272/2008, where the CMR hazards are not assigned to specific routes of exposure or when they are assigned explicitly to the dermal route of exposure. Where the CMR classification of a substance is only associated with oral or inhalation routes of exposure, its use in cosmetic products does not result in the same level of risk for end-users, since oral and inhalation exposure are incidental (for example, cosmetic products used on lips, teeth or mucous membranes of the oral cavity or cosmetic products used in spray are not intended to be ingested or inhaled). Therefore, such substances should not be subject to a prohibition under Article 15 of Regulation (EC) No 1223/2009. However, the fact that a substance used in oral or sprayable cosmetic products is classified as CMR due to its oral or inhalation route of exposure, may raise concerns for human health. In such cases, the Commission should mandate the SCCS to assess the safety of such substances when used in cosmetic products and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.		
(21) Often a substance can also be a constituent of natural complex substances, for example essential oils. In such cases, the prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 is relevant only to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. This means that natural complex substances that contain a CMR classified constituent		

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are not subject to the prohibition, except if that natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent may raise concerns as to the safety of the natural complex substances when used in cosmetic products, the Commission should mandate the SCCS to assess the impact of such constituent on the safety of natural complex substances, if a safety concern arises, and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.		
(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Therefore, periods of 12 months for placing and 24 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.		
(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, only one notification of the cosmetic products should be required before placing them on the Union market. The conditions of such notification		

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should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them. To maintain vigilance on nanomaterials, it should be required that the specific information on nanomaterials used in a cosmetic product is provided in the cosmetic product safety report so that it can be consulted by the competent authorities where the concerns over the potential risk to human health arise from the use of a particular nanomaterial		
(24) In accordance with Regulation (EU) 2019/1020[16], the Commission has developed an information and communication system for the collection, processing and storing of information on issues relating to the enforcement of Union product legislation, including Regulation (EC) No 1223/2009. In practice this system has replaced the reporting obligation laid down in Article 22 of Regulation (EC) No 1223/2009 requiring the Member States to regularly submit the review and assessment of their surveillance activities to the Commission and other Member States. This reporting obligation should therefore be abolished.		
(25) Cosmetics are globally traded goods. It is therefore important that the ingredient names present on their labels reflect the current state of scientific and technological development. The use of internationally recognised cosmetic ingredient' names is an important		

[16] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

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factor promoting transparency and facilitating cross-border trade in cosmetics. This Regulation should enable internationally recognised names to be used on the labelling of cosmetic products without any additional regulatory action from the Commission. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.		
(26) In line with the Commission's objective to rationalise and simplify reporting requirements and to promote the 'digital by default' principle to support digital transformations, economic operators dealing with EU fertilising products in accordance with Regulation (EU) 2019/1009 should provide a digital contact through which they can be reached, draw up the EU declaration of conformity in electronic form and make it accessible via an internet address or data carrier, and provide authorities, upon request, with all relevant information and documentation in electronic form. Documents and correspondence to and from notified bodies related to conformity assessments of EU fertilising products should also be provided in electronic form. Where a digital label is used, manufacturers should use the same data carrier used for the digital label to provide access to the EU declaration of conformity, to avoid the presence of multiple data carriers on the same product. Where a Digital Product Passport is required for EU fertilising products under other EU legislation, the digital labelling information		

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and the EU declaration of conformity should be provided in that Digital Product Passport.		
(27) Under Regulation (EU) 2019/1009, only micro-organisms listed on a positive list in Annex II to that Regulation may be used as component material in microbial plant biostimulants. The Commission is empowered to add new micro-organisms or strains of micro-organisms to that list after an assessment concluding that none of the strains presents a risk to human, animal or plant health, to safety or to the environment and that it ensures agronomic efficiency. Given the large number of micro-organisms on the market, the assessment and subsequent inclusion of new micro-organisms or strains of micro-organism to the positive list are lagging scientific progress. The current mechanism slows down the development of microbial plant biostimulants and delays farmers' access to those innovative fertilising products which may stimulate plant nutrition processes and thereby reduce the use of traditional fertilisers.		
(28) In order to accelerate the assessment of micro-organisms and to open the single market for more microbial plant biostimulants, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Annex II, Part II, component material category (CMC) 7, to Regulation (EU) 2019/1009 to allow the Commission to introduce general criteria and a methodology for the assessment of micro-organisms. Those criteria and the		

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methodology should allow manufacturers and notified bodies to demonstrate and verify that micro-organisms used in microbial plant biostimulants, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment and ensure agronomic efficiency. In order to refine and validate the criteria and methodology to be introduced, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[17]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
(29) Where the Commission makes use of its empowerment to amend the component material categories in Annex II to Regulation (EU) 2019/1009, it may currently only do so via separate delegated acts in respect of each component material category. Considering the need to introduce additional materials to the various component material categories in the future and the constant technical and scientific progress in the fertilising product sector, there is a		

[17] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

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frequent need to amend the different component material categories. In some cases, for instance where a new raw material may be allowed in multiple CMCs, the Commission would introduce the same change in all relevant CMCs, each of them covered by a different delegated act. To speed up the adoption of the respective delegated acts, the Commission should be allowed to amend several component material categories by one delegated act.		
(30) Chemical substances, on their own or in mixtures, if manufactured or imported in quantities above 1 tonne per company per year, need to be registered in accordance with Regulation (EC) No 1907/2006, with information requirements depending on the actual volume. Regulation (EU) 2019/1009, going beyond the requirements of Regulation (EC) No 1907/2006, requires that all substances used in an EU fertilising products, regardless of the quantity in which they are manufactured or imported, are 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, together with a chemical safety report covering their use in a fertilising product, in accordance with Article 14 of that Regulation. Those extensive information requirements might prevent manufacturers, especially small and medium-sized enterprises, from using substances that are not yet registered according to those requirements or force them to place their products only on national markets		

Commission proposal	Drafting Suggestions	Justifications
according to national rules. For the sake of proportionality, and considering the general obligation of manufactures and importers of substances and EU fertilising products under Regulation (EC) No 1907/2006 and Regulation (EU) 2019/1009, respectively, to ensure the safety of the products that they place on the market, registration of substances used in EU fertilising products should only follow the requirements, including the relevant gradations, set out in Regulation (EC) No 1907/2006.		
(31) To ensure a smooth and effective transition, to minimise disruptions, and to provide a reasonable timeframe for economic operators and authorities to adjust to the new requirements, the application of the amendments to Regulation (EU) 2019/1009 concerning digitalisation should be deferred.		
(32) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of the amendments to Regulation (EU) 2019/1009 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with that Regulation in its version applicable before that date.		
(33) Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 should therefore be amended accordingly,		

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HAVE ADOPTED THIS REGULATION:		
Article 1		
Amendments to Regulation (EC) No 1272/2008		
Regulation (EC) No 1272/2008 is amended as follows:		
(1) in Article 2, the following point is added:		
'42. "digital contact" means any up-to-date and accessible online communication channel through which a supplier can be reached or engaged without the need to register or to download an application.';		
(2) in Article 17(1), point (a) is replaced by the following:		
'(a) the name, address and digital contact of the suppliers;';	'(a) the name, address and digital contact of the supplier~~s~~;';	For the sake of clarity, BE would like to request that it be 'supplier' so that a single address on the physical label is sufficient.
(3) in Article 25(6), the third subparagraph is replaced by the following:		
'The label shall also include the product identifier referred to in Article 18 and the name, address and digital contact of the supplier of the mixture.';		

Commission proposal	Drafting Suggestions	Justifications
(4) in Article 29, paragraph 2 is replaced by the following:		
'2. The label elements set out in Article 17(1) may be reduced in accordance with the rules set out in section 1.5.2 of Annex I.';		
(5) in Article 30, paragraph 1 is replaced by the following:		
'1. In the event of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.';	'1. In the event of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay **and in any event no later than 9 months** after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.';	BE considers that a fixed time limit is essential to ensure legal certainty and a levelled playing field for suppliers, as well as promt and proper information to users of dangerous products. Given that the time limit would be applicable separately to each operator in the supply chain, a time limit of 9 months would ensure a good balance between operators' burden and protection of health and the environmemt.
(6) in Article 31, paragraph 3 is replaced by the following:		
'3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall 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.';	'3.The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall 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.	BE would like to keep clear formating requirements to ensure legal certainty for economic operators and market surveillance authorities. In order to minimise constrains for economic operators, and considering that specific provisions are foreseen for small packagings next to the possibility to use fold-out

Commission proposal	Drafting Suggestions	Justifications
	They shall be formatted in accordance with section 1.2.1 of Annex I.’;	labels, BE proposes to apply the minimum font size of 1,2 mm to all capacities of packagings, instead of 1,4 to 2,0 mm for packagings exceeding 0,5 litres. However, for small packagings, smaller texts may be allowed, following the model used for foodstuffs: the font size may be as small as 0.9 mm for packaging whose longest side has a surface area of less than 80 cm². (see also proposal for Annex I, section 1.2.1.5.)
(7) Article 48 is replaced by the following:		
‘Article 48		
Advertisement		
1. Any advertisement to the general public for a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II shall include the sentence: ‘Always read the label and product information before use.’.	1**. Any advertisement to the general public for a substance or a mixture classified as hazardous shall indicate, as applicable, the hazard pictograms set out in the tables indicating the label elements required for each hazard class in Annex I. By way of derogation, the hazard pictograms may be omitted where the advertisement is non-visual.** **1’.** Any advertisement to the general public for a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II shall include the sentence: ‘Always read the label and product information before use.’.	BE proposes to keep the obligation to indicate the hazard pictograms only for all advertisements in order to inform the general public, as well as professional and industrial users that the product is hazardous. The deletion of the indication of signal words, hazard statements and EUH statements is a substantial simplification.

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2. Any advertisement for a substance or a mixture classified as hazardous shall not contain statements that are not allowed to appear on the label or packaging of that substance or mixture in accordance with Article 25(4).'		
(8) Article 48a is replaced by the following:		
'Article 48a		
Distance sales offers		
When substances or mixtures are placed on the market for the general public through distance sales, the offer shall clearly and visibly indicate the label elements referred to in Article 17.'		BE agrees that the B2B regime can be more flexible than the B2C one, as businesses have other sources of information besides the website (such as internal prevention advisors, etc.). Requiring the adaptation of purely professional websites is a disproportionate demand.
(9) Article 61 is amended as follows:		
(a) paragraph 8 is replaced by the following:		
'8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3) as applicable on 9 December 2024 and which were placed on the market before 1 January 2027 shall not be required to be classified, labelled and packaged in accordance with this Regulation as amended by		

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Regulation (EU) 2024/2865 of the European Parliament and of the Council until 1 January 2029.'		
(b) the following paragraph is added:		
'9. Substances and mixtures which have been labelled in accordance with Article 17(1), Article 25(6) and section 1.5.1.2 and section 1.6 of Annex I as applicable on [*OP: please insert the date of the day before the date of entry into force of this Regulation*] and which were placed on the market before [*OP: please insert 36 months after entry into force of this Regulation*] shall not be required to be labelled in accordance with this Regulation as amended by [*OP: please add reference to this Regulation*] until [*OP: please insert 60 months after entry into force of this Regulation*].'		
(10) Annexes I and II are amended in accordance with Annex I to this Regulation.		
Article 2		
Amendments to Regulation (EC) No 1223/2009		
Regulation (EC) No 1223/2009 is amended as follows:		
(1) The following Article is inserted:		

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'Article 14a		
Requests for inclusion of substances used as colorants, preservatives or UV-filters in Annexes IV, V or VI		
1. A request for a substance to be used as a colorant, preservative or UV-filter to be included in Annex IV, Annex V or Annex VI, as applicable, may be submitted to the Commission. It shall be accompanied by scientific evidence and documentation showing that due to the latest technical and scientific progress, the substance is safe for use in cosmetic products.		
2. After receiving the request referred to in paragraph 1, the Commission shall seek an opinion of the SCCS on the safety of the substance for use in cosmetic products without undue delay.		
3. The SCCS shall transmit its opinion to the Commission within 12 months after receiving the request from the Commission referred to in paragraph 2. The Commission may extend that deadline if additional evidence is required.'		
(2) Article 15 is amended as follows:		
(a) paragraph 2 is amended as follows:		

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(i) the second subparagraph is replaced by the following:		
'2. However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after at the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as CMR substance of category 1A or 1B. The Commission shall grant the derogation where all of the following conditions are fulfilled:		
(a) there are no suitable alternative substances available as documented in an analysis of alternatives;		
(b) the substances have been evaluated and found safe by the SCCS for a particular use of the cosmetic product category, considering exposure to those products, overall exposure from sources other than cosmetics and of vulnerable population groups.'.		
(ii) the third subparagraph is replaced by the following:		
'For the purpose of the second subparagraph, point (a), a substance shall be considered a suitable alternative if it fulfils all of the following conditions:		

Commission proposal	Drafting Suggestions	Justifications
(a) its use in cosmetic products results in reduced overall risk to human health and the environment;		
(b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy;		
(c) is technically feasible and economically viable;		
(d) it is not restricted, not protected by exclusive rights, and is available on the market at scale, in quantities large enough to meet current and expected demand.'		
(iii) the following subparagraph is inserted after the fourth subparagraph:		
'The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into application of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of category 1A, or 1B.';		
(b) the following paragraphs 5, 6 and 7 are added:		
'5. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance where the oral or inhalation route of exposure for CMR harmonised classification has been explicitly indicated in the 'Hazard statement Code(s)' column under the 'Classification' in Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a		

Commission proposal	Drafting Suggestions	Justifications
potential risk to human health arises from cosmetic products containing such substance due to incidental ingestion or inhalation, the Commission shall request an SCCS opinion on the safety of the substance concerned in those specific product types without undue delay.		
6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from the use of such substance in cosmetic products, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without undue delay.		
For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.		
7. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for 12 months and be made available on the market for 24 months after		

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the entry into force of the relevant amendments to the relevant Annexes to this Regulation.'		
;		
(3) In Article 16, paragraphs 3 and 7 are deleted;		
(4) In Article 19, paragraph 6 is replaced by the following:		
'6. The information mentioned in paragraph 1, point (g) shall be expressed by using the common ingredient name in accordance with the internationally recognised nomenclature and in the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.'		
;		
(5) In Article 22, fourth subparagraph, the second sentence is deleted;		
(6) Article 33 is deleted;		
(7) Annex I is amended in accordance with Annex II to this Regulation;		
(8) Annexes II to VI are amended in accordance with Annex III this Regulation.		

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Article 3		
Amendments to Regulation (EU) 2019/1009		
Regulation (EU) 2019/1009 is amended as follows:		
(1) in Article 2, the following point (15a) is inserted:		
'(15a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;'		
;		
(2) Article 6 is amended as follows:		
(a) paragraph 2 is amended as follows:		
(i) the second subparagraph is replaced by the following:		
'Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.';		

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(ii) the following subparagraph is added:		
'Manufacturers shall ensure that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.';		
(b) in paragraph 3, the second subparagraph is replaced by the following:		
'On request, manufacturers shall make the EU declaration of conformity available to other economic operators in electronic form.';		
(c) in paragraph 6, first subparagraph, the first and second sentences are replaced by the following:		
'Manufacturers shall indicate on the packaging of the EU fertilising product their name, registered trade name or registered trademark as well as their postal address and digital contact or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.'		
(d) in paragraph 9, the first sentence is replaced by the following:		
'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and		

Commission proposal	Drafting Suggestions	Justifications
documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.'		
;		
(3) in Article 7(2), point (b) is replaced by the following:		
'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;'		
;		
(4) Article 8 is amended as follows:		
(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:		
'They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).'		

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;		
(b) in paragraph 3, the first sentence is replaced by the following:		
'Importers shall indicate their name, registered trade name or registered trade mark as well as their postal address and digital contact on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product.'		
;		
(c) paragraph 8 is replaced by the following:		
'8. Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.		
On request, importers shall make the EU declaration of conformity available to other economic operators in electronic form.'		
;		
(d) in paragraph 9, the first sentence is replaced by the following:		

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'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority.'		
;		
(5) Article 9 is amended as follows:		
(a) in paragraph 2, the first subparagraph is replaced by the following:		
'Before making an EU fertilising product available on the market, distributors shall verify that it is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, including the information referred to in Article 6(7) or Article 8(4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.'		
;		

Commission proposal	Drafting Suggestions	Justifications
(b) in paragraph 5, the first sentence is replaced by the following:		
'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation.'		
;		
(6) Article 15 is amended as follows:		
(a) paragraph 2 is replaced by the following:		
'2. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures is established or in a language accepted by that body.'		
(b) the following paragraph 3 is added:		
'3. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.'		
;		

Commission proposal	Drafting Suggestions	Justifications
(7) in Article 16, the following paragraphs 5 and 6 are added:		
'5. The EU declaration of conformity shall be provided in a machine-readable and open format as defined in Article 2, points (13) and (14), of Directive (EU) 2019/1024 of the European Parliament and of the Council* and meet the requirements for digital labels set out in Article 11b(4), points (a) to (d).		
Where a data carrier is used for providing access to the EU declaration of conformity, it should accompany the product in accordance with Article 11b(5) and be based on one of the electronic technical solutions which economic operators can use for providing the digital label established on the basis of Article 42(9). Economic operators providing the EU declaration of conformity using a data carrier shall not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the relevant information digitally.		
Where a digital label is used in accordance with Article 11a, the data carrier used for the digital label shall also provide access to the EU declaration of conformity.		
*Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, (OJ L 172, 26.06.2019, p. 56, ELI: http://data.europa.eu/eli/dir/2019/1024/oj).'		

Commission proposal	Drafting Suggestions	Justifications
6. Where other Union legislation applicable to EU fertilising products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity in a digital product passport, the information set out in Annex V to be included in the EU declaration of conformity and any digital labelling information in accordance with Article 11b, if applicable, shall be provided only in that digital product passport.'		
;		
(8) in Article 41(1), point (c) is replaced by the following:		
'(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly, or the EU fertilising product is not accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.'		
(9) Article 42 is amended as follows:		
(a) in paragraph 4, the introductory statement is replaced by the following:		
'The Commission may adopt delegated acts pursuant to paragraph 1 amending Annex II to add new micro-organisms or strains of micro-organisms, or additional		

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processing methods to the component material category for such organisms after having verified which strains of the additional micro-organism fulfil the criteria in paragraph 1, point (b), on the basis of the following data:'		
;		
(b) the following paragraph 4a is inserted:		
'4a. The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to set out criteria and a methodology for the assessment of micro-organisms other than those listed in Annex II, which, if compliance with those criteria is demonstrated in the conformity assessment of the EU fertilising product in accordance with that methodology, may be used as component material in EU fertilising products. The criteria and methodology shall allow for verification that the micro-organisms fulfil the criteria in paragraph 1, point (b), and provide, as a minimum, for the consideration of the following elements:		
(a) scientific literature reporting about safe production, conservation and use of the micro-organism;		
(b) taxonomic relation of the micro-organism to micro-organisms species fulfilling the requirements for a Qualified Presumption of Safety as established by the European Food Safety Authority;		

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(c) information on the production process of the micro-organism, including, where relevant, the composition of the cultivation medium, processing methods such as spray drying, fluid-bed drying, static drying, centrifugation, deactivation by heat, filtration and grinding;		
(d) information on the identity and residue levels of residual intermediates, toxins or microbial metabolites in the component material;		
(e) natural occurrence, survival and mobility in the environment;		
(f) susceptibility to all relevant antimicrobial agents as defined in the Annex, Introduction to Part B, point (ii)(28), to Commission Regulation (EU) No 283/2013*, with the exception of intrinsic resistance.		
*Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/283/oj).'		
;		
(10) Article 43 is deleted;		

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(11) Annexes I, II and IV to Regulation (EU) 2019/1009 are amended in accordance with Annex IV to this Regulation.		
Article 4		
Transitional provisions		
1. By way of derogation from section 1.5.2.4.1 and section 1.5.2.4.2 of Annex I to Regulation (EC) No 1272/2008 as applicable on 9 December 2024 substances and mixtures may until 30 June 2026 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by points (5), (6) and (7) of Annex I to this Regulation.		
By way of derogation from Article 30 and Article 48 of Regulation (EC) No 1272/2008 and Part 5 of Annex II to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may until 31 December 2027 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (5), (7) and (8) of this Regulation and point (9) of Annex I to this Regulation.		
By way of derogation from Article 17(1), Article 25(6) of Regulation (EC) No 1272/2008, section 1.5.1.2 and section 1.6 of Annex I to Regulation (EC) No 1272/2008 as applicable on [*OP: please insert the date of the day before the date of entry into force of this Regulation*],		

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substances and mixtures may until [*OP: please insert the date of the last day of the month following 35 months after the date of entry into force of this Regulation*] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (2) and (3) of this Regulation and points (3) and (8) of Annex I to this Regulation.		
2. Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulation (EU) 2019/1009 before [*OP: please insert 24 months after entry into force of this amending Regulation)*].		
Article 5		
Entry into force and application		
1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.		
2. Points (4) to (7) of Annex I shall apply from 1 July 2026.		
3. Article 1, points (5) to (8) and points (1), (2) and (9) of Annex I shall apply from 1 January 2028.		
4. Article 1, points (1), (2) and (3), points (3) and (8) of Annex I shall apply from [O*P: please insert the*		

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date of 36 months after the entry into force of this Regulation)]		
5. Article 2, point (1) to (8) shall apply from [OP: please insert the date of entry into force of this Regulation)]		
6. Article 3, point (1) to (8), and Annex IV, point (1) and (3), shall apply from [OP: please insert 24 months after entry into force of this Regulation].		
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
ANNEX I		
Annexes I and II to Regulation (EC) No 1272/2008 are amended as follows		
(1) in Annex I, section 1.2.1.4 is replaced by the following:		
'1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:		
Table 1.3 **Minimum dimensions of labels and pictograms**		
Capacity of the package / **Dimensions of the label (in millimetres) for** / **Dimensions of each pictogram (in millimetres)**		

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	the information required by Article 17			
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16		
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23		
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32×32		
Greater than 500 litres:	At least 148 × 210	At least 46×46		
’;				
(2) in Annex I, section 1.2.1.5 is deleted;			(2) in Annex I, section 1.2.1.5 is **replaced by the following:** **‘The text on the label shall have the following characteristics:** **(a) printed in black on a white background;**	BE would like to keep clear formating requirements to ensure legal certainty for economic operators and market surveillance authorities. In order to minimise constrains for economic operators, and considering that specific provisions are foreseen for small packagings next to the possibility to use fold-out labels, BE proposes to apply the minimum font size of 1,2 mm to all capacities of packagings, instead of 1,4 to

Commission proposal	Drafting Suggestions	Justifications
	(b) <u>the distance between two lines shall be at least 120 % of the font size;</u> **(c) <u>a single font that is easily legible and without serifs shall be used;</u>** **(d) <u>the letter spacing shall be appropriate for the selected font to be easily legible;</u>** **(e) <u>the minimum font size shall be at least 1,2 mm x-height. For the labelling of inner packaging where the content do not exceed 10 ml, the font size may be smaller, 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.'</u>** **(f) <u>For the labelling of packaging the largest surface of which has an area of less than 80 cm^2, the font size shall be equal to or greater than 0,9 mm x-height.</u>**	2,0 mm for packagings exceeding 0,5 litres. However, taking into account the Belgian context where sometimes three languages are required on the label, BE proposes to make an exception for small packages. Smaller texts may be allowed, following the model used for foodstuffs: the font size may be as small as 0.9 mm for packaging whose longest side has a surface area of less than 80 cm^2.

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(3) in Annex I, section 1.5.1.2 is replaced by the following:		
'1.5.1.2. Where section 1.5.1.1 applies, the label on any inner packaging shall contain at least the hazard pictograms, the signal words, the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and digital contact of the suppliers of the substance or mixture.';		
(4) the heading of section 1.5.2.4 is replaced by the following:		
'1.5.2.4 Labelling of packages where the contents do not exceed 10 ml ';		
(5) in Annex I, section 1.5.2.4.1 is replaced by the following:		
'1.5.2.4.1. The label elements set out in Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml, the outer packaging meets the requirements set out in Article 17(1) and any of the following applies:		BE would maintain flexibility if certain Member States propose possible relaxations for slightly larger containers (e.g., 75 ml as proposed by France).
the substance or mixture is placed on the market for scientific research and development or quality control analysis;		
the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II, except for	the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II~~, except for~~	BE does not support the exception foreseen in the new section 1.5.2.4.3., when section 2.8 of Part 2 of Annex

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section 2.8 of Part 2 of Annex II, and is not classified in any of the following hazard classes and categories:	~~section 2.8 of Part 2 of Annex II~~, and is not classified in any of the following hazard classes and categories:	II applies, because skin sensitizing hazard and skin allergens (EUH208) would not be labelled anymore, nor on the inner/primary packaging, nor on an eventual outer packaging. **This information should be labelled at least on the outer packaging where applicable; if there is no outer packaging, this information should be mentioned on the primary packaging.**
acute toxicity, any category;		
specific target organ toxicity – single exposure, categories 1 and 2;		
specific target organ toxicity – repeated exposure, any category;		
skin corrosion, category 1, any sub-category;		
serious eye damage, category 1;		
respiratory sensitisation, any category;		
aspiration hazard;		
germ cell mutagenicity, any category;		
carcinogenicity, any category;		

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reproductive toxicity, any category;		
endocrine disruption for human health, any category.';		
(6) in Annex I, section 1.5.2.4.2 is replaced by the following:		
'1.5.2.4.2. Where section 1.5.2.4.1 applies, the label on the inner packaging shall contain the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and, where applicable, the hazard pictograms 'GHS01', 'GHS05', 'GHS06' or 'GHS08'. Where more than two pictograms are assigned, 'GHS06' and 'GHS08' may take precedence over 'GHS01' and 'GHS05'.';		
(7) in Annex I, section 1.5.2.4.3 is added:	~~(~~7) in Annex I, section 1.5.2.4.3 is added:	BE: When a substance or mixture requires labelling in accordance with section 2.8 of Part 2 of Annex II (mixtures containing at least one sensitising substance), the EUH208 statement informing on the sensitising substance and the danger of allergic reaction, **should be labelled at least on the outer packaging; if there is no outer packaging, this information should be mentioned on the primary packaging.**
'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted from the package provided that the following conditions are met:	'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted from the package provided that the following conditions are met:	

Commission proposal	Drafting Suggestions	Justifications
the contents of the package do not exceed 10 ml;	the contents of the package do not exceed 10 ml;	BE would maintain flexibility if certain Member States propose possible relaxations for slightly larger containers (e.g., 75 ml as proposed by France).
the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II, except for section 2.8 of Part 2 of Annex II;	the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II, ~~except for section 2.8 of Part 2 of Annex II~~;	
the substance or mixture is not classified in any of the hazard classes and categories referred to in point (b) of section 1.5.2.4.1.';	the substance or mixture is not classified in any of the hazard classes and categories referred to in point (b) of section 1.5.2.4.1.';	
(8) in Annex I, section 1.6 is replaced by the following:		
'1.6. Label elements that may be provided on a digital label only		
(a) Supplemental information referred to in Article 25(3);		
(b) Where more than one supplier is indicated on the label in accordance with Article 17(1), point (a), the name, address and digital contact of the suppliers may be provided on a digital label only, as long as the supplier referred to in in Article 4(11) is indicated on the physical label.';		
(9) in Annex II, Part 5 is replaced by the following:		

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'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES		
Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.		
For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the copy of the label elements referred to in Article 17, points (c) to (h) shall be provided on a visible place on the respective pump. The unique formula identifier referred to in Article 25(7) does not need to be provided.		
When a vehicle fuel is supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a copy of the label elements referred to in Article 17, points (c) to (h), shall be provided to be attached to the receptacle, unless the receptacle is already appropriately labelled. The unique formula identifier referred to in Article 25(7) does not need to be provided.'.		
ANNEX II		
In Annex I to Regulation (EC) No 1223/2009 Part A, point 2 is replaced by the following:		

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'2. Physical/chemical characteristics and stability of the cosmetic product		
The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.		
The stability of the cosmetics product under reasonably foreseeable storage conditions.		
The specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the preamble to Annexes II to VI, size of particles, physical and chemical properties.		
The safety data of the nanomaterial (including its toxicological profile and exposure conditions) relating to the category of cosmetic product, as used in such products.'		
ANNEX III		
Annexes II to VI to Regulation (EC) No 1223/2009 are amended as follows:		
(1) in the preamble to Annexes II to VI, point 2, the fifth indent is replaced by the following:		
'- the name included in the internationally recognised nomenclature.';		
(2) in the heading of tables in Annexes III to VI the title 'Name of Common Ingredients Glossary' is		

Commission proposal	Drafting Suggestions	Justifications
replaced by 'Name in the Internationally Recognised Nomenclature'.		
ANNEX IV		
Annexes I, II and IV to Regulation (EU) 2019/1009 are amended as follows:		
(1) in Annex I, Part II, PFC 7: FERTILISING PRODUCT BLEND, point 4(c) is replaced by the following:		
'(c) Article 8(8) (importers' obligation to keep the EU declaration of conformity at the disposal of the market surveillance authorities).';		
in Annex II, Part II, is amended as follows:		
in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is deleted;		
in CMC 3: COMPOST, point 1(d) is replaced by the following:		
'(d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';		
CMC 4: FRESH CROP DIGESTATE is amended as follows:		

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(i) point 1(b) is replaced by the following:		
'(b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';		
(ii) point 3d is replaced by the following:		
'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.';		
CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE is amended as follows		
(i) point 1(d) is replaced by the following:		
'(d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';		
(ii) point 3d is replaced by the following:		
'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b		

Commission proposal	Drafting Suggestions	Justifications
and 3c may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.’;		
in CMC 6: FOOD INDUSTRY BY-PRODUCTS, point 2 is deleted;		
in CMC 8: NUTRIENT POLYMERS, point 1 is replaced by the following:		
‘1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in point 1 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.’;		
in CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) No 1069/2009, the table, point 1.3 is replaced by the following:		
‘1.3. Additives needed in the processing referred to in points 1.1 and 1.2 may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the processed manure or fraction used as input in the respective process.’;		
in CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC, point 2 is deleted;		

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in CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES, point 13 is deleted;		
in CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES, point 8 is deleted;		
in CMC 14: PYROLYSIS AND GASIFICATION MATERIALS, point 7 is deleted;		
in CMC 15: RECOVERED HIGH PURITY MATERIALS, point 10 is deleted;		
in Annex IV, Part II is amended as follows:		
MODULE A – INTERNAL PRODUCTION CONTROL is amended as follows:		
(i) in point 4.2, the first sentence is replaced by the following:		
'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.';		
(ii) point 4.3. is replaced by the following:		
'4.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and		

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documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’;		
MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING is amended as follows:		
(i) point 2.2.(f) is replaced by the following:		
‘(f) the names, postal addresses and digital contacts of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,’;		
(ii) in point 5.2., the first sentence is replaced by the following:		
‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;		
(iii) point 5.3. is replaced by the following:		
‘5.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this		

Commission proposal	Drafting Suggestions	Justifications
Regulation, in a language which can be easily understood by that authority.’;		
MODULE B – EU-TYPE EXAMINATION is amended as follows:		
(i) point 3.2.(a) is replaced by the following:		
‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,’;		
(ii) in point 6.1., the second sentence is replaced by the following:		
‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;		
MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL is amended as follows:		
(i) in point 3.2., the first sentence is replaced by the following:		
‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical		

Commission proposal	Drafting Suggestions	Justifications
documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;		
(ii) point 3.3. is replaced by the following:		
‘3.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’;		
MODULE D1 - QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:		
(i) in point 5.2., the first indent is replaced by the following:		
‘the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,’;		
(ii) in point 7.2., the first sentence is replaced by the following:		
‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national		

Commission proposal	Drafting Suggestions	Justifications
authorities for 5 years after the EU fertilising product has been placed on the market.’;		
(iii) point 7.3. is replaced by the following:		
‘The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’		

Italy

Commission proposal	Drafting Suggestions	Justifications
General Comments		
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		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national Parliaments,		
Having regard to the opinion of the European Economic and Social Committee[18],		

[18] OJ C [...], [...], p. [...].

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Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) High quality and safety requirements for products on the Single Market ensure a high level of protection of human health and the environment and contribute to a fair and sustainable economy. In international competition, the reputation of high-grade products manufactured in the Union can create an advantage for Union companies.		
(2) The findings of the 2024 Draghi report[19] indicated that the increasing number and complexity of rules risks limiting room for manoeuvre for Union businesses and preventing them from remaining competitive. Against this background, certain procedures and requirements laid down in Regulations (EC) No 1272/2008[20], (EC) No 1223/2009[21] and (EU) 2019/1009[22] of the European Parliament and of the Council should be simplified and unnecessary regulatory burdens should be removed, while		

[19] 2024 report by Mario Draghi on the future of European competitiveness: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059

[20] 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).

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

[22] 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).

Commission proposal	Drafting Suggestions	Justifications
maintaining the same level of protection of human health and of the environment.		
(3) In line with the Commission's objective to promote the 'digital by default' principle to support digital transformations and in order to facilitate communication between economic operators and national authorities responsible for enforcement, the indication of a digital contact on the label of hazardous substances and mixtures is necessary to enhance the effectiveness of official controls and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008. Currently, suppliers are required to indicate their address and telephone number on the label of the packaging of hazardous substances or mixtures, but this is not always sufficient to ensure that authorities responsible for enforcement can establish rapid contact. It is therefore necessary to require suppliers to provide a digital contact, which could be any up-to-date and accessible online communication channel with the supplier.		
(4) Regulation (EC) No 1272/2008 laid down the exemptions from labelling and packaging requirements for packaging of specific shapes, forms or sizes. Those exemptions can only be triggered if all required label elements do not fit on the outer packaging or on a tie-on tag. To simplify the use of those exemptions, it is appropriate to allow the existing exemptions to be applied to smaller packages without the need to prove		

Commission proposal	Drafting Suggestions	Justifications
the impossibility of using the outer packaging or tie-on tag.		
(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[23] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208. It is also necessary to clarify the requirements for inner and outer packaging in cases where the 10 ml derogation is applied.	(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[24] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, further simplifications are needed with regard to the application of this derogation in cases where these packages are subject **only** to the supplementary hazard statement EUH 208. It is also necessary to clarify the requirements for inner and outer packaging in cases where the 10 ml derogation is applied.	We agree with the need to clarify the requirements for inner and outer packaging. Does the Commission could offer an addition clarification on the relevant sector that could benefit on the semplificationon EUH208, please? Please refer to the comment on Annex I, section 1.5.2.4.1
(6) In order to provide the flexibility for suppliers of substances and mixtures, to create equal conditions for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to remove a fixed six months relabelling deadline and to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.		
(7) Regulation (EU) 2024/2865 laid down rules on mandatory requirements for label formatting. New		

[23] 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).

[24] 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).

Commission proposal	Drafting Suggestions	Justifications
information[25] pointed to excessive administrative burden and costs, associated with these requirements. To balance the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[26], it is necessary to simplify the current formatting obligations without reducing the level of protection of human health and the environment. Economic operators and enforcement authorities must remain responsible for ensuring that the labels are legible in accordance with the legal requirements.		
(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, requirements for advertisements and distance offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[27] already provides clear		

[25] Detailed analysis of costs associated with new formatting requirements is provided in the Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

[26] As outlined in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10, available at: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

[27] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and

Commission proposal	Drafting Suggestions	Justifications
obligations on information flows in supply chains for substances and mixtures.		
(9) Before the amendments introduced by Regulation (EU) 2024/2865, Regulation (EC) No 1272/2008 required the advertisements for hazardous mixtures, for which a member of the general public is allowed to conclude a contract for purchase without first having sight of the label, to mention the type or types of hazards indicated on the label, and required advertisements for substances to mention the hazard classes or hazard categories concerned. Regulation (EU) 2024/2865 introduced a new requirement for all distance sales of hazardous substances and mixtures to include all labelling information in the offer, thus ensuring that the buyer is always informed about the hazards before buying the product. That Regulation also expanded requirements for advertisements, requiring them to indicate the hazard pictograms, signal words, hazard statements and supplemental statements and, in addition, to invite general public to follow the information on the product label. Advertisements are means of promoting the sale or use of chemical products, and at the moment of sale the label on the packaging of the substance or mixture or the label information in the distance offer provides full information about the hazards associated with that substance or mixture. It would therefore be appropriate to require advertisements to invite customers to read		

Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

Commission proposal	Drafting Suggestions	Justifications
the label and product information before use, but not to duplicate the hazard information from the label.		
(10) As Regulation (EC) No 1107/2009 of the European Parliament and of the Council[28] and Regulation (EU) No 528/2012 of the European Parliament and of the Council[29] require advertisements for authorised plant protection products and biocidal products to use the statement 'Always read the label and product information before use', it would be appropriate to use the same requirement for advertisements of hazardous substances and mixtures to ensure consistency, especially in cases where advertised hazardous substances and mixtures are also authorised plant protection products or biocidal products.		
(11) Regulation (EU) 2024/2865 introduced specific provisions for the labelling of fuels supplied at fuelling stations. To remove unnecessary burdens on businesses, without undermining the protection of human health and the environment, it is necessary to clarify in Annex II of Regulation (EC) No 1272/2008 which of the label elements required by Article 17(1) of that Regulation are not needed on the pump.		

[28] 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).

[29] 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).

Commission proposal	Drafting Suggestions	Justifications
(12) Regulation (EU) 2024/2865 introduced the possibility to include certain labelling elements in the digital label only. To ensure broader use of technology and to allow a simpler and more flexible approach to labelling, suppliers should be allowed to place contact details of any additional suppliers on the digital label only. Inclusion of the digital contact would also be appropriate where contact details of additional suppliers are provided in the digital label.		
(13) To ensure that suppliers of substances and mixtures have time to adapt to the new rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should not be required to be reclassified or relabelled in accordance with this Regulation, to avoid an additional burden on suppliers of substances and mixtures.		
(14) In line with the transitional provisions of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the new classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before the date of the deferred application of these provisions.		
(15) In accordance with Regulation (EC) No 1223/2009, colorants, preservatives and UV filters may only be used in cosmetic products if they are listed		

Commission proposal	Drafting Suggestions	Justifications
in Annexes IV to VI to that Regulation. To ensure legal certainty for economic operators, a procedure should be provided specifying the different steps in the process for a substance to be included into the respective Annex for the purposes of adapting the Annexes to technical and scientific progress in accordance with Article 31(2) of Regulation (EC) No 1223/2009.		
(16) Regulation (EC) No 1223/2009 provides the possibility to use in cosmetic products substances classified as CMR substances of category 1A and 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 under certain conditions. A request for derogation should be submitted to the Commission at the latest three months after the entry into force of the respective changes to Part 3 of Annex VI to Regulation (EC) No 1272/2008. As the relevant opinion of the Committee for Risk Assessment proposing the substances for the harmonised classification is made publicly available several months before the Commission follows with the regulatory measure, such deadline is sufficient.		
(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not		

Commission proposal	Drafting Suggestions	Justifications
enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.		
(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be specified. In particular, it should be provided that the use of alternative substance should result in reduced overall risk to human health and the environment and the substance should provide an equivalent or similar function in a cosmetic product, be available on the market in sufficient quantities, so that it can be technically feasible and economically viable for businesses and especially for SMEs. In addition, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives.		
(19) In addition, in order to streamline the derogation procedure, the condition that the derogation request is made for a particular use of a product category with a known exposure should become part of the SCCS assessment criterion. Currently, the scientific committee is already assessing the safety of the substance considering its hazard properties and exposure, (i.e., namely specific use in particular product category), therefore, a separate criterion is redundant.		

Commission proposal	Drafting Suggestions	Justifications
(20) Due account should be taken of the specific exposure of cosmetic products, which are mainly placed in contact with the external parts of human body (for example epidermis, hair system, nails, external genital organs) and that they are not ingested, inhaled, injected or implanted into the human body. The prohibition triggered by Article 15 of Regulation (EC) No 1223/2009 should cover the substances with CMR harmonised classification under the Regulation (EC) No 1272/2008, where the CMR hazards are not assigned to specific routes of exposure or when they are assigned explicitly to the dermal route of exposure. Where the CMR classification of a substance is only associated with oral or inhalation routes of exposure, its use in cosmetic products does not result in the same level of risk for end-users, since oral and inhalation exposure are incidental (for example, cosmetic products used on lips, teeth or mucous membranes of the oral cavity or cosmetic products used in spray are not intended to be ingested or inhaled). Therefore, such substances should not be subject to a prohibition under Article 15 of Regulation (EC) No 1223/2009. However, the fact that a substance used in oral or sprayable cosmetic products is classified as CMR due to its oral or inhalation route of exposure, may raise concerns for human health. In such cases, the Commission should mandate the SCCS to assess the safety of such substances when used in cosmetic products and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.		

Commission proposal	Drafting Suggestions	Justifications
(21) Often a substance can also be a constituent of natural complex substances, for example essential oils. In such cases, the prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 is relevant only to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. This means that natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except if that natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent may raise concerns as to the safety of the natural complex substances when used in cosmetic products, the Commission should mandate the SCCS to assess the impact of such constituent on the safety of natural complex substances, if a safety concern arises, and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.		
(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Therefore, periods of 12 months for placing and 24 months for making available on the market of cosmetic products		

Commission proposal	Drafting Suggestions	Justifications
containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.		
(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, only one notification of the cosmetic products should be required before placing them on the Union market. The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them. To maintain vigilance on nanomaterials, it should be required that the specific information on nanomaterials used in a cosmetic product is provided in the cosmetic product safety report so that it can be consulted by the competent authorities where the concerns over the potential risk to human health arise from the use of a particular nanomaterial		
(24) In accordance with Regulation (EU) 2019/1020[30], the Commission has developed an information and communication system for the collection, processing and storing of information on issues relating to the enforcement of Union product legislation, including Regulation (EC) No 1223/2009. In practice this system has replaced the reporting obligation laid down in Article 22 of Regulation (EC) No 1223/2009 requiring the Member States to regularly		

[30] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

Commission proposal	Drafting Suggestions	Justifications
submit the review and assessment of their surveillance activities to the Commission and other Member States. This reporting obligation should therefore be abolished.		
(25) Cosmetics are globally traded goods. It is therefore important that the ingredient names present on their labels reflect the current state of scientific and technological development. The use of internationally recognised cosmetic ingredient' names is an important factor promoting transparency and facilitating cross-border trade in cosmetics. This Regulation should enable internationally recognised names to be used on the labelling of cosmetic products without any additional regulatory action from the Commission. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.		
(26) In line with the Commission's objective to rationalise and simplify reporting requirements and to promote the 'digital by default' principle to support digital transformations, economic operators dealing with EU fertilising products in accordance with Regulation (EU) 2019/1009 should provide a digital contact through which they can be reached, draw up the EU declaration of conformity in electronic form and make it accessible via an internet address or data carrier, and provide authorities, upon request, with all relevant information and documentation in electronic form. Documents and correspondence to and from notified bodies related to conformity assessments of EU		

Commission proposal	Drafting Suggestions	Justifications
fertilising products should also be provided in electronic form. Where a digital label is used, manufacturers should use the same data carrier used for the digital label to provide access to the EU declaration of conformity, to avoid the presence of multiple data carriers on the same product. Where a Digital Product Passport is required for EU fertilising products under other EU legislation, the digital labelling information and the EU declaration of conformity should be provided in that Digital Product Passport.		
(27) Under Regulation (EU) 2019/1009, only micro-organisms listed on a positive list in Annex II to that Regulation may be used as component material in microbial plant biostimulants. The Commission is empowered to add new micro-organisms or strains of micro-organisms to that list after an assessment concluding that none of the strains presents a risk to human, animal or plant health, to safety or to the environment and that it ensures agronomic efficiency. Given the large number of micro-organisms on the market, the assessment and subsequent inclusion of new micro-organisms or strains of micro-organism to the positive list are lagging scientific progress. The current mechanism slows down the development of microbial plant biostimulants and delays farmers' access to those innovative fertilising products which may stimulate plant nutrition processes and thereby reduce the use of traditional fertilisers.		
(28) In order to accelerate the assessment of micro-organisms and to open the single market for more		

Commission proposal	Drafting Suggestions	Justifications
microbial plant biostimulants, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Annex II, Part II, component material category (CMC) 7, to Regulation (EU) 2019/1009 to allow the Commission to introduce general criteria and a methodology for the assessment of micro-organisms. Those criteria and the methodology should allow manufacturers and notified bodies to demonstrate and verify that micro-organisms used in microbial plant biostimulants, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment and ensure agronomic efficiency. In order to refine and validate the criteria and methodology to be introduced, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[31]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		

[31] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

Commission proposal	Drafting Suggestions	Justifications
(29) Where the Commission makes use of its empowerment to amend the component material categories in Annex II to Regulation (EU) 2019/1009, it may currently only do so via separate delegated acts in respect of each component material category. Considering the need to introduce additional materials to the various component material categories in the future and the constant technical and scientific progress in the fertilising product sector, there is a frequent need to amend the different component material categories. In some cases, for instance where a new raw material may be allowed in multiple CMCs, the Commission would introduce the same change in all relevant CMCs, each of them covered by a different delegated act. To speed up the adoption of the respective delegated acts, the Commission should be allowed to amend several component material categories by one delegated act.		
(30) Chemical substances, on their own or in mixtures, if manufactured or imported in quantities above 1 tonne per company per year, need to be registered in accordance with Regulation (EC) No 1907/2006, with information requirements depending on the actual volume. Regulation (EU) 2019/1009, going beyond the requirements of Regulation (EC) No 1907/2006, requires that all substances used in an EU fertilising products, regardless of the quantity in which they are manufactured or imported, are registered, as a minimum, with the information requirements set out by Regulation (EC)		

Commission proposal	Drafting Suggestions	Justifications
No 1907/2006 for substances manufactured or imported in quantities of 10 to 100 tonnes per company per year, together with a chemical safety report covering their use in a fertilising product, in accordance with Article 14 of that Regulation. Those extensive information requirements might prevent manufacturers, especially small and medium-sized enterprises, from using substances that are not yet registered according to those requirements or force them to place their products only on national markets according to national rules. For the sake of proportionality, and considering the general obligation of manufactures and importers of substances and EU fertilising products under Regulation (EC) No 1907/2006 and Regulation (EU) 2019/1009, respectively, to ensure the safety of the products that they place on the market, registration of substances used in EU fertilising products should only follow the requirements, including the relevant gradations, set out in Regulation (EC) No 1907/2006.		
(31) To ensure a smooth and effective transition, to minimise disruptions, and to provide a reasonable timeframe for economic operators and authorities to adjust to the new requirements, the application of the amendments to Regulation (EU) 2019/1009 concerning digitalisation should be deferred.		
(32) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of the amendments to Regulation (EU) 2019/1009 concerning		

Commission proposal	Drafting Suggestions	Justifications
digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with that Regulation in its version applicable before that date.		
(33) Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 should therefore be amended accordingly,		
HAVE ADOPTED THIS REGULATION:		
Article 1		
Amendments to Regulation (EC) No 1272/2008		
Regulation (EC) No 1272/2008 is amended as follows:		
(1) in Article 2, the following point is added:		
'42. "digital contact" means any up-to-date and accessible online communication channel through which a supplier can be reached or engaged without the need to register or to download an application.';		
(2) in Article 17(1), point (a) is replaced by the following:		
'(a) the name, address and digital contact of the suppliers;';		

Commission proposal	Drafting Suggestions	Justifications
(3) in Article 25(6), the third subparagraph is replaced by the following:		
'The label shall also include the product identifier referred to in Article 18 and the name, address and digital contact of the supplier of the mixture.';		
(4) in Article 29, paragraph 2 is replaced by the following:		
'2. The label elements set out in Article 17(1) may be reduced in accordance with the rules set out in section 1.5.2 of Annex I.';		
(5) in Article 30, paragraph 1 is replaced by the following:		
'1. In the event of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.';		
(6) in Article 31, paragraph 3 is replaced by the following:		

Commission proposal	Drafting Suggestions	Justifications
'3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall 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.';		
(7) Article 48 is replaced by the following:		
'Article 48		
Advertisement		
1. Any advertisement to the general public for a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II shall include the sentence: 'Always read the label and product information before use.'.		
2. Any advertisement for a substance or a mixture classified as hazardous shall not contain statements that are not allowed to appear on the label or packaging of that substance or mixture in accordance with Article 25(4).'		
(8) Article 48a is replaced by the following:		
'Article 48a		
Distance sales offers		

Commission proposal	Drafting Suggestions	Justifications
When substances or mixtures are placed on the market for the general public through distance sales, the offer shall clearly and visibly indicate the label elements referred to in Article 17.'		
(9) Article 61 is amended as follows:		
(a) paragraph 8 is replaced by the following:		
'8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3) as applicable on 9 December 2024 and which were placed on the market before 1 January 2027 shall not be required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation (EU) 2024/2865 of the European Parliament and of the Council until 1 January 2029.'		
(b) the following paragraph is added:		
'9. Substances and mixtures which have been labelled in accordance with Article 17(1), Article 25(6) and section 1.5.1.2 and section 1.6 of Annex I as applicable on [*OP: please insert the date of the day before the date of entry into force of this Regulation*] and which were placed on the market before [*OP: please insert 36 months after entry into force of this Regulation*] shall not be required to be labelled in accordance with this Regulation as amended by [*OP: please add reference to this Regulation*] until [*OP: please insert 60 months after entry into force of this Regulation*].'		

Commission proposal	Drafting Suggestions	Justifications
(10) Annexes I and II are amended in accordance with Annex I to this Regulation.		
Article 2		
Amendments to Regulation (EC) No 1223/2009		
Regulation (EC) No 1223/2009 is amended as follows:		
(1) The following Article is inserted:		
'Article 14a		
Requests for inclusion of substances used as colorants, preservatives or UV-filters in Annexes IV, V or VI		
1. A request for a substance to be used as a colorant, preservative or UV-filter to be included in Annex IV, Annex V or Annex VI, as applicable, may be submitted to the Commission. It shall be accompanied by scientific evidence and documentation showing that due to the latest technical and scientific progress, the substance is safe for use in cosmetic products.		
2. After receiving the request referred to in paragraph 1, the Commission shall seek an opinion of the SCCS on the safety of the substance for use in cosmetic products without undue delay.		

Commission proposal	Drafting Suggestions	Justifications
3. The SCCS shall transmit its opinion to the Commission within 12 months after receiving the request from the Commission referred to in paragraph 2. The Commission may extend that deadline if additional evidence is required.'		
(2) Article 15 is amended as follows:		
(a) paragraph 2 is amended as follows:		
(i) the second subparagraph is replaced by the following:		
'2. However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after at the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as CMR substance of category 1A or 1B. The Commission shall grant the derogation where all of the following conditions are fulfilled:		
(a) there are no suitable alternative substances available as documented in an analysis of alternatives;		
(b) the substances have been evaluated and found safe by the SCCS for a particular use of the cosmetic product category, considering exposure to those		

Commission proposal	Drafting Suggestions	Justifications
products, overall exposure from sources other than cosmetics and of vulnerable population groups.'.		
(ii) the third subparagraph is replaced by the following:		
'For the purpose of the second subparagraph, point (a), a substance shall be considered a suitable alternative if it fulfils all of the following conditions:		
(a) its use in cosmetic products results in reduced overall risk to human health and the environment;		
(b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy;		
(c) is technically feasible and economically viable;		
(d) it is not restricted, not protected by exclusive rights, and is available on the market at scale, in quantities large enough to meet current and expected demand.'		
(iii) the following subparagraph is inserted after the fourth subparagraph:		
'The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into application of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying		

Commission proposal	Drafting Suggestions	Justifications
the substance concerned as CMR substance of category 1A, or 1B.’;		
(b) the following paragraphs 5, 6 and 7 are added:		
‘5. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance where the oral or inhalation route of exposure for CMR harmonised classification has been explicitly indicated in the ‘Hazard statement Code(s)’ column under the ‘Classification’ in Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from cosmetic products containing such substance due to incidental ingestion or inhalation, the Commission shall request an SCCS opinion on the safety of the substance concerned in those specific product types without undue delay.		
6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from the use of such substance in cosmetic products, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without undue delay.		

Commission proposal	Drafting Suggestions	Justifications
For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.		
7. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for 12 months and be made available on the market for 24 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.'		
;		
(3) In Article 16, paragraphs 3 and 7 are deleted;		
(4) In Article 19, paragraph 6 is replaced by the following:		
'6. The information mentioned in paragraph 1, point (g) shall be expressed by using the common ingredient name in accordance with the internationally recognised nomenclature and in the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.'		
;		

Commission proposal	Drafting Suggestions	Justifications
(5) In Article 22, fourth subparagraph, the second sentence is deleted;		
(6) Article 33 is deleted;		
(7) Annex I is amended in accordance with Annex II to this Regulation;		
(8) Annexes II to VI are amended in accordance with Annex III this Regulation.		
Article 3		
Amendments to Regulation (EU) 2019/1009		
Regulation (EU) 2019/1009 is amended as follows:		
(1) in Article 2, the following point (15a) is inserted:		
'(15a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;'		
;		
(2) Article 6 is amended as follows:		

Commission proposal	Drafting Suggestions	Justifications
(a) paragraph 2 is amended as follows:		
(i) the second subparagraph is replaced by the following:		
'Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.';		
(ii) the following subparagraph is added:		
'Manufacturers shall ensure that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.';		
(b) in paragraph 3, the second subparagraph is replaced by the following:		
'On request, manufacturers shall make the EU declaration of conformity available to other economic operators in electronic form.';		
(c) in paragraph 6, first subparagraph, the first and second sentences are replaced by the following:		
'Manufacturers shall indicate on the packaging of the EU fertilising product their name, registered trade name or registered trademark as well as their postal		

Commission proposal	Drafting Suggestions	Justifications
address and digital contact or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.'		
(d) in paragraph 9, the first sentence is replaced by the following:		
'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.'		
;		
(3) in Article 7(2), point (b) is replaced by the following:		
'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;'		
;		
(4) Article 8 is amended as follows:		

Commission proposal	Drafting Suggestions	Justifications
(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:		
'They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).'		
;		
(b) in paragraph 3, the first sentence is replaced by the following:		
'Importers shall indicate their name, registered trade name or registered trade mark as well as their postal address and digital contact on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product.'		
;		
(c) paragraph 8 is replaced by the following:		
'8. Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical		

Commission proposal	Drafting Suggestions	Justifications
documentation can be made available to those authorities, upon request.		
On request, importers shall make the EU declaration of conformity available to other economic operators in electronic form.'		
;		
(d) in paragraph 9, the first sentence is replaced by the following:		
'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority.'		
;		
(5) Article 9 is amended as follows:		
(a) in paragraph 2, the first subparagraph is replaced by the following:		
'Before making an EU fertilising product available on the market, distributors shall verify that it is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, including the information referred to in		

Commission proposal	Drafting Suggestions	Justifications
Article 6(7) or Article 8(4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.'		
;		
(b) in paragraph 5, the first sentence is replaced by the following:		
'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation.'		
;		
(6) Article 15 is amended as follows:		
(a) paragraph 2 is replaced by the following:		
'2. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures is established or in a language accepted by that body.'		

Commission proposal	Drafting Suggestions	Justifications
(b) the following paragraph 3 is added:		
'3. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.'		
;		
(7) in Article 16, the following paragraphs 5 and 6 are added:		
'5. The EU declaration of conformity shall be provided in a machine-readable and open format as defined in Article 2, points (13) and (14), of Directive (EU) 2019/1024 of the European Parliament and of the Council* and meet the requirements for digital labels set out in Article 11b(4), points (a) to (d).		
Where a data carrier is used for providing access to the EU declaration of conformity, it should accompany the product in accordance with Article 11b(5) and be based on one of the electronic technical solutions which economic operators can use for providing the digital label established on the basis of Article 42(9). Economic operators providing the EU declaration of conformity using a data carrier shall not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the relevant information digitally.		

Commission proposal	Drafting Suggestions	Justifications
Where a digital label is used in accordance with Article 11a, the data carrier used for the digital label shall also provide access to the EU declaration of conformity.		
*Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, (OJ L 172, 26.06.2019, p. 56, ELI: http://data.europa.eu/eli/dir/2019/1024/oj).'		
6. Where other Union legislation applicable to EU fertilising products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity in a digital product passport, the information set out in Annex V to be included in the EU declaration of conformity and any digital labelling information in accordance with Article 11b, if applicable, shall be provided only in that digital product passport.'		
;		
(8) in Article 41(1), point (c) is replaced by the following:		
'(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly, or the EU fertilising product is not accompanied by the internet		

Commission proposal	Drafting Suggestions	Justifications
address or data carrier through which the EU declaration of conformity can be accessed.'		
(9) Article 42 is amended as follows:		
(a) in paragraph 4, the introductory statement is replaced by the following:		
'The Commission may adopt delegated acts pursuant to paragraph 1 amending Annex II to add new micro-organisms or strains of micro-organisms, or additional processing methods to the component material category for such organisms after having verified which strains of the additional micro-organism fulfil the criteria in paragraph 1, point (b), on the basis of the following data:'		
;		
(b) the following paragraph 4a is inserted:		
'4a. The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to set out criteria and a methodology for the assessment of micro-organisms other than those listed in Annex II, which, if compliance with those criteria is demonstrated in the conformity assessment of the EU fertilising product in accordance with that methodology, may be used as component material in EU fertilising products. The criteria and methodology shall allow for verification that the micro-organisms fulfil the criteria in		

Commission proposal	Drafting Suggestions	Justifications
paragraph 1, point (b), and provide, as a minimum, for the consideration of the following elements:		
(a) scientific literature reporting about safe production, conservation and use of the micro-organism;		
(b) taxonomic relation of the micro-organism to micro-organisms species fulfilling the requirements for a Qualified Presumption of Safety as established by the European Food Safety Authority;		
(c) information on the production process of the micro-organism, including, where relevant, the composition of the cultivation medium, processing methods such as spray drying, fluid-bed drying, static drying, centrifugation, deactivation by heat, filtration and grinding;		
(d) information on the identity and residue levels of residual intermediates, toxins or microbial metabolites in the component material;		
(e) natural occurrence, survival and mobility in the environment;		
(f) susceptibility to all relevant antimicrobial agents as defined in the Annex, Introduction to Part B, point (ii)(28), to Commission Regulation (EU) No 283/2013*, with the exception of intrinsic resistance.		
*Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in		

Commission proposal	Drafting Suggestions	Justifications
accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/283/oj).'		
;		
(10) Article 43 is deleted;		
(11) Annexes I, II and IV to Regulation (EU) 2019/1009 are amended in accordance with Annex IV to this Regulation.		
Article 4		
Transitional provisions		
1. By way of derogation from section 1.5.2.4.1 and section 1.5.2.4.2 of Annex I to Regulation (EC) No 1272/2008 as applicable on 9 December 2024 substances and mixtures may until 30 June 2026 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by points (5), (6) and (7) of Annex I to this Regulation.		
By way of derogation from Article 30 and Article 48 of Regulation (EC) No 1272/2008 and Part 5 of Annex II to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may until 31 December 2027 be classified, labelled and packaged		

Commission proposal	Drafting Suggestions	Justifications
in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (5), (7) and (8) of this Regulation and point (9) of Annex I to this Regulation.		
By way of derogation from Article 17(1), Article 25(6) of Regulation (EC) No 1272/2008, section 1.5.1.2 and section 1.6 of Annex I to Regulation (EC) No 1272/2008 as applicable on [*OP: please insert the date of the day before the date of entry into force of this Regulation*], substances and mixtures may until [*OP: please insert the date of the last day of the month following 35 months after the date of entry into force of this Regulation*] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (2) and (3) of this Regulation and points (3) and (8) of Annex I to this Regulation.		
2. Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulation (EU) 2019/1009 before [*OP: please insert 24 months after entry into force of this amending Regulation)*].		
Article 5		
Entry into force and application		

Commission proposal	Drafting Suggestions	Justifications
1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.		
2. Points (4) to (7) of Annex I shall apply from 1 July 2026.		
3. Article 1, points (5) to (8) and points (1), (2) and (9) of Annex I shall apply from 1 January 2028.		
4. Article 1, points (1), (2) and (3), points (3) and (8) of Annex I shall apply from [O*P: please insert the date of 36 months after the entry into force of this Regulation)*]		
5. Article 2, point (1) to (8) shall apply from [OP: please insert the date of entry into force of this Regulation)]		
6. Article 3, point (1) to (8), and Annex IV, point (1) and (3), shall apply from [OP: please insert 24 months after entry into force of this Regulation].		
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
ANNEX I		
Annexes I and II to Regulation (EC) No 1272/2008 are amended as follows		

<table>
<tr><th colspan="3">Commission proposal</th><th>Drafting Suggestions</th><th>Justifications</th></tr>
<tr><td colspan="3">(1) in Annex I, section 1.2.1.4 is replaced by the following:</td><td></td><td></td></tr>
<tr><td colspan="3">‘1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:</td><td></td><td></td></tr>
<tr><td colspan="3">Table 1.3
Minimum dimensions of labels and pictograms</td><td></td><td></td></tr>
<tr><td>Capacity of the package</td><td>Dimensions of the label (in millimetres) for the information required by Article 17</td><td>Dimensions of each pictogram (in millimetres)</td><td></td><td></td></tr>
<tr><td>Not exceeding 3 litres:</td><td>If possible, at least 52 × 74</td><td>Not smaller than 10 × 10
If possible, at least 16 × 16</td><td></td><td></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></td><td></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></td><td></td></tr>
</table>

Commission proposal			Drafting Suggestions	Justifications
Greater than 500 litres:	At least 148 × 210	At least 46×46		
’;				
(2) in Annex I, section 1.2.1.5 is deleted;				
(3) in Annex I, section 1.5.1.2 is replaced by the following:				
‘1.5.1.2. Where section 1.5.1.1 applies, the label on any inner packaging shall contain at least the hazard pictograms, the signal words, the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and digital contact of the suppliers of the substance or mixture.’;				
(4) the heading of section 1.5.2.4 is replaced by the following:				
‘1.5.2.4 Labelling of packages where the contents do not exceed 10 ml ’;				We agree
(5) in Annex I, section 1.5.2.4.1 is replaced by the following:				
‘1.5.2.4.1. The label elements set out in Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml,				We agree

Commission proposal	Drafting Suggestions	Justifications
the outer packaging meets the requirements set out in Article 17(1) and any of the following applies:		
the substance or mixture is placed on the market for scientific research and development or quality control analysis;		We agree
the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II, except for section 2.8 of Part 2 of Annex II, and is not classified in any of the following hazard classes and categories:	the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II, ~~except for section 2.8 of Part 2 of Annex II~~, and is not classified in any of the following hazard classes and categories. If the substance or mixture requires labelling in accordance only with section 2.8 of Part 2 of Annex II, the label is set out under 1.5.2.4.3	In order to have a more comprensible text we propose an additional sentence only if a compromise for section 1.5.2.4.3 will be reachable
acute toxicity, any category;		
specific target organ toxicity – single exposure, categories 1 and 2;		
specific target organ toxicity – repeated exposure, any category;		
skin corrosion, category 1, any sub-category;		
serious eye damage, category 1;		
respiratory sensitisation, any category;		
aspiration hazard;		

Commission proposal	Drafting Suggestions	Justifications
germ cell mutagenicity, any category;		
carcinogenicity, any category;		
reproductive toxicity, any category;		
endocrine disruption for human health, any category.';		
(6) in Annex I, section 1.5.2.4.2 is replaced by the following:		
'1.5.2.4.2. Where section 1.5.2.4.1 applies, the label on the inner packaging shall contain the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and, where applicable, the hazard pictograms 'GHS01', 'GHS05', 'GHS06' or 'GHS08'. Where more than two pictograms are assigned, 'GHS06' and 'GHS08' may take precedence over 'GHS01' and 'GHS05'.';		
(7) in Annex I, section 1.5.2.4.3 is added:		
'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted from the package provided that the following conditions are met:	'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted, execept elements of article 17 (1), point (a) and the sentence EUH208, from the package provided that the following conditions are met:	In order to avoid to give the possibility to a put on the market a product without any information on the package, after a better understanding of the kind of sector that could benefict of the semplification, we could indicate that supplier's contact and the EUH208 sentence should be present in a label on the package. If a compromise can be accepted a new paragraph has

Commission proposal	Drafting Suggestions	Justifications
		to be addedd “execept elements of article 17 (1), point (a) and the sentence EUH208”
the contents of the package do not exceed 10 ml;		
the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II, except for section 2.8 of Part 2 of Annex II;	the substance or mixture ~~does not~~ requires only labelling in accordance with ~~Part 1 or~~ 2 of Annex II for section 2.8 of Part 2 of Annex II**;**	We suggest rephrasing it to make it clearer what kind of product can use the simplification.
the substance or mixture is not classified in any of the hazard classes and categories referred to in point (b) of section 1.5.2.4.1.’;		
(8) in Annex I, section 1.6 is replaced by the following:		
‘1.6. Label elements that may be provided on a digital label only		
(a) Supplemental information referred to in Article 25(3);		
(b) Where more than one supplier is indicated on the label in accordance with Article 17(1), point (a), the name, address and digital contact of the suppliers may be provided on a digital label only, as long as the supplier referred to in in Article 4(11) is indicated on the physical label.’;		

Commission proposal	Drafting Suggestions	Justifications
(9) in Annex II, Part 5 is replaced by the following:		
'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES		
Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.		
For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the copy of the label elements referred to in Article 17, points (c) to (h) shall be provided on a visible place on the respective pump. The unique formula identifier referred to in Article 25(7) does not need to be provided.		
When a vehicle fuel is supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a copy of the label elements referred to in Article 17, points (c) to (h), shall be provided to be attached to the receptacle, unless the receptacle is already appropriately labelled. The unique formula identifier referred to in Article 25(7) does not need to be provided.'.		
ANNEX II		

Commission proposal	Drafting Suggestions	Justifications
In Annex I to Regulation (EC) No 1223/2009 Part A, point 2 is replaced by the following:		
'2. Physical/chemical characteristics and stability of the cosmetic product		
The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.		
The stability of the cosmetics product under reasonably foreseeable storage conditions.		
The specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the preamble to Annexes II to VI, size of particles, physical and chemical properties.		
The safety data of the nanomaterial (including its toxicological profile and exposure conditions) relating to the category of cosmetic product, as used in such products.'		
ANNEX III		
Annexes II to VI to Regulation (EC) No 1223/2009 are amended as follows:		
(1) in the preamble to Annexes II to VI, point 2, the fifth indent is replaced by the following:		

Commission proposal	Drafting Suggestions	Justifications
'- the name included in the internationally recognised nomenclature.';		
(2) in the heading of tables in Annexes III to VI the title 'Name of Common Ingredients Glossary' is replaced by 'Name in the Internationally Recognised Nomenclature'.		
ANNEX IV		
Annexes I, II and IV to Regulation (EU) 2019/1009 are amended as follows:		
(1) in Annex I, Part II, PFC 7: FERTILISING PRODUCT BLEND, point 4(c) is replaced by the following:		
'(c) Article 8(8) (importers' obligation to keep the EU declaration of conformity at the disposal of the market surveillance authorities).';		
in Annex II, Part II, is amended as follows:		
in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is deleted;		
in CMC 3: COMPOST, point 1(d) is replaced by the following:		
'(d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process, provided that		

Commission proposal	Drafting Suggestions	Justifications
the total concentration of all additives does not exceed 5% of the total input material weight; or’;		
CMC 4: FRESH CROP DIGESTATE is amended as follows:		
(i) point 1(b) is replaced by the following:		
‘(b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or’;		
(ii) point 3d is replaced by the following:		
‘3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.’;		
CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE is amended as follows		
(i) point 1(d) is replaced by the following:		
‘(d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or’;		

Commission proposal	Drafting Suggestions	Justifications
(ii) point 3d is replaced by the following:		
'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.';		
in CMC 6: FOOD INDUSTRY BY-PRODUCTS, point 2 is deleted;		
in CMC 8: NUTRIENT POLYMERS, point 1 is replaced by the following:		
'1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in point 1 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.';		
in CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) No 1069/2009, the table, point 1.3 is replaced by the following:		
'1.3. Additives needed in the processing referred to in points 1.1 and 1.2 may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the		

Commission proposal	Drafting Suggestions	Justifications
processed manure or fraction used as input in the respective process.’;		
in CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC, point 2 is deleted;		
in CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES, point 13 is deleted;		
in CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES, point 8 is deleted;		
in CMC 14: PYROLYSIS AND GASIFICATION MATERIALS, point 7 is deleted;		
in CMC 15: RECOVERED HIGH PURITY MATERIALS, point 10 is deleted;		
in Annex IV, Part II is amended as follows:		
MODULE A – INTERNAL PRODUCTION CONTROL is amended as follows:		
(i) in point 4.2, the first sentence is replaced by the following:		
‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;		

Commission proposal	Drafting Suggestions	Justifications
(ii) point 4.3. is replaced by the following:		
'4.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.';		
MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING is amended as follows:		
(i) point 2.2.(f) is replaced by the following:		
'(f) the names, postal addresses and digital contacts of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,';		
(ii) in point 5.2., the first sentence is replaced by the following:		
'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.';		
(iii) point 5.3. is replaced by the following:		

Commission proposal	Drafting Suggestions	Justifications
'5.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.';		
MODULE B – EU-TYPE EXAMINATION is amended as follows:		
(i) point 3.2.(a) is replaced by the following:		
'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,';		
(ii) in point 6.1., the second sentence is replaced by the following:		
'The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.';		
MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL is amended as follows:		

Commission proposal	Drafting Suggestions	Justifications
(i) in point 3.2., the first sentence is replaced by the following:		
'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.';		
(ii) point 3.3. is replaced by the following:		
'3.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.';		
MODULE D1 - QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:		
(i) in point 5.2., the first indent is replaced by the following:		
'the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,';		

Commission proposal	Drafting Suggestions	Justifications
(ii) in point 7.2., the first sentence is replaced by the following:		
'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.';		
(iii) point 7.3. is replaced by the following:		
'The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.'		

Nuova tempistica per la modifica degli allegati

Nella proposta della Commissione viene presentata una nuova tempistica per il divieto delle sostanze CMR nei prodotti cosmetici ai sensi del CPR. Alcuni Stati membri esprimono preoccupazione per l'impatto sulla tutela della salute umana, poiché le sostanze CMR saranno presenti nei prodotti cosmetici per un periodo più lungo.

Domanda 2: Gli Stati membri possono sostenere l'approccio suggerito dalla Commissione e ritengono accettabile il periodo di tempo suggerito?

ANSWER 2

The Commission proposal to publish a Commission regulation amending the Annexes to CPR within 15 months after the date of application of the ATP of the CLP is not acceptable.

The reason is that such a way substances not under derogation, for which safe use in cosmetics has not been reassessed in light of their CMR properties, would stay on the market for a longer period than it is at the moment before being prohibited. Furthermore, the proposed conditions could have a negative impact on the end users health and would not fulfill art. 1 of the CPR.

At this regard, taking into account art. 1 and 3 of CPR, it should be pointed out that Competent Authorities on cosmetics can not support measures aiming at prolonging the exposure of end users to substances once these sustances are classified as substances of concern. Time issues should or could be managed in advance of the classification and the ATP of the CLP.

Proposal to manage CMR substances under two channels;

a) for CMR substances NOT UNDER DEROGATION procedure
b) for CMR substances UNDER DEROGATION procedure

a) Substances not under derogation procedure

A Commission regulation aiming at amending Annexes to CPR should be published within 15 months after the entry into force of the ATP of CLP and CMR substances shall be prohibited from use in cosmetic products **in line** with the date of application of the ATP of the CLP.

- The principle of automatic ban on CMR substances is maintained for those substances for which Industry shows no interest and/or that are of no interest in cosmetic products.

- The safe use of these substances as CMR substances in cosmetics has not been investigated and their impact on health through cosmetic products is not known. No reasons to prolonge the exposure of end users to such substances.

- The economic operators involved have time to put their products in conformity with the new provisions, placing on the market and making available products on the market, from the date of publication of the ATP of the CLP (generally 15-18 months).
- Furthermore the economic operators are aware of the CMR classification when the RAC opinion is published and even before, when a substance is listed in the registry of intention in order to undergo an evaluation for a CMR classification.

- Therefore, it seems there is time to manage both the placing on the market and the making available on the market in advance to the Commission regulation amending the Annexes to the CLP.

b) Sustances under derogation procedure

A Commission regulation aiming at amending Annexes to CPR should be published within 15 months (if necessary, a longer period of time might be foreseen) after **the entry into force** of the ATP of CLP.
Any ban or restrictions in use for CMR substances, prohibited from use in cosmetic products or not compliant with a restriction, could be applied with transitional periods if the prolonged exposure of end users to these substances is deemed safe by the SCCS and transitional period are specifically contained in the opinion issued under the derogation procedure. This is linked to the prospect of obtaining this specification from the SCCS opinion, depending on how the Commission mandate for scientific advice is formulated. It should be clarified if SCCS can set out transitional periods. Conversely, if the SCCS is not responsible for indicating transitional periods, these could be established on a case-by-case basis, not exceeding the x months periods, that should be the shorter as possible.(*e.g.* 12 months for both placing and making available a product on the market)

- Comment on economic operators and time managing are the same as above for case a).
- It should be discussed if transitional period can be established by SCCS. If not, transitional period for making available a product on the market could be established on a case-by-case basis within a maximum period of time of x months. This period should anyway be the shorter as possible.
- **On the other hand, taking into account any possible negative effect of CMR substances on end users health, transitional measures should not be only set as regulatory measures.**

The different approach towards possible transitional periods in the event of derogation procedures lay in the submission of a derogation dossier containing data to be assessed for the granting of transitional periods.

Article 15

Substances classified as CMR substances

1. 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.

2. The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as CMR substance of category 1A or 1B.
The Commission shall grant the derogation where all of the following conditions are fulfilled:

(a) there are no suitable alternative substances available as documented in an analysis of alternatives;

(b) the substances have been evaluated and found safe by the SCCS for a particular use of the cosmetic product category, considering exposure to those products, overall exposure from sources other than cosmetics and of vulnerable population groups.'.

'For the purpose of the second subparagraph, point (a), a substance shall be considered a suitable alternative if it fulfils all of the following conditions:
(a) its use in cosmetic products results in reduced overall risk to human health and the environment;

(b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy;
(c) is technically feasible and economically viable;
(d) it is not restricted, not protected by exclusive rights, and is available on the market at scale, in quantities large enough to meet current and expected demand.'

~~In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.~~
"In order to implement **paragraph 1 and 2**, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation within 15 months of the entry into force of the ATP of the CLP which includes the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008."

'The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into ~~application~~ force of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of **category 2, 1A, or 1B**.';

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4) of this Regulation.

The Commission shall mandate the SCCS to re-evaluate those substances as soon as safety concerns arise, and at the latest five years after their inclusion in Annexes III to VI to this Regulation, and at least every subsequent five years.

3. By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing, as appropriate, on relevant best practice.

4. When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

5. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance where the oral or inhalation route of exposure for CMR harmonised classification has been explicitly indicated in the 'Hazard statement Code(s)' column under the 'Classification' in Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from cosmetic products containing such substance due to incidental ingestion or inhalation, the Commission shall request an SCCS opinion on the safety of the substance concerned in those specific product types without undue delay.

6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from the use of such substance in cosmetic products, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without undue delay. For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.

7. ~~Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for 12 months and be made available on the market for 24 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.'~~

7.

Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC)

No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction, and for which a derogation procedure has been submitted to the Commission, may continue to be placed on the market and to be made available on the market for **a maximum period of x months (e.g. 12 months)** after the entry into force of the amendments to the relevant Annexes to this Regulation.' At this end, the Commission may, after consulting the SCCS on the safe use of the substance concerned, set out transitional measures.

Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008, for which a derogation procedure has not been submitted to the Commission, are not place on the market and made available on the market at the date of application of the amendements of the relevant Annexes to this regulation and in line with CLP ATP relevant amendments to the Regulation (EC) No 1272/2008.'

Greece

EL Comments on Presidency Discussion Note WK 11188/2025 INIT

Regulation on Classification, Labelling and Packaging (CLP) COM(2025)531

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

Options regarding formatting and readability:

a) Retaining certain elements of the formatting rules introduced in 2024.

b) Further clarification in the text or the recitals on how readability should be understood.

Question 2: Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred)

Answer to Question 2:

We support option a for section 1.2.1.4 of Annex I. Specifically, for packages larger than 3 litres, the minimum font size should remain as defined in the 4th column of Table 1.3 of section 1.2.1.4 in the CLP revision, since there is sufficient space on their label.

For section 1.2.1.5, we accept that all label text specifications should be maintained. Alternatively, for point (a), instead of the current requirement ("printed in black on a white background"), it could be defined in the legal text – and not in a recital – the acceptable (or unacceptable) color combinations of font and background and/or the acceptable level of contrast between them.

Updating labels (Article 30(1))

Options on updating the labels and ensuring legal clarity:

a) Clarifying in a recital how the "without undue delay" formulation should be understood.

b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.

c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: Can Member States support one or more of the above-mentioned options?

Answer to Question 3:

Our main concern is that the phrase "without undue delay" creates legal uncertainty and carries the risk of inconsistent application of the legislation across Member States. We believe that a specific time period should be set out in the main text in order to ensure clarity and equal treatment. For this reason, we can support options b or c, or even a combination of the two, whereby a shorter period would apply to CMR substances and endocrine disruptors, and a longer period to the other hazard classes. In any case, we support the establishment of a specific time frame for compliance with this provision.

Advertising (Article 48) and distance sales offers (Article 48a)

Question 4: The PCY encourages Member States to prepare answers to the following questions on advertisements:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

b) Which, if any, label elements can be removed from the rules on advertising in Article 48?

c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

Answer to Question 4:

We believe that the term "advertisement" should be clarified, as well as the precise scope of Article 48, i.e., whether it concerns advertisements presented on online platforms or on other advertising

channels. Advertisements displayed on online platforms often include the possibility to effect a purchase through a link. If this is the case, they should incorporate the elements specified in Article 48 of the revised CLP.

For other advertising channels (e.g., television), at a minimum, the presence of hazardous substances should be indicated, together with the phrase: "Always read the label and product information before use," in order to enhance consumer awareness. Alternatively, we could also support the proposal of other Member States to display the hazard pictograms.

Furthermore, we agree that advertisements should include the name and digital contact details of the responsible supplier, to assist market surveillance authorities in conducting automated controls of advertisements.

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

Answer to Question 5:

We believe that professional users should be informed of product hazards before completing distance-sale purchases. The argument that professional users can be informed of product hazards via the safety data sheet is not entirely accurate, because according to Article 31(8) of REACH, the safety data sheet must be provided no later than the date of first supply. If advertisements or offers directed at professional users do not include the hazard information required for consumer-oriented products, they may proceed to purchase products without knowing the associated risks until delivery. Furthermore, it is unclear how access by the general public to offers lacking hazard information—intended solely for professional users—would be restricted, should such a differentiation in information provision be adopted.

Digitalisation digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

Question 6: Do Member States have any objections to the PCY proposed approach on digitalisation?

Answer to Question 6:

We support maintaining the possibility for the product label to include either the telephone number and/or digital contact, as this avoids imposing additional mandatory costs on small and medium-sized enterprises that may not be able to support the creation and maintenance of a digital contact. In any case, the definition of "digital contact" should be clarified further, possibly in a recital, so that it is clear whether it could simply be email communication or something more elaborate.

Cosmetic Products Regulation (CPR) – COM(2025)531

Amendments to Article 15

Member States highlight that for the proposed amendments to Article 15 in particular, simplifications must not be made at the expense of human health and consumer safety. In the Staff Working Document (SWD (2025) 531), the Commission aims to explain the timelines.

New timeline for submitting an application for derogation for using CMR substances in cosmetic products

The Commission proposal suggest a new timeline for submitting an application for a derogation for using a CMR substance in cosmetic products. Some Member States express concern for the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

Answer to Question 1: ***We support the new timeline as suggested by Commission***

New timeline for amending the Annexes

In the Commission proposal, a new timeline is presented for the prohibition of CMR substances in cosmetic products under CPR. Some Member States express their concern about the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

Answer to Question 2: ***We support the approach as suggested by Commission***

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

Answer to Question 3: ***We support the approach as suggested by Commission***

Amendments of criteria for derogation

The Commission proposes that the criteria for derogation be narrowed down from four to two.

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

Answer to Question 4 : ***We support the approach as suggested by Commission***

Introduction of criteria for alternative assessment

The Commission proposal introduces criteria for assessing whether alternatives are available when evaluating a derogation application for using a CMR substance in cosmetic products.

Some Member States are concerned that the criteria are too broad and will almost always result in the conclusion that no alternatives are available or that an alternative method or technical solution will not be recognised as a suitable alternative.

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?

Answer to Question 5a : The criteria for alternative assessment should be specified in Regulation

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?

Answer to Question 5b: Yes the criteria for what constitutes alternatives should be widened

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

Answer to Question 5c : we support the inclusion of environmental and economic aspects in the criteria for assessing alternatives

Natural complex substances containing CMR-substances

The aim of the Commission proposal on natural complex substances is to create clarity when natural complex substances contain CMR-classified components. Some Member States express concern for the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

c. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

Answer to Question 6 : We support option b

Classifications based on ingestion or inhalation route of exposure

The Commission proposes to exclude CMR-substances from the generic ban under CPR if the CMR-substance is explicitly based on oral or inhalation route of exposure.

Some Member States find that these substances still pose a risk, as many cosmetic products are used in the mouth area or are in a spray form, and are therefore concerned about the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

Answer to Question 7 : We support option b

Abolishment of pre-notification of nano-material ingredients (Article 16)

The Commission proposes to abolish the requirement for pre-notification for nano-material ingredients in cosmetic products, suggesting that these products should be notified to the Commission when placed on the market like other cosmetic products.

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

Answer to Question 8 : We disagree with deletion of paragraphs 3 and 7 of article 16 concerning nanomaterials

Abolishment of the glossary (Article 19 and 33)

While no Member State expressed opposition to the proposal regarding the suggested use of "internationally recognised nomenclature" instead of the current Glossary of common ingredient names, several member States call for greater legal certainty, and expressed a need for clear naming.

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

Answer to Question 9 : International nomenclature should refer to the International Nomenclature of Cosmetic Ingredients (INCI) in Cosing

Fertilising Products Regulation (FPR) COM(2025)531

The comments we expressed during the meeting of 15.09.25 remain applicable.

Sweden

Swedish replies to questions in steering note following meeting 15 September 2025 on Omnibus VI

In addition to the comments provided at the AGS meeting on 15 September Sweden would like to raise the following;

"Stop-the-clock" – COM(2025)526

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

Sweden proposes to include Article 29(3) in Article 1(6) of the Amending Regulation. Part 5 of Annex II is already proposed to be included in the deferred application date to 31 December 2027. It would be inconsistent if the new Article 29(3) started to apply from 1 July 2026 and the contents of Part 5 of Annex II from 31 December 2027, since it refers to that Annex.

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Question 4a: Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

Sweden is flexible regarding the information requirements in connection with advertising, provided that sufficient information is available at the time of purchase in cases of distance sales.

However, Sweden questions the point of dividing Article 48 into online and other types of advertising, and what it would mean to "simplify rules for other advertising channels." Advertising rules have existed in the CLP Regulation since its adoption. Sweden understands that the amendment regulation adopted in 2024 clearly regulates, on the one hand, "advertising" in Article 48, which applies regardless of the medium used, and on the other hand, "distance sales offers" in Article 48a, which includes online marketplaces. The latter rules are designed to be applied in conjunction with Regulation (EU) 2022/2065 (DSA). Sweden is therefore hesitant to support the proposal in point a.

Question 4b: Which, if any, label elements can be removed from the rules on advertising in Article 48?

Sweden is flexible regarding the information requirements in connection with advertising, provided that sufficient information is available at the time of purchase in cases of distance sales.

Question 4c: The Commission proposes the prompt: "Always read the label and product information before use." Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

Sweden is flexible and can support the Commission's proposal. It should be noted that similar labelling requirements exist in the regulations for plant protection products and biocidal products. Duplicate requirements with the same purpose should be avoided.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

It is our understanding that the proposal entails that the different exemption possibilities in Articles 29(1) and 29(2) can be used independently of each other.

We wonder whether this could be interpreted to mean that even larger packages, up to 125 ml, do not need to carry full labelling—even if there is space for full labelling on the label. Is this the intention of the proposal?

We also understand that the proposal removes the requirement to provide information on allergenic substances, which is currently required under CLP. Is this the intention of the proposal?

Cosmetic Products Regulation (CPR) – COM(2025)53

Question 6: Can Member States support one or more of the above-mentioned options?

Sweden questions that the Council should continue negotiating the proposed amendments to Article 15 as they imply a lowered level of protection against carcinogenic, mutagenic and reprotoxic substances in cosmetic products. Thus Sweden can not support alternative a or b.

The Commission has not presented any scientific evidence to support the claim that CMR substances contained in plant extracts and plant parts always have a reduced effect compared to the isolated CMR substance. A high level of consumer safety cannot be ensured if CMR substances present in plant extracts and plant parts are automatically exempted from prohibition.

Question 7: Can Member States support one or more of the above-mentioned options?

Sweden questions that the Council should continue negotiating the proposed amendments to Article 15 as they imply a lowered level of protection against carcinogenic, mutagenic and reprotoxic substances in cosmetic products. Thus Sweden can not support alternative a or b.

Exempting cosmetic products containing a substance that is explicitly classified as CMR on the basis of oral or inhalation route will potentially lead to an increased risk for consumers.

Fertilising Products Regulation (FPR) – COM(2025)531

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

Sweden can be flexible on the points regarding the Fertilising Products Regulation as the regulation only applies to EU fertilising products (products labelled as EU fertilising products).

Coordination with Omnibus IV is important to ensure a clear and consistent approach to the digitalisation of EU product legislation.

Spain

Omnibus VI – CLP
Comments on the debate raised by the PRES
"Stop-the-clock" – COM (2025) 526

- **Q1 – Can Member States support the Commission's proposal to postpone the application date of the 2024 CLP revisions (label format, re-labelling, distance sales, petrol station labelling) until 1 January 2028?**
  Yes, we support the Commission's proposal to postpone the application of the 2024 CLP revisions until 1 January 2028. We consider that this delay is necessary to provide legal certainty and to align this update with other regulatory changes. However, we request that the decision be adopted as quickly as possible, in order to avoid uncertainty, duplication, and administrative complexity.

Label format (Article 31(3) and Annex I)

- **Q2 – Which option do Member States support? If (a), which elements should be retained? If (b), what should be clarified?**
  We understand the concerns about removing explicit references to legibility standards in the revised CLP, but we believe that reintroducing rigid requirements, such as minimum font sizes or fixed proportions, would recreate the problems that motivated their removal, especially for small packaging and labels with large amounts of mandatory information.
  In this regard, we prefer option (b). If deemed necessary, guidelines or practical examples could be provided on how to assess "legibility," without imposing uniform parameters that are not adaptable to all formats. Alternatively, conditions for legibility could be limited only to very specific and minimal aspects. Strongly promoting digital labelling would also resolve the legibility problem.

Label updates (Article 30(1))

- **Q3 – Which option(s) can Member States support?**
  We support option (b): keeping a fixed deadline for updating labels of self-classified substances and mixtures, extending it to 12 months, although we could support longer periods.
  A fixed deadline provides legal certainty and consistency: operators and authorities know exactly from when the change applies, avoiding disputes over what constitutes "undue delay."
  Extending the current 6-month limit reflects operational reality: redesigning and reprinting labels, updating databases, managing stock, and training staff require longer periods, especially for SMEs or products with multiple formats. A one-year period allows the transition to be scheduled within normal production cycles, without wasting packaging or creating disproportionate burdens, while still providing a clear horizon for health and environmental protection.

Advertising (Article 48) and distance sales (Article 48a)

- **Q4**
  a) *Should Article 48 cover only online advertising?*
  Spain supports the current wording of Article 48. We believe that all advertising channels, including online, should be covered. The only requirement should be a generic warning referring the user to consult the label before using the product. We do not consider it effective to maintain detailed obligations regarding hazard elements in advertisements; what matters is that full information is available on the label or, where relevant, at the point of sale.

b) *Which label elements (if any) may be removed?*
We believe that specific label elements (pictograms, H- and P-phrases, signal words, supplier details) may be removed from advertisements. Their inclusion does not add value in channels with limited space or time and may confuse consumers. A simple reminder to read the label for risk and safe-use information is sufficient.

c) *Do you support the proposed warning? Or should it include (a) reference to hazardous substances and/or (b) supplier's digital contact details to facilitate market surveillance?*
We consider the Commission's proposed wording appropriate: *"Always read the label and product information before use"*, due to its clarity and brevity. We do not consider it necessary to add references to the presence of hazardous substances or supplier contact details, since that information must already appear on the label or in the safety data sheet. Keeping the message concise improves its visibility and coherence across all media.

- **Q5 – Should Articles 48 and 48a apply only to consumer products?**
Spain believes that Articles 48 and 48a should apply only to products intended for consumers, not for professional use. Professionals already have access to safety data sheets and specific training.
Limiting the scope to consumer products simplifies implementation, avoids unnecessary burdens for industrial operators, and focuses protection on the public that truly needs early warnings.

Digitalisation – digital contact details (Article 17(1)) and digital labelling (Annex I)

- **Q6 – Do Member States have objections to this approach?**
Spain supports allowing suppliers to use a digital contact (email, website, online form, etc.) instead of a postal address or phone number, and to provide supplementary information only on the digital label, in line with the "Omnibus IV" approach. However, we consider it important to maintain as an option a phone number or another basic channel for operators without digital solutions, thereby ensuring accessibility for all users and continuity of supply in markets where connectivity may be limited.

Packaging of less than 10 ml (Article 29(2) and Annex I)
Spain supports the Commission's proposal. We agree that solutions such as fold-out, multi-layer, or leaflet-type labels are not practical and create unnecessary burdens for operators. Once again, we stress that the development of digital labelling can be a useful tool to ensure access to complete safety information in these small formats.

Finland

Omnibus VI (chemicals) 18.9.2025
written comments of Finland

- **Finland's preliminary notes on the Omnibus VI proposals on simplification of certain requirements and procedures for chemical products "Stop-the-clock" – COM(2025)526**

The targeted revision of the CLP in 2024 introduced new rules on label formatting, relabelling, distance sales, and fuelling station labelling, which will apply either from 1 July 2026 or 1 January 2027. To provide a short-term certainty for suppliers, the Commission proposes to postpone the date of application for these revisions until 1 January 2028. The more substantive changes to the CLP Regulation, revised in 2024, are addressed in the main Omnibus VI proposal.

The PCY intends to proceed swiftly with the "Stop-the-Clock"-proposal and invites Member States to indicate their support for the Commission proposal in the first part of the Working Party meeting.

Question 1: Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?

FI can support the Stop-the-Clock -proposal as is.

- **Finland's preliminary notes on the Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531**

Member States are broadly supportive of the efforts to simplify the CLP Regulation, although several Member States stress the need to balance reduced administrative burdens with maintaining the Regulation's core objectives.

Key issues for debate concern the label formatting, the updating of labels for self-classified substances and mixtures, and certain distance sales rules on advertisements and online sales offers. The Member States also commented on digital contacts, digital labelling, and adjustments to the rules on packages under 10 ml.

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

Many Member States raised concerns on eliminating enforceable readability standards, underlining the need to balance simplification with consumer safety and legal clarity.

Based upon the Member States' responses, the PCY has identified the following indicative options regarding formatting and readability:

a) Retaining certain elements of the formatting rules introduced in 2024.

b) Further clarification in the text or the recitals on how readability should be understood.

Question 2: Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).

As it is not clear to us what is meant by "retaining certain elements" FI supports option b at this time, but we are open to further discussions.

Updating labels (Article 30(1))

The Commission proposes repealing the six-month deadline for updating labels for self-classified substances and mixtures. The Member States recognise the cost implications for suppliers of updating the labels, particularly for SMEs. While some Member States welcomed a greater flexibility

to reflect complex supply chains, many cautioned that returning to the formulation – "without undue delay" – creates legal uncertainty and puts consumers and workers at risk.

Based upon the Member States' responses, the PCY has identified the following indicative options on updating the labels and ensuring legal clarity:

a) Clarifying in a recital how the "without undue delay" formulation should be understood.

b) Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months.

c) Retaining the six-month deadline for CMR substances and endocrine disruptors, while reverting to "without undue delay" for other classifications.

Question 3: Can Member States support one or more of the above-mentioned options?

FI can support options a and b. If option b is chosen, we would prefer the longer 12-month deadline to ensure that also long and complex supply chains will be able to comply in a controlled and realistic manner. We fear that option c would not address the identified problem.

Advertising (Article 48) and distance sales offers (Article 48a)

The 2024 CLP-revision adds additional requirements to the existing rules on which label elements/hazard information must be displayed in advertisements. The revision also introduced a new requirement on distance sales, including online sales, requiring that full label information is available at the point of sale. To reduce costs and avoid confusing consumers on the environmental performance of products, the Commission proposes to remove all requirements for displaying label elements/ hazard information in advertisements, replacing it with an amended prompt encouraging consumers to read the label before use. Furthermore, for both advertisement and distance sales offers, the Commission proposes waiving these rules for professional users, as professionals have access to safety data sheets.

While some Member States have backed the Commission's approach. Others highlight the need to deliver on the core purpose of the rules – early warning for users - and ensure a level playing field for online sales, particularly with regard to third country sellers, where the advertising rules in the CLP 2024 revision are adapted to the existing enforcement mechanisms under the DSA with regards to illegal online content.

Issues raised by delegates include defining what constitutes an "advertisement", balancing simplification with safety and advance warning of users, and linking obligations with other regulations for consistency. The Member States were also divided on whether the rules on advertisements and distance sales offers should apply to professional use.

Question 4: The PCY encourages Member States to prepare answers to the following questions on advertisements:

a) Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?

FI supports a similar approach to be applied to online and other advertising channels (with the obvious exception regarding audio advertising).

b) Which, if any, label elements can be removed from the rules on advertising in Article 48?

FI believes that it is not necessary to duplicate all hazard information from the label.

c) The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?

FI supports the Com proposal regarding the inclusion of the text prompting users to read the label and product information prior to use.

Question 5: Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?

FI can support this.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

The Commission proposes that CLP labels should include a "digital contact" instead of the current requirement for postal address and telephone number. A similar proposal is included in the Omnibus IV package (Digitalisation and Common Specifications).

The PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position. The Commission also proposes the simplification of that supplier contact details by allowing information on additional suppliers to appear only on the digital label.

Member States expressed openness towards expanding the digital labelling. Based on the comments received, the PCY considers that the Commission's proposal strikes the right balance, albeit slight editorial amendments may be needed.

Question 6: Do Member States have any objections to the PCY's proposed approach on digitalisation?

FI supports the approach that the in the end of this exercise rules on digitalisation should be aligned between Omnibuses IV and VI.

Packaging under 10 ml (Article 29(2) and Annex I, section 1.5.2.4)

Member states are broadly supportive of the Commission's proposal on exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, some concerns remain on legal clarity and consumer protection for vulnerable groups.

Some have asked for slight editorial changes, alignment with other EU rules, and for clarification on the use of multilayer, booklet, or leaflet labels. The PCY will carefully examine the received editorial suggestions.

Based on the feedback so far, our intention is to proceed with the proposal in its current form.

- **Finland's preliminary notes on the Cosmetic Products Regulation (CPR) – COM(2025)531**

Some Member States have questioned the Commission's assertion that the proposed amendments to the CPR will not affect consumer safety negatively, and particularly with regard to the presence of CMR substances in cosmetic products.

The PCY intends to raise this issue as central to the discussions.

Amendments to Article 15

Member States highlight that for the proposed amendments to Article 15 in particular, simplifications must not be made at the expense of human health and consumer safety. In the Staff Working Document (SWD (2025) 531), the Commission aims to explain the timelines.

New timeline for submitting an application for derogation for using CMR substances in cosmetic products

The Commission proposal suggest a new timeline for submitting an application for a derogation for using a CMR substance in cosmetic products. Some Member States express concern for the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 1: Can Member States support the new timeline for submitting an application for derogation as suggested by the Commission?

FI can support the timeline presented in the Com proposal.

New timeline for amending the Annexes

In the Commission proposal, a new timeline is presented for the prohibition of CMR substances in cosmetic products under CPR. Some Member States express their concern about the impact on the protection of human health, as CMR-substances will be present in cosmetic products for a longer period.

Question 2: Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?

FI can support the approach and finds the time period acceptable as long as the overall level of protection is not compromised.

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

The Commission proposes the introduction of transitional periods for placing products on the market (12 months) and making products available on the market (24 months). Some Member States support the introduction of periods for placing and making available on the market, but call for shorter timeframes to ensure a high level of protection for human health

Question 3: Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?

FI can support the proposed timelines but can be flexible provided that the overall level of protection is not compromised.

Amendments of criteria for derogation

The Commission proposes that the criteria for derogation be narrowed down from four to two.

Question 4: Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?

FI can support the proposed approach provided that the overall level of safety to human health is not compromised.

Introduction of criteria for alternative assessment

The Commission proposal introduces criteria for assessing whether alternatives are available when evaluating a derogation application for using a CMR substance in cosmetic products.

Some Member States are concerned that the criteria are too broad and will almost always result in the conclusion that no alternatives are available or that an alternative method or technical solution will not be recognised as a suitable alternative.

Question 5: The PCY invites the Member States to participate in setting the direction:

a. Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?

FI supports the inclusion of criteria in a guidance document that can be updated regularly but can be flexible.

b. Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?

FI can support a more flexible and future-proof approach to what can be regarded as an alternative in this context.

c. Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?

FI believes that safety considerations – both related to human health and the environment - must always take precedence.

Natural complex substances containing CMR-substances

The aim of the Commission proposal on natural complex substances is to create clarity when natural complex substances contain CMR-classified components. Some Member States express concern for the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.

c. CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.

Question 6: Can Member States support one or more of the above-mentioned options?

FI supports option b. as regards CMR-containing natural complex substances. FI supports a case-by-case approach, neither a categorical exemption nor a ban, as we believe that this approach would best ensure that safety concerns are addressed, and unnecessary bans avoided.

Classifications based on ingestion or inhalation route of exposure

The Commission proposes to exclude CMR-substances from the generic ban under CPR if the CMR-substance is explicitly based on oral or inhalation route of exposure.

Some Member States find that these substances still pose a risk, as many cosmetic products are used in the mouth area or are in a spray form, and are therefore concerned about the impact on the protection of human health.

Below are some indicative options identified by the PCY.

a. CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.

b. As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.

c. CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.

Question 7: Can Member States support one or more of the above-mentioned options?

FI believes that the relevancy of the exposure route should always be assessed on a case-by-case basis, and no automatic exemptions for CMR-substances based on exposure route should be granted.

Abolishment of pre-notification of nano-material ingredients (Article 16)

The Commission proposes to abolish the requirement for pre-notification for nano-material ingredients in cosmetic products, suggesting that these products should be notified to the Commission when placed on the market like other cosmetic products.

Question 8: If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?

FI supports the abolishment of the nano-catalogue. We believe that it is sufficient that such information is submitted as a part of the Cosmetic Product Safety Report which is required to be submitted before a cosmetic product is placed on the market.

Abolishment of the glossary (Article 19 and 33)

While no Member State expressed opposition to the proposal regarding the suggested use of "internationally recognised nomenclature" instead of the current Glossary of common ingredient names, several member States call for greater legal certainty, and expressed a need for clear naming.

Question 9: Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?

FI can support both the abolishment of the nano-catalogue and the glossary. At this point we have no suggestions regarding the issue concerning the legal certainly in case of only using one specific international nomenclature.

- **Finland's preliminary notes on the Fertilising Products Regulation (FPR) – COM(2025)531**

Based on previous AGS meetings and written comments, the following areas have been identified as the key issues for further discussions. The PCY invites Member States to prepare their replies to the accompanied questions.

The deletion of the "unbundling clause" attached to the adoption of delegated acts

Generally, a positive attitude to this part of the proposal. The PCY notes, nonetheless, that some Member States have expressed doubts on whether the proposal's scope is too wide. In other interventions, Member States queried whether the removal of the "unbundling clause" might even lead to delays in the process.

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?

FI has no comment at this time.

Question 1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

FI can support this option.

The digitalisation of the EU-conformity assessment declaration

Similar to the Commission's Omnibus IV package, focusing on the digital transformation of product compliance, the PCY understands that the fertilising products market will also benefit from further digitalisation. Some Member States have indicated, that there might exist situations where the use of an analogue document may be appropriate.

In this regard, the PCY suggests that Omnibus VI should be aligned to reflect the final outcome of Omnibus IV position.

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

FI has no objections against proposed approach.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

The PCY recognises that the Member States generally agree that the long process for allowing new micro-organisms in microbial biostimulants constitutes an obstacle to European innovation. Hence, the Commission's proposal for a simpler approval procedure receives broad support among delegations. Nonetheless, the PCY notes that some Member States prefer to involve an independent body in the approval procedure. 10

Question 3: In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

FI considers it important to include an independent scientific body in the process.

Removal of the extended REACH-registration requirement for EU-fertilising products.

Member States generally support the removal of the extended REACH-registration requirement for the final EU-fertilising product and for the individual chemical substances of the fertiliser product. However, the PCY notes that some Member States express concerns when it comes to the ability of the national market surveillance authorities to supervise the

market and avoid bringing public safety into jeopardy if certain products are exempted from the REACH-registration requirements.

In this regard, one Member State suggests that the Commission should draw up a “positive list” of safe, traditional and well known “historical” fertilising products that do not need to be REACH-registered (the list would in this case have to be developed).

Question 4: Do Member States support creating a possible “positive list” of fertilising products exempted from REACH-registration, as a way forward?

FI can support the proposal of creating a positive list.

Romania

Romania

General Comments

1. **Stop the Clock** - We can support the mechanism as part of the Omnibus VI package, to avoid additional delays in the legislative process.
2. **Digital Contact** - A clear definition is required, accompanied by minimum functionality standards (e.g. response time, accessibility). A dual option (digital + telephone) during a transitional period would be preferable to avoid excluding consumers without digital access (according to statistical information provided by the RO National Institute of Statistics for 2023).
3. **Digital Labels** – in our view, a transitional period should have a minimum of 18–24 months, considering the need to develop technical guidelines and adapt infrastructure.
4. **Label Format and Readability** - We request the **inclusion of practical examples** in future guidelines for various types of chemical products, as well as **clarification** of the role of inspection authorities in assessing readability, to avoid arbitrary interpretations.
5. **Labelling of Small Packages** (≤250 ml and ≤10 ml) – The proposal to eliminate the requirement for justifying the impossibility of applying complete labelling is **reasonable** and offers flexibility, reflecting market realities.
6. **Label Updates** - Reverting to the formulation "without undue delay" **is acceptable**, provided there are clarifications and examples in the technical guidelines.
7. **Advertising of Hazardous Chemical Products** - We recommend **clarifying** the term "advertising" in the guidelines. The COM proposal is also supported by the information obligations under the REACH Regulation for professional users (B2B) through safety data sheets.

8. **Distance Sales** - The COM proposal to impose the obligation to display all CLP labelling elements in distance sales offers exclusively for consumers (excluding professional users/B2B) is **welcome**. For the B2B segment, communication is already carried out through safety data sheets (SDS), in accordance with REACH Regulation requirements.
An important aspect here would be the practical implementation for online platforms that serve both categories of users (consumers and professionals). A possible mechanism for clear selection of user type when accessing the offer, with validation through fiscal identification (e.g., CIF, VAT code). Based on this selection, the platform could display the corresponding labelling information, avoiding information overload unnecessary for professional users, while ensuring transparency and protection for consumers. This approach could be detailed in technical guidelines with practical examples for e-commerce platforms.

Fertilising Products Regulation (FPR) – COM(2025)531 (replies to questions in Presidency discussion note *WK 11188/2025 INIT***)**

- *Question 3: In light of both the positive potential and the possible risks from new microorganisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?*

Regarding the method for evaluating and introducing new microorganisms into the CMC 7, it is important to maintain a rigorous approach to their introduction in order to prevent negative effects on human, animal and environmental health (based on the EFSA assessment).

- *Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?*

We believe that the REACH evaluation should be maintained for the same reasons. We therefore believe that the introduction of a second evaluation pathway is not sufficiently certain.

Malta

Malta's Comments on the Presidency Note WK 11188/25 on Omnibus VI (Chemicals)

Below please find Malta's comments, as made during the Working Party of 15 September 2025, as well as additional comments:

"Stop-the-clock" – COM(2025)526

1. *Can Member States support the current "Stop-the-Clock" proposal as put forward by the Commission?*

Malta supports the "STOP THE CLOCK" proposal and believes that different dates for the same type of obligations should be streamlined into one single deadline. Nevertheless, MT believes it is preferable that such a measure is postponed until the date of application of the Regulation on packaging and packaging waste. Lastly, MT recommends that utmost care is taken to ensure that the final result of these proposals is indeed a simplification effort, that makes implementation for national authorities as well as compliance for operators, especially small businesses, as smooth and simplified as possible.

Regulation on Classification, Labelling and Packaging (CLP) – COM(2025)531

Formatting of labels (Article 31(3) and Annex 1, section 1.2.1.4 and 1.2.1.5)

2. *Can Member States support one of the above-mentioned options? Please specify which elements should be retained (if option (a) is chosen) or explicitly clarified (if option (b) is preferred).*

Malta believes that it is of utmost importance that the simplification exercise being undertaken does not result in the outright watering down of safety provisions. Based on the premise that the rules introduced in 2024 were underpinned by an informed rationale and therefore enjoyed a solid basis for their introduction, MT would be more inclined to opt for Option a ("Retaining certain elements of the formatting rules introduced in 2024.")

Malta prefers that all formatting elements introduced via Regulation (EU) 2024/2865 should be retained i.e. Article 31(3), Annex I, Sections 1.2.1.4 and 1.2.1.5.

Updating labels (Article 30(1))

3. *Can Member States support one or more of the above-mentioned options?*

From the options provided, Malta would prefer Option b ("Retaining a fixed deadline for updating the labels for self-classified substances and mixtures, extending it to 9 or 12 months").

Advertising (Article 48) and distance sales offers (Article 48a)

4. *The PCY encourages Member States to prepare answers to the following questions on advertisements:*

a. *Would you be in favour of restricting the rules in Article 48 to only cover online advertisements, thereby clarifying the scope of the term "advertisement", while also simplifying rules for other advertising channels?*

Malta would not be in favour of restricting the rules in Article 48. Malta recalls that clarifying the rules applicable to advertisements along the value chain was one of the objectives of the CLP review. It is important to raise awareness among operators, in order to prioritise the purchase of less hazardous products where appropriate. Ensuring the same level of information for consumers online as for consumers in stores, where they have access to the label, is an essential principle of consumer protection.

b. *Which, if any, label elements can be removed from the rules on advertising in Article 48?*

Kindly vide answer provided to 4a.

c. *The Commission proposes the prompt: 'Always read the label and product information before use.' Do you support this wording as it stands, or should the prompt also include a reference to (a) the presence of hazardous substances to improve consumer awareness, and/or (b) the name and digital contact details of the responsible supplier, as required under Article 4(11), which can assist market surveillance authorities in conducting automatic control of advertisements?*

Malta supports the inclusion of reference (a) and (b) in addition to the proposed prompt by the Commission. Safeguarding human health remains imperative and the inclusion of such references will further aid market surveillance authorities when conducting automatic control of advertisements.

5. *Can you support restricting Article 48 on advertisements and Article 48a on distance sales offers to only cover consumer products?*

Malta does not support this. Kindly refer to the reply to question 4.

Digitalisation – digital contacts (Article 17(1)) and digital labelling (Annex I, section 1.6)

6. *Do Member States have any objections to the PCY's proposed approach on digitalisation?*

Malta has concerns on the proposed replacement of the telephone number with "digital contact". Such a proposal limits access to information to digital channels only.

Malta strongly supports calls for the phrase "telephone number and digital contact" to be included.

<u>Cosmetic Products Regulation (CPR) – COM(2025)531</u>

Amendments to Article 15 - New timeline for submitting an application for derogation for using CMR substances in cosmetic products

1. *Can Member States support the new timeline for submitting an application for derogation as* suggested by the Commission?

Malta does not support the new timeline for submitting an application for derogation as suggested by the Commission. The possibility of derogation for using CMR substances in cosmetic products will only prolong public exposure to that CMR.

New timeline for amending the Annexes

2. *Can Member States support the approach as suggested by the Commission, and do the Member States find the suggested time period acceptable?*

Kindly see Malta's reply to question 1.

Implementation of transitional periods for placing on the market and making available on the market of cosmetic products containing CMR substances

3. *Can Member States support the implementation of transitional periods for both placing on the market and making available on the market for cosmetic products containing CMR substances? If so, how long should these transitional periods be?*

   Malta strongly advocates for the prioritisation of consumer protection. Malta thanks the Commission for the explanations provided during the Working Party on 15 September 2025 but would welcome further explanations and information on the justification and reasoning for the implementation of transitional periods for placing and/or making available on the market cosmetic products containing CMR substances.

Amendments of criteria for derogation

4. *Can Member States support the deletion of the criteria a) and the merging of the criteria c) and d), meaning that the specifications for use are listed as part of the criteria for safety evaluation by the SCCS?*

   Malta can support the merging of criteria (c) and (d) while criteria (a) should be kept for cosmetic products that may be ingested as a result of their intended use.

Introduction of criteria for alternative assessment

5. *The PCY invites the Member States to participate in setting the direction:*

a. *Should the criteria for alternative assessment be specified in the Regulation or in a guidance document?* Malta would prefer to have such alternative assessment criteria stipulated in a guidance document.

b. *Should the criteria for what constitutes alternative be widened (e.g., alternative methods, combinations of alternatives, other)?*

   No objections to widening the said criteria, as long as these are included in the guidance.

c. *Is the inclusion of environmental and economic aspects in the criteria for assessing alternatives within the scope of the CPR, or should these criteria be removed?*

   Malta considers that both environmental and economic aspects should be included in the criteria taken into consideration when assessing alternatives. Malta would also suggest that economic feasibility is given higher priority and be considered mandatory for any alternative to meet. Otherwise, it would not be possible to expect economic operators to utilise said alternative.

Natural complex substances containing CMR-substances

6. *Can Member States support one or more of the above-mentioned options?*

a. *CMR substances contained within a natural complex substance should be exempted from the prohibition of CMR substances in cosmetic products.*

b. *As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances present in a natural complex substance and prove that their use is safe.*

c. *CMR substances present within a natural complex substance should be included in the ban on CMR substances in cosmetic products.*

   Malta would prefer Option B. Malta is of the opinion that a substance may be used in a cosmetic product as long as that substance is deemed acceptable and safe for use for the consumer following the SCCS safety assessment.

Classifications based on ingestion or inhalation route of exposure

7. *Can Member States support one or more of the above-mentioned options?*

a. *CMR substances that are explicitly classified on the basis of oral or inhalation route of exposure, should be exempt from the prohibition of CMR substances in cosmetic products.*

b. *As above, including an amendment requiring that the SCCS must always assess the safety of CMR-substances that are explicitly classified on the basis of oral or inhalation route of exposure, and prove that their use is safe.*

c. *CMR substances that are explicitly classified based upon oral or inhalation route of exposure should be included in the ban on CMR substances in cosmetic products.*

Similar to Malta's reply under Question 6 above, Malta would opt for Option B. Malta is of the view that if a substance classified as CMR for inhalation is used in cosmetic products that are (potentially) inhaled, Article 15 would still apply. The same applies for substances with an oral classification. Therefore, even in such cases, a toxicological assessment by the SCCS would be necessary to ensure a high level of protection for consumers.

Abolishment of pre-notification of nano-material ingredients (Article 16)

8. *If the nano-material catalogue is abolished, do the Member States still find that this information should be made available? If so, in what form?*

Malta does not agree with the abolishment of pre-notification of nanomaterial in Article 16. Consideration of the safety of nanomaterials in cosmetic products should continue to be subject to assessment from the SCCS in order to ensure a high level of protection to the consumer.

Abolishment of the glossary (Article 19 and 33)

9. *Do the Member States have any suggestions on how legal certainty is ensured on the matter of having one specific international nomenclature as the primary source of ingredients names?*

Malta has no suggestions to put forward.

<u>Fertilising Products Regulation (FPR) – COM(2025)531</u>

The deletion of the "unbundling clause" attached to the adoption of delegated acts

1. *The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide?*

a. *Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?*

The rationale for the deletion of the unbundling clause in order to expedite the Commission's work is still unclear. If serious concerns or issues arise in relation to one part of a bundled proposal, there is a factual risk of delaying/stalling the proposal in its entirety, including the non-contentious parts thereof.

The digitalisation of the EU-conformity assessment declaration

2. *Do Member States have any objections to the PCY's proposed approach on digitalisation?*

Malta welcomes the proposed digitalisation of the EU-conformity assessment declaration. Having said that, the option for written/physical information should be kept available, nonetheless.

A simpler assessment procedure for new micro-organisms in microbial biostimulants

3. *In light of both the positive potential and the possible risks from new micro-organisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?*

   Malta supports that an independent scientific body (such as the EFSA) shall provide an assessment on the safe use of microbial biostimulants before it is added in the list of permitted fertilisers.

Removal of the extended REACH-registration requirement for EU-fertilising products

4. *Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?*

   This proposal can be considered during the discussions on REACH once the proposal for its revision and negotiations thereon commence.

France

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Égalité
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Secrétariat général des affaires européennes

<u>Objet</u> : Commentaires à la réunion du groupe de travail du Conseil omnibus simplification chimie du 15 septembre 2025

A la suite de la réunion du groupe simplification du 15 septembre portant sur l'omnibus chimie, les autorités françaises font parvenir les commentaires suivants.

<u>I. CLP</u>

Question 1 - Concernant l'arrêt d'horloge (« *stop the clock* »)

Pour les ventes à distance et l'étiquetage dans les stations-service, les autorités françaises peuvent se montrer flexibles pour permettre une bonne prise en compte de ces dispositions par les opérateurs.

Question 2 - Concernant la mise en forme des étiquettes

Les deux options suivantes ont été identifiées :
a) Conserver certains éléments des règles de mise en forme introduites en 2024.
b) Clarifier davantage dans le texte ou les considérants la manière dont la lisibilité doit être comprise.

Comme déjà indiqué par commentaires, les autorités françaises ne peuvent soutenir l'option a).

L'option b) peut être soutenue si certaines règles sont prescrites par le corps du règlement CLP pour garantir la lisibilité des étiquettes. En effet, certains fournisseurs ne reconnaissent pas le caractère restrictif des orientations pratiques publiées par l'ECHA et légalement, il n'est pas possible d'engager des poursuites pénales pour non-respect des orientations publiées par l'ECHA. Il est donc important que certaines règles restent prescrites par le corps du règlement CLP pour garantir la lisibilité des étiquettes.

A cet effet, les autorités françaises proposent de s'aligner sur le règlement FIC relatif à la fourniture d'informations sur les denrées alimentaires aux consommateurs (1169/2011). Pour les substances et mélanges destinés au grand public, une taille minimale de caractères de 1,2 mm, hauteur du x, sans contrainte pour l'interligne, est proposée, avec une réduction possible à 0,9 mm pour les emballages ne dépassant pas 10 ml afin de garantir la lisibilité des étiquettes.

Question 3 - Concernant la mise à jour des étiquettes

Les trois options suivantes ont été identifiées :
a) Clarifier dans un considérant comment la formulation « sans retard injustifié » doit être comprise ;
b) Conserver un délai fixe pour la mise à jour des étiquettes des substances et mélanges auto-classés, en le prolongeant à 9 ou 12 mois ;
c) Conserver le délai de six mois pour les substances CMR et les perturbateurs endocriniens, tout en revenant à « sans retard injustifié » pour les autres classifications.

Les autorités françaises considèrent que la proposition a) n'est pas acceptable.

En effet, la suppression d'un délai fixe est gênante pour les autorités de surveillance du marché. La notion de « sans retard injustifié » est trop subjective pour être mise en œuvre par les autorités de surveillance du marché et le règlement 1907/2006 REACH n'impose pas non plus de délai clair pour la transmission d'une FDS mise à jour. La suppression du délai de six mois équivaut à autoriser un délai de 18 mois, clairement accordé pour les modifications mineures.
Malgré les avantages de cette mesure en termes de rationalisation des coûts pour les entreprises pour les produits peu préoccupants, le délai de ré-étiquetage de plus de six mois ne devrait pas être une raison pour éliminer les stocks de produits qui ne sont pas correctement étiquetés et qui peuvent être particulièrement nocifs pour la santé des consommateurs ou l'environnement.

Un délai supérieur à 6 mois n'est pas acceptable pour les CMR et les perturbateurs endocriniens.

<u>Les autorités françaises considèrent que l'application de l'option c) est fondamentale pour les autorités françaises et correspond aux propositions transmises à la Commission.</u>

Pour les mélanges dangereux non CMR et non perturbateurs endocriniens, l'option b) peut être acceptée.

Question 4 - Concernant la publicité et offres de vente à distance

Les questions suivantes sont posées dans la note de cadrage :

a) Seriez-vous favorable à ce que les règles de l'article 48 soient limitées aux publicités en ligne, ce qui permettrait de clarifier la portée du terme « publicité » tout en simplifiant les règles applicables aux autres canaux publicitaires ?
b) Quels éléments de l'étiquette pourraient être supprimés des règles relatives à la publicité figurant à l'article 48 ?

c) La Commission propose la mention suivante : « Toujours lire l'étiquette et les informations sur le produit avant utilisation. » Êtes-vous favorable à cette formulation telle quelle, ou pensez-vous que le message devrait également mentionner (a) la présence de substances dangereuses afin de sensibiliser davantage les consommateurs, et/ou (b) le nom et les coordonnées numériques du fournisseur responsable, comme l'exige l'article 4, paragraphe 11, ce qui peut aider les autorités de surveillance du marché à effectuer un contrôle automatique des publicités ?

Concernant la publicité et offres de vente à distance, les autorités françaises considèrent que la clarification des règles applicables à la publicité tout au long de la chaîne de valeur était l'un des objectifs de la révision du CLP. Il est important de sensibiliser les opérateurs, y compris lors des échanges commerciaux, afin de privilégier l'achat de produits moins dangereux lorsque cela est approprié. Les propositions a) et b) étant moins protectrices que le règlement CLP 1272/2008 initial, les autorités françaises ne pourront en aucun cas les soutenir.

Les autorités françaises demandent à ce que la proposition c) doit être complétée de la façon suivante, comme indiqué dans les commentaires transmis, pour être acceptable et alignée sur les dispositions existantes :
« Utilisez les produits chimiques avec précaution. Lisez toujours l'étiquette et les informations sur le produit avant utilisation ».
Ces phrases doivent être facilement lisibles et clairement distinguables par rapport à l'ensemble de la publicité. Le terme « chimique » peut être remplacé par une description plus précise de la catégorie de produits. »

Cette formulation devrait être complétée par la reprise des identificateurs de produits imposés par l'article 18 de CLP, des mentions additionnelles de l'annexe II et inclure le nom et les coordonnées numériques du fournisseur responsable, comme l'exige l'article 4, paragraphe 11.

Question 5 - concernant la publicité

Pouvez-vous soutenir la restriction de l'article 48 sur les publicités et de l'article 48a sur les offres de vente à distance afin qu'ils ne couvrent que les produits de consommation ?
Les autorités françaises ne sont pas favorables à la proposition de la Présidence, car tous les professionnels n'ont pas le même niveau de connaissance et de compréhension du règlement CLP 1272/2008. C'est particulièrement le cas des professionnels qui achètent des produits chimiques sans lien direct avec leur activité : acheteurs publics ou PME qui achètent des consommables pour leur personnel ou leurs bâtiments. De plus certains sites initialement destinés aux professionnels acceptent les commandes passées par des particuliers.

Question 5 - relative à la digitalisation – contacts numériques et étiquetage numérique

Les autorités françaises sont défavorables à la réduction des moyens de contact au numérique ; le contact numérique est un complément des voies de contact existantes (téléphone et adresse postale) et non un substitut.

Concernant les emballages de moins de 10 ml, la Présidence a indiqué son intention de continuer dans le sens des propositions de la Commission.

Les autorités françaises maintiennent leurs réticences au regard des propositions de la Commission qui entraînent une perte importante d'informations pour le grand public pour les emballages de moins de 125 ml. Par exemple, les gels hydroalcooliques de moins de 125 ml ne peuvent pas porter les mentions de danger et les conseils de prudence correspondants, même s'ils sont inflammables

H225 ou H226 et le plus souvent irritants pour les yeux H319. Seule la mention EUH202 resterait obligatoire pour les colles cyanoacrylates, même si celles-ci sont également irritantes pour la peau et les yeux (H315/H319).

II. Cosmétiques

Les Autorités françaises remercient la présidence pour cette initiative et accueillent favorablement l'objectif de simplification des démarches administratives pour les metteurs sur le marché de produits cosmétiques, notamment à l'article (15) du règlement cosmétique, les clarifications des délais pour la modification des annexes, les délais de dépôt de dossier de demandes de dérogations et l'insertion de durée pour les périodes transitoires. Elles souhaitent rappeler que les deux propositions de simplification suivantes (I) constituent des lignes rouges pour la France. Les Autorités françaises estiment que les propositions de la Commission ne sont pas suffisantes pour garantir la sécurité des consommateurs. Les Autorités françaises considèrent que l'objectif de cet omnibus de simplification doit maintenir le niveau élevé de sécurité, tel qu'il est actuellement défini dans le règlement cosmétiques. Par ailleurs, elles souhaitent rappeler leur soutien à la prise en compte des aspects économiques dans les critères d'évaluation des solutions de remplacement (II).

A. Lignes rouges des autorités françaises

1. Exclusion des substances classées CMR1 lorsque les classifications sont fondées sur la voie d'exposition par ingestion ou par inhalation (article 2 paragraphe (2) (b) de la proposition de règlement omnibus)
La Commission propose d'exclure les substances CMR de l'interdiction si la substance CMR est explicitement fondée sur une voie d'exposition orale ou par inhalation.

Les autorités françaises rappellent leur soutien à l'option c suivante indiquée par la présidence dans sa note (WK 11188/2025 INIT) **: «** *Les substances CMR qui sont explicitement classées sur la base d'une voie d'exposition orale ou par inhalation devraient être incluses dans l'interdiction des substances CMR dans les produits cosmétiques* **».**

Les Autorités françaises sont donc opposées à la proposition d'exclure systématiquement les substances CMR de l'interdiction si le classement de la substance CMR est explicitement fondé sur une voie d'exposition orale ou par inhalation pour toutes les raisons suivantes :

1) Les consommateurs sont explosés quotidiennement à des substances dangereuses. Les produits cosmétiques sont utilisés quotidiennement par les consommateurs, (y compris des personnes vulnérables : nourrissons, femmes enceintes, personnes âgées, personnes en mauvaise santé…) tout au long de leur vie.
   Si les substances CMR 1 n'étaient pas soumises à l'interdiction générale d'utilisation dans les produits cosmétiques, sauf dérogation, alors, les produits cosmétiques contenant de telles substances pourraient rester sur le marché pendant une longue période – parfois plusieurs années – avant d'être évalués par le CSSC, alors même qu'ils présentent un risque pour la santé humaine.
2) Selon les notes d'orientation du CSSC, les voies d'entrée les plus importantes pour les ingrédients cosmétiques sont : la peau mais aussi les voies respiratoires et la bouche. Concernant l'exposition orale, les zones d'utilisation cibles, à savoir les « lèvres », « dents » et « muqueuses de la cavité buccale » (termes inclus dans la définition d'un produit cosmétique à l'article 2 du règlement), font que l'exposition orale doit être incluse comme raisonnablement prévisible pour certains produits cosmétiques et doit donc être prise en compte dans l'évaluation des risques. Par ailleurs, les produits cosmétiques destinés à être

appliqués sur la peau peuvent également être ingérés par contact main-bouche. Ce comportement est fréquent chez les bébés et les jeunes enfants, mais aussi chez les adultes : utilisation des mains (avec de la crème et du vernis à ongles) pour préparer les repas, rongement des ongles, etc. Concernant la voie d'inhalation, les produits volatils lors de l'évaporation et tous les produits appliqués par pulvérisation ou en poudre sont particulièrement concernés.

3) L'approche actuelle consistant à interdire les produits chimiques les plus nocifs pour la santé s'inscrit pleinement dans la stratégie de durabilité dans le domaine des produits chimiques. La notion de voie d'exposition serait l'exception dans la législation européenne. Elle pourrait conduire à la présence d'une substance CMR dans les produits cosmétiques alors que cette même substance serait interdite dans d'autres produits (ex : phytosanitaires, biocides, jouets, etc.).

4) De plus, l'exclusion de certaines voies d'exposition nécessite de produire des données toxicologiques spécifiques pour ces voies d'exposition, qui ne peuvent pas être facilement obtenues à partir de données *in vitro*.

2.Suppression de la notification préalable des ingrédients des nanomatériaux (article (3) de la proposition de règlement omnibus modifiant l'article 16 du règlement cosmétiques)
La Commission propose de supprimer l'obligation de notification préalable pour les ingrédients de nanomatériaux dans les produits cosmétiques, en proposant que ces produits soient notifiés à la Commission lorsqu'ils sont mis sur le marché comme d'autres produits cosmétiques.

Les Autorités françaises considèrent que la proposition de la Commission pourrait en effet réduire la charge administrative pour les opérateurs économiques mais ne renforcera pas la sécurité des produits contenant des nanomatériaux comme le recommande le rapport 2021 de la Commission au Parlement européen et au Conseil.

En conséquence, les Autorités françaises soutiennent la conservation de l'obligation de notification préalable, pour les raisons suivantes :

1) L'objectif de l'article 16 règlement cosmétiques est différent de celui de l'article 13 du même règlement. A l'article 16, la Commission doit collecter toutes les données sur les nanomatériaux afin d'avoir une vue d'ensemble de l'utilisation qualitative et quantitative des nanomatériaux et donc demander au CSSC d'évaluer la sécurité de ces nanomatériaux si besoin est. En outre, les informations des paragraphes 3 et 7 (de l'article 16) dont la suppression est proposée ne sont ni repris dans le dossier d'information, ni lors de la notification des produits cosmétiques au titre de l'article 13.
2) Les États membres sont actuellement confrontés à de nombreuses inquiétudes concernant les nanomatériaux: manque de données fournies par les opérateurs économiques afin d'évaluer la sécurité des nanomatériaux inclus dans les cosmétiques, définition des nanomatériaux qui devrait être mise à jour, difficultés pour les autorités de surveillance du marché à vérifier la conformité des produits cosmétiques contenant des nanomatériaux, inquiétudes liées à la qualité du dossier d'information des produits en particulier pour la partie sécurité.
3) S'agissant d'un problème de santé publique, si les dispositions actuelles devaient évoluer, les autorités françaises souhaitent que ces modifications soient abordées dans le cadre des futures discussions qui auront lieu lors du processus de révision du règlement cosmétique.

B. Rappel du soutien des Autorités françaises à la disposition suivante

1. Introduction de critères pour l'évaluation d'alternative

La proposition de la Commission introduit des critères permettant d'évaluer s'il existe des solutions de remplacement lors de l'évaluation d'une demande de dérogation pour l'utilisation d'une substance CMR dans des produits cosmétiques.

Les Autorités françaises sont favorables au principe de compléter la notion de substance de substitution appropriée à celle de combinaisons de substances ainsi qu'à la possibilité d'utiliser des procédés alternatifs seuls ou associés si la sécurité du produit fini est démontrée, et que la performance technique, la faisabilité industrielle, l'impact économique et les contraintes de propriété intellectuelles sont prises en compte dans ce cadre. Les Autorités françaises rappellent que ces nouvelles notions pourraient mériter d'être précisées dans le projet de guide en cours de discussion.

Les Autorités françaises soutiennent l'inclusion des aspects économiques dans les critères d'évaluation des solutions de remplacement. En effet, comme pour tout nouveau produit mis sur le marché, il est indispensable que les opérateurs puissent vérifier que la solution alternative soit économiquement atteignable et que ces enjeux soient appréhendés, en particulier pour les PME.

III. Fertilisants

Question 1 : La délégation de pouvoir prévue à l'article 43, qui impose à la Commission d'exercer son pouvoir en adoptant des actes délégués distincts pour différentes catégories de matières constitutives, conduit-elle à une situation où la délégation de pouvoir à la Commission devient trop large ?

Question 1a : Une reformulation du considérant 19 pourrait-elle clarifier la portée de la délégation de pouvoir tout en offrant à la Commission une plus grande marge de manœuvre ? La délégation pourrait-elle être mieux encadrée en reformulant le considérant 29 de la proposition afin de préciser que l'introduction des mêmes matériaux supplémentaires dans différentes catégories de matières constitutives (CMC) devrait être mise en œuvre par un seul acte délégué ?

Concernant la question 1, la suppression de l'article 43 conduit effectivement à élargir le pouvoir de délégation de la Commission européenne car celle-ci pourra proposer des modifications portant sur plusieurs catégories de matières constitutives (CMC) dans un même acte délégué.

Concernant la question 1a, la Commission européenne a toujours été attentive à ce qu'une matière ne soit pas incluse dans plusieurs catégories de matières constitutives (CMC) (par ex : les déchets autorisés dans le cadre de ce règlement sont inclus dans des CMC dédiées aux déchets car les exigences applicables sont adaptées à ces matières). Le fait qu'un même acte modifie plusieurs CMC ne remettra pas en cause ce principe.

Les autorités françaises considèrent ainsi que la suppression de l'article 43 ne soulève pas de problématiques particulières.

Question 2 : Les États membres ont-ils des objections à l'approche proposée par le PCY en matière de numérisation ?

Les autorités françaises rappellent qu'elles sont favorables à ce que le règlement UE laisse le choix de l'option numérique ou de l'option papier pour la fourniture de la documentation technique. Elles sont disposées à revoir leur position en acceptant le tout numérique, si la Commission européenne est certaine que cela ne pose pas de difficulté aux opérateurs.

Question 3 : Compte tenu à la fois des effets positifs et des risques éventuels liés aux nouveaux micro-organismes, les États membres estiment-ils qu'un organisme scientifique indépendant (par exemple, l'Autorité européenne de sécurité des aliments – EFSA) devrait jouer un rôle central dans le processus d'autorisation des nouveaux micro-organismes utilisés dans les biostimulants microbiens ?

Les autorités françaises remercient la présidence pour cette proposition et sont favorables à ce qu'un organisme scientifique indépendant joue un rôle central en évaluant l'efficacité et la sécurité des nouveaux microorganismes.

Question 4 : Les États membres soutiennent-ils la création d'une éventuelle « liste positive » de fertilisants exemptés de l'enregistrement REACH, comme voie à suivre ?

Les autorités françaises soutiennent la création d'une liste positive de substances.

Les autorités françaises remercient la Présidence de cette proposition de création d'une liste positive de substances (et non de fertilisants comme l'indique la question) exemptées de l'enregistrement REACH telle que suggérée par les autorités françaises comme solution alternative à la suppression de la disposition spécifique REACH.

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Courtesy translation

I. CLP

Question 1 – Regarding the "stop of the clock", the French authorities can be flexible to allow operators to properly take these provisions into account.

Question 2 - Regarding the formatting of labels, as already indicated in its comments, the French authorities cannot support option a). Option b) can be supported if certain rules are laid down in the CLP Regulation to ensure the legibility of labels. It is therefore proposed to align with the FIC Regulation on the provision of food information to consumers (1169/2011). For substances and mixtures intended for the general public, a minimum font size of 1.2 mm x-height, with no restrictions on line spacing, is proposed, with a possible reduction to 0.9 mm for packaging not exceeding 10 ml in order to ensure the legibility of labels.

Question 3 - Regarding the updating of labels, Proposal (a) is not acceptable. The removal of a fixed deadline is problematic for market surveillance authorities.

The concept of 'without undue delay' is too subjective to be implemented by market surveillance authorities, and Regulation 1907/2006 REACH does not impose a clear deadline for the transmission of an updated SDS either. Removing the six-month deadline is equivalent to allowing a period of 18 months, which is clearly granted for minor changes.

A period of more than six months is not acceptable for CMRs and endocrine disruptors, so the application of option c) is fundamental for the French authorities and corresponds to the proposals submitted to the Commission.

For hazardous mixtures that are not CMRs or endocrine disruptors, option (b) can be accepted.

Question 4 - With regard to advertising and distance sales offers, for the French authorities, clarifying the rules applicable to advertising throughout the value chain was one of the objectives of the CLP revision. It is important to raise awareness among operators, including during commercial exchanges, in order to promote the purchase of less hazardous products where appropriate. Proposals a) and b) offer less protection than the initial CLP Regulation 1272/2008, and the French authorities cannot support them.

Proposal c) must be supplemented as follows, as indicated in the comments submitted, in order to be acceptable and aligned with existing provisions:

'**Use chemical products safely**. Always read the label and product information before use''

These sentences shall be easily legible and clearly distinguishable in relation to the whole advertisement. The words 'chemical' may be replaced by a more precise description of the product category

This wording should be supplemented by the product identifiers required by Article 18 of CLP, the additional information in Annex II and the name and contact details of the responsible supplier, as required by Article 4(11).

Question 5 - concerning advertising, the French authorities are not in favour of the Presidency's proposal, as not all professionals have the same level of knowledge and understanding of CLP Regulation 1272/2008. This is particularly the case for professionals who purchase chemicals that are not directly related to their activity: public purchasers or SMEs that purchase consumables for their staff or buildings. In addition, some websites initially intended for professionals accept orders placed by individuals.

Question 6 - concerning digitisation – digital contacts and digital labelling, the French authorities are opposed to reducing the channels of contact to only digital; digital contact is a complement to existing means of contact (telephone and postal address) and not a substitute.

With regard to packaging of less than 10 ml, the Presidency has indicated its intention to continue in line with the Commission's proposals.

The French authorities remain reluctant to accept the Commission's proposals, which would result in a significant loss of information for the general public for packaging of less than 125 ml. For example, hydroalcoholic gels of less than 125 ml cannot carry the corresponding hazard statements and safety advice, even if they are flammable H225 or H226 and, in most cases, irritating to the eyes H319. Only the EUH202 warning would remain mandatory for cyanoacrylate adhesives, even though these are also irritating to the skin and eyes (H315/H319).

II. Cosmetic products

The French authorities thank the Presidency for this initiative and welcome the objective of simplifying administrative procedures for cosmetics marketers, in particular in Article (15) of the Cosmetics Regulation, the clarification of the deadlines for amending the annexes, the deadlines for submitting applications for derogations and the insertion of duration for transitional periods. They would like to recall that the following two simplification proposals (I) constitute red lines for France. The French authorities consider that the Commission's proposals are not sufficient to guarantee consumer safety. The French authorities consider that the objective of this simplification omnibus must maintain the high level of safety, as currently defined in the Cosmetics Regulation. Furthermore, they would like to reiterate their support for the inclusion of economic aspects in the criteria for the assessment of alternatives (II).

A. Red lines of the French authorities

1. Exclusion of substances classified as CMR1 when classifications are based on route of exposure by ingestion or inhalation (Article 2(2)(b) of the proposed Omnibus Regulation)
The Commission proposes to exclude CMR substances from the prohibition if the CMR substance is explicitly based on an oral or inhalation route of exposure.

We would like to reiterate our support for the following option c indicated by the Presidency in its note (WK11188/2025 INIT): *CMR* **substances that are explicitly classified on the basis of an oral or inhalation route of exposure should be included in the prohibition of CMR substances in cosmetic products.**

The French authorities are therefore opposed to the proposal to systematically exclude CMR substances from the prohibition if the classification of the CMR substance is explicitly based on an oral or inhalation route of exposure for all of the following reasons:

5) Consumers are detonated daily with dangerous substances. Cosmetic products are used daily by consumers (including vulnerable people: infants, pregnant women, elderly people, people in poor health...) throughout their lives.
   If CMR 1 substances were not subject to the general prohibition of use in cosmetic products, unless a derogation is granted, then cosmetic products containing such substances could remain on the market for a long period – sometimes several years – before being assessed by the SCCS, even though they pose a risk to human health.
6) According to the SCCS guidance notes, the most important entry routes for cosmetic ingredients are: the skin but also the respiratory tract and mouth. As regards oral exposure, the target areas of use, namely ‘lips’, ‘tooth’ and ‘mucous membranes of the oral cavity’ (terms included in the definition of a cosmetic product in Article 2 of the Regulation), mean that oral exposure must be included as reasonably foreseeable for certain cosmetic products and must therefore be taken into account in the risk assessment. In addition,

cosmetic products intended to be applied to the skin can also be ingested by hand-to-mouth contact. This behaviour is common in babies and young children, but also in adults: use of hands (with cream and nail polish) to prepare meals, nail gnawing, etc. Concerning the inhalation route, volatile products during evaporation and all products applied by spraying or powder are particularly concerned.

7) The current approach of banning the most harmful chemicals for health is fully in line with the Chemicals Sustainability Strategy. The concept of route of exposure would be the exception in European legislation. It could lead to the presence of a CMR substance in cosmetic products, whereas the same substance would be prohibited in other products (e.g. phytosanitary products, biocides, toys, etc.).

8) In addition, the exclusion of certain routes of exposure requires the production of specific toxicological data for those routes of exposure, which cannot be easily obtained from *in vitro* data.

2.Deletion of pre-notification of nanomaterial ingredients (Article (3) of the proposed Omnibus Regulation amending Article 16 of the Cosmetics Regulation)
The Commission proposes to remove the prior notification requirement for nanomaterial ingredients in cosmetic products, by proposing that these products be notified to the Commission when they are placed on the market like other cosmetic products.

The French authorities consider that the Commission proposal could indeed reduce the administrative burden for economic operators but will not enhance the safety of products containing nanomaterials as recommended in the 2021 Commission report to the European Parliament and the Council.

Consequently, the French authorities support the retention of the obligation of prior notification, for the following reasons:

C. The objective of Article 16 of the Cosmetics Regulation is different from that of Article 13 of that regulation. In Article 16, the Commission must collect all data on nanomaterials in order to have an overview of the qualitative and quantitative use of nanomaterials and therefore ask the SCCS to assess the safety of these nanomaterials if necessary. In addition, the information in paragraphs 3 and 7 (of Article 16) proposed to be deleted is not included in the information file or in the notification of cosmetic products under Article 13.
D. Member States currently face many concerns regarding nanomaterials: lack of data provided by economic operators to assess the safety of nanomaterials included in cosmetics, definition of nanomaterials that should be updated, difficulties for market surveillance authorities in verifying the compliance of cosmetic products containing nanomaterials, concerns related to the quality of the product information package in particular for the safety part.
E. With regard to a public health problem, should the current provisions evolve, we would like these changes to be addressed in future discussions during the process of revising the Cosmetics Regulation.

B. Reminder of the support of the French authorities to the following provision

1. Introduction of criteria for alternative assessment
The Commission proposal introduces criteria to assess whether there are alternatives when assessing an application for a derogation for the use of a CMR substance in cosmetic products.

The French authorities are in favour of the principle of supplementing the concept of an appropriate substitute substance with that of combinations of substances and of the possibility of using alternative

processes alone or in combination if the safety of the finished product is demonstrated, and that technical performance, industrial feasibility, economic impact and intellectual property constraints are taken into account in this context. The French authorities would point out that these new concepts might merit clarification in the draft guide currently under discussion.

The French authorities support the inclusion of economic aspects in the criteria for assessing alternatives. Indeed, as with any new product placed on the market, it is essential that operators can verify that the alternative solution is economically achievable and that these issues are addressed, particularly for SMEs.

I. Fertilising products

Question 1: The empowerment laid down in Article 43 relates to the Commission's right to exercise its power to adopt separate delegated acts for separate component material categories. leads to a situation where the delegated empowerment to the Commission becomes too wide? Question

1a. Could a rewording of recital 19 provide clarity on the scope of the empowerment whilst providing more flexibility to the Commission's room for manoeuvring? the empowerment be better framed by rewording recital 29 of the proposal to specify that the introduction of the same additional materials to various CMCs should be implemented through a single delegated act?

Concerning question 1, the deletion of article 43 effectively broadens the European Commission's power to delegate, as it will be able to propose amendments relating to several categories of constituent materials (CMC) in a single delegated act.

With regard to question 1a, the European Commission has always been careful to ensure that a material is not included in several categories of constituent materials (CMC) (e.g.: waste authorised under this regulation is included in CMCs dedicated to waste, as the applicable requirements are adapted to these materials). The fact that a single act modifies several CMCs will not call this principle into question.

The French authorities therefore consider that the deletion of article 43 does not raise any particular problems.

Question 2: Do Member States have any objections to the PCY's proposed approach on digitalisation?

The French authorities reiterate that they are in favour of the EU regulation allowing a choice between digital and paper formats for the provision of technical documentation. They are willing to reconsider their position and accept a fully digital format if the European Commission is certain that this will not cause difficulties for operators.

Question 3: In light of both the positive potential and the possible risks from new microorganisms, do Member States believe that an independent scientific body (e.g. the European Food Safety Authority) should have a prominent role in the approval process of new micro-organisms in microbial biostimulants?

The French authorities thank the Presidency for this proposal and indicate that they are in favour of an independent scientific body playing a central role in assessing the efficacy and safety of new microorganisms.

Question 4: Do Member States support creating a possible "positive list" of fertilising products exempted from REACH-registration, as a way forward?

The French authorities support the creation of a positive list of substances.

The French authorities thank the Presidency for this proposal to create a positive list of substances (and not fertilising products as indicated in the question) exempt from REACH registration, as suggested by the French authorities as an alternative solution to the deletion of the specific REACH provision.