

Von: XXX

Gesendet: Dienstag, 5. Mai 2026 15:07

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Betreff: Chemikalien-Omnibus hier: Trilog

Guten Tag

wir wenden uns heute an Sie, um Ihnen über unsere Position zum „Chemikalien-Omnibus“ zu informieren. Wie Sie vielleicht wissen, hat am 29. April 2026 auch das EP Einigung erzielt. Nun gibt es Positionen aller 3 Institutionen zu dem am 8. Juli 25 von der EU-Kommission vorgelegten Vorschlag. Alle 3 Vorschläge ermöglichen die weitere Verwendung einzelner wichtiger Inhaltsstoffe in Kosmetika ohne das hohe Verbraucherschutzniveau abzusenken.

Unser Europäischer Dachverband Cosmetics Europe hat eine Übersicht erstellt mit 4 Spalten: EU-Kommission, Rat, Parlament und unsere Kommentierung dazu. Dieses Dokument gibt einen guten Überblick über unsere Position. Wir möchten im Folgenden noch die Themen hervorheben, die wir als besonders wichtig ansehen.

1. Definition und Kriterien zur Bewertung der Abwesenheit „geeigneter Ersatzstoffe“ im Rahmen von Artikel 15 (2) der EG-KVO:

Die Definition eines „geeigneten Ersatzstoffes“ sollte objektiv bleiben und sich auf einen **direkten Ersatz von Inhaltsstoff zu Inhaltsstoff (1:1-Ersatz)** fokussieren. Das SCCS führt Sicherheitsbewertungen für bestimmte Inhaltsstoffe durch, nicht für „Stoffkombinationen“, „Gemische“ oder „alternative Technologien“. Dies spiegelt sich konsequent in den Leitlinien des SCCS wider, die toxikologische Methoden und Expositionsszenarien ausschließlich für einzelne Stoffe festlegen, sowie in den Stellungnahmen des SCCS, die Identität, Reinheit, Verunreinigungsprofil, Toxikokinetik und toxikologische Daten für jeden einzelnen Inhaltsstoff bewerten. Daher befürwortet der IKW, das bestehende Prinzip der stoffbezogenen Bewertung auch für die Analyse geeigneter Ersatzstoffe anzuwenden.

Geeignete Ersatzstoffe sollten das gleiche Maß an Wirksamkeit und Leistungsfähigkeit im Vergleich zum neu eingestuftem Stoff aufweisen – ein „vergleichbares“ Maß (wie vom Rat der Europäischen Union und auch vom Europäischen Parlament vorgeschlagen) – ermöglicht hier einen Interpretationsspielraum, der zur Verringerung der Rechtsklarheit führt.

2. Ausreichende Übergangsfristen für Rezepturanpassungen und Abverkauf betroffener Produkte bei CMR-Einstufungen von Inhaltsstoffen:

Wird der Einsatz eines Stoffes in Kosmetikprodukten aufgrund einer harmonisierten CMR-Einstufung verboten oder eingeschränkt, sollte den Herstellern, Importeuren, Händlern und verantwortlichen Personen eine angemessene Frist eingeräumt werden, um die erforderlichen Maßnahmen zur Neuformulierung, Prüfung und Neukennzeichnung ihrer Produkte zu ergreifen sowie die nicht den neuen Anforderungen entsprechenden, unverkauften Produkte aus dem Vertrieb zu nehmen und zu vernichten. Dabei sind **situationsangepasste Übergangsfristen** erforderlich:

1. Sofern kein Antrag auf Ausnahmegenehmigung gestellt wurde - eine Frist von 12 Monaten für das Inverkehrbringen und von 24 Monaten für das Bereitstellen auf dem Markt für Kosmetikprodukte, die den betreffenden Stoff enthalten, nach Inkrafttreten der jeweiligen Änderungen der EG-KVO.
2. Wurde ein Antrag auf Ausnahmegenehmigung gestellt und die SCCS-Stellungnahme ist negativ, sollten diese Fristen auf einen Zeitraum von 3 Monaten für das Inverkehrbringen und 12 Monaten für die Bereitstellung auf dem Markt verkürzt werden.

3. Wurde ein Antrag auf Ausnahmegenehmigung gestellt und die SCCS-Stellungnahme ist positiv, der Antrag jedoch aufgrund der Verfügbarkeit geeigneter Alternativen abgelehnt, sollten diese Fristen auf 24 Monate für das Inverkehrbringen und auf 48 Monate für die Bereitstellung auf dem Markt verlängert werden, unter der Voraussetzung, dass jederzeit ein aktueller Sicherheitsbericht vorliegt.

Die Sicherheit des kosmetischen Mittels wird auch während der Übergangsfrist durch die Sicherheitsbewertung und einen aktuellen Sicherheitsbericht gewährleistet.

Der IKW unterstützt diesen differenzierten Ansatz für Übergangsfristen.

Wir würden es begrüßen, wenn Ihr Haus unsere Anmerkungen berücksichtigen könnte. Zur näheren Erläuterung unserer Ausführung oder bei weiteren Fragen stehen wir jederzeit gerne zur Verfügung.

Mit freundlichen Grüßen

XXX

Industrieverband Körperpflege- und Waschmittel e. V.

The German Cosmetic, Toiletry, Perfumery and Detergent Association

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Cosmetics Europe
the personal care association

Omnibus VI on Chemicals – 4-column overview (CPR related amendments)

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
Recital 16 a (new)			
New text	<i>(16 a) The assessment of the fulfilment of the derogation criteria requires multiple consultations and deliberations. The assessment of the Scientific Committee on Consumer Safety (SCCS) of the safety of the substance for human health requires a minimum of twelve months, the assessment of the compliance with other derogation criteria require consultations with experts and discussions with the Member States and the industry representatives. Once the draft measure is prepared by the Commission it is subject to notification under the WTO Technical Barriers to Trade (TBT) procedure for a minimum of two months. The draft Commission measure falls under the obligatory scrutiny by the European Parliament and the Council</i>		Support Council proposal.

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	<p><i>which lasts three months before its final adoption and publication in the Official Journal. The analysis of the fulfilment of the derogation criteria and the obligatory sequential steps which must be followed by the Commission while adopting a regulatory measure require that sufficient time is accorded to the Commission for the adoption of the measure from the submission of the request for derogation.</i></p>		
<p>Justification: the derogation process requires several consultative, deliberative and regulatory steps. Therefore, it is fundamental to underline that a sufficient time should be guaranteed for the different actors involved to proceed in the process and for the European Commission to adopt the agreed measure.</p>			
<p>Recital 17</p>			
<p>(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.</p>	<p>(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.</p>	<p>(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined without lowering the high level of human health and safety and consumer protection, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not necessarily enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.</p>	<p>Support the EP position, with amendments:</p> <p>(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined without lowering the high level of human health and safety and consumer protection, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not necessarily enhance the safety of cosmetic products as both categories of products are</p>

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			inherently different. It is, therefore, appropriate to abolish this condition.
<p>Justification: Cosmetics Europe considers it essential to stress that the Omnibus proposal is targeted at pragmatic improvements of the current CPR text to render the ban of CMR substances and the related derogation process clearer from a legal point of view and implementable in practice without lowering the high safety standards already enshrined in the text of the CPR.</p>			
<p>However, it is also suggested to not include the word “necessarily” in relation to the food safety requirements. As the Commission stated in the chapeau of the Omnibus VI proposal, “food and cosmetics are distinct products and the fact that a product containing a substance is not eatable does not mean that this substance will not be safe when used in a cosmetic formula which is to be applied on the human skin.” The compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different.</p>			
<p>Recital 18</p>			
<p>(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be specified. In particular, it should be provided that the use of alternative substance should result in reduced overall risk to human health and the environment and the substance should provide an equivalent or similar function in a cosmetic product, be available on the market in sufficient quantities, so that it can be technically feasible and economically viable for businesses and especially for SMEs. In addition, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives.</p>	<p>(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be specified outlined. In particular, it should be provided that the use of an alternative substance, a combination of substances, or, where relevant, an alternative technology that replaces the need for the substance, should result in reduced overall risk to be safe for human health and the environment and the substance. The alternative should provide an equivalent or similar a function in a cosmetic product and level of efficacy comparable to the classified substance, be available on the market in sufficient quantities, or likely to be available within a reasonable timeframe, so that it can be technically feasible and economically viable feasible also for businesses and especially for SMEs. In addition</p>	<p>(18) Furthermore, the elements to be considered under the availability of suitable alternatives condition should be outlined. In particular, it should be provided that the use of any alternative substance to replace the classified substance is safe for human health. The alternative should provide an equivalent function and comparable level of efficacy and performance and should be available on the market in sufficient quantities, or likely to be available in sufficient quantities to meet current demand and has the demonstrated potential to meet expected demands in a reasonable timeframe. Its use should be technically and economically feasible for businesses and especially for SMEs to allow sustained production. To assess economic feasibility, the economic aspects, such as costs of reformulation and comparative contribution to overall</p>	<p>Support the EP position with amendment: 18) Furthermore, the elements to be considered under the availability of suitable alternatives condition should be outlined. In particular, it should be provided that the use of any alternative substance to replace the classified substance is safe for human health. The alternative should provide an equivalent function and comparable same level of efficacy and performance and should be available on the market in sufficient quantities, or likely to be available in sufficient quantities to meet current and expected demands—in a reasonable timeframe. Its use should be technically and economically feasible for businesses and especially for SMEs to allow sustained production. To assess economic feasibility, the economic aspects, such as costs of reformulation</p>

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	<p>particular, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the to assess economic feasibility, economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives, should be considered.</p>	<p>production costs, as relevant factors in the analysis of the suitability of alternatives, can be considered.</p>	<p>and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives, can be considered.</p>
<p>Justification: Cosmetics Europe suggests supporting the EP position with amendments in alignment with the reasoning and justification for our recommendations on:</p> <ul style="list-style-type: none"> - Article 2 – paragraph 1 – point 2 – point a – point ii amending Article 15 – paragraph 2 – subparagraph 2 – introductory part - Article 2 – paragraph 1 – point 2 – point a – point ii amending Article 15 – paragraph 2 – subparagraph 3 – points b, c, and d. 			
<p>Recital 18 a (new)</p>			
<p>New text</p>	<p>(18 a) Regarding the assessment of alternatives, the words "similar" and "comparable" means all possible alternatives available, and not only alternatives providing 1:1 substitution. "Technically feasible" highlights that it has to be possible to apply the alternative with technologies and methods generally available. This Regulation does not set out detailed definitions of these terms as their precise interpretation and application may depend on the specific context of the assessment of suitable alternatives. To promote consistency and predictability of the assessment of alternatives, the Commission should be encouraged to develop guidance, in consultation with the SCCS, ECHA, Member States and relevant</p>	<p>N/A</p>	<p>Oppose Council position.</p>

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	<p><i>stakeholders, which could provide further clarification of these concepts. Such guidance should at least explain criteria for economically and technically feasible alternatives, practical examples on alternative technologies and indications of established best practices.</i></p>		
<p>Justification: Cosmetics Europe suggests not accepting the Council suggestion in alignment with the reasoning and justification for our recommendations on recital 18 and Article 2 – paragraph 1 – point 2 – point a – point ii (Article 15 – paragraph 2 – subparagraph 3 – point b).</p>			
<p>Recital 21</p>			
<p>(21) Often a substance can also be a constituent of natural complex substances, for example essential oils. In such cases, the prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 is relevant only to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. This means that natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except if that natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent may raise concerns as to the safety of the natural complex substances when used in cosmetic products, the Commission should mandate the SCCS to assess the impact of such constituent on the safety of natural complex</p>	<p>(21) Article 5 of Regulation (EC) No 1272/2008 provides a specific rule for identification and examination of available information when evaluating the hazardous properties of substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006. Such substances, often referred to as 'of Natural complex substances', or 'NCS' may contain one or more substances classified as CMR substances, for example essential oils. In such cases, while the overall Natural complex substance is not itself classified as a CMR substance. The prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 is relevant only applies to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. This</p>	<p>(21) Substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, are often referred to as natural complex substances, or 'NCS'. They might contain one or more constituents classified as CMR substances, while the overall natural complex substance is not itself classified as a CMR substance. A high level of consumer protection must apply to such substances and should be based on scientific knowledge and the actual conditions of exposure arising from their use in cosmetic products. The prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 only applies to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Natural complex substances that contain a CMR classified</p>	<p>Support EP proposal with amendments:</p> <p>(21) Substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, are often referred to as natural complex substances, or 'NCS'. They might contain one or more constituents classified as CMR substances, while the overall natural complex substance is not itself classified as a CMR substance. A high level of consumer protection must apply to such substances and should be based on scientific knowledge and the actual conditions of exposure arising from their use in cosmetic products. The prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 only applies to the substance as it appears in Part 3 of Annex VI to the Regulation (EC)</p>

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<p>substances, if a safety concern arises, and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.</p>	<p>means that Natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except if that Natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of When a constituent may raise concerns as to the safety of the of a Natural complex substances when used in cosmetic products substance is classified as a CMR (categories 1A, 1B or 2), this raises concerns about its safe use in cosmetics. In such cases, the Commission should mandate systematically request the SCCS to assess the impact of such constituent on the safety of natural complex substances, if a safety concern arises, and is to follow up with the appropriate such constituents and, where necessary, take regulatory measures in accordance with action under Article 31(1) of Regulation (EC) No 1223/2009.</p>	<p>constituent are not subject to the prohibition, except where the natural complex substance itself is classified as a CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent raises concerns about the use and safety of the natural complex substances when used in cosmetic products, the Commission should without delay mandate the SCCS to assess the safety of such substances and, where necessary, take appropriate regulatory action in accordance with Article 31(1) of Regulation (EC) No 1223/2009. The assessment of the SCCS should be timely to ensure predictability for the industry.</p>	<p>No 1272/2008. Natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except where the natural complex substance itself is classified as a CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent raises concerns about the use and safety of the natural complex substances when used in cosmetic products, the Commission should without delay mandate the SCCS to assess the safety of such substances constituent and, where necessary, take appropriate regulatory action in accordance with Article 31(1) of Regulation (EC) No 1223/2009. The assessment of the SCCS should be timely to ensure predictability for the industry.</p>
<p>Justification: CE supports the EP text provided that the word “substance” is replaced with “constituent”. The prohibition of use in cosmetic products under Article 15 only applies to the constituent of the natural complex substance (NCS). Referring to “such substance” is legally ambiguous and inconsistent with Article 15(6), which instead refers to the “constituents”. Recital 21 should therefore be amended accordingly to resolve this inconsistency and refer to “the safety of such constituents”. This prevents the misinterpretation that the SCCS shall issue opinions on the natural complex substance as a whole, rather than focusing on its individual constituents, as per Article 15(6).</p>			
<p>Recital 22</p>			
<p>(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers,</p>	<p>(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers,</p>	<p>(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers,</p>	<p>Support EP text with amendments:</p>

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<p>distributors and responsible persons should be given appropriate time to take necessary measures to reformulate and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Therefore, periods of 12 months for placing and 24 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.</p>	<p>distributors and responsible persons should be given appropriate time to take necessary measures. To enable manufacturers of cosmetic to reformulate and relabel their products to secure the suitable alternative substances, to carry out tests as part of reformulation process and to proceed with the safety assessment of the final products and their re-labelling and mandatory notifications, they should be provided with appropriate adjustment period. During this period distributors and retailers continue to receive cosmetic products containing the substance subject to regulatory measures. Therefore, they need additional time to withdraw such products from the distribution chain and to and destroy the unsold products not complying with the new requirements. Therefore, periods of 12These actions impact the existing contractual arrangements and requires substantial logistical efforts. Accordingly, a period of 6 months for placing and 2412 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.</p>	<p>distributors and responsible persons should be given appropriate time to take necessary measures to reformulate, test and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Accordingly, if no derogation request was submitted, a period of 6 months for placing and 15 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided. In case a request for derogation has been submitted and the SCCS has found that the substance is not safe, those deadlines should be shortened to a period of 3 months for placing and 12 months for making available on the market. In case a request for derogation has been submitted and the SCCS has found that the substance is safe, but the request has been refused due to the availability of suitable alternatives, those deadlines should be extended to a period of 24 months for placing and 48 months for making available on the market, under the condition that an up-to-date Cosmetic Product Safety Report (CPSR) remains available at all times.</p>	<p>(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate, test and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Accordingly, if no derogation request was submitted, a period of 612 months for placing and 1524 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided. In case a request for derogation has been submitted and the SCCS has found that the substance is not safe In case of a final negative opinion of the SCCS, those deadlines should be shortened to a period of 3 months for placing and 12 months for making available on the market. In case a request for derogation has been submitted and the SCCS has found that the substance is safe, but the request has been refused due to the availability of suitable alternatives, those deadlines should be extended to a period of 24 months for placing and 48 months for making available on the market, under the condition that an up-to-date Cosmetic Product Safety Report (CPSR) remains available at all times.</p>

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<p>Justification: CE supports a differentiated approach for transition periods as proposed in the EP text. However, given that the 15-month deadline to adapt the CPR Annexes has been shortened to start at the time of entry into force of the inclusion of the classified substances in the Part 3 of Annex VI of CLP regulation, the industry will need more time to start the reformulation to comply with the restriction. This is especially critical when no derogation dossier is submitted. Choosing not to pursue a derogation is often a strategic decision to invest in reformulation as the industry is aware that an alternative exists and a derogation request would not be successful; it is not an indication that the substance is unsafe for cosmetic use. Consumer safety remains assured throughout this transition period via updated CPSR. In all cases, should there be any safety concern, the urgency procedure through Art. 32(4) of the CPR can be activated.</p> <p>Moreover, it is legally and scientifically incorrect to say that a negative SCCS opinion means that the substance at stake is not safe. The SCCS is asked to assess safety for use of the substance in cosmetics, not the intrinsic hazard or general safety of the substance. Moreover, a negative SCCS opinion means either that there is insufficient data (e.g. on the exposure assessment) or that safety is not demonstrated for the proposed use/concentration <u>relative to the margin of safety</u>.</p>			
<p>Recital 23</p>			
<p>(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, only one notification of the cosmetic products should be required before placing them on the Union market. The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them. To maintain vigilance on nanomaterials, it should be required that the specific information on nanomaterials used in a cosmetic product is provided in the cosmetic product safety report so that it can be consulted by the competent authorities where the concerns over the potential risk to human health arise from the use of a particular nanomaterial</p>	<p>(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, only one notification notifications of the cosmetic products should only be required before placing them on the Union market. The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them. To maintain vigilance on nanomaterials, it should be required that the specific information on nanomaterials used in a cosmetic product is should continue to be provided in the cosmetic by the responsible persons through the existing process before the product safety report so that it can be consulted by the competent authorities where the concerns over the potential risk to human health arise from the use of a particular nanomaterial is placed on the market.</p>	<p>(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, notifications of the cosmetic products to the Commission should be required before placing them on the Union market. To maintain vigilance on nanomaterials in cosmetic products, it should be required that this notification includes the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI, and the specification of the nanomaterial including size of particles, physical and chemical properties, intended to be placed on the market per year. This is necessary so that a safety assessment can be requested by the Commission in case of concerns. It should also be explicitly required that specific information on nanomaterials used in a cosmetic product is provided in the Cosmetic Products Notification Portal</p>	<p>Support EP position with minor editorial correction:</p> <p>(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, notifications of the cosmetic products to the Commission notifications of the cosmetic products containing nanomaterials should be required before placing them on the Union market. To maintain vigilance on nanomaterials in cosmetic products, it should be required that this these notifications includes the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI, and the specification of the nanomaterial including size of particles, physical and chemical properties. ,intended to be placed on the market per year. This is necessary so that a safety assessment can be requested by the Commission in case of concerns. It</p>

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		<i>(CPNP) notification and in the cosmetic product safety report that are both accessible to the competent authorities and can be consulted by the competent authorities, where concerns over the potential risk to human health arise from the use of a particular nanomaterial in cosmetic products.</i>	<i>should also be explicitly required that specific information on nanomaterials used in a cosmetic product is provided in the Cosmetic Products Notification Portal (CPNP) notification and in the cosmetic product safety report that are both accessible to the competent authorities and can be consulted by the competent authorities, where concerns over the potential risk to human health arise from the use of a particular nanomaterial in cosmetic products.</i>
<p>Justification: the EP text introduces significant reporting burden reduction while maintaining a high level of transparency. In fact, the information that has to be notified to the Commission under article 16 also has to be notified to member states under Article 13 and/or, be held accessible to them under Article 10/Annex I and the Implementing Decision 764/2013 (Product Safety Assessment). The only information that is unique under Article 16 is the projected annual use tonnage of the nanomaterial. The Commission has repeatedly expressed that they are not competent to assess the information they receive under Article 16 and to decide whether a nanomaterial poses safety concerns or not. As a consequence, the Commission systematically refers all nanomaterials to SCCS without actually considering the information notified under Article 16. By deleting the notification of detailed technical/safety information under Article 16, Member States will retain access to the same level of information as before (through the Article 13 notification and the safety assessment under Article 10/Annex I), but the industry will no longer need to carry out full duplicate notification of the same information to the Commission, which in any case would not make any use of them. To ensure continued transparency for the Commission on the appearance of new nanomaterials on the EU market, the notification under Article 16 should be maintained for the identification and specification of such nanomaterials, but it should no longer include the full detailed technical/safety information that is already submitted/available under Article 13 and Article 10/Annex I.</p>			
<p>Recital 25</p>			
(25) Cosmetics are globally traded goods. It is therefore important that the ingredient names present on their labels reflect the current state of scientific and technological development. The use of internationally recognised cosmetic ingredient' names is an important factor promoting transparency and facilitating cross-border trade in cosmetics. This Regulation should enable internationally	(25) Cosmetics are globally traded goods- important and essential that the ingredient names present on their labels reflect the current state of scientific and technological development in a timely manner . The use of internationally recognised nomenclature, such as the International Nomenclature of Cosmetic ingredient' names is an important factor	(25) Cosmetics are globally traded goods and it is therefore essential that the ingredient names present on their labels reflect the current state of scientific and technological development in a timely manner . The use of internationally recognised nomenclature, such as the International Nomenclature of Cosmetic ingredient (INCI) names is an important factor promoting Ingredients	Support Council position.

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
<p>recognised names to be used on the labelling of cosmetic products without any additional regulatory action from the Commission. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.</p>	<p>promoting Ingredients (INCI) promotes transparency for consumers, ensures consistency across jurisdictions, and facilitates and facilitating cross-border trade in cosmetics. INCI names are maintained by the Personal Care Products Council (PCPC) as an international industry standard and are widely recognised by regulators and stakeholders worldwide. This Regulation should enable the direct use of internationally recognised names nomenclature, such as INCI, to be used on the labelling of cosmetic products without any additional further regulatory action from the Commission. Where a common ingredient name is not available in INCI, other generally accepted nomenclature should be used, for example names established in recognised international chemical or pharmacopoeia references, or in other authoritative sources commonly relied upon by industry and regulators. This approach ensures flexibility, avoids unnecessary administrative burden, and guarantees that ingredient names used on cosmetic product labelling remain up to date, internationally coherent, and easily understandable to consumers. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished. The Commission is encouraged to facilitate access to the internationally recognised nomenclature</p>	<p>transparency for consumers, ensures consistency across jurisdictions, and facilitates cross-border trade in cosmetics. INCI names are maintained by the Personal Care Products Council (PCPC) as an international industry standard and are widely recognised by regulators and stakeholders worldwide. This Regulation should enable the direct use of internationally recognised nomenclature, such as INCI, to be used on the labelling of cosmetic products without any additional further regulatory action from the Commission. Where a common ingredient name is not available in INCI, other generally accepted nomenclature should be used, for example names established in recognised international chemical or pharmacopoeia references, or in other authoritative sources commonly relied upon by industry and regulators. This approach ensures flexibility, avoids unnecessary administrative burden, and guarantees that ingredient names used on cosmetic product labelling remain up to date, internationally coherent, and easily understandable to consumers. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.</p>	

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	<i>through digital tools, such as the Cosmetic ingredients (CosIng) database.</i>		
<p>Justification: The Commission proposes to delete Article 33 and change article 19 to enable businesses and competent authorities to rely on the internationally recognised nomenclature of labelling cosmetic products and facilitate the product's international acceptability. The proposed text deletes the published 'paper' glossary and replaces this by a requirement for ingredient labelling to be "in accordance with the internationally recognised nomenclature". However, the proposal does not specify what this nomenclature is. The Commission proposal should be complemented with the confirmation introduced by the Council in its general approach in Recital 25 that this should be interpreted as the International Nomenclature of Cosmetics Ingredients (INCI).</p>			
<p>Recital 25 a (new)</p>			
New text	N/A	<p><i>(25 a) In order to ensure a high level of protection of human health, all operators placing cosmetic products on the Union market, whether offline or online, should be subject to equivalent obligations and effective enforcement. This is particularly important given the growing sale of cosmetics via online marketplaces, including products originating from third countries that are not subject to the same health and safety requirements. Therefore, it is necessary to require certain labelling information referred to in Article 19 to be clearly and visibly indicated in case of distance sales, including via online marketplaces. This requirement will simplify enforcement of Regulation (EC) No 1223/2009 and thereby contribute to fair competition and a high level of protection of human health. Furthermore, post-market surveillance should be strengthened, notably for online sales and imports, and cosmetic products identified as non-compliant through the Union rapid alert system (Safety Gate)</i></p>	<p>CE does not support the EP provision as it is out of the scope of the Omnibus. However, if included in line with the EP's proposal, CE stresses that certain product information cannot be displayed online, namely the date of minimum durability (DOMD) (Article 19(1)(c)) and the batch number (Article 19(1)(e)) and should therefore, be excluded from the provision.</p>

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
		<i>should not be listed or offered for sale. To this end, online platforms should verify the identity of the responsible person before allowing products to be placed on the Union market, and the online sale, offering for sale and promotion, including via social media, of banned cosmetics, in particular mercury-added products, should be explicitly prohibited.</i>	
<p>Justification: Cosmetics Europe does not support this provision as it is out of the scope of the Omnibus. The proposal fails to account for the technical reality of supply chains. Specifically, certain product information cannot be displayed online, namely the date of minimum durability (DOMD) (Article 19(1)(c)) and the batch number (Article 19(1)(e)) and should therefore, be excluded from the provision. In fact, while most of the information in Article 19(1) can be displayed online as it is the same at SKU level, the DOMD and the batch number letter are dependent on each individual product item. While for sales in a shop a consumer knows exactly which product item they are buying on the shelf, for online sales it is not known at the moment of the purchase which specific item will be delivered to the customer, and therefore the DOMD and batch number cannot be displayed accordingly.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point i Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 2 – introductory part</p>			
<p>Article 15 is amended as follows:</p> <p>(a) paragraph 2 is amended as follows:</p> <p>(i) the second subparagraph is replaced by the following:</p> <p>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</p>	<p>Article 15 is amended as follows:</p> <p>(a) paragraph 2 is amended as follows:</p> <p>;</p> <p>(i) the second subparagraph is replaced by the following:</p> <p>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</p>	<p>Article 15 is amended as follows:</p> <p>(a) paragraph 2 is amended as follows:</p> <p>(i) the second subparagraph is replaced by the following:</p> <p>2. However, such substances may be used in cosmetic products exceptionally, 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</p>	<p>Support Council position.</p>

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
substance of category 1A or 1B. The Commission shall grant the derogation where all of the following conditions are fulfilled:	substance of category 1A or 1B. The Commission shall grant the derogation and where all of the following conditions are fulfilled:	CMR substance of category 1A or 1B, and the Commission grants the derogation from the general prohibition laid out in subparagraph 1. The Commission may grant the derogation where all of the following conditions are fulfilled:	
<p>Justification: It is essential to preserve legal certainty in Article 15(2) by maintaining the rule that a derogation <u>must</u> be granted when all derogation criteria are met. The wording "<i>The Commission <u>may</u> grant the derogation where all of the following conditions are fulfilled</i>" weakens legal certainty and contradicts the overall objective of the Omnibus.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point i Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 2 – point b</p>			
(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.	(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.	(b) the substances have been evaluated and found safe by the SCCS for one or more particular uses of one or more cosmetic product categories considering overall exposure from the uses in those products categories as well as from sources other than cosmetics and of vulnerable population groups.	Support EP position.
<p>Justification: it is crucial that the derogation criteria reflects that cosmetics ingredients can have multiple uses for which derogation requests can be submitted. Moreover, the EP text also stresses that the SCCS assessment includes a comprehensive exposure analysis encompassing exposure from both uses in cosmetics and from other sources.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point ii Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 2 – introductory part</p>			
For the purpose of the second subparagraph, point (a), a substance shall	'For the purpose of the second subparagraph, point (a), a substance, a combination of substances, or where	N/A	Support Commission position

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
be considered a suitable alternative if it fulfils all of the following conditions:	relevant, an alternative technology, that replaces the need for the substance shall be considered a suitable alternative if it fulfils all of the following conditions:		
<p>Evaluating “combinations of substances” or “alternative technologies” is technically unfeasible and risks illogical outcomes. The Scientific Committee on Consumer Safety (SCCS) evaluates individual ingredients - not “mixtures,” or “alternative technologies” – as established in the SCCS Notes of Guidance (latest version available HERE). Because a substance can be used in thousands of compositions, a combination-based approach would require specific, formula-by-formula assessments. This is unfeasible at scale and would lead to a systematic failure to meet the “absence of suitable alternative” criterion, even when no viable replacement exists in practice. Moreover, to be a true “alternative”, a solution must deliver the same function, be stable in the formulation, allow predictable exposure, and demonstrate equivalent or improved safety profile. It would be impossible for a company to evaluate all the possible existing combinations, let alone in the limited time allowed by the regulatory process.</p> <p>This proposal is partly inspired by the REACH Authorisation approach as a model for the alternatives assessment. The REACH approach is not suitable for the Cosmetic Products Regulation (CPR) since it is evaluated against socio-economic benefits, and for SVHCs that have not been evaluated as safe. The cosmetic sector is further constrained by the lack of easily accessible data necessary for a comparative analysis. REACH is also a horizontal legislation, covering many different uses. By contrast, the CPR is a sector-specific regulation and the alternatives assessment applies to ingredients for which the SCCS has already established as safe in consumer uses. Importing REACH’s substitution logic would ignore the CPR’s product-level risk assessment.</p> <p>Finally, alternative technologies cannot be considered substitutes for substances. The concept creates significant uncertainty and could result in the de facto replacement of cosmetic products as a whole rather than a substitution of specific substances. For example, considering an UV lamp mask a substitute for hydrating cream fundamentally alters the scope of the regulatory framework.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point ii Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 3 – point a</p>			
(a) its use in cosmetic products results in reduced overall risk to human health and the environment ;	(a) its use in cosmetic products results in reduced overall risk to human health and the environment;	(a) its use in cosmetic products is safe and results in reduction of overall risk to human health, when assessed against the substance it is intended to replace ;	Support EP position.
<p>Justification: CE supports the EP position as it balances the accent on safety and risk reduction with the objective need to focus suitable alternative assessment on a 1:1 substitution basis.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point ii</p>			

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 3 – point b			
(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;	(b) it provides an equivalent a similar function to the classified substance, in a finished cosmetic product with a similar comparable effect and the same level of efficacy;	(b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a comparable effect, level of efficacy and performance ;	Support EP position with change: (b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a comparable effect, and the same level of efficacy and performance ;
<p>Justification: Criteria for analysing potential alternatives must be objective to provide industry with a clear framework and legal certainty. The assessment should focus on whether an alternative to offers the “same” performance as the substance it might replace. The level of efficacy for suitable alternatives in Article 15(2)(b) must be “the same” as the substance it replaces. Replacing “the same” with flexible terms like “similar”, “equivalent” or “comparable” introduces subjectivity and legal uncertainty. This risks undermining product safety, performance, and consumer trust, particularly for critical ingredients where efficacy is paramount for consumer protection – such us sodium fluoride against cavities in oral care products.</p>			
Article 2 – paragraph 1 – point 2 – point a – point ii Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 3 – point c			
(c) is technically feasible and economically viable ;	(c) is technically feasible and economically viable feasible ;	(c) is technically feasible and economically feasible provided costs and supply conditions allow sustained production ;	Support EP position. The EP text improves on the Council approach but still leaves residual legal uncertainty, which would be best addressed through closer alignment with the Commission proposal ‘economically viable’
<p>Justification: while we support the EP position, it is important to stress that in legal terms, the term “feasibility” taken in isolation provides insufficient certainty, as it may be interpreted as referring solely to the theoretical possibility of substitution, without due consideration of actual market and supply conditions. This is why the concept of “viability” is more robust and appropriate, as it better captures the concrete, long term ability of manufacturers to substitute a substance. However, the text proposed by the EP takes these aspects into considerations to a greater extent than the Council text. Still, criteria should be framed as closed and assessable conditions. “Economically</p>			

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
viable" meets this requirement, whereas conditioning feasibility on evolving cost and supply conditions is a sub-optimal solution that introduces open-ended uncertainty that undermines legal predictability.			
Article 2 – paragraph 1 – point 2 – point a – point ii Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 3 – point d			
(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.'	(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.	(d) it is not restricted and is either available on the market at scale and in quantities sufficient to meet current demand or has the potential to meet current or expected demand in a reasonable timeframe .	Support COM position with elements from EP position: (d) it is not restricted, not protected by exclusive rights, and is either available on the market at scale and in quantities sufficient to meet current and expected demand or has the potential to meet current or expected demand in a reasonable timeframe .
Justification: the second part of the EP proposals adds vagueness and subjectivity to the criterion, jeopardising consistent interpretation in the future. Such a wording shifts the burden onto companies to demonstrate hypothetical future (what would "reasonable timeframe" mean?) availability, rather than relying on objectively verifiable market and supply conditions at the time of assessment. Moreover, if a CMR substance is banned, the expected demand of the alternative(s) will increase, therefore it is important to have the option to take this into account of the AoA assessment e.g., REACH tonnages could increase and form a blocker for market availability. Expected demand could also be driven by other sectors other than cosmetics, and this should also be taken into account in the assessment. Reintroducing the wording "expected" demand originally suggested by the Commission and supported by the Council provides more legal certainty.			
Article 2 – paragraph 1 – point 2 – point a – point ii a (new) Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 3 a (new)			
New text	N/A	(ii a) The following subparagraph is inserted after the third subparagraph: 'The Commission shall consult relevant stakeholders for the purpose of the second subparagraph, point (a) and for the purpose of the third subparagraph.'	Oppose EP position.

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<p>Justification: Cosmetics Europe considers that it is not necessary to formalise this aspect in the legal text as the Commission already envisages developing such mechanism as part of the decision-making process on derogations under the CPR.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point iii – introductory part Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 5</p>			
(iii) the following subparagraph is inserted after the fourth subparagraph:	(iii) the following subparagraph is inserted after the fourth subparagraph:	(iii) the following subparagraphs are inserted after the fourth subparagraph:	Support Council and EP position.
<p>Justification: necessary for legal text consistency within Article 2 – paragraph 1 – point 2 – point a – point iii.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a – point iii Regulation (EC) No 1223/2009 Article 15 – paragraph 2 – subparagraph 5</p>			
<p>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.;</p>	<p>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, 1B, or 2 or 1B;</p>	<p>The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into force of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of category 1A, or 1B.</p>	<p>Support the Council position to extend subparagraph 5 a to CMR Cat.2.</p> <p>However, we remain strongly critical of the Council and EP position setting the deadline start at the moment of entry into force of the amendments to Annex VI CLP.</p>
<p>Justification: Cosmetics Europe continuously advocated for the deadline to start at the moment of entry into application of the amendments to Annex VI CLP. This additional 15-month period for the European Commission to update the CPR Annex is fundamental to allow sufficient time to cover all the regulatory steps mentioned in recital 16 a as proposed by the Council. Triggering this window at "entry into force" forces the Commission to update the CPR Annex before the SCCS can even complete its evaluation, which typically requires 12–15 months. Without this additional lead time, the Annex' updates would be based on partial data, often requiring later corrections (corrigenda) and depriving the Commission of the time needed to assess if suitable alternatives exist. This would force companies to begin costly reformulations before the outcome of a derogation request is even known.</p>			
<p>Article 2 – paragraph 1 – point 2 – point a Regulation (EC) No 1223/2009</p>			

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
Article 15 – paragraph 2 – subparagraph 5 a (new)			
New text	<i>Where a derogation request referred to in the second subparagraph of paragraph 2 has been submitted for CMR substances of category 1A, or 1B, this deadline shall be extended by nine months.</i>	<i>5 a. Where a derogation request referred to in the second subparagraph of paragraph 2 has been submitted for CMR substances of category 1A, or 1B, this deadline may, where relevant, be extended by twelve months.</i>	Support EP position.
Justification: CE supports the EP proposal. The 12-month period ensures that the Scientific Committee (SCCS) has sufficient time to conduct a thorough and high-quality risk assessment for complex CMR dossiers. This realistic timeframe supports a high level of consumer protection by avoiding rushed scientific conclusions.			
Article 2 – paragraph 1 – point 2 – point b Regulation (EC) No 1223/2009 Article 15 – paragraph 6			
<p>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.</p> <p>For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.</p>	<p>6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance substances 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. As a potential risk to human health arises from the use of such substance in cosmetic products of a substance containing a constituent classified as CMR category 1A, 1B or 2, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without undue delay request the SCCS to give its opinion on the safety of the CMR-constituents present in the substance for</p>	<p>6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to substances 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. As a potential risk to human health arises from the presence of such constituent classified as CMR category 1A, 1B or 2 in such substances in cosmetic products, the Commission shall without delay request an opinion of the SCCS on the safety of that constituent for its presence in cosmetic products. The SCCS shall deliver its opinion within 12 months of the Commission's request. The Commission may extend that deadline by six months if additional evidence is</p>	<p>Support Council position with amendment:</p> <p>6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance substances 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. As a potential risk to human health arises from the use of such substance in cosmetic products of a substance containing a constituent classified as CMR category 1A, 1B or 2, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without</p>

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
	<p><i>a particular use of the cosmetic product category, as part of the exposure assessment.</i></p> <p>For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.</p>	<p><i>required. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available. Taking into account the opinion of the SCCS, and where a potential risk to human health arises from the use of a substance referred to in the first subparagraph in cosmetic products containing a constituent classified as CMR category 1A, 1B or 2 for human health, the Commission shall, without undue delay, amend the Annexes to this Regulation.</i></p> <p>For the purposes of this paragraph, "plants" means living or dead organisms from the kingdoms Plantae and Fungi, including algae, lichens and yeasts.</p>	<p>undue delay <i>request the SCCS to give its opinion on the safety of the CMR-constituents present in the substance for a particular use of the cosmetic product category, as part of the exposure assessment.</i></p> <p>For the purpose of this paragraph, 'plants' means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.</p>
<p>Justification: the Council position provides a clearer text.</p>			
<p>Article 2 – paragraph 1 – point 2 – point b Regulation (EC) No 1223/2009 Article 15 – paragraph 7</p>			
<p>7. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for 12 months and be made available on the market for 24 months after the entry into force of the</p>	<p>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 2412 months after the entry</p>	<p><i>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 and for which no derogation request was submitted in accordance with paragraph 2 or such substance is not compliant with a restriction may continue to be placed on</i></p>	<p>Support EP position with amendment:</p> <p><i>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 and for which no derogation request was submitted in accordance with paragraph 2 or such</i></p>

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relevant amendments to the relevant Annexes to this Regulation.'	into force of the relevant amendments to the relevant Annexes to this Regulation.'	<p><i>the market for 6 months, and be available on the market for 15 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation. 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 and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to safety concerns by the SCCS or such substance not compliant with a restriction may continue to be placed on the market for 3 months, and be available on the market for 12 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to the availability of a suitable alternative, may continue to be placed on the market for 24 months and be made available on the market for 48 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation, and where needed updated the cosmetic product safety report (CPSR) remains available.</i></p>	<p>substance is not compliant with a restriction may continue to be placed on the market for 6-12 months, and be available on the market for 15-24 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation. 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 and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to safety concerns by the SCCS or such substance not compliant with a restriction may continue to be placed on the market for 3 months, and be available on the market for 12 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to the availability of a suitable alternative, may continue to be placed on the market for 24 months and be made available on the market for 48 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation, and where needed</p>

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
			updated the cosmetic product safety report (CPSR) remains available.
<p>Justification: CE proposes removing the wording “or such substance not compliant with a restriction” for legal consistency. If no derogation request has been submitted, the substance is simply prohibited; therefore, no “restriction” exists.</p>			
<p>Cosmetics Europe supports the differentiated approach proposed by the Parliament. However, longer transitional periods specifically for the scenario where no derogation request is submitted are needed. The decision not to submit a derogation request should not be interpreted as an indication that a substance is unsafe. Often, this is a proactive strategic decision by companies to divert significant resources away from expensive, lengthy derogation dossiers and instead invest directly in the research and development of reformulations. This is particularly common when the industry is aware that suitable alternatives exist, making the success of a derogation request unlikely. Consumer safety remains the absolute priority and is guaranteed throughout the transition. All cosmetic products on the market are backed by a robust Cosmetic Product Safety Report (CPSR). During any transition, companies ensure these reports remain updated to reflect the current safety profile of the product. The regulatory framework already contains the necessary safeguards for public health. In all cases, should there be any safety concern, the urgency through Art. 32(4) of the CPR can be activated.</p>			
<p>Article 2 – paragraph 1 – point 3 Regulation (EC) No 1223/2009 Article 16 – paragraph 3</p>			
<p>(3) In Article 16, paragraphs 3 and 7 are deleted;</p>	<p>(3) In Article 16, paragraphs 3 and 7 are deleted paragraph 3 is replaced by the following;</p> <p>3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means prior to being placed on the market.</p> <p>The first subparagraph shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III.</p> <p>The information notified to the Commission shall contain at least the following:</p>	<p>(3) In Article 16, paragraphs 3 is replaced by the following:</p> <p>3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means prior to being placed on the market. The first subparagraphs shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III. The information notified to the Commission shall contain at least:</p> <p style="padding-left: 40px;">(a) the identification of the nanomaterial including its chemical name (IUPAC) and</p>	<p>Cosmetics Europe believes that any additions on nanomaterials to Annex I Part A should be under Paragraph 8 Toxicological part, and not under Point 2.</p> <p>Other than that, Cosmetics Europe supports the EP position with the amendment:</p> <p>(3) In Article 16, paragraphs 3 is replaced by the following:</p> <p>3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means prior to being placed on</p>

Commission proposal	Council General Approach	European Parliament (as per ENVI/IMCO vote, April 15)	Cosmetics Europe's recommended compromise
	<p>(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;</p> <p>(b) the specification of the nanomaterial including size of particles, physical and chemical properties;</p> <p>(c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;</p> <p>(d) the toxicological profile of the nanomaterial;</p> <p>(e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;</p> <p>(f) the reasonably foreseeable exposure conditions.</p> <p>The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof. The Commission shall provide a reference number for the submission of the toxicological profile, which may substitute the information to be notified under point (d).;</p>	<p>other descriptors as specified in point 2 of the Preamble to Annexes II to VI, and</p> <p>(b) the specification of the nanomaterial including size of particles, physical and chemical properties.</p> <p>The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof. The Commission shall provide a reference number for the submission of, which may substitute the information to be notified in case of the same nanomaterial used in different products.</p>	<p>the market. The first subparagraph shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III. The information notified to the Commission shall contain at least:</p> <p>(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI, and</p> <p>(b) the specification of the nanomaterial including size of particles, physical and chemical properties.</p> <p>The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof. The Commission shall provide a reference number for the submission of the notification, which may substitute the information to be notified in case of the same nanomaterial used in different products.</p>

Justification: the EP text introduces significant reporting burden reduction while maintaining a high level of transparency. In fact, the information that has to be notified to the Commission under article 16 also has to be notified to member states under Article 13 and/or, be held accessible to them under Article 10/Annex I and the Implementing Decision 764/2013 (Product Safety Assessment). The only information that is unique under Article 16 is the projected annual use tonnage of the nanomaterial. The Commission has repeatedly expressed that stated that they are not competent to assess the information they receive under Article 16 and to decide whether a nanomaterial poses safety concerns or not. As a consequence, the Commission systematically refers all nanomaterials to SCCS without actually considering the information notified under Article 16. By deleting the notification of detailed technical/safety information under Article 16, Member States will retain access to the same level of information as before (through the Article 13 notification and the safety assessment under Article 10/Annex I), but the industry will no longer need to carry out full duplicate notification of the same information to the Commission, which in any case would not make any use of them. To ensure continued transparency for the Commission on the appearance of new

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<p>nanomaterials on the EU market, the notification under Article 16 should be maintained for the identification and specification of such nanomaterials, but it should no longer include the full detailed technical/safety information that is already submitted/available under Article 13 and Article 10/Annex I.</p> <p>We also suggest two minor amendments to the EP position to address text coherence.</p>			
<p>Article 2 – paragraph 1 – point 4 a (new) Regulation (EC) No 1223/2009 Article 19 – paragraph 6 a (new)</p>			
New text	N/A	<p>(4 a) In Article 19, paragraph 6a is added:</p> <p>'6a. When cosmetic products are made available on the market through distance sales, the offer shall clearly and visibly indicate the information referred to in paragraph 1.'</p>	<p>CE does not support the EP provision as this is already covered by the GPSR Article 19, which applies to cosmetic products. Furthermore, certain product information cannot be displayed online, namely the date of minimum durability (DOMD) (Article 19(1)(c)) and the batch number (Article 19(1)(e)).</p>
<p>Justification: CE does not support the EP provision as this is already covered by the GPSR Article 19, which applies to cosmetic products. Furthermore, certain product information cannot be displayed online, namely the date of minimum durability (DOMD) (Article 19(1)(c)) and the batch number (Article 19(1)(e)). The DOMD and the batch number are dynamic datapoints that change in time as the product continues to be manufactured. While for sales in a shop a consumer knows exactly which product item they are buying on the shelf, for online sales it is not known at the moment of the purchase which specific item will be delivered to the customer, and therefore the DOMD and batch number cannot be displayed accordingly.</p>			
<p>Article 2 – paragraph 1 – point 8</p>			
Annexes II to VI are amended in accordance with Annex III this Regulation.	Annexes II to VI are amended in accordance with Annex III to this Regulation.	Deleted.	Support Council position.
<p>Justification: the Council proposal is necessary to change the word 'Glossary name' to 'INCI name' in the column headers of the Annexes, in line with recital 25.</p>			