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PUBLIC

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
N° Cion doc.:	IM 6999 2025
Subject:	Omnibus VI (Regulation on chemical products) - Compilation of written comments

Delegations will find enclosed questions and comments, as recieved, by 24 July 2025 from AT, BE, DE, EE, ES, FI, FR, IE, IT, LV, NL, PL, PT, SE and SI on the Omnibus VI package (Regulation on chemical products).

Austria's initial Comments on the Commission's Omnibus VI Proposals

Regarding CLP regulation

We welcome the amendments introduced in the context of simplification, which in our view are a valuable contribution to deregulation and strengthening of the competitiveness while keeping the high level of protection. **From an employee protection perspective**, Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures is particularly relevant, as it forms the basis for relevant employee protection regulations and has a direct impact on workplaces. From an employee protection perspective, it is therefore important that labelling and packaging continue to be carried out in such a way that employers and employees receive all relevant information about the chemical agents used in the company. This information should be easily accessible, easily recognizable and legible. Under no circumstances, should there be a degradation of the level of protection for employees.

<u>On COM(2025) 531</u>

1. Bringing flexibility to companies to ensure legibility of labels (Article 31(3), Annex I)

Comment on Recital 7:

- Recital 7 of the proposal states, "economic operators and enforcement authorities must remain responsible for ensuring that the labels are legible in accordance with the legal requirements".
- We consider this formulation problematic. Under the CLP Regulation (Article 4), it is clearly the responsibility of economic operators to ensure compliance, including labelling rules.
- We therefore request that the reference to enforcement authorities in Recital 7 be deleted or revised, as it could imply an unwarranted legal responsibility or even liability risk for market surveillance authorities.

2. Simplification of advertisement (Articles 48)

- Austria supports the proposed simplifications of advertising rules for hazardous chemicals intended for the general public. These changes are considered more practical and proportionate.
- To preserve a minimum level of hazard communication, Austria proposes to strengthen the generic phrase required by Article 48 by adding "contains hazardous substances", especially when no pictograms or H-statements are shown.
- It would be helpful if the term "advertisement" under Article 48 could be further clarified, ideally through guidance. In particular, it should be specified whether commonly used promotional formats such as product catalogues, flyers, social media posts or price lists fall under the advertising rules of the CLP Regulation. This would enhance legal certainty for both companies and enforcement authorities.

We, therefore, ask the Commission:

- Will the Commission clarify the scope of "advertisement" under Article 48, and define which types of promotional material are covered or provide guidance?

3. Timing of relabelling after classification changes (Article 30)

- The deletion of the fixed six-month deadline is intended to address concerns over complex supply chains. The replacement wording "without undue delay" lacks legal precision, however.

- We support more flexible deadlines in principle, but call for clear interpretative guidance, or alternatively, the reinstatement of a longer but fixed timeframe (e.g. 12 months) to ensure legal certainty and enforceability.

We, therefore, ask the Commission:

a) How is "undue delay" to be interpreted in practice?
b) Will guidance be developed to ensure a uniform approach across Member States?

4. Further simplification of certain labelling rules (Article 29, Annex I)

- Austria supports the proposed flexibility for small packaging and the clarification of labelling rules for fuel dispensers and portable canisters.
- The clarification in Article 29(2), allowing the use of certain labelling derogations without having to demonstrate the impossibility of using an outer package or tag, is welcomed. However, it should be made explicitly clear that Articles 29(1) and 29(2) cannot be applied cumulatively. A legislative clarification would improve legal certainty.
- Regarding Annex I Sections 1.5.2.4.1 to 1.5.2.4.3:
  The interplay between these provisions remains unclear. Specifically, it appears that Section 1.5.2.4.3 allows no labelling at all (Art. 17(1)) under certain conditions, even though 1.5.2.4.1 requires both inner and outer packaging, and 1.5.2.4.2 describes the necessary label content for inner packaging.
  This may lead to misunderstandings regarding whether *any* labelling is needed. In addition, the different wording ("package" in 1.5.2.4.3 vs. "inner packaging" in 1.5.2.4.2) introduces further uncertainty about their respective scope. We recommend that the internal logic, hierarchy and applicability of these sections be clarified.
- A further inconsistency is observed in Section 1.5.2.4.1 regarding hazard statements for sensitising substances. While H317 ("may cause allergic skin reaction") appears to be eligible for labelling exemptions under certain conditions, EUH208 ("contains … may cause allergic reaction") is not. This unequal treatment of closely related hazard communications is difficult to justify and should be reviewed.
- Clarification is also requested regarding the use of multilayer or booklet labels, which are widely used in practice and offer equivalent functionality to fold-out labels. Austria would welcome guidance clarifying under which conditions such formats may be considered compliant with the requirements for fold-out labels under the CLP Regulation.

We, therefore, would like to request clarification on:

a) Does 1.5.2.4.3 apply only where no outer or inner packaging exists (e.g. unitary container?
b) Should 1.5.2.4.3 override 1.5.2.4.1 and 1.5.2.4.2 entirely?
c) Moreover, requirements for tactile warnings (Annex II Section 3.2) are not mentioned in these derogation rules. Since tactile warnings are still required for certain flammable substances (e.g. flammable gases), how should they be applied in combination with the new 1.5.2.4.3 exception?
d) Is there a rationale why EUH208 is excluded from labelling exemptions while H317 is not, despite both referring to skin sensitisation risks?
e) We would welcome an early clarification via guidance on whether and under which conditions multilayer or booklet labels may be considered functionally equivalent to fold-out labels.

5. Digitalisation (Articles 17, 25; Annex I Sections 1.1.1.2 and 1.4)

- Austria supports the proposed developments related to digital labelling, including:
  - the possibility to indicate multiple suppliers digitally (except for the main supplier under Article 4(11)),
  - and the introduction of a mandatory "digital contact point".
- These measures are seen as appropriate steps toward future-proofing hazard communication and improving practical feasibility in complex supply chains.

6. Additional remarks

- Austria also draws attention to the specific situation of customised fragrance mixtures that are individually prepared on demand at the point of sale.
- These mixtures present particular challenges in relation to the PCN notification requirements. While some labelling relief is offered, the overall administrative burden remains significant. Further targeted simplification for such low-volume custom mixtures should be explored.

Regarding the CPR

From a health perspective:

In principle, we welcome the amendments introduced in the context of simplification of the Regulation (EC) No 1223/2009. However, concerns remain regarding the proposed exemptions under Article 15.

The exemption from the ban according to Article 15 applies, among other cases, when the CMR classification of a substance in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 explicitly refers only to oral or inhalation routes of exposure. Such a substance could therefore be used in cosmetic products. However, a CMR classification based solely on oral or inhalation exposure does not exclude the possibility that comparable systemic effects may occur after dermal exposure. Therefore, even in such cases, a toxicological assessment by the SCCS would be necessary to ensure a high level of protection for consumers.

These concerns also apply in the context of the exemption from the ban under Article 15 for natural based substances. The prohibition under Article 15 does according this proposal not apply to substances that are derived from plants and not chemically modified, even if at least one component is classified as a CMR substance of category 1A, 1B, or 2.

In our professional view, if natural-based substances contain components classified as CMR substances, a scientific assessment of the respective component by the SCCS is essential to properly evaluate potential risks. If the SCCS delivers a positive opinion on the component, it should then be authorised accordingly as part of natural based substance.

In this context, Article 15 should therefore ensure the following:

If a substance is classified as CMR category 1A or 1B, or 2 the following should apply:

- Article 15 must be applied.
- If a substance is a component of a natural based substance:
  - Article 15 does not apply to the natural based substance as such, unless the natural based substance itself is classified as a CMR substance (category 1A or 1B or 2).
  - The component must undergo a mandatory safety assessment by the SCCS.

- Following a positive SCCS opinion:
  - The component should remain prohibited as a pure substance (unless the exemption provisions of Article 15 apply).
  - The component should be permitted as part of a natural raw material, in accordance with the SCCS assessment.

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BE comments

We finally do have questions regarding the Fertilising Products Regulation.

Thanks for joining those questions with those regarding CLP and Cosmetics below.

1) Article 42 on Microorganisms

The Fertilising Products Regulation is currently under evaluation, and the Commission is expected to issue a report by mid-2026. This report will likely lead to amendments to the Regulation. Could you please explain why the amendment of Article 42 concerning microorganisms cannot wait until the revision planned for next year?

2) REACH Requirements – Removal of Extended Registration Obligations
It is at this moment difficult to accurately assess the implications of modifying the application of REACH within the context of the Fertilising Products Regulation. Could you provide specific examples of products or raw materials that would be impacted by the proposed relaxation of REACH requirements

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Omnibus VI – „chemicals“

German questions/commentaries

18.07.25

PUBLIC

We welcome and thank the EU Commission for the proposals which we are currently examining in detail.

Fertilizing Products Regulation (FPR):

- We welcome the proposed expanded options for providing documents in a digital form. Will companies retain the option to provide information by other means?
- During the negotiations on the current FPR Regulation, the Commission consistently emphasized the importance of the enhanced REACH requirements as a key safety element for substances used in the manufacture of EU fertilizing products. How does the Commission intend to ensure the safety of EU fertilizing products with the planned, less demanding requirements?
- The Commission proposes repealing the "unbundling clause" in the EU Fertilizing Products Regulation by repealing Article 43 of the Regulation. This clause was a key demand of many Member States during the negotiations on the Regulation, given that it would otherwise not be possible to grant the Commission the option of adopting delegated acts to adapt the Regulation. So far, this clause does not seem to have been an obstacle for the Commission with regard to the numerous delegated acts already adopted. We therefore wonder why the deletion of this clause is now proposed? Under Article 49 of the FPR, the Commission is required to submit a report to the Council and Parliament by 16 July 2026 assessing the application of this Regulation and its overall impact on the achievement of its objectives, including the impact on small and medium-sized enterprises. In our opinion it could make sense to wait for the outcome of this process in order to make specific amendments to the Regulation on the basis of the report to be submitted?

Cosmetic products regulation (CPR)

- The proposed amendments to Article 15 represent a new approach to dealing with CMR substances. Due to the possibility of continued use after applying for an exemption, as well as the long transition periods, it is expected that public exposure to CMR substances in categories 1 and 2 may increase. Furthermore, oral and inhalation exposure routes are not taken into account. Germany is interested in finding out how human health impacts were considered in the impact assessment or respectively, why a full-fledged impact assessment was not carried out. If an impact assessment was not carried out - like it was mentioned by the Commission in the Antici group on 11/7 – how can the Commission assume that the same level of protection of human health and of the environment is ensured as stated in the explanatory memorandum?
- The proposed amendment to Article 16 eliminates the notification requirement for nanomaterials. How does the Commission intend to ensure that the data previously submitted with the notification will continue to be available in the future, that an overview of nanomaterials on the market will continue to be maintained, and that their risk assessment by the SCCS will be made possible?

- What is the relationship between this proposal and the other measures announced by the Commission, e.g. the evaluation of the CPR, the revision of the CPR and the revision of the CMR guidelines? Will these be pursued in parallel?

Classification, labelling and packaging of chemicals regulation (CLP)

We welcome the Commission proposal and its aim to achieve substantial simplifications and bureaucracy reduction while at the same time ensuring the protection of human health and the environment, as set out in Article 1(1) of the CLP-Regulation:

- The withdrawal of all formatting requirements (font size, font type, line spacing, character spacing, and contrast) introduced as part of the last amendment should be thoroughly examined, as it could prove problematic with regard to the readability of labels. Would a provision suffice that requires in an enforceable manner that labels have to be readable?
- Could the Commission elaborate on the cost-benefit analysis of its proposal with regard to limiting the applicability on consumer products as well as the significant reduction of requirements for advertising (estimated benefit of this limitation due to less costs for companies vs. estimated health costs of this limitation)?
- Concerning the removal of the six-month deadline for updating the label elements, we would like to know how sufficient legal certainty with regard to the phrase “without undue delay” can be ensured? The introduction of the deadline was meant to provide this certainty in the first place.

EE comments

A question from the Estonian Ministry of Regional Affairs and Agriculture concerning the regulation of fertilisers included in the simplification package VI.

How is it ensured that under the new rules (where the approval of new microorganisms is actually carried out by notified bodies), the assessment results are transparent and impartial? What identified risks are associated with the evaluation of new microorganisms by notified bodies? How, under the new rules, will Member States and, for instance, research institutions know which microorganisms can be used in microbial plant biostimulants?

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ES comments

On simplification proposal Regulation CLPs

Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures ('CLP Regulation')

With regard to the modifications that the Omnibus proposes to Regulation (EC) 2008/1272, ES initially considers the amendments proposed to be correct. On the basis that the changes proposed seem not to compromise the safety of users or pose a risk to the environment, and instead establish conditions and deadlines that are more realistic in terms of compliance by the industry.

On simplification proposal Regulation Cosmetics

First of all, we would like to highlight that, in general, the AEMPS (Spanish Agency on Medicines and Health Products) supports the Commission's package on simplification measures with the aim of reducing administrative burdens and costs for different industries. However, we believe that these measures should never simplify product safety or reduce the legislative requirements that directly guarantee the safety of European citizens. To achieve this, a planned and detailed impact assessment is necessary to identify the possible consequences of the proposed measures.

Regarding the inclusion of cosmetic products in this Omnibus, it is important to remember that these products have always been regulated separately of chemicals legislation due to the specific need to establish additional safety guarantees for them. This differentiation between the regulations for chemicals and cosmetics has not been considered in this proposal.

Please, find below the comments from Spain on **Regulation (EC) 1223/2009 on cosmetic products**

As we indicated at the beginning, from ES supports the Commission's simplification action plan, always ensuring that the legislative requirements guaranteeing the availability of safe cosmetic products on the European market are not diminished. In line with this simplification, AEMPS agrees with the modifications proposed regarding the following articles of Regulation 1223/2009:

- Addition of Article 14a, clarifying the application process for the inclusion of substances used as colorants, preservatives, or UV filters in Annexes IV, V, and VI, provided that it is ensured that the SCCS will be able to carry out these evaluations within the proposed timeframe.
- Elimination of paragraphs 3 to 7 of Article 16
- New wording of point 6 of Article 19
- Elimination of the second paragraph of Article 22
- Elimination of Article 33
- Annexes

Regarding the proposed **modifications to Article 15**, ES considers that many of them diminish significantly the legislative requirements established in 2009 that ensure the chemical substances composing cosmetic products are safe for their intended use. In this particular case of Article 15, it is not considered that the Commission has carried out an adequate and detailed impact study to determine the short and long term consequences on safety of the measures applied. Such a significant change as the evaluation process and deadlines for the use or not in cosmetic products of substances classified as CMR cannot be based on some discussions by the Cosmetics Committee and the conclusions of the 2-hour Reality Check that took place on May 16.

Please, find below our comments and rationales regarding the proposed modifications to Article 15:

General comment:

This modification to Article 15 implies a reduction of the conditions (from 4 to 2) that a CMR substance must meet to enable a request for derogation to the Commission. It also establish a delay of more than 2 years before the SCCS evaluation begins to check the safety of the product, in addition to the 2 years the product is allowed to remain on the market. This proposed modification to Article 15 does not simplify the administrative burden but rather reduces the safety of cosmetic products by delaying the evaluation of substances classified as CMR.

Regarding the proposed deadlines for the evaluation process for the use or not of a substance classified as CMR, it is important to remember that a CMR substance is considered safe for its use in a cosmetic product only when it has been evaluated by the SCCS. The proposal includes a delay in the deadline to request the derogation by industry, another delay of 18 months for the start of the SCCS evaluation, plus the 15 months established for the evaluation itself. Additionally, it allows that cosmetic products containing CMR substances continue to be placed on the market for 12 months and be made available on the market for a total of 24 months.

As a general comment, the proposal specifically refers to the role and obligations of the Commission, which were not directly addressed in the current text. This new mention to Commission activities in the new wording does not identify and clarify the role of the Member States in this process. At this moment, decisions on Article 15 are made through Comitology with the vote of the Member States. The text should clearly state the functions and roles of the authorities for this process.

Ø *(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.

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ES comment:

Although it extends the current timeline, we consider this change to the deadline appropriate, as long as it is added that the industry must begin gathering data once the RAC opinion is available.

Ø *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.'.

ES comment:

We consider appropriate the proposal of merging points c) and d). However, we do not agree to eliminate point a) related to fulfilment of food safety requirements, since certain cosmetics (such as lipsticks or cosmetics intended for oral mucosa) may be ingested. For this reason, we propose that condition a) be maintained exclusively for this type of cosmetic products that, due to their intended use, may be ingested.

Ø *(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.'

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ES comment:

We belive that it is not acceptable to include these four conditions and require compliance with all of them to consider a substance as an alternative. This wording implies that point a) of the previous two conditions will automatically always be met, meaning the Commission must start the procedure to issue a derogation for substances classified as CMR. Conditions a), c) regarding economic viability, and d) are not adequate to justify the absence of suitable alternatives allowing the use of a substance classified as CMR in a cosmetic.

Ø *(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.';

ES comment:

We strongly disagree on delaying the start of the SCCS evaluation of substances classified as CMR and setting it from the date of application of the corresponding classification regulation. This proposal implies an 18-month delay before the SCCS evaluation begins, counting from when the substance's CMR classification comes into force. To this period, one must add the delay already applied in subparagraph 2. The SCCS evaluation should begin at least when the ATP comes into force.

Ø *(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.

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ES comment:

We consider that this exception should not apply to cosmetics that may present a risk of inhalation or ingestion due to their intended use. Therefore, the Commission in all cases where the use of the cosmetic may pose this risk of ingestion or inhalation, must submit an evaluation to the SCCS.

Ø 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.

ES comment:

The Agency considers that in cases where a constituent of a substance is classified as CMR, the Commission should automatically, in all cases, submit a request for evaluation to the SCCS.

Ø *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*

ES comment:

As previously indicated, the we consider it necessary to include a transitional period to adapt formulations after the classification of a substance as CMR and the corresponding assessment by the SCCS. However, allowing 12 months to continue placing products on the market with CMR substances and 24 months for their continued availability on the market represents a risk to the population that is not considered justified.

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On simplification proposal Regulation Fertilising Products

Regarding the proposal to amend 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:

- Digitalisation: We agree in principle, although it would be positive to be able to consult the industry representattives and the Autonomous Communities (as it also has implications on market surveillance) on the feasibility of the proposal, as well as on the proposed transitional period.
- New microorganisms. We are concerned that the adoption of criteria and methodologies by the COMM would mean that new microorganisms could be placed on the market with the sole evaluation by a notified body. ES has extensive experience in the market for fertilising products based on microorganisms and their evaluation is complex.
- ES not in favour of removing Art. 43. According to the wording of recital (29), it's our interpretation that it was intended to make possible the amendment of several CMCs through a single delegated act, whenever the same change was intended for all these CMCs. Instead, what is proposed is to remove Art. 43, without further specification, enabling the modification of anything that is wanted in all the CMCs under the scope of this single delegated act.
- ES is in favour of removing the requirements that go beyond the REACH regulation for fertilising products.

FI comments on Omnibus VI (chemicals) 18.7.2025

Please find below in writing the comments made during the Working Party meeting:

- We thank the Commission for the Chemicals Omnibus proposal but would like to highlight that due to the ongoing holiday season our remarks are preliminary and of very general nature at this point, (and we thus have a general scrutiny reservation).

- We support the Commission's effort to reduce the administrative burden for both the industry and authorities where possible, but want to stress, that the level of protection of human health and environment must not be compromised.

- In this spirit, we can generally give our support to any changes to the CLP regulation that will streamline and simplify labelling requirements, lift unnecessary reporting, and increase legal clarity without weakening the level of protection.

- Regarding the CPR, the proposed clarifications to the timeline of the exemption process regarding CMR substances, and the new process facilitating the inclusion of new UV filters and colorants into the annexes of the regulation are very welcome, as is the deletion of certain notification and reporting duties.

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Objet : Commentaires et questions des autorités françaises concernant les projets de règlements Omnibus chimie visant à simplifier la réglementation CLP, cosmétiques et fertilisants

I . CLP

Question générale sur la procédure en cours

Le règlement 1272/2008/CE relatif à la classification, à l'étiquetage et à l'emballage des produits chimiques (CLP) a fait l'objet d'une révision récente. Le **règlement (UE) 2024/2865** a en effet apporté des modifications au règlement CLP. Publié le 20 novembre 2024, il est **entré en vigueur le 10 décembre 2024** et doit être appliqué dans un délai de 18 mois ou 2 ans, selon les dispositions concernées.

Plusieurs dispositions du règlement CLP modifié récemment adopté sont remises en débat dans la proposition d'omnibus de simplification de la Commission, répondant à l'objectif de réduction des coûts administratifs d'au moins 25 % pour l'ensemble des entreprises et d'au moins 35 % pour les PME. Les propositions formulées s'inscrivent à la suite des remontées effectuées lors d'une session d'échanges « reality check » au cours de laquelle les opérateurs économiques ont mis en avant les coûts administratifs et financiers, ainsi que la complexité de mise en œuvre des modifications introduites en fin d'année dernière.

La Commission a indiqué lors du Caracal-55 (comité des autorités compétentes REACH et CLP) que les groupes **« reality check » constituaient des outils parmi d'autres** leur permettant d'affiner leurs études d'impact sur les simplifications proposées.

Question 1 : les autorités françaises souhaitent interroger la Commission sur les outils utilisés en complément du « reality check » permettant :

- **La prise en compte des bénéfices** pour la société versus les nombreuses données de coûts rapportés par les opérateurs économiques, afin **d'apprécier la proportionnalité et l'impact des mesures de simplification proposées**. En l'état, le document d'accompagnement (« *staff working document* ») se réfère essentiellement aux remontées issues du « reality check » ou à des documents d'évaluation de fédérations professionnelles transmis à la Commission.
- **La prise en compte de la capacité de contrôle (« enforceability ») des mesures proposées,** comme sur la question des délais de mise à jour des étiquettes à la suite d'un changement de classification, ou la notion de lisibilité en omettant de préciser la taille et l'espacement des polices de caractère.

Questions relatives aux points de réserve et demande de clarification

a. Taille des caractères

Pour les produits grand public, la lisibilité de l'étiquette constitue un outil essentiel pour la clarté de l'information du consommateur et dans le but d'une d'application uniforme de la réglementation par

les autorités de surveillance de marché. Lors de la négociation du règlement n° 2024/2865, il avait été rappelé le besoin pour certains groupes de population d'une taille de police adaptée pour s'assurer d'une lisibilité suffisante.

En outre, en 2023, 11 associations[1] se sont mobilisées pour soutenir un alignement de CLP avec le guide de l'ECHA et la hauteur d'x de 1,2 mm.

Question 2 : Dans un objectif de **simplification** du texte du règlement n° 2024/2865, la Commission a-t-elle analysé l'option du maintien de cette **taille minimum de caractères de 1.2mm** pour toutes les contenances d'emballage, tout en tenant compte des coûts supplémentaires pour les entreprises ?

Question 3 : Le document de travail de la Commission précise : "*Some companies indicated that they would alternatively welcome an alignment with the Food Information to Consumers (FIC) Regulation, where the font size is 1.2 mm with a possibility to use 0.9 mm for smaller labels and packaging*[2]". **L'étude d'impact et les consultations menées ont-elles analysé cette option ?**

Question 4 : Le document de travail de la Commission rapporte des difficultés avec les étiquettes déroulantes. **La Commission a-t-elle évalué la possibilité de retravailler la répétition d'informations** (entre l'étiquette principale et l'étiquette déroulante) pour **simplifier le nombre d'informations** à placer au global sur les étiquetages ?

b. Publicité

Concernant la publicité, la proposition de la Commission, outre le fait qu'elle modifie la dernière négociation, apparait **également moins exigeante que la version du règlement CLP précédant sa révision.** Or, **les objectifs visés dans la dernière version du règlement constituent en la matière pour les autorités françaises un seuil minimal d'exigences qui doit être conservé**. Certaines dispositions proposées semblent également **inapplicables en termes de surveillance du marché.**

Plus spécifiquement, la Commission entend limiter les exigences aux publicités grand public. La clarification des règles applicables aux publicités, tout au long de la chaîne de valeur, était un des objectifs de la révision de CLP. Il est important de sensibiliser les opérateurs, **y compris lors des échanges commerciaux**, afin de privilégier l'achat de produits moins dangereux le cas échéant.

Par ailleurs, les opérateurs signalent des « coûts exorbitants » liés aux nouvelles exigences en matière de publicité. Or, les obligations supplémentaires en matière de publicité TV ne conduisent pas nécessairement à un allongement de la durée, les opérateurs peuvent répondre à leurs obligations **par un bandeau déroulant par exemple**.

Question 5 : la Commission a-t-elle évalué si dans le cas d'un bandeau déroulant l'augmentation des coûts signalée lors du « reality check » sont en effet élevés de manière disproportionnée ?

Question 6 : La Commission a-t-elle envisagé **l'articulation des obligations en matière d'information entre le règlement CLP révisé et les obligations issues des autres réglementations sur les produits chimiques(notamment concernant le règlement REACH)** dans le prolongement des travaux « one substance one assessment » visant à rendre interopérables les données produites dans le cadre des différentes réglementations et réduire la charge administrative qui en est issu ?

[1] https://www.efcc.eu/sites/default/files/documents/1.%20Cross-sector%20call%20for%20urgent%20dialogue%20and%20a%20rethink%20regarding%20CLP%20Revision.pdf

[2] C'est à dire dans le cas d'emballages ou de récipients dont la face la plus grande a une surface inférieure à 80 cm^2.

c. Vente à distance

Garantir un même niveau d'information pour le consommateur en ligne que pour le consommateur en magasin, où ce dernier a accès à l'étiquette, constitue un principe essentiel de protection des consommateurs auquel les autorités françaises sont attachées.

Les autorités françaises considèrent que la mesure proposée ne constitue pas une simplification adaptée dans la mesure où la mise en œuvre d'éventuels outils de vérification du caractère professionnel des acheteurs serait très complexe. Dans l'état actuel des textes sur la vente en ligne, cette vérification (au même titre que celle de l'âge de l'acheteur pour certains produits) est même illusoire, d'autant qu'en France l'interdiction du refus de vente protège l'acheteur. En outre, certains sites, notamment des plateformes, sont susceptibles de vendre à la fois des produits grands publics et des produits professionnels, il leur serait aisé de classer dans la partie produits professionnels tous les produits pour lesquels ils ne communiquent pas suffisamment d'informations

Question 7 : La Commission a-t-elle évalué en quoi la limitation des obligations aux seuls produits grand public constituerait une simplification ?

Question 8 : La mise à jour des informations disponibles en ligne étant plus immédiate que celle des étiquettes imprimées, la Commission a-t-elle évalué le bénéfice pour les opérateurs d'une telle mesure ?

Question 9 : Afin de permettre l'applicabilité des disposition proposées, la Commission envisage-t-elle d'engager des travaux sur le DSA (*Digital Services* Act) et DMA (*Digital Markets* Act) pour obtenir des sites et plateformes l'obligation de vérifier le caractère professionnel de l'acheteur et de vérifier son rattachement professionnel au secteur des produits proposés sur le site de vente à distance ?

A titre d'exemple, le **futur règlement détergents ajoute un article spécifique relatif à la vente à distance** (art 17.a) qui prévoit des dispositions applicables pour tous produits :

Article 17a When detergents or surfactants are made available on the market through distance sales, the offer shall clearly and visibly indicate the label elements referred to in Article 15, and a digital copy of the data carrier or the unique product identifier.

Il serait très surprenant que les exigences soient moindres sur les produits classés dangereux.

Question 10 : Comment la Commission envisage-t-elle de tenir compte du compromis obtenu sur le règlement détergents, dans un objectif de simplification et de cohérence entre les réglementations relatives aux produits chimiques ?

d. Mise à jour des étiquettes

En cas de changement d'auto-classification (nouvelle classe de danger ou classification plus sévère), le nouveau CLP laisse 6 mois à chaque acteur d'une chaîne d'approvisionnement pour adapter l'étiquette. La Commission propose de supprimer ce délai. La suppression de ce délai est **extrêmement inconfortable pour les autorités de surveillance de marché**, malgré les intérêts de cette mesure en matière de rationalisation des coûts pour les entreprises, en particulier concernant l'écoulement des stocks des étiquettes et contenants déjà produits des produits peu préoccupants et la lutte contre le gaspillage.

Question 11 : La Commission a-t-elle considérée la possibilité de distinguer les situations concernant les classes de danger les plus préoccupantes (comme les CMR ou les perturbateurs endocriniens) ? **le délai de réétiquetage supérieur à 6 mois ne devrait pas constituer un motif pour écouler les stocks** de produits non étiquetés correctement et **pouvant porter atteinte à la santé des consommateurs ou de l'environnement**.

e. Petite taille de contenant

La Commission propose de permettre aux opérateurs économiques de réduire les tailles d'étiquettes et informations à fournir sur l'étiquette des emballages contenant de plus petites quantités de substances chimiques ou de mélanges.

En **application du règlement (UE) 2024/2865** (CLP révisé), il est prévu, à compter du 1er juillet 2026, une dispense totale d'étiquetage pour les matériels dont le contenu de l'emballage intérieur n'excède pas 10 ml, mais **cette dispense est conditionnée au respect de certaines conditions** (prévues à la section 1.5.2.4.1 (b) de l'annexe I du règlement CLP). Par exemple, les mélanges classés comme irritant oculaire pourront bénéficier de cette dérogation alors que les mélanges entrainant des lésions oculaires graves en seront exclus. Cette mesure semble **proportionnée pour des raisons de santé publique**. Il convient de préciser que cette dérogation concerne notamment certaines fournitures scolaires ; or l'enquête menée en 2023 par les autorités françaises de surveillance du marché a montré que **la plupart des stylos ne remplissaient pas les conditions pour accéder à la dérogation**, du fait du classement de danger (lésions oculaires graves par exemple) ; il s'agit d'une contrainte pour les opérateurs de ce secteur car pour bénéficier de la dérogation, ils devraient reformuler leurs mélanges, en changeant par exemple de conservateur. Toutefois, aller plus loin dans les dérogations possibles pour les petits emballages, en particulier en ce qui concerne les **fournitures scolaires**, poserait problème pour la santé des consommateurs, **notamment des enfants** et constituerait un recul de l'arsenal réglementaire visant à inciter les opérateurs à faire évoluer leurs formules vers des alternatives moins dangereuses pour leur santé.

Question 12: La Commission a-t-elle évalué la proportionnalité d'accorder des dérogations pour des mélanges présentant de tels dangers et qui sont utilisés par un public sensible ?

Question 13 : La Commission a-t-elle envisagée d'étendue cette mesure aux contenants jusqu'à 75ml au regard de l'augmentation de la taille de police et des difficultés à mettre en place une étiquette dépliante sur les petits contenants ?

II. Cosmétiques

Les autorités françaises **remercient la Commission européenne pour la présentation de sa proposition d'omnibus simplification relative au règlement sur les produits cosmétiques**.

Les autorités françaises **accueillent favorablement l'objectif de simplification des démarches administratives pour les metteurs sur le marché de produits cosmétiques, et pour les administrations**, **notamment 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. Les autorités françaises saluent également** les objectifs de simplification et de clarification que constituent notamment l'introduction d'une procédure claire pour l'inclusion des colorants, conservateurs et filtres UV dans les annexes du règlement cosmétiques.

Toutefois, elles insistent sur le fait que l'objectif de simplification ne doit pas conduire à fragiliser les équilibres du règlement cosmétiques qui répond également à des objectifs de santé publique et de protection de la sécurité des consommateurs, en particulier vis-à-vis des substances les plus dangereuses (cancérigènes, mutagènes, toxiques pour la reproduction ou CMR).

Pour certaines dispositions structurantes, les autorités françaises s'interrogent sur la pertinence du cadre de discussion choisi par la Commission européenne en privilégiant un omnibus simplification alors que les travaux en vue de la révision du règlement cosmétiques sont en cours.

Les autorités françaises émettent une réserve d'examen sur les dispositions de l'article 2.2 b) du règlement Omnibus (ajout du paragraphe 5 à l'article 15 du règlement 1223/2009), fourniront des commentaires écrits spécifiques sur ces dispositions ultérieurement et partagent ci-après leurs remarques sur les différentes propositions de la Commission européenne, dans l'ordre de leur apparition dans l'article 2 de la proposition de règlement omnibus VI.

Ajout de l'article 14 bis

Comme rappelé précédemment, l'objectif étant de donner de la visibilité aux industriels en précisant une procédure, et d'accélérer la possibilité d'utiliser de nouveaux ingrédients cosmétiques, **les autorités françaises sont favorables à l'ajout de cet article**.

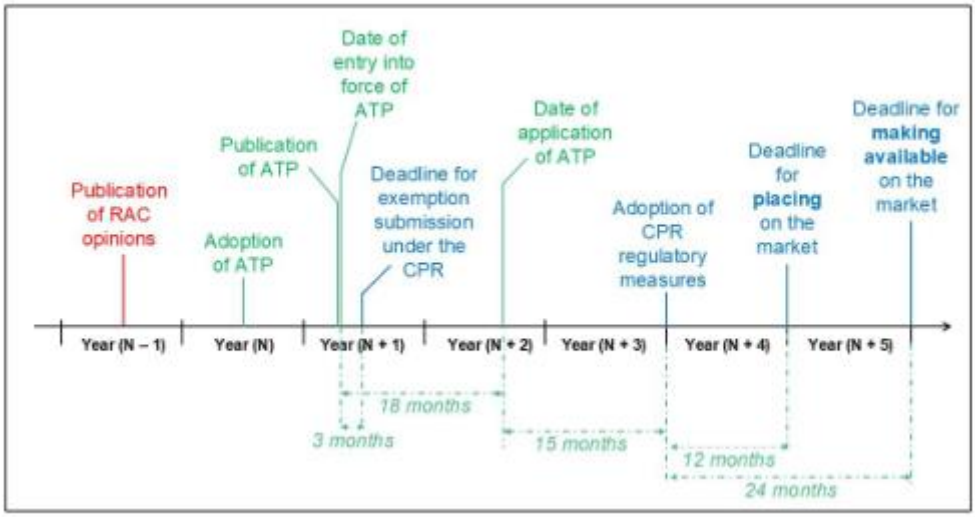
Amendements de l'article 15

Précisions sur le délai pour soumettre un dossier de demande de dérogation

La Commission propose que les opérateurs économiques aient jusqu'à 3 mois après la date d'entrée en vigueur de l'adaptation au progrès technique (ATP) du règlement CLP pour déposer une demande de dérogation.

Les autorités françaises sont favorables à la **proposition d'allonger la fenêtre de dépôt de dossier pour les opérateurs économiques,** dans le délai imparti pour l'entrée en application de l'interdiction ou de la restriction de la substance concernée dans le règlement cosmétiques.

Les autorités françaises notent que de fait, le temps supplémentaire laissé aux opérateurs économiques empiète sur le temps dévolu à l'instruction des dossiers par la Commission européenne et s'interrogent de fait sur la capacité du comité scientifique pour la sécurité des consommateurs (CSSC) à instruire les dossiers dans ce laps de temps connaissant la charge de travail des experts de ce comité. Les moyens dont sera doté le CSSC apparaît donc comme un élément important de la réussite de cette proposition.



Révision des critères qui conditionnent l'obtention d'une dérogation

Les autorités françaises notent que le critère lié à la conformité de la substance à la réglementation alimentaire (critère a) et celui lié à la demande de dérogation pour un usage particulier de la catégorie de produits avec une exposition déterminée (critère c) ont été supprimés.

Les autorités françaises n'ont **pas d'opposition à la suppression du critère a) dans la mesure où ce critère manquait d'informations opérationnelles adéquates. Pour le critère c)**, la délégation française soutient cette suppression dans la mesure où il sera pris en charge dans l'évaluation du risque par le CSSC (nouveau critère b).

Les autorités françaises constatent que la Commission européenne entend également **préciser** à travers l'omnibus la notion **de « substances de substitution appropriées »**. Les autorités françaises sont favorables au principe d'ajout des critères dans la réglementation cosmétiques. Ces critères devraient être précisés ensuite dans un guide (en cours de révision) sur la mise en œuvre de l'article 15. La révision du guide a d'ailleurs été saluée par les autorités françaises car elle apporte des éléments de clarification et simplification importants.

Les autorités françaises souhaitent avoir des précisions sur la caractérisation des différents critères afin de clarifier l'équilibre entre la recherche de solutions de remplacements, nécessaires à l'examen des dérogations pour pouvoir utiliser des substances dangereuses, et les capacités des opérateurs économiques à y parvenir de manière raisonnable et viable.

Le premier critère fait appel à une évaluation des risques sur la santé humaine et environnementale : il est à noter que le risque environnemental n'est pas du ressort du règlement cosmétique mais du règlement REACH. Par ailleurs, la notion de réduction du risque global n'est pas claire.

S'agissant du critère pouvant se traduire par « fournit une fonction équivalente à la substance classée, dans un produit cosmétique fini ayant un effet similaire et le même niveau d'efficacité », les autorités françaises se questionnent sur sa mise en œuvre concrète et pointe un risque de restriction du champ des possibles en orientant vers une substitution « 1 pour 1 ». Dans quelle mesure la Commission européenne peut-elle donner des exemples de mise en œuvre de ce critère et dans quelle mesure le recours à une combinaison de substances ou à des solutions techniques non chimiques, pour la conservation par exemple, ne serait-il pas une alternative possible ? En outre, les autorités françaises se questionnent sur la notion d'efficacité qui ne semble pouvoir s'appliquer à l'ensemble des substances présentes dans les produits cosmétiques. Le critère « techniquement et économiquement viable » est aussi à clarifier, notamment la notion de viabilité. Les autorités françaises souhaitent demander à la Commission européenne si elle retiendra les clarifications proposées dans le projet guide pour la mise en œuvre de l'article 15 de février 2025 en tenant compte des questions et suggestions qui ont été adressées par les autorités françaises Enfin, pour le dernier critère, la notion pouvant se traduire par « large quantités » est à clarifier. Dans ce contexte, les autorités françaises sont favorables à l'ajout de critères ouverts qui devraient être précisés ensuite dans le projet de révision du guide en cours sur la mise en œuvre de l'article 15. Cette révision a d'ailleurs été saluée par les autorités françaises car elle apporte des éléments de clarification et simplification importants.

Clarification dans le règlement du point de départ du délai de 15 mois pour modifier les annexes du règlement cosmétiques

Les autorités françaises estiment que cette **clarification est bienvenue** puisqu'elle supprime l'ambiguïté quant au point de départ (date d'application de l'ATP).

Ajout d'un paragraphe clarifiant que les substances naturelles complexes dont un constituant a été classé comme substance CMR des catégories 1A, 1B ou 2 sont hors du champ de l'article 15 du règlement cosmétiques

Les autorités françaises **accueillent favorablement la clarification du statut de ces substances vis-à-vis de l'article 15 du règlement cosmétiques.** La Commission européenne avait transmis une interprétation juridique [3] à ce sujet, présentée lors du groupe de travail cosmétiques de mars 2025 en utilisant le cas du p.cymene classé CMR1.

[3] Dans le document rédigé par la Commission (cf pièce jointe), *il est mentionné* : » La concentration potentiellement élevée d'une substance classée CMR dans un extrait de plante pourrait soulever des inquiétudes quant à la sécurité de cette substance pour la santé humaine. L'article 31, paragraphe 1, du RPDC permet de répondre à ces préoccupations puisqu'il permet à la Commission de modifier les annexes II à VI du RPDC « lorsqu'il existe un risque potentiel pour la santé humaine, résultant de l'utilisation de substances dans des produits cosmétiques, qui doit être traité à l'échelle communautaire ». La Commission doit consulter le CSSC avant de prendre les mesures appropriées.
La Commission a l'intention de lancer un appel de données peu après la publication de l'avis du RAC sur le p-cymène, suivi de la demande au CSSC d'un avis scientifique sur la sécurité du p-cymène présent dans les extraits de plantes utilisés en cosmétique.
Bien que l'article 31 du RPC ne prévoit aucun délai légal, l'évaluation du CSSC et l'action réglementaire ultérieure de la Commission seraient une question prioritaire, car il est entendu que les consommateurs doivent être rassurés quant à la sécurité des cosmétiques contenant les extraits de plantes concernés et que les entreprises bénéficieraient de la sécurité juridique ».

Cependant, les autorités françaises soulignent que dans sa note distribuée lors de ce groupe, la Commission proposait une **évaluation systématique et *a priori* des extraits naturels contenant une substance classée CMR. Les autorités françaises souhaitent que soit fait mention de cette évaluation systématique des risques. Elles estiment en effet que dès lors qu'une substance naturelle complexe comporte un constituant classé CMR, il existe un risque potentiel pour la santé humaine.**

Ajout d'un paragraphe 7 sur les périodes transitoires après interdiction ou restriction d'une substance dangereuse dans un produit cosmétique

Les autorités françaises constatent que la Commission européenne propose des périodes de transition suite à la publication des actes modifiant les annexes du règlement cosmétiques pour interdire ou restreindre les substances dangereuses classées CMR. Ces périodes permettent de donner du temps pour la première mise sur le marché de produits et l'écoulement de stocks.

Les autorités françaises **soutiennent le principe de cette mesure mais s'interrogent sur la lecture qu'il convient d'avoir : s'agit-il d'une période maximale**, étant entendu dans ce cas que la définition de la période de transition serait définie au cas par cas, comme cela a été fait jusqu'à présent, ou bien s'agit-il d'une période fixe, applicable à tous les cas ?

Les autorités françaises sont favorables à un encadrement des périodes de transition :

- En conservant une définition au cas par cas des périodes transitoires. L'expérience montre que les périodes transitoires varient selon les substances,
- **Et en fixant un terme à ne pas dépasser, (une période maximale)**, les autorités françaises estiment nécessaire de fixer *a priori* une période de transition maximale, qui serait différente selon le sort réservé à une substance classée CMR 1 :
    1) **en établissant une possibilité de définir des délais plus raccourcis au cas par cas en fonction de circonstances exceptionnelles ou d'urgence impérieuse.** Pour les substances pour lesquelles aucune dérogation n'a été obtenue (soit du fait d'une absence de demande d'exemption, soit après examen conduisant au rejet de la demande d'exemption), un délai maximal devrait être défini pour la première mise sur le marché et un autre pour les mises à disposition sur le marché aux autres stades de commercialisation. Les autorités françaises proposent respectivement, les délais suivants, de 6 et 9 mois, en tant que délais maximaux.

    2) Pour les substances qui font l'objet d'une dérogation, permettant l'utilisation d'une substance, sous condition, un délai maximal devrait être défini pour la première mise sur le marché et un autre pour les mises à disposition sur le marché aux autres stades de commercialisation. Les autorités françaises proposent respectivement, les délais suivants, de 9 et 18 mois, en tant que délais maximaux.

<u>Amendements de l'article 16</u>

La Commission européenne estime que la notification préalable à la mise sur le marché de produits cosmétiques contenant de nanomatériaux, par l'intermédiaire de la plateforme européenne de notification des produits cosmétiques est superfétatoire puisque tout produit doit être notifié dès sa mise sur le marché. En conséquence, la Commission européenne propose de supprimer cette notification préalable.

Les autorités françaises rappellent que la notification préalable des produits contenant des nanomatériaux, pour lesquels des informations complémentaires sont demandées, doit permettre de s'assurer de la sécurité des produits contenant des nanomatériaux. Cette procédure a pour objectif d'alerter la Commission qui, en cas de doute, peut mandater en urgence le CSSC pour évaluer la sécurité de ces produits procédure de saisine qui n'est toutefois pas remise en cause par l'omnibus présenté par la Commission.

Les autorités françaises souhaitent également mettre en avant le **rapport de situation sur les nanomatériaux de 2021 de la Commission adressé au Conseil et au Parlement** (prévu par l'article 16 point 10 du règlement cosmétiques) qui mentionne en page 22 : « *L'évaluation scientifique de la sécurité des nanomatériaux pourrait être renforcée, en particulier parce que l'expérience a montré que la majorité des évaluations réalisées par le comité scientifique pour la sécurité des consommateurs n'étaient pas concluantes en raison du manque de données. La situation actuelle devrait certes s'améliorer quelque peu grâce à une mise en œuvre améliorée, mais d'autres progrès pourraient être envisagés, comme la possibilité d'étendre aux nanomatériaux le système d'autorisation existant, tel que prévu par l'article 14 du règlement sur les cosmétiques pour les colorants, les conservateurs et les filtres ultraviolets, qui fonctionne correctement* »

Dans ce contexte, les autorités françaises souhaitent que la Commission européenne explicite comment elle compte garantir le même niveau de vigilance et de sécurité vis-à-vis des nanomatériaux, si les informations sont uniquement à fournir dans le dossier d'informations produits (DIP).

Amendements de l'article 19 et 33 :

La Commission européenne propose de supprimer le glossaire **des dénominations communes des ingrédients** (glossaire) compte tenu de la difficulté de sa mise à jour et de l'existence d'une base de données dite « Cosing » qui contient déjà un grand nombre de références d'ingrédient d'utilisation courante et qui est utilisée par les partie prenantes.

Les autorités françaises sont favorables à cette proposition. Cependant, elles s'interrogent sur le statut juridique de cette base de données. En effet, cette base de données ne fait pas l'objet d'une publication au JOUE, contrairement au glossaire, conférant à ce dernier un statut juridique. Les autorités françaises souhaitent savoir comment cette base de données sera mise à jour.

Amendement de l'article 22 :

La Commission européenne propose de supprimer l'obligation d'examen et d'évaluation périodique par les États membres de leurs activités de surveillance du marché et de communication des résultats de cet examen aux autres États membres et à la Commission.

Les autorités françaises sont favorables à cette proposition qui contribue à la baisse de la charge administrative des Etats membres.

III. Fertilisants

Pour les fertilisants, les propositions de simplification sont les suivantes :

1. **Supprimer la disposition REACH spécifique introduite dans le Règlement (UE) 2019/1009 consistant à rendre obligatoire l'enregistrement REACH de toutes les substances utilisées dans la composition d'un fertilisant UE**

Les autorités françaises ne sont pas favorables à la proposition visant à supprimer la disposition du règlement (UE) 2019/1009 imposant l'enregistrement REACH de toutes les substances utilisées dans la composition d'un fertilisant mis sur le marché de l'Union.

Justification : le règlement 2019/1009 exige l'enregistrement REACH de toutes les substances entrant dans la composition d'un fertilisant UE et quel que soit le tonnage de la substance produite ou importée dans l'UE afin de les recenser et contrôler leur usage. Cette disposition est justifiée

par le fait que le règlement2019/1009 ne liste pas de façon exhaustive les substances autorisées à entrer dans la composition d'un fertilisant UE (la liste est ouverte).

L'enregistrement REACH permet ainsi de recenser et de contrôler l'usage de ces substances, notamment celles qui sont dangereuses (classés CMR : substances chimiques cancérogènes et/ou mutagènes et/ou toxiques pour la reproduction).

La **suppression de cette disposition est susceptible de compromettre la sécurité et l'efficacité des fertilisants** dans la mesure où certaines substances qui entrent dans la composition ne seraient plus contrôlées (via REACH).

La disposition REACH telle que prévue par le règlement 2019/1009 devrait être maintenue. Une dérogation à l'enregistrement REACH pourrait être prévue pour les substances utilisées historiquement dans la composition de fertilisants et ne posant pas de problème de sécurité. Une liste de substances éligibles à cette dérogation pourrait être élaborée par le GT UE « fertilisants ».

Questions à l'attention de la Commission

I. Justification de la suppression de la disposition REACH

1. Comment la Commission répond-elle aux inquiétudes concernant la suppression d'un outil de recensement et de contrôle des substances potentiellement dangereuses (notamment CMR) ?
2. La Commission considère-t-elle que les autres dispositifs réglementaires en place suffisent à assurer un niveau équivalent de sécurité et de transparence ? Si oui, lesquels ?

II. Préservation de la sécurité et du contrôle

5. Quels mécanismes de contrôle alternatifs sont envisagés pour garantir que les substances utilisées dans les fertilisants UE ne présentent pas de risques pour la santé humaine, animale et pour l'environnement ?
6. Comment la Commission compte-t-elle garantir que l'ouverture de la liste des substances autorisées ne mène pas à l'introduction de substances non évaluées ou à risque dans les fertilisants ?
7. Un dispositif de suivi post-commercialisation des fertilisants est-il prévu pour détecter d'éventuels effets indésirables liés à des substances non enregistrées ?

III. Voies de compromis et modalités d'encadrement

8. La Commission pourrait-t-elle envisager un mécanisme de dérogation ciblée, par exemple pour les substances historiquement utilisées et identifiées comme sûres ?
9. Serait-il envisageable de mettre en place pour ces substances, en lieu et place de l'enregistrement REACH systématique, une liste positive de substances validées par un groupe d'experts européens (par exemple le GT « fertilisants ») ?
10. Quels engagements prendrait la Commission pour réévaluer périodiquement les substances non soumises à REACH si la disposition venait à être supprimée ?

2. <u>Habiliter la Commission européenne par acte délégué à établir des critères et une méthodologie pour évaluer les microorganismes afin de les ajouter dans la CMC 7</u>

Les autorités françaises sont favorables sous réserve et à la condition stricte que la future méthodologie intègre une évaluation par un organisme indépendant reconnu par les Etats membres.

Justification : Il pourrait être utile qu'il existe des critères UE homogènes sur l'efficacité des biostimulants fixés par actes délégués mais il est demandé à ce que la future méthodologie intègre une évaluation par un organisme indépendant qui serait reconnu en tant que tel par les états membres.

Les microorganismes peuvent poser des risques pour l'environnement ainsi que pour la santé des hommes et des animaux. Ainsi, l'évaluation de l'efficacité et de la sécurité des microorganismes destinés à entrer dans la composition d'un fertilisant UE doit être confiée à un organisme scientifique compétent en la matière et non aux fabricants.

Questionnaire à l'attention de la Commission

1. Quels mécanismes de contrôle ou de validation scientifique sont prévus pour assurer la sécurité et l'efficacité des microorganismes introduits dans les fertilisants UE ?

2. Si l'évaluation des microorganismes sera exclusivement menée par les fabricants, comment la Commission peut-elle garantir que la simplification réglementaire ne se fera pas au détriment de la sécurité des utilisateurs, des animaux, ni de l'environnement ?

3. <u>Supprimer l'article 43 obligeant la Commission européenne à adopter un acte délégué distinct pour chaque catégorie de matière constitutive (CMC)</u>

Les autorités françaises sont favorables à cette proposition de simplification

4. <u>Introduire des obligations de digitaliser : fournir obligatoirement l'attestation UE de conformité sous format numérique, ajouter une adresse numérique des opérateurs économiques</u>

Si les autorités françaises sont favorables à la digitalisation des documents, cela ne doit pas revenir pour autant que à imposer le format numérique pour la fourniture de tous les documents relatifs à la conformité des fertilisants. En effet, il convient de laisser le choix aux fabricants de fournir l'attestation de conformité sous un format numérique ou non. De <u>même il convient de laisser le choix aux opérateurs économiques de communiquer les documents prouvant la conformité d'un fertilisant UE sous format numérique ou sur support papier</u> aux autorités compétentes ou de surveillance du marché.

La **rédaction actuelle du règlement (UE) 2019/1009** prévoit déjà la possibilité de digitalisation (avec aussi l'option de fournir sous format papier) **et <u>ne devrait pas être modifiée pour imposer le format numérique</u>** : certains opérateurs préfèrent transmettre sous format papier.

Questionnaire à l'attention de la Commission :

1. Quels avantages concrets la Commission envisage-t-elle en imposant un format numérique par rapport au maintien du choix entre format papier et numérique ? Comment ces avantages ont-ils été estimés ?
2. Pourquoi la rédaction actuelle du règlement (UE) 2019/1009, qui permet déjà la digitalisation tout en laissant l'option du format papier, ne serait-elle plus jugée suffisante ?
3. Comment la Commission entend-elle prendre en compte les besoins des opérateurs qui, pour des raisons organisationnelles ou techniques, préfèrent transmettre ou recevoir les documents au format papier ?
4. La Commission envisage-t-elle de maintenir une certaine flexibilité dans les modalités de transmission des documents de conformité, afin de respecter le principe de proportionnalité et de faciliter la mise en œuvre pour l'ensemble des opérateurs concernés ?

IE comments

Comments Regarding the Proposed Changes to the Classification, Labelling and Packaging (CLP) Regulation.

In general, IE recognises that certain aspects of the CLP Regulation could potentially create a heavy administrative burden and generate high costs for industry. However, IE stresses the importance of achieving the correct balance between reducing the burden for industry, while still maintaining the highest level of protection of human health and the environment and protecting the integrity of the legislative process.

Labelling: Amendment to Article 31(3) and Annex I section 1.2.1

IE understands the reasoning behind the reintroduction of flexibility in the rules on label formatting. While we are open to agreeing to the proposals in the Omnibus Regulation, we have concerns that with the removal of the mandatory label formatting rules introduced by Regulation 2024/2865, the issues identified in the Fitness Check (2019), which showed that labels were overcrowded and difficult to read, will simply remain. While we appreciate that the plan is to strengthen ECHA's guidance on this issue, IE is of the opinion that issues with enforceability of the legal text will arise. Experience has shown that there are issues with enforcing '*easily read'*, as it is subject to interpretation. For those reasons, IE asks if further consideration could be given in particular to addressing the labelling of consumer products.

Digital labelling

IE supports and welcomes the amendment of Article 17(1)(a) which will require a digital contact to be indicated on the label. IE also welcomes the amendment to section 1.6 of Annex I, which broadens the use of digital labelling introduced by Regulation 2024/2865. While that amendment will save space on physical labels, IE proposes that digital labelling is further embraced and that it is examined as to whether there are other label elements (e.g. precautionary statements if the number of precautionary statements go beyond 3 for example, some EUH statements) that could be provided on the digital label only. In the interests of balancing protection of health and the environment and reducing the burden on industry, we propose that the pertinent information regarding hazards and protective measures are clearly visible and legible on the label, with further information provided on the digital label. Focusing on what consumers take note of on CLP labels and their general level of understanding of the information on labels should be considered. This would go towards addressing the finding in the Fitness Check (2019) that labels are overcrowded and address the concerns outlined above, in addition to aligning with the Commission's efforts to promote the 'digital by default' principle.

Updating labels

Informing users about a change in classification is crucial in the protection of human health and the environment. While we appreciate that the deadline of 6 months to update labels following a change in self-classification appears not to be feasible for industry, IE is concerned with the proposal that there is now no deadline set for industry in Article 30(1) to update their labels and instead the requirement is to change the labels 'without undue delay' once the new data is obtained by, or communicated to, a supplier. This provision will be very difficult to enforce and for that reason, the IE preference is for there to be an agreement on an ultimate deadline (somewhat longer) provided for in Article 30(1). We note that companies highlighted that the increased outsourcing of label printing extends the supply chain for labels by 2 to 3 months. With that in mind and acknowledging that the deadline applies to each actor in the supply chain, IE is of the opinion that there is merit in setting a deadline in Article

30(1) and would propose that this deadline is set at between 9 and 12 months, while still encouraging suppliers to update labels without undue delay and no later than the deadline.

Derogations from labelling requirements for small packaging

IE supports the amendments proposed for Article 29(2) and section 1.5.2.4 of Annex I.

Advertisements and on-line sales

IE supports the amendments proposed for Articles 48 and 48(a) regarding advertisements and on-line sales. IE is of the opinion that a definition of 'advertisement' may still be warranted.

PUBLIC

CLP

Italian Comments on the proposed amendments to EU Regulation 2024/2865:

PUBLIC

Overall, we believe that most of the amendments and simplifications introduced by the Omnibus are acceptable. However, we believe it is essential to offer some observations on the parts of our concerns.

Article 17(1), point (a); Article 25(6); Annex I, sections 1.5.1.2 and 1.6.

Adding 'digital contact' to replace the telephone number completely appears unacceptable and reductive, as it would limit access to information to digital channels only.

There is a fear that with only digital contact, the direct interaction (as need by institution, inspector, consumer, etc) with the company could not happen. Therefore, we propose the expression ***'telephone number or*** *digital contact'*.

Article 30, paragraph 1:

Effective communication throughout the supply chain when the hazard identified is more severe than previously recognised is essential for safeguarding workers' health. However, the term 'without undue delay', which is intended to ensure the prompt updating of hazard information without setting a strict deadline, **is unacceptable** as it would lead to uncertainty in the application of the legislation. There must be certainty regarding the updating of hazard information for downstream users (and their employers, for appropriate workplace safety compliance), and this must form a clear basis for regulatory action. **The proposed change cannot be considered a simplification**; rather, it is an attempt to mitigate companies' obligations at the expense of health protection. We therefore request that the phrase *'without undue delay* ***and in any event no later than six months'*** be reinstated in REG 2865. However, we are flexible on the six-month term, should you wish to extend it by a few months.

Article 31(3)

The requirement for more legible labels was requested by civil society, considered by inspectors based on years of experience, and a key focus during the negotiation phase of Regulation 2865. While the industry's concerns about operational difficulties are partially understandable, to reach a fair compromise, we propose inserting the phrase ***'By two years, the Commission shall present a report regarding a proposal to set elements to improve legibility as an integral part of this regulation***'. Although a guideline could recommend a suitable font size and background, we believe that setting the formatting characteristics in the regulatory text would better meet civil society's and inspectors demands.

Article 48

While we appreciate the sense of extreme simplification, we believe it would be useful to amend the phrase included in the advertisement to read: *'Always read the label and product information before* ***purchase and*** *use.'*

Stop the clock

The proposal for a "STOP THE CLOCK" measure is welcomed because it avoids different dates for the same type of obligations and that ensures legal certainty. However, **we propose the postponement of the application of the amended provisions until 1 January 2030**, when the EU

Regulation 2025/40 on packaging and packaging waste will apply to all chemicals. Considering the overall circumstances, the postponement to 1 January 2028 seems too optimistic.

Suggestions for improvement

- Possibility of further extending the use of digital labelling, to supplement or partially replace usage information, packaging information and information derived from other legislation by simplifying (more readable) physical label information, as well as reducing the quantity of label materials used (paper, ink, etc.).

- the amendment introduced by revision Reg. EU 2024/2865 to Article 9(4) significantly restricts the use of expert judgement in the classification of chemical mixtures, to the selection of reference mixtures for bridging principles, so it would be desirable to return to the previous version.

COSMETICS

Italian Comments on the proposed amendments to EU Regulation 2009/1223:

We recognise the urgent need expressed by the stakeholders to enhance clarity, preciseness and effectiveness of the cosmetics regulation. At the same time, the process of amending legal provisions must support measures to protect the health of citizens as consumers and especially the most vulnerable ones, such as children

Colorants, preservatives and UV filters art.14a

We support the proposal, under the condition that tacit approval mechanisms are excluded when the SCCS does not comply with the deadline for delivering its opinion. In this case, **in the absence of a positive opinion from the SCCS, the substances concerned shall not be included in the positive lists** according to the principle "no data no market".

Ban of Carcinogenic, Mutagenic or Reprotoxic (CMR) substances

In this respect, careful assessment is required when establishing a priori transitional periods for the placing on the market and making available on the market of cosmetics in the event of a derogation from the ban on the use of CMR. However, where such derogations are granted, they must be supported by scientific evidence on safety in use expressed by the Scientific Committee for Consumer Safety (SCCS), involved by the Commission to express an opinion on the safe use conditions of these substances. The opinion is based on the evaluation of exposure risks to all possible categories of end-users.

Therefore, we consider necessary to start a discussion at council level on the transitional period proposed with the amendment of art. 15. Bearing in mind the need to protect human health, we would need to assess the necessity to link transitional periods to the safety in use of CMR substances according to the specific characteristics of each substance, being able also to foresee different disposal times, also more restrictive when imposed for reasons of safety for the health of consumers.

With that regard, we note that the change in the management procedure for derogations in art.15 already extends by 15 months the deadline for the adoption of measures for the use of CMR substances, introducing already, as opposed to now, a period of consumer exposure to products containing banned CMRs. At this period, we should add the transitional periods for placing on the market and making available on the market. In fact, the derogation provisions will have to be adopted within 15 months from the application of the CLP ATP, whereas today the derogations apply at the same time as the application of the CLP ATP. In particular, this amendment to Article 15 paragraph 2 invalidates the principle of automatic prohibition of use of CMR substances which had guided the legislator in preparing Regulation 1223/2009. **Therefore, we express our negative opinion to this proposal.**

Secondly, if the amendment was adopted, it would be appropriate to reiterate the concept of automatic ban for CMR substances for which no request for a derogation has been submitted within the 3-month period, requiring at least the inclusion of an express provision with this regard.

The provisions related to the amendment of the exemption criteria and Natural Complex Substance are acceptable as they would be supported by the SCCS safety assessment opinion covering all requirements necessary for issuing a safety use opinion of the substances in the different types of cosmetic product.

Regarding the proposal to link the ban to the use of CMR only to skin exposure we recognize its benefits in reducing the administrative burdens and the complexity of the current system. At the same time, the provision does not seem sufficiently clear when it describes the procedure that the Commission should activate to obtain the opinion of the SCCS. In addition, it is not justified why the compliance with the food safety requirement is not needed anymore while the same level of human health protection is ensured even with the change of the usage and exposure conditions.
We would therefore appreciate if the Commission could provide clarifications to address these concerns.

Notification nanomaterial art. 16.3 and 16.6

The proposal to delete the notification in art. 16.3, considering it to be a simple pre-notification, an administrative act, and therefore a duplication of burden for Industry, is inappropriate.

We would like to draw your attention to the fact that for the safety assessment of colorants, preservatives and UV filters in the form of nanomaterials (in positive lists in Annexes IV to VI), specific assessments are carried out by the SCCS even if the corresponding non-nano form exists in the annexes. This safety assessment appears to be a fundamental element for the protection of citizens' health.

In addition, for products containing nanomaterials other than those authorised by the European Commission, safety data on the use of nanomaterials in cosmetics, which could also be intended for children, must be evaluated by the European Commission, as is the case with colorants, preservatives and UV filters in nano form included in the positive lists.

Therefore, we consider that the notification of the dossier related to the substance of a nanomaterial and to the safety of cosmetic products containing it should continue to be subject to independent assessment by SCCS in order to maintain a high level of health protection for users, as well as this happens for colorants, preservatives and UV filters.

ART. 22 and ART. 33

We support the proposed amendment. The simplification provision is compensated by other solutions like the sharing of data in ICSMS and consultation of the Cosing.

'Reality Check' (workshop) on cosmetics (16 May 2025; 226 participants)

We would like to point out that the results of the workshop must take into account the proportion of participants and their votes when they are evaluated.
In particular, the figures provided by the Commission show that 65% of the workshop participants were from industry, 23% from CAs and 12% from others.

FERTILIZERS

Italian Comments on the proposed amendments to EU Regulation 2019/1009:

We appreciate the scope and the objectives of the proposal and we have a couple of suggestions:

- Digitalisation: the provisions are appreciated, furthermore we would appreciate that the digitalisations provisions considered also the exchange of information between the manufacturers and the farmers.
- Another possible improvement of the proposal may relate to the usage of new materials (like by-products of animal origin) to be allowed after a thorough scientific assessment.

Please, note that we still have a scrutiny reserve on this proposal and we may come back with more precise observations.

PUBLIC

LATVIA

Written comments

Proposal for an Omnibus on simplification for certain chemicals:

1. Concerning amendments to the Fertilising Products Regulation (Regulation (EU) 2019/1009)

In general, Latvia supports the amendments to the Fertilising Products Regulation provided in the proposal as they aim at reducing the administrative burden on companies.

As Latvian legislation on fertilisers does not provide for extended REACH registration requirements for substances used in fertilisers other than those already established under Regulation (EC) No 1907/20069 ('REACH'), Latvia therefore supports amendments to the Fertilising Products Regulation, which provides for the removal of the extended REACH registration requirement. Latvia supports these amendments as this will reduce the administrative burden on EU fertilising products' manufacturers, substance manufacturers/importers and reduce the cost of some EU fertilising products containing certain substances in small quantities. The EU will therefore have uniform requirements for the registration of substances for both EU fertilising products placed on the single market and fertilisers placed on the market under national legislation on fertilisers.

Latvia supports the amendments to Article 42 of Regulation (EU) 2019/1009, which empowers the Commission to establish criteria and methodology for the evaluation of micro-organisms. Whereas microbial plant biostimulants are produced in Latvia and currently Regulation (EU) 2019/1009 allows only four groups of micro-organisms to be used as component material (CMC 7) in microbial plant biostimulants: *Azotobacter spp., Mycorrhizal mushrooms, Rhizobium spp. and Azospirillum spp.*, therefore manufacturers choose to place their microbial plant biostimulants on the market in accordance with national regulations and use mutual recognition to market their products in other Member States. To place microbial biostimulants on market according to national regulation there are no limits on micro-organisms used but the products require two years field trials and show yield increase. Currently 82 different micro-organism strains have been used in various products that give yield increases. By establishing criteria and methodology for the assessment of micro-organisms by the Commission, manufacturers of microbial plant biostimulators will be able to assess and demonstrate compliance with those criteria themselves, as well as taking into account that notified bodies will have to approve that assessment, so that new innovative products that do not pose a risk to human, animal or plant health, safety or the environment and ensure agronomic efficiency could be placed on the EU single market.

In general, Latvia supports amendments to digitise the Fertilising Products Regulation, where appropriate in line with the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/1009 as regards digitalisation and common specifications.

Question:

Latvia would greatly appreciate additional clarification of the term "data carrier," particularly clarification on the devices used to read the data carrier. Specifically, will it necessitate downloading additional applications into mobile devices to read linear bar

code symbols and two-dimensional symbols, and could practical examples be provided to clarify the concept of "digital contact"? Considering previous amendments regarding digital labelling and the proposed changes regarding "digital contact" and "data carrier", we urge the Commission to update guidance document for manufacturers and market surveillance authorities with clear information and examples concerning the visual appearance of labels referred to in Annex III to Regulation (EU) 2019/1009.

2. <u>With regard to the amendments to the Cosmetics Regulation</u> there are no objections in principle, as their objective and necessity are set out in recitals 15 to 25 of the preamble. Overall, the amendments clarify the requirements and address some previously identified shortcomings, but in some cases, there are concerns about how the improvements are to be achieved through these amendments.

There would be no objection to abolishing the requirement to notify nanomaterials six-month before cosmetic products are placed on the market, but this would mean that the safety assessment of nanomaterials would be left solely to the responsible person and the controlling authorities that verify it. There could arise risks to consumer safety, as the safety of nanomaterials is more difficult to assess and the responsible person and authority may not have sufficient expertise and resources for that. One possible solution would be to allow only nanomaterials listed in Annexes III to VI.

In essence, there are no objections to simplifying the procedure for adopting ingredient names, so that the glossary would not have to be adopted by the Commission and published in the Official Journal of the EU. instead, the names could be published in an electronic database (CosIng) that would serve as a recognized source of cosmetic ingredient names. There is sizeable concern that confusion may arise with ingredient names indication on the labelling if the use of any international nomenclature is allowed, not without prioritizing of INCI names. With the amendments in Cosmetic regulation should be stipulated that the INCI name or name available in the CosIng database shall be used as a priority, while another international nomenclature name shall be used only if these names are not available.

This requirement should be incorporated into the amendments to Article 19(6) so that it is not lost when Article 33 is deleted.

The question of how to organize Member States' reporting on monitoring measures also needs to be discussed. It is currently proposed to delete the last sentence of Article 22, whereas it could simply be amended to indicate a different reporting method.

Regarding Annex II to Omnibus4, which provides for the addition in section 2 of Annex I to the Cosmetics Regulation with certain information on nanomaterials, it should also be corrected, as part of what is added here in section 2, rather belongs in section 8, as it relates to the characterization of the toxicological effects of substances.

Regarding Annex III to Omnibus4, which provides amendment in the Preamble to Annexes II to VI, point 2, the fifth indent to replace the reference to glossary with the reference to internationally recognised nomenclature, instead, the use of International Nomenclature of Cosmetic Ingredients should be prioritised.

With regard to Article 15(2), it is expected that difficulties may arise in implementing the condition "it provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy". As is known from the case of formaldehyde, the mechanism of action of the alternative substance is different from that of the classified substance.

3. <u>With regard to amendments to the CLP Regulation</u>

We propose to clarify the definition of "digital contact".

This definition is not sufficiently clear to be applied unambiguously in labelling and monitoring practices. There are several ambiguities in interpretation that may lead to misunderstandings on the part of manufacturers/importers and to different approaches by monitoring authorities.

Firstly, it is not clearly defined what exactly constitutes "registration" – does it refer only to registration on the provider's website or also, for example, to having an account on social networks (Facebook Messenger requires a Facebook account, for example). Secondly, it is not specified whether popular communication tools that technically require authentication or an app, such as Messenger (Facebook), WhatsApp, Instagram DM, are also excluded.

These tools are practically available to the general public, but cannot be accessed without an account, which may not formally meet the "no registration" criterion included in the definition.

Examples should be provided to ensure a common understanding or to exclude cases that would help to apply the labelling requirements consistently.

An email address could be an option intended by this amendment, but this could lead to confusion, as technically an email account is required to use email, and such an account is already a generally accepted means of communication and is not linked to the supplier's platform. Clear confirmation is therefore needed that email falls within this definition. For example, the preamble could state, "...such as an email address or a web-based contact form that does not require user authentication."

The greatest concern is the removal of conditions for clear labelling. There are no objections to reducing the burden on businesses, but this should not be done by removing all conditions, but rather by simplifying them in a reasonable manner.

We also support the separation of requirements for advertising and distance selling offers in Articles 48 and 48a, but the wording should be clarified with regard to the amount of hazard information, specifically whether a pictogram is necessary or whether H and P phrases and signal words would suffice.

PUBLIC

NL initial comments and questions on Omnibus VI

Regarding: Regulation (EC) No 1272/2008 - CLP

1. Under Article 2, a new definition; "digital contact" is added, which requires an online communication channel from suppliers. What forms of online communication channels are foreseen under this definition and would the use of an AI chatbot be permitted? NL finds it important that the supplier can be reached or engaged directly.
2. Regarding the proposed amendment to Article 17(1) point (a), we have an editorial remark as we believe it should read supplier(s) instead of suppliers: "*(a) the name, address and at least either the digital contact or telephone number of the supplier(s);".*
3. Regarding the proposed amendments to Article 29 and sections 1.5.2.4, 1.2.4.1 and 1.5.2.4.2 of Annex I and the new section 1.5.2.4.3 of Annex I for derogations for small packaging, there is an inconsistent use of Article 17 as a whole versus Article 17(1). We believe the proposed amendment to section 1.5.2.4.1 of Annex I should be as follows: "*The label elements set out in Article 17(1) may be omitted from the inner packaging…*". This would make sure that all label elements that are present are written in the official language(s) of the Member State(s). Furthermore, we believe inserting the proposed text in section 1.5.2.4.3 before the proposed section 1.5.2.4.1 in Annex I would make the order of the derogations more logical.
4. Regarding the proposed amendment of Article 30(1), where the deadline for updating the label is removed, we foresee an increased burden for enforcement. How was this been weighed? Without a fixed deadline, proofing incompliance is difficult. We would propose to align the deadline with the CLH timeline (18 months) instead, which would alleviate most of the burden. To prevent a cascade of 18-month deadlines with every subsequent supply chain member, the deadline could be 18 months total with a requirement to inform users down in the supply chain (exempting the general public), e.g. within 3 months, to ensure every supplier is informed in due time. Furthermore, has the Commission investigated the option of setting different set deadlines for new products versus products that are already on the market to avoid unnecessary waste, but unsure efficient hazard communication?
5. Regarding the proposed amendments to Article 31(3), sections 1.2.1.4 and 1.2.1.5 of Annex I for label formatting rules, we again see a risk for an increased burden for enforcement, as there would only be guidance and no set rules? The amendments as proposed have led to many difficult to read labels in the past without the possibility to enforce improvements. In addition, we propose to amend section 1.2.1.5 in Annex I instead of complete removal to unsure readability, by omitting only (b) and amending (a) and (d) as follows:
   "*The text on the label shall have the following characteristics:*
   (a) printed in a contrasting colour compared to the background (e.g. dark on light background or vice versa);
   (b) A single font that is easily legible and without serifs should be used;
   (c) the letter spacing shall be appropriate for the selected font to be easily legible."
   Furthermore, we propose to leave the reference to the labelling requirements in Annex I within Article 31(3), to allow for an easier process with future changes to the label formatting rules.
6. Regarding the proposed amendments to Article 48 for advertisements, the sentence 'always read the product label…' only refers to the use and gives no indication that the products contains hazards. We suggest adding an additional statement, e.g. "This product contains hazard(s)." with the option for visual advertisements to show the hazard pictograms instead. In addition, how it ensured that an advertisement only reaches professionals? We prefer to keep the requirement for professional users. Lastly, why was there no definition for advertisement added while stakeholders, including industry, asked for this for sake of clarity?
7. Regarding the proposed amendments to Article 48a, we wonder how it can be ensured that a distance sale is only accessible for professional users. Furthermore, to allow for less burdensome enforcement and clarity for industry, it could be wise to give definition to what "*clearly and visibly*" entails. For example, the label elements should not be hidden behind a click nor at the bottom of a webpage, but rather displayed next to/below the product picture.

8. Regarding the proposed amendments to Part 5 in Annex II, we have one editorial suggestion for clarification under point (c): "*When vehicle fuels are supplied at a filling station through pumping into portable receptacles designed to be used for transportation of fuels, …*".
9. Regarding the proposed amendments to Article 61, we suggest to not only remove Article 31(3) as proposed from Article 61(8) but also add it to the added Article 61(9): "*Substances and mixtures which have been labelled in accordance with Article 17(1), Article 25(6), Article 31(3) and section …*".

Regarding: Regulation (EC) No 1223/2009 on cosmetic products

1. The proposal raises concerns about both its timing and proportionality. The Cosmetics Regulation is currently under evaluation, with a public consultation open from 5 May to 28 July 2025. This consultation, that explicitly invites suggestions for simplification, will inform the upcoming REFIT. How is this process and it outcomes being streamlined with the simplification omnibus? Is it proportionate to introduce simplification measures now, knowing a comprehensive revision is planned? We would appreciate clarification on the need to advance these measures at this stage.
2. On article 15, para 2, the suitable alternative criteria: by including this directly in the CPR, there is a risk of creating an exhaustive list that may prove restrictive in the future. Would it be possible to consider a reference to guidance instead, in order to maintain a degree of legal weight without creating a rigid framework? As currently formulated, we are concerned this may lead to unintended consequences over time (for instance: what is considered technically and economically feasible today may not be the same in five years time).
3. On article 15, para 5: we understand the reasoning behind this proposal and the urgency, but we have concerns about CMR substances within cosmetics that are (potentially) inhaled or ingested. We would suggest at the very least clarifying 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 should hold for substances with an oral classification used in oral cosmetic products (although in practice, oral-specific classifications are extremely rare).
4. On article 15, para 6: this new para states that the prohibition does not apply to natural complex substances (NCS). Could the Commission clarify how this does not pre-empt the outcome of the evaluation of Article 54a(1) of the CLP Regulation?
5. On article 15, para 7: CMR substances (carcinogenic, mutagenic, or reprotoxic) are prohibited in cosmetic products. Once a substance expected to be classified as CMR is placed on the Registry of Intentions, industry typically has about two years before the classification process is finalized: meaning they should not feel caught by surprise that one of their ingredients can no longer be used. Currently, CMR substances are banned from cosmetic products as soon as possible after their classification, with a maximum of 15 months after their inclusion in the CLP Regulation. However, the newly introduced paragraph 7 of Article 15 allows cosmetic products containing such substances to be placed on the market for 12 months and made available for sale for 24 months after the substance has been included in the annexes of the Cosmetics Regulation. This represents a significant extension compared to the current system and raises serious concerns. Allowing cosmetic products containing hazardous substances to remain on the market for such prolonged periods increases consumer exposure to CMR substances, which is deeply concerning from a public health perspective.

   Would you agree that this is not a simplification, but rather a relaxation of existing rules?

   How can we credibly explain to consumers that stricter rules apply to products like paint, while cosmetics (products intended for direct application to the body) are subject to more lenient deadlines?

   What safeguards are in place to prevent companies from dumping products on the market in large quantities before the restrictions apply? We are already seeing this happen in practice.

Intern gebruik

We would be open to considering alignment of the date of application for substances under the CLP Regulation and the prohibition of CMR substances in cosmetic products.

Regarding: Regulation (EU) 2019/1009 on EU fertilising products

1. The first proposal concerns aligning the information requirements and the preparation of safety reports for substances added to fertilizers (e.g., dyes) with the REACH requirements. These substances are generally added to fertilisers in very small quantities. REACH contains provisions that reduce the information requirement for small quantities of chemical substances supplied by the manufacturer of the substances in question, below the annual supply of 10 tons per year. For very hazardous substances ('very hazardous' in the REACH classification), the requirement for a comprehensive information obligation and safety reporting/assessment remains.

   The Netherlands can agree with this proposal. It is positive that various EU regulations are well-integrated. This proposal removes a significant hurdle for businesses.

   For very hazardous substances, it remains important to comply with the comprehensive information obligation and safety reporting. How is this guaranteed in this proposal?

2. The second proposal concerns a proposal to simplify the authorization for microbial biostimulants. Currently, national regulations in the Netherlands do not regulate the authorization of biostimulants. The intention is also not to do so. The Netherlands wants all authorizations to eventually go through the European Fertilizer Regulation (FPR).

   The FPR does include a possibility for authorization of microbial biostimulants. The proposal states that Article 42 of the FPR, annex II, part II, CMC 7 will be amended to include general safety and efficacy requirements for microorganisms and a methodology based on which companies can demonstrate compliance. Notified Bodies (NoBo's) (supervisory bodies) must monitor compliance with this.

   The Netherlands can support the introduction of harmonized protocols for assessing the safety of such products, but is of the opinion that an independent assessment (via EFSA, etc.) must have taken place before a biostimulant can be added to the list of permitted fertilizers in the FPR. Thus, the Netherlands is critical on this proposal, where the safety assessments can be demonstrated by the companies and supervised by NoBo's. The NoBo's lack the required knowledge to judge this requirement.

   The Netherlands considers it important that prior to inclusion on the list of authorized microbial biostimulants on the list CMC7 there is an assessment of the safety and efficacy of these products. How can safety and efficacy, including safety during use and when putting the product into the environment be assessed prior to authorization? The Netherlands is of the opinion that this should be an independent thorough assessment prior to authorisation (e.g. EFSA authorisation).

   In terms of efficiency and clarity, establishing a protocol for companies based on which they can do this assessment and submit it for authorization would help in the efficiency of this pathway. What is the view of the Commission on this matter?

   This discussion on authorization of biostimulants may fit better in the context of the evaluation of the FPR, which could also look more broadly at fertiliser authorization procedures under other categories as well.

3. The third proposal concerns the possibility of being able to add products other than products derived from animal by-products to the FPR's CMC-10 list, following a safety and efficacy

Intern gebruik

assessment. The Netherlands is in favor of the possibility of adding certain product categories to these CMC-10 lists of the FPR, provided it is secured through safety and quality assessments.

4. The fourth proposal is about digitalization of the information to be transmitted with the marketing of fertilizers. Currently, digital transmission is still optional. Stakeholders experience ambiguities because of this, too often written, hard copy information is unnecessarily requested by buyers. It is proposed that information transmission be exclusively digital. The proposal shows that both industry and authorities are in favor of this. The Netherlands can support this proposal, but possibly written information can still be satisfied in exceptional cases.

   In all cases of amendment, should the information be provided digitally? What if this is unexpectedly not possible (trade from third countries?, system errors).

5. The Commission proposes that amendments/addition of substances of a category (CMC) in the FPR should be regulated by a separate delegated act. It wants to remove the so-called 'unbundling clause'. The Netherlands can support this proposal, however this should not lead to delay if proposals are bundled.

   Does the bundling of proposals for amendments with the different categories not also lead to delay if unexpectedly within the bundled proposal on one part that causes a lot of discussion, the other part is unexpectedly delayed by this?

Intern gebruik

Ministry of Economic Development and Technology
Republic of Poland

PUBLIC

Warsaw, July 21, 2025

Comments by Poland on OMNIBUS package covering the following drafted regulations:

- **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 relating to chemical products - TARGETED AMENDMENTS - COM(2025)531;**
- **proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2024/2865 as regards the dates of application and transitional rules - STOP THE CLOCK - COM(2025)526.**

Poland welcomes the European Chemicals Industry Action Plan and the accompanying Omnibus legislative proposal on simplification for 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 relating to chemical products (COM(2025)531 and proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2024/2865 as regards the dates of application and transitional provisions (COM(2025)526), both proceeded under OMNIBUS VI regulatory package.

In our opinion, the abovementioned proposals are a step in the right direction, aimed at simplifying and rationalizing the regulatory framework in the area of chemicals without reducing the level of protection of health and the environment.

We do appreciate the European Commission initiative as its response for postulates of Member States and the industry indicating the urgent need for simplifications and clarifications of the EU law, for reduction of unnecessary administrative burdens and to creation of conducive conditions to innovation and competitiveness, especially from the perspective of SMEs.

The chemical industry, as a sector of strategic importance to the economic and technological and energetic security of the European Union, is characterized by complex production processes and significant capital intensity. Being in operation and long-term development of this industry are only possible in a predictable and stable regulatory environment. From the perspective of chemical companies it is crucial to ensure clear, proportionate, and implementable regulations that support competitiveness and enable the effective implementation of environmental objectives. The proposed changes meet these expectations, but it seems that further simplification of other regulations are still very much needed.

Due to the regulatory uncertainty impacting the smooth operation of the chemical sector, we think that adoption of the OMNIBUS VI package should be proceeded as soon as possible. Otherwise, we recommend developing interim interpretative guidelines that would support businesses in implementation of existing current legal framework.

- **As for simplifications as regards the CLP Regulation:**

Regarding the changes proposed in the Omnibus package, the most significant changes for chemical companies are those related to labeling and formatting. The Commission proposed repealing or modifying certain provisions introduced by Regulation 2024/2865 (the so-called CLP revision), which were expected to enter into force in January 2027. This included the requirement to use

+48 222 500 123
kancelaria@mrit.gov.pl
gov.pl/development-technology

Pl. Trzech Krzyży 3/5
00-507 Warsaw
Ministry of Economic Development and Technology

specific font sizes, fixed line spacing, white backgrounds, and black characters. These regulations may generate significant implementation costs for companies without a documented impact on the increase safety level. The proposed withdrawal restores flexibility in label design and allows for multiple language versions on a single label, which will reduce the number of packaging variants and lower logistics and warehousing costs.

We support the European's Commission proposal to remove mentioned above rigid technical requirements concerning labelling rules More flexible approach to labeling based on circularity principles will prevent unnecessary product's relabeling, reduce packaging waste, and avoid excessive costs especially for SMEs.

However, we would like to emphasize, that, in accordance with Article 3(2) of the draft, the CLP provisions in question "shall not apply and shall not be enforced" until the amendment enters into force. Although the "stop the clock" mechanism is not here explicitly used, the regulatory effects are similar. Nevertheless, Regulation 2024/2865 remains formally in force, and the proposed suspension of the provisions is contingent upon the decision making process to be completed. Until then, the status of regulatory uncertainty will persist, which, from the industry's perspective, may be considered as highly undesirable.

We also appreciate the proposal enabling partial label digitization (e.g., via a QR code or website link) for selected information, such as EUH statements or supplier contact details. This is the first formal step towards e-label solutions, which can be a tool for increasing label readability and reducing operational burdens. Allowing the use of label colors other than black and white, while maintaining the requirement for label readability, is also beneficial from the industry's perspective. This proposal paves the way for greater use of recycled packaging and supports the achievement of circular economy goals.

We support the proposed simplification of advertising rules for hazardous products sold to the general public. The revised approach focuses on a clear call to action such as "Always follow the information on the product label", which strikes a better balance between safety and practicality. It also contributes to better alignment of CLP with other sectoral legislation, such as that governing pharmaceuticals.

This change is particularly important for digital and audio formats, where space and time are limited. The current rules are requiring full hazard information in all advertisements, risking overwhelming consumers with complex details, ultimately reducing attention to the actual product label and undermining effective hazard communication.

We support the proposed simplification for small packaging, which introduces automatic derogations for containers under 10 ml and clarifies the rules for other compact formats. Under the previous rules, companies had to justify that a package was too small to meet full labelling requirements, an inefficient and burdensome process. The new approach avoids unnecessary administrative hurdles and prevents companies from having to increase packaging size solely to fit label contents, in alignment with EU objectives on packaging minimization and circularity under the Packaging and Packaging Waste Regulation (PPWR), while ensuring that essential safety information remains accessible

- **As for simplifications as regards the CPR Regulation:**

In particular, we welcome the proposed amendments to Article 15 of the CPR, which regulates the use of substances classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) under the CLP. These amendments aim to simplify procedures and reduce the administrative burden and costs associated with complying with regulatory requirements, while maintaining the overarching goal of ensuring the safety of cosmetic products for human health. It should be clearly emphasized that

the overriding objective of the Cosmetics Regulation is to ensure the safety of cosmetic products for human health.

Poland is ready to consider amendments to Article 15 of the CPR. We believe that it would be appropriate to develop simplified procedures, but the overriding objective is to ensure the safety of cosmetic products for human health.
In the current system, classifying an ingredient as CMR category 1 automatically results in a ban on its use, even if there is evidence of its safe use. The Commission's proposed approach, which includes simplifying the derogation process, is a step in the right direction and deserves support:

- Establishing a deadline for submitting derogation applications of 3 months after the entry into force of the amendments to the CLP Regulation classifying a substance as CMR category 1A or 1B. This solution gives industry more time (12-18 months) to prepare a derogation application (the actual timeframe depends on the publication date of the Committee for Risk Assessment opinion). Current practice does not guarantee sufficient time, which often constitutes a barrier to preparing dossiers in a timely manner.

- Implementation of transitional periods for established prohibitions and restrictions: 12 months for placing on the market and 24 months for making available. Current regulations do not provide for any transitional periods, which exposes companies to the risk of lack of time to adapt to the new requirements. The proposed transitional periods are a significant improvement, enabling rational planning for the withdrawal of products containing banned or restricted ingredients from the market and the potential development of alternatives.

We are ready to discuss this issue. However, the proposed solution requires in-depth analysis. In its preliminary opinion the deadlines proposed by the European Commission appear to be too long in terms of ensuring consumer health protection.

- As for simplification of the derogation criteria for Article 15.2:
    - Removal of the "food criterion" eliminates a confusing and unjustified restriction that does not directly relate to consumer risk assessment in the context of cosmetic products.

Poland is ready to support the proposed removal of the food criterion.

    - The criterion regarding use at known exposure has been moved to the SCCS safety assessment criterion. The proposal to combine the ban on CMR substances to dermal exposure is particularly important because it significantly reduces administrative burden and regulatory complexity while maintaining a high level of consumer safety.

Initially we are ready to support this element of the proposal. The safety assessment of an ingredient is also carried out taking into account the exposure assessment of the substance.

    - Cosmetic products are typically applied topically to the skin - general prohibitions under Article 15 should only apply when the CMR classification is relevant for the dermal route of exposure. We think that extending hazard-based bans to irrelevant exposure routes for cosmetics introduces disproportionate regulatory impacts without providing additional consumer protection.

In our opinion, this element of the proposal requires further analysis. We therefore propose considering a more differentiated approach based on risk assessment for specific applications, in particular allowing for derogations from the ban in cases where no risk to health has been demonstrated under realistic use scenarios.

- As for clarification of the approach to natural complex substances (NCS):

  The proposed wording in recital 21 makes it clear that substances classified as CMRs can occur as components of natural complex substances (NCSs), e.g., essential oils. In such situations, the use of ban under Article 15 of the Cosmetics Regulation applies only to substances listed in Part 3 of Annex VI to the CLP Regulation. This means that NSCs containing CMR ingredients themselves are not subject to the ban, unless they are listed in Annex VI to the CLP Regulation as CMR category 1A, 1B, or 2. Since Article 15 does not prohibit entire NCSs containing CMRs, but only the substances listed in the Annex, it would be appropriate to clarify that individual SCCS assessments are not required for each NCS containing traces of a CMR ingredient. Instead, the SCCS might assess the safe levels of classified ingredients in the final product, regardless of whether they were introduced intentionally or as a natural, integral part of the NCS.

Poland welcomes the proposal to clarify the approach to NCS. The proposal still requires discussion. We are of the view that the SCCS should determine safe levels of classified ingredients in the final product on a case-by-case basis. Therefore the proposed wording reads: "the SCCS may assess".

For point concerning procedure for the addition of colorants, preservatives, and UV filters to Annexes IV–VI of the CPR - Poland is ready to consider the proposal of the Commission to add an article outlining the procedural steps involved, the role of the European Commission, and reaffirming the responsibility of the SCCS in assessing the safety of any substance which will be proposed for inclusion in the list of mentioned above substances.

- **As for simplifications as regards the Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilizing products:**

Amendments to the Fertilizer Regulation aim to reduce procedural complexity and increase producers' operational flexibility. Standardizing the allowable level of technological additives in composting and fermentation (up to 5% of the input weight) should be considered a rational and pragmatic approach.

A modified definition of controlled release polymers (CMC 8)—while maintaining room for innovation and biodegradability—could provide a significant development impetus for this product group.

We also welcome the full digitalization of compliance documentation and declarations of conformity, which will translate into reduced administrative costs and improved communication with supervisory authorities. Allowing electronic communication to be equivalent to physical communication is further evidence of progress toward a modern compliance management model.

At the same time, we would like to draw attention to the difficulties in interpreting point 1 of Annex V of the Regulation 2019/1009 regarding product traceability. The literal approach of supervisory authorities, resulting in the expectation of preparing and signing separate declarations of conformity for each manufactured batch, leads to serious operational difficulties, especially in the case of large-volume, continuous production. In order to ensure the regulatory transparency and predictability, clarification of the regulations seem to be needed in a way that takes into account the practical realities of industrial processes and the principle of the manufacturer's responsibility for the compliance of the entire manufacturing process.

- **As for stop the clock CLP Regulation:**

We can also support the Commission's proposal COM(2025) 526, which amends Regulation (EU) 2024/2865 to postpone the application dates of several burdensome provisions. Such a revised time schedule will ensure legal certainty and operational feasibility for entrepreneurs, especially in transitional period of adaptation a simplified regulatory framework.

+48 222 500 123
kancelaria@mrit.gov.pl
gov.pl/development-technology

Pl. Trzech Krzyży 3/5
00-507 Warsaw
Ministry of Economic
Development and Technology

PT questions and comments on the Omnibus VI (chemicals)

22.07.2025

PUBLIC

General comments regarding the simplification of Regulation 1272/2008

1) As a general comment, while we support the proposed simplification measures, we believe it is essential to safeguard the core objectives of Regulation 1272/2008, particularly the need to maintain the current level of protection for both public health and the environment.

2) The revision of the CLP carried out through Regulation 2024/2865 sought to overcome a set of difficulties identified in terms of adequate communication of hazards in the supply chain (both in terms of the content of the information and in terms of the eligibility of that information), as well as in terms of legal clarity and inspection capacity. We must ensure that the current proposal does not constitute a disproportionate step backward in relation to these matters.

Proposal for a Regulation amending Regulations 1272/2008, 1223/2009 and 2019/1009 as regards simplification of certain requirements and procedures for chemical products

3) Regarding the proposed amendments to Articles 14a and 31, it would be important to clarify how the participation of Member States will be ensured, particularly with respect to the consultation and approval of the opinions issued by the Scientific Committee on Consumer Safety (SCCS). Additionally, we would suggest further clarification regarding the removal of the requirement to comply with food safety standards, insofar as for certain purposes it is important to have relevant information on, in particular, oral and systemic exposure.

4) Regarding Article 29(2) and section 1.5.2.4 of Annex I on provisions for small containers under 10 ml, to reduce the information required – we would welcome more detail from the Commission to assess if this change ensures the desired level of protection.

5) Article 30(1) removes the fixed deadline for the obligation to update the label, and return to the previous wording stating that the labels have to be updated "without undue delay" after new data was obtained by or communicated to a supplier. It should be noted that this was the wording contained in the original Regulation and was amended for greater legal clarity and predictability and to allow the respective enforcement. We have, therefore, reservations regarding this proposal.

6) Article 31(3) and section 1.2.1 of Annex I removes the mandatory label formatting rules introduced by Regulation 2024/2865 in order to guarantee/improve the readability of the labels and to ensure better legal clarity and enforcement. This proposal takes back the previous wording "easily read", which can be subject to different interpretations. We have, therefore, reservations regarding this proposal.

7) Articles 48 simplifies information requirements in advertisements to the general public. The amended provisions will require advertisements to encourage customers to read the label and product information before use. Regulation 2024/2865 established that advertisements of hazardous substances and mixtures should include the relevant label elements (hazard pictograms, signal words, hazard statements and supplemental EUH statements), which were removed in this proposal. We have therefore reservations regarding this proposal.

8) Regarding the Part 5 of Annex II on fueling stations, the proposal totally removes the measures introduced under Regulation 2024/2865. We have reservations regarding this proposal.

PUBLIC

Proposal for a Regulation amending Regulation 2024/2865 as regards dates of application and transitional provisions

9) Taking into consideration the current proposal to simplify the CLP Regulation, we believe it is appropriate to postpone ("Stop-the clock") the application dates of the relevant obligation introduced by Regulation (EU) 2024/2865 to allow negotiation between the co-legislators.

PUBLIC

SE preliminary comments and questions on the proposal for an Omnibus VI on chemicals, 18 July 2025

PUBLIC

Sweden welcomes the European Commission's intentions to simplify legislation. In this context, we wish to emphasize the importance of ensuring that new or amended regulations are clear—both to make them easy for businesses to comply with and for authorities to enforce.

Sweden encourages identifying potential simplification proposals within the relevant legal acts. However, since the purpose of these acts is to provide a high level of protection for human health and the environment, the potential impact of the proposals on the level of protection must be carefully analysed. Sweden is still reviewing the proposals in their entirety.

With that reservation, Sweden's preliminary assessment is that some of the proposals are more suitable than others for simplification negotiations within the Antici Group. This includes, for example, provisions in the CLP Regulation regarding labels on petrol pumps and regarding advertising, as well as provisions removing food safety requirements on CMR substances in cosmetics.

Our preliminary assessment is that several other proposals cannot be regarded solely as simplification measures, as they clearly affect the balance between protecting health and the environment and strengthening the internal market. These proposals appear more suitable for regular reviews of the respective legal acts. This applies in particular to the proposed easings of the ban on CMR substances under the Cosmetics Regulation, as well as the proposal to withdraw certain labelling requirements in the CLP Regulation.

It should be noted in this context that the CLP Regulation was recently subject to a comprehensive revision following a Fitness Check, a public consultation, and a full impact assessment. It should also be noted that a proposal to revise the EU's chemicals regulation REACH is promised by the end of 2025, and that the Commission is conducting a review of the Cosmetics Regulation, with a report expected to be published at the end of 2026.

Regulation (EU) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP)

One of the main objectives of the CLP Regulation is to inform both consumers and professional users about the hazards of chemical products and how users can protect themselves and the environment. For this information to be useful, it must be clear and easy to read. In the recently concluded revision of the regulation, the legislator introduced minimum font size requirements.
On what grounds does the Commission now consider repealing these provisions—without a full impact assessment and based solely on cost data from industry?
For what proportion of chemical products will it become difficult or impossible to absorb information about

their hazardous properties and how users can protect themselves and the environment?
Does the Commission assess that removing these requirements could cause harm to human health and the environment? What would be the societal cost of such harm?

The minimum formatting requirements also significantly facilitate enforcement by national authorities.
Will the absence of minimum requirements and reliance solely on guidance increase the workload for supervisory authorities?
What impact could this have on enforcement across the EU and thus on the level of protection?

Regulation (EC) No 1223/2009 on Cosmetic Products

According to the Commission's proposal, the evaluation of suitable alternatives introduces requirements for technical feasibility, economic viability, market availability and sustainable supply. Furthermore, the ban would not apply if the harmonised classification is based solely on oral or inhalation exposure. Longer deadlines for evaluation and phase-out are also proposed.
Could the Commission elaborate on how it concluded that these changes, individually and collectively, do not lower the level of protection?

According to Swedish authorities, studies identifying CMR properties via dermal exposure are rare, are they are guided by information requirements and validated methods under the REACH Regulation. Thus, most substances where CMR properties are identified via oral or inhalation exposure would fall under the proposed exemption from the ban. This, according to Swedish authorities, contradicts the precautionary principle and could negatively impact consumer safety.
What consequences for consumer safety does the Commission foresee from this proposal?

The proposal implies that a significantly larger number of carcinogenic substances than today will be subject to risk assessment by the SCCS and to comitology discussions.
To what extent does the Commission assess that the intended simplification for cosmetic companies will lead to increased administrative burden for ECHA, the scientific committees and national competent authorities?

The Commission also proposes that the CMR ban should not apply to ingredients in "natural complex substances".
What scientific basis does the Commission have for proposing this exemption?

The EU's Beating Cancer Plan states that reducing exposure to hazardous substances and radiation will significantly contribute to cancer prevention. It emphasizes the importance of increasing safety in products for consumers and professional users.
To what extent does the Commission consider the current proposal compatible with the commitments in the EU's Beating Cancer Plan to reduce exposure to carcinogens?

PUBLIC

Regulation (EU) 2019/1009 on Fertilising Products

The current regulation imposes extended data requirements on the hazardous properties of component substances in EU fertilising products, beyond the basic REACH requirements. These higher standards are justified by the need to ensure safety equivalent to that of other product regulations for use on agricultural land or crops. The Commission's proposal removes these extended requirements, allowing substances manufactured or imported in quantities <1 tonne/year to be used without any data requirements.
Could the Commission elaborate on how it concluded that these changes can be made without lowering the level of protection?

PUBLIC

Slovenia's Comments on the Proposal for an Omnibus on Simplification for Certain Chemicals, following the AGS Meeting of 11 July 2025

PUBLIC

Regulation (EC) No 1223/2009 (Cosmetic Products Regulation, CPR)

Use of the environmental criterion under point (a):

- Considering that Regulation 1223/2009 addresses the safety of cosmetic ingredients solely from the perspective of human health, on what basis is the environmental criterion included under point (a)? Would it not be more appropriate to exclude this criterion or justify it more explicitly?

Article 15 – CMR substances: timeline and transitional period:

- As Article 15 concerns CMR substances that pose a risk to human health, what is the justification for the relatively long timeline proposed for the Commission to prepare the legislative act?
- Could you further explain the reasons behind the proposed transitional periods (12 months for placing on the market and 24 months for making available)? Would it be possible to shorten these periods in order to ensure more rapid consumer protection from CMR substances?

Article 16 – nanomaterials (deletion of paragraphs 3 and 7):

- Given the specific properties and potential risks of nanomaterials, what are the reasons for the proposed deletion of the notification requirement for cosmetic products containing nanomaterials? Does this mean that the safety assessment of such products would be left to the producer, and market control authorities? Would it not be more appropriate to maintain the current control mechanism that ensures a proper uniform assessment of these substances before their use?