Von: xxx
Gesendet: Dienstag, 12. März 2024 12:01
An: xxx, BMUV
Betreff: Anstehende Sitzung der Mitgliedstaaten

Guten Tag xxx

im Vorfeld zur Sitzung der „EU Working Group on Cosmetic Products“ (CPWG) am 15. März 2024 möchten wir Sie auf einige Tagesordnungspunkte hinweisen, die aus unserer Sicht besonders wichtig für die Kosmetikindustrie sind. Hier möchten wir Sie um Ihre Unterstützung bei diesen Fragestellungen bitten, da es unseres Erachtens sowohl der Industrie als auch der Bundesregierung ein Anliegen ist bzw. sein sollte, eine praktikable und rechtsichere Situation zu schaffen bzw. beizubehalten.

Insbesondere auf folgende Punkte der Agenda der CPWG am 15. März 2024 möchten wir hinweisen:

Zum **Punkt 3f** der Tagesordnung, dort 1. Anstrich (UPDATE ON CLP (forthcoming harmonized classification; developements on the MOCS under the CLP Revision) – **in Verbindung mit Punkt 4a** “JOINT PRESENTATION FROM CE AND IFRA …..” haben wir folgende Anmerkung:
Wie Sie sicherlich wissen, hat die Frage der MOCS (*more-than-one constituent substances)* insbesondere auch in Bezug auf natürliche Inhaltsstoffe für große Diskussionen und Unsicherheit im Zusammenhang mit der Revision der EU-CLP-Verordnung 1272/2008 im Chemikalienrecht geführt. Diese wurden nun zumindest vorläufig beigelegt:
Pressemitteilung des EU Councils: https://www.consilium.europa.eu/en/press/press-releases/2023/12/05/safer-chemicals-council-and-parliament-strike-deal-on-the-regulation-for-classification-labelling-and-packaging-of-chemical-substances/
“On MOCS it states that: “*For substances with more-than-one constituent (MOCS) the provisional agreement includes a 5 year derogation for MOCS of plant or plant parts which are not chemically modified. After this time, the Commission may propose new legislation for those products based on scientific report. Other MOCS, like petrochemicals, will be under the scope of the regulation*.”

Diese Regelung ist aus unserer Sicht besonders wichtig, da derzeit eine ganze Reihe von Naturstoffen aus diversen natürlichen Quellen unter dem Chemikalienrecht bewertet und gegebenenfalls eingestuft werden, aktuell z. B. das auch in verschiedenen Gewürzen vorkommende p-Cymol (englisch p-Cymene), das auf dem Weg ist, als CMR-1-Stoff im Chemikalienrecht eingestuft zu werden. Damit stellt sich die Frage, wie im Kosmetikrecht unter Artikel 15 Absatz 2 der EG-Kosmetik-Verordnung hiermit umgegangen werden soll; in Anbetracht der Tatsache, dass p-Cymol ein sehr relevanter Inhaltsstoffe diverser Pflanzen ist, die auch als Basis für Kosmetikrohstoffe eine Rolle spielen bzw. in Form von Ölen oder Extrakten direkt als solche eingesetzt werden. Eine solche Fragestellung kann zukünftig auch für weitere Naturstoffe aufkommen und hat daher eine grundsätzliche Bedeutung für die Verwendung einer Vielzahl von Materialien natürlichen Ursprungs (Pflanzen, Algen etc.) in kosmetischen Mitteln.

Angesichts des fortgeschrittenen Stadiums des Einstufungsprozesses nach der CLP-Verordnung von p-Cymol ist es aus Sicht der Kosmetikhersteller dringend erforderlich, in der CPWG eine grundsätzliche Einigung darüber zu erzielen, wie insbesondere mit als CMR eingestuften Bestandteilen von NCS (Natural Complex Substances – ein Unterbegriff der oben genannten MOCS), zukünftig umzugehen ist. Ein Verbot von p-Cymol würde ein Verbot von Hunderten von NCS bedeuten, die in praktisch jedem Parfümöl enthalten sind, das auf natürlichen Inhaltsstoffen basiert. Folglich könnte ein Verbot von p-Cymol dazu führen, dass Zehntausende von kosmetischen Mitteln,

die sich derzeit sicher auf dem Markt befinden, sozusagen über Nacht nicht mehr rechtskonform sein werden.

Eine Präsentation, die am 15. März gezeigt werden soll, sowie ein Hintergrunddokument, das den Sachverhalt näher beschreibt, sind hier beigefügt. Ziel des Vortrags ist es, das Bewusstsein für die Folgen von Artikel 15 der EG-Kosmetik-Verordnung in Bezug auf die harmonisierte CMR-Einstufung chemischer Stoffe, die Bestandteile von NCS sind, zu schärfen. Das Problem ergibt sich im Wesentlichen aus der Tatsache, dass die regulatorischen Folgen von CMR-Einstufungen gemäß Artikel 15 Absatz 2 der EG-Kosmetikverordnung für Einzelstoffe konzipiert wurden, die als solche als Kosmetik-Inhaltsstoffe verwendet werden. Die Auswirkungen, die die Einstufung eines Stoffes auf das breite Spektrum von zum Teil Hunderten von NCS haben könnte, die diesen natürlicherweise als Bestandteil enthalten, wurden jedoch nicht berücksichtigt. Eine angemessene, praktikable Anwendung von Artikel 15 der EG-Kosmetikverordnung ist hier erforderlich, um unerwünschte und unverhältnismäßige Auswirkungen zu vermeiden.

Ähnlich wie bei den "Praktischen Leitlinien für die Verfahrensschritte zur Durchsetzung des Verbots oder möglicher Ausnahmen vom Verbot von CMR-Stoffen in kosmetischen Mitteln (Februar 2020) (Arbeitsdokument der Arbeitsgruppe für kosmetische Mittel)" fordern Cosmetics Europe und IFRA letztlich auch die Entwicklung detaillierter, praktikabler Leitlinien für die Anwendung von Artikel 15 Absatz 2 der EG-Kosmetikverordnung. Solche Leitlinien, in denen die Zuständigkeiten und Fristen sowohl für die Industrie als auch für die Mitgliedstaaten festgelegt werden können, sollten eine verbesserte Transparenz über den Entscheidungsprozess und damit Rechtsklarheit und Rechtssicherheit für alle am Freistellungsverfahren nach Artikel 15 Absatz 2 beteiligten Akteure schaffen.

Zum **Punkt 3e** – Artikel 2(4) CPR Procedure
Die Einstufung eines Produkts durch die Kommission auf Basis von Art. 2 (4) ist aus unserer Sicht eine „a last resort measure“, die also nur sehr selten vorkommen sollte. Im Rahmen eines solchen Verfahrens würden die relevanten Stakeholder gehört.

Wir möchten gegenüber der Bundesregierung nochmal betonen, dass aus unserer Sicht dieses Verfahren allenfalls in extrem seltenen Fällen zur Anwendung kommen dürfte. In der Regel werden ja auch im „Borderline Manual“ zu Recht nur Kriterien definiert, die bei bestimmten Abgrenzungsfällen besonders zu beachten sind und im Übrigen auf die regelmäßig notwendige Einzelfallprüfung verwiesen. Die Einstufung eines konkreten Produkts als kosmetisches Mittel ist aber regelmäßig von der durch die gesamte Aufmachung geweckten Verbrauchererwartung abhängig. Bei in mehreren Mitgliedstaaten vertriebenen Produkten kann u. U. schon die unterschiedliche Übersetzung einzelner Auslobungen (wie „Pickelcreme“ oder „Akne-Behandlung“) zu unterschiedlichen Einstufungen auf Basis der in den jeweiligen Mitgliedstaaten geweckten abweichenden Verbrauchererwartungen führen.

Zum **Punkt 3c** möchten wir Sie um Unterstützung des vom Industriekonsortium geplanten weiteren Vorgehens zur Absicherung von Titandioxid bei oraler Exposition bitten. Dem (aktuell noch als vorläufig) veröffentlichten „Scientific Advice“ des SCCS (https://health.ec.europa.eu/document/download/d811b2cc-e951-41f6-bfcd-2d8be21f0d79_en?filename=sccs_o_282.pdf) zufolge konnten bisher nur zwei Spezifikationen von Titandioxid gemäß dem vom SCCS geforderten aktuellsten Stand der Technik eindeutig vom Verdacht der Genotoxizität freigesprochen werden. Das Konsortium hat dem SCCS einen Vorschlag für die analoge Prüfung weiterer Spezifikationen vorgelegt, die für die in Kosmetika aktuell verwendeten Materialien repräsentativ sind. Diesem Vorschlag wurde ein konkreter Arbeits- und Zeitplan beigefügt. Cosmetics Europe und das Konsortium bitten daher die CPWG, eine Frist bis zum Ende dieses Jahres (2024) zu gewähren, um alle erforderlichen weiteren Tests durchführen und die Ergebnisse dem SCCS zur abschließenden Prüfung vorlegen zu können. Weitere Erläuterungen und

Hintergrundinformationen zum Einsatz von Titandioxid in Kosmetika entnehmen Sie bei Interesse gerne der beigefügten Präsentation.

Zum **Punkt 4c** (bestimmte Prostaglandinderivate) möchten wir anmerken, dass die weitere Verwendung dieser Inhaltsstoffe für einige deutsche Unternehmen von großem Interesse ist. Es wurden mit großem fachlichen und finanziellem Aufwand neue Studien zu definierten Einzelstoffen eingereicht, die offene Fragen aus einer früheren SCCS-Stellungnahme zu der gesamten Stoffgruppe adressieren.

Für eventuelle Rückfragen stehen wir gerne zur Verfügung.

Mit freundlichen Grüßen
xxx
Industrieverband Körperpflege- und Waschmittel e. V.
The German Cosmetic, Toiletry, Perfumery and Detergent Association
Mainzer Landstraße 55, 60329 Frankfurt am Main

Titanium Dioxide (TiO_2)

Industry update and proposal for additional testing

Working Group on Cosmetic Products

March 15th, 2024

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the personal care association

Who are we?

Cosmetics Europe Titanium Dioxide Consortium (CE TD Cons)

- Managed by Cosmetics Europe (the personal care association)
- 21 members - Cosmetic Product producers & major Cosmetic ingredient Suppliers
- Gather scientific information, conduct research, and share knowledge on TiO_2 use in cosmetics
- Our goal is to demonstrate and promote a safe, sustainable and responsible use of TiO_2 in cosmetics.

Titanium Dioxide Manufacturers Association (TDMA)

- The TDMA is a sector group of Cefic (the European Chemical Industry Council)
- TDMA serves as a collective voice for TiO_2 manufacturers, working to address common challenges and promote the responsible and sustainable use of TiO_2
- Provide comprehensive, authoritative and trusted information about the safety and use of TiO_2

Working together to prioritize and promote health & safety, protecting consumers & advancing industry

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What is Titanium Dioxide?

- Titanium dioxide (TiO_2) also known as Titanium (IV) oxide has the following CAS/EC Numbers:

  CAS Number: 13463-67-7 / EC Number: 236-675-5
  CAS Number: 1317-70-2 / EC Number: 215-280-1
  CAS Number: 1317-80-2 / EC Number: 215-282-2

- TiO2 has been used for decades in beauty and personal care products:
  - ✓ make-up products
  - ✓ nail varnish products
  - ✓ sun care products
  - ✓ hair products
  - ✓skin care products
  - ✓oral care products
  - ✓soap products

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Why using Titanium Dioxide in cosmetics

Colour	Pigmentary form of TiO_2 is a white colour (CI 77891), also allowing colour shades adjustment with other colourants for make-up and suits all skin types in foundations.
Opacity	Pigmentary form of TiO_2 through its high refractive index provides the highest opacity – a key characteristic to cover skin imperfections.
Light	TiO_2 helps soak up oils in the skin, while lending it an opacity that reduces any unwanted shine – a key selling point for any matte-based cosmetic.
UV	Non-pigment form TiO_2 is a key ingredient as UV filter (absorbing and scattering both UV-A and UV-B rays) which help to prevent sun burn, premature ageing and protecting the skin from harmful, cancer-causing UV rays.
Staying power	Resistance to heat, light and insoluble material, TiO_2 is prized for its long-lasting and waterproof properties, which is important for sun care products, in particular.

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Titanium Dioxide application and use in cosmetic products

- Pigmentary grades used in Cosmetics:
  - Adhere to E171 purity criteria
  - < 50% (by number) of constituent (primary) particles < 100 nm
  - May differ from grades used in food products (e.g., coatings)
  - Function: opacity or coloration and/or UV (ultraviolet) attenuation (UV filter).
- Nano grades used in Cosmetics:
  - purity ≥ 99 %, rutile form (< 5 % anatase) with median particle size based on number size distribution ≥ 30 nm (based on CPS, LUMisizer and DLS measurements)
  - 100 % of constituent (primary) particles < 100 nm
  - Function: UV (ultraviolet) attenuation (UV filter)

TiO_2 Grades Used in Cosmetics		Uncoated	Coated
Anatase	Pigmentary	**Y**	**Y**
	Nano	**N**	**N**
Rutile	Pigmentary	**Y**	**Y**
	Nano	**N**	**Y** (UV filter)

Where, Y= Yes (allowed), N (not allowed)

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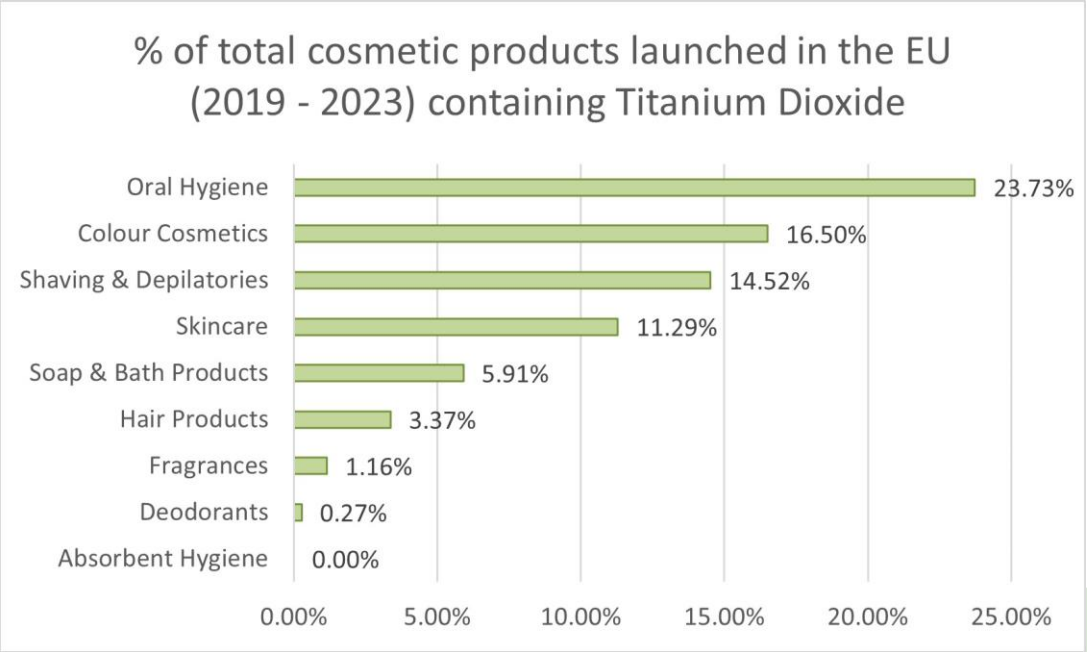
Economic importance of Titanium Dioxide in Cosmetics

- The global titanium dioxide market size is expected to reach USD 30.62 billion by 2030, registering a CAGR of 6.3* (for all applications industrial, pharmaceutical, cosmetics etc.)
- The market value of cosmetic products containing TiO_2 is estimated at

  >> 100M € in Europe
  >> 400M € globally
- 377970 Cosmetic products were launched in last 5 years. Approx. 12% of these contained TiO_2.
- The widespread use of titanium dioxide contributes to revenue generation for cosmetic manufacturers, suppliers, retailers, and associated businesses in the value chain.
- TiO_2 has a promising marketing potential, driving economic growth and investment opportunities within the EU.



*Source: Titanium Dioxide Market Size, Share & Trends Analysis Report By Grade (Anatase, Rutile), By Production Process (Sulfate, Chloride), By Application, By Region, And Segment Forecasts, 2023 - 2030 (researchandmarkets.com)

**Source: Mintel 2024

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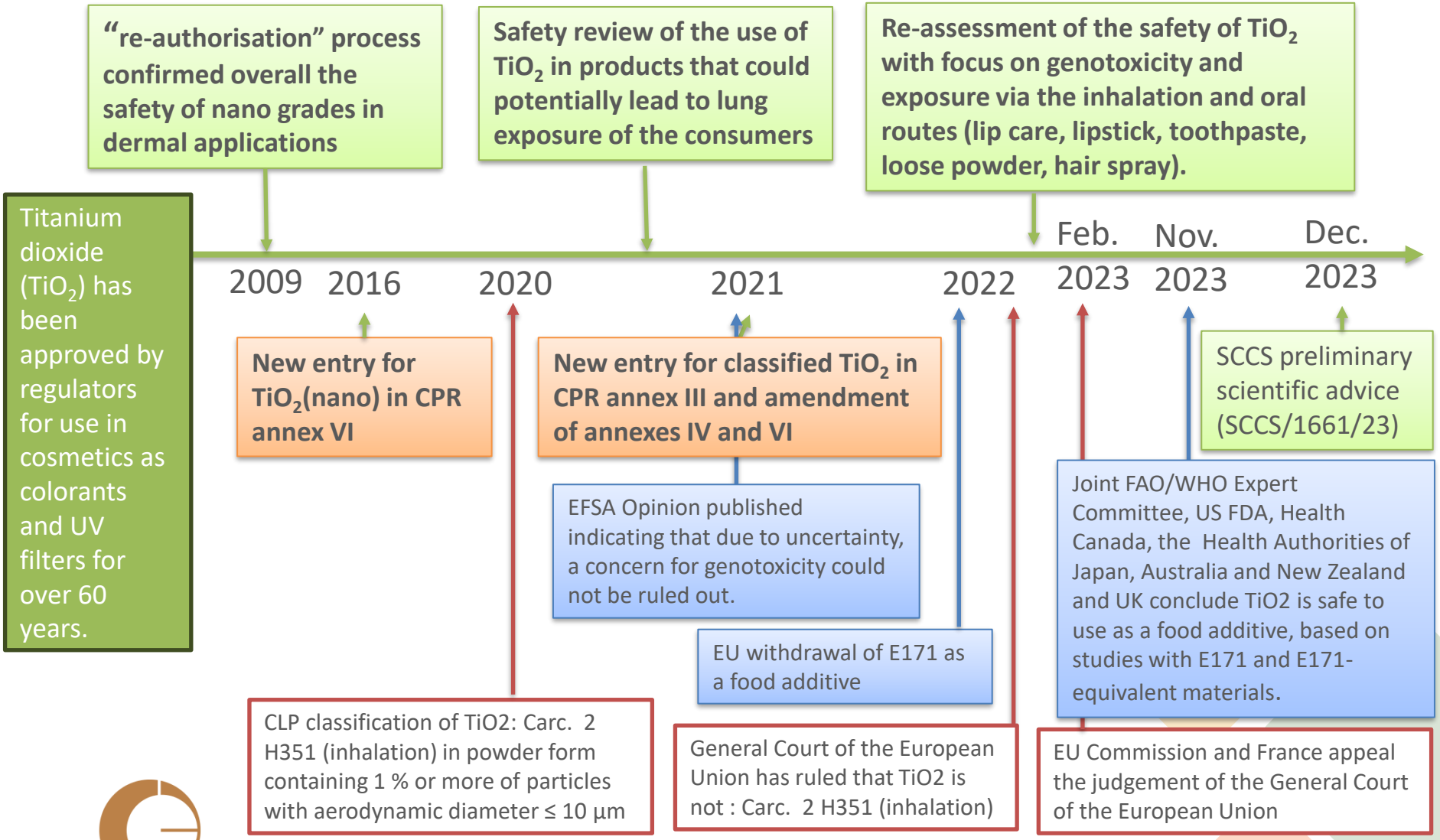
Regulatory Journey of TiO2: Safety and Compliance



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The SCCS preliminary scientific advice on TiO2 - SCCS/1661/23

In December 2023, the SCCS published a preliminary scientific advice (SCCS/1661/23) for public consultation.

Conclusions of SCCS on TiO_2

DERMAL

Dermal applications are safe as previous SCCS Opinions SCCS/1516/13, SCCS/1580/16 remain valid

INHALATION

Inhalation exposure of TiO_2 is not of concern due to restrictive conditions of use in Regulation (EC) No 1223/2009

ORAL

Genotoxicity cannot be excluded as data not sufficient to conclude a safe use for all grades in oral applications (except for two materials: RM09, RM11)

In order to conclude on the safety for oral use more data needed on:

- Genotoxicity (as part of a read-across approach to cover all grades)
- Potential uptake of TiO_2 in oral mucosa from oral care use applications
- RM specifications

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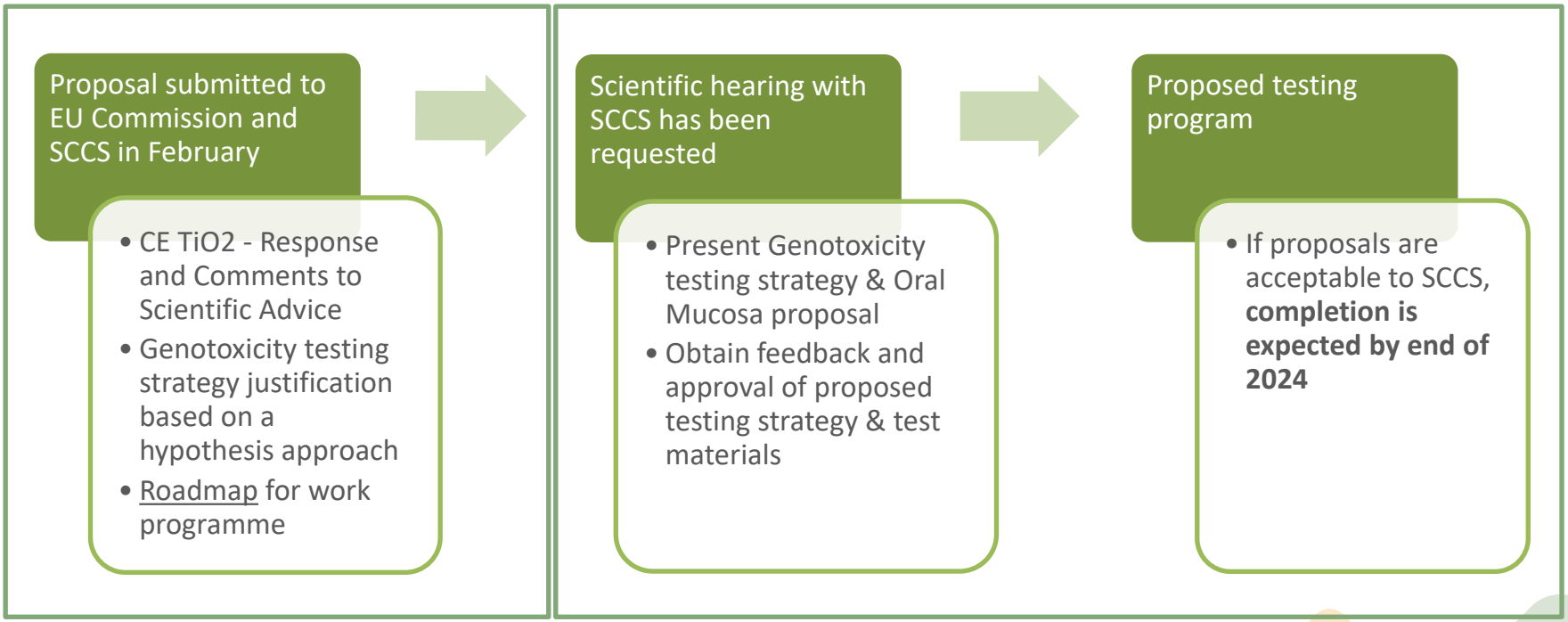
Recent and proposed industry actions and timings



Recent document submission

Proposed roadmap activities and timings

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Industry's request to CPWG

Industry is convinced of the safety of TiO2 used in cosmetic products

The SCCS has **approved the safety of two grades** of titanium dioxide and has **requested more data** on other grades

Encouraged by this, industry requests regulators to **grant additional sufficient time** to allow the generation of the necessary data on more grades of titanium dioxide

This will allow the SCCS to accurately complete a **comprehensive assessment and evaluation** of titanium dioxide's safety for consumers

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Thank you!

Working Group on Cosmetic Products

March 15th, 2024

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the personal care association

Brussels, 15 February 2024

Joint IFRA – Cosmetics Europe paper to ensure the continued safe use of Natural Complex Substances (NCS) in cosmetic products in the context of Article 15.2 of the Cosmetic Products Regulation.

Similar to global trends, European consumers are increasingly interested in **eco-friendly and sustainable fragrances and cosmetic products**. Factors like consumer awareness of **natural and organic products** contribute to the dynamics of the market.[1] These trends are also supported by the ambitions of the EU circular and bio-economy strategies, addressing circularity aspects of bio-based products and the sustainable use of renewable natural resources.

Cosmetics Europe and **the International Fragrance Association (IFRA)** have prepared the following paper to **raise awareness over unintended immediate and severe consequences that the harmonized classification of constituents of NCS[2] as CMR Category 1 (CMR1) can have on the use of these NCS in cosmetics.**

EXECUTIVE SUMMARY

Although the CLP classification process typically addresses substances that are single chemicals and the regulatory consequences and procedure under the CPR are well defined, this is not necessarily the case for substances that are also constituents of NCS. **The aim of this document is to address the consequences under Article 15 of the Cosmetic Products Regulation (CPR), resulting from the CMR harmonized classification of chemical substances that are constituents of NCS.**

The issue arises from the fact that the regulatory consequences of CMR classifications under Article 15.2 of the CPR were designed **for single substances that are used as such as ingredients. No consideration was given to NCS and the impact that the classification of a substance could have on the wide range of NCSs that naturally contain it as a constituent** The compositions of NCS vary widely in complexity ranging from simple (with only a few constituents) to very complex (in excess of 100 constituents) that in combination deliver the benefit of a unique aroma signature of the specific natural ingredient.

A suitable, workable application of Article 15 of the CPR is essential for substances which are also constituents of NCS, to avoid unwanted and disproportionate impact. Finding an agreement in the European Commission Cosmetic Products Working Group (CPWG) on how to approach classified constituents of NCS is a matter of urgency, given the advanced stage of the CLH process in ECHA/RAC of p-cymene, which is naturally present in several hundreds of NCS used in cosmetics.

Ultimately, and similarly to the "*Practical guidelines on the procedural steps to enforce the ban or possible exemptions to the ban of CMR substances in cosmetic products (February 2020) (Working document of the Working Group on Cosmetic Products)*", Cosmetics Europe and IFRA would also call for more detailed guidelines to be developed for the application of the Article 15.2 of CPR, not only for constituents of NCS but for any substance subjected to the CMR Cat 1 derogation process. **Such guidelines, laying down the responsibilities and deadlines for both industry and Member States, will provide transparency on the decision-making process and consequently legal clarity and certainty for all stakeholders involved in the Article 15.2 exemption process.**

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[1] Based on the sector's internal assessment, the predicted compounded annual growth rates, global 2023 to 2032 are the following:
- Natural/organic cosmetics market 9.49 %
- Total cosmetics market 5.8%

[2] Natural complex substances are defined by the EFEO-IFRA Guidelines on substance identification and sameness of Natural Complex Substances (NCS) under REACH and CLP as " *(…) a very diverse family of substances that are notably used as ingredients in fragrance formulations and [directly or indirectly] added to cosmetic and other consumer products. NCS are well described in ISO standard 9235:20138 (Aromatic natural raw materials - Vocabulary).* Many NCS **are naturally present in edible plants and are widely present in our daily diet.**

Cosmetics Europe
the personal care association

The International Fragrance Association

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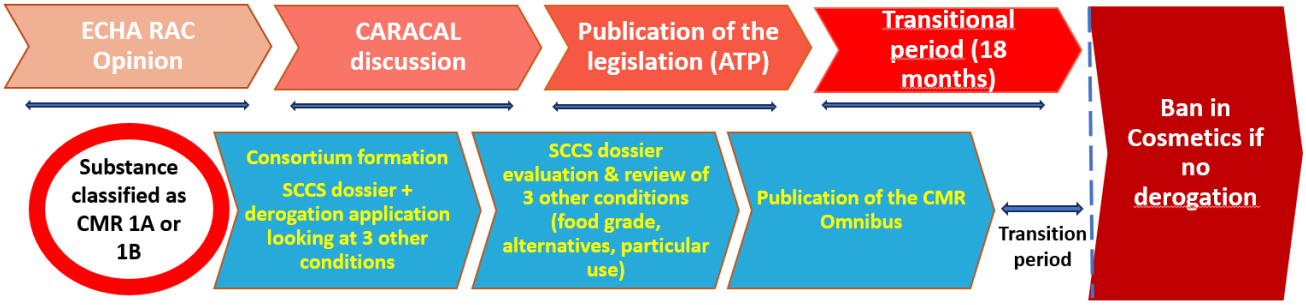
1. The issue: the anticipated forced discontinuation of hundreds of NCS safely used in cosmetics unless a derogation is granted for their constituents (Article 15 of CPR)

In accordance with Article 15.2 of CPR, the use of **a substance which is classified as CMR category 1A or 1B is prohibited in cosmetics**, **unless derogation is granted**. This also applies to substances that are constituents of NCS.

The adoption of an **opinion on the harmonized classification of a chemical substance** by the **European Chemicals Agency (ECHA)** is therefore the **starting point** for the **possible ban of CMR substances in cosmetic products.**



Article 15.2 does foresee a derogation process from the ban, provided that four conditions are fulfilled:

a) comply with food safety requirements;

b) no suitable alternatives;

c) the application for a particular use with a known exposure; and

d) evaluated and found safe by the SCCS (Scientific Committee for Consumer Safety).

As of today, there is **no precedent for such a derogation for a substance classified as CMR Cat. 1A/1B**. Although in the two cases of single chemical substances where industry submitted a dossier and the SCCS supported the safety of use, Member States concluded – without transparency on the decision making process - that there were suitable alternatives to the substance.

The situation is even more complex for substances that are also constituents of NCS since a decision on the substance can have consequences beyond the use of the substance itself. In the case of a CMR Cat 1 classification, **a resulting ban (which requires listing in Annex II of the CPR) would not only cover the use of the substance as such as a cosmetic ingredient.** In addition, **it would also ban the use of all NCS containing the constituent since Annex II of the CPR prohibits the presence of the substance in finished cosmetic products.** In other words, listing in Annex II of one common constituent of NCS could mean the ban of hundreds of natural ingredients.

→ **For this reason, Cosmetics Europe – IFRA requests a discussion on the practical application of the exemption process under Article 15 specifically for constituent(s) of NCS.**

2. *A concrete illustration: the p-cymene case*

By their very nature, NCS can be composed of more than a hundred constituents (e.g. thyme oil, lavender oil, rosemary oil, orange oil, etc.) that are naturally present at various concentrations in a specific NCS.

p-Cymene (CAS 99-87-6) is known to be present in **around 350 NCS at a different concentration**. As an example, these are the typical concentrations of p-cymene in:

- Neroli (bigarade) oil: 0,3%;
- Thyme oil: 20%;
- Lemon oil: 0,5%;
- Cumin oil: 9,7%.

The ECHA Committee for Risk Assessment (RAC) is expected to adopt its **opinion on the classification of p-cymene** (and other substances part of this same "*p-cymene group*", i.e. cyclamen aldehyde, cuminic aldehyde that are also constituents of many NCS) **mid-2024**.

Given the widespread natural presence of p-cymene in NCS (present in around 350 NCS at a different concentration) used in fragrance and cosmetics, a ban of this constituent would potentially render a very large number of cosmetic products on the market today non-compliant with the EU cosmetic legislation.

Therefore, if the RAC adopts the opinion with CMR classification 1B for p-cymene[3], industry will **apply for a derogation as per Article 15.2 for this constituent in order to allow for continued safe use of the wide range of NCS containing it.**

The derogation request has to fulfill the four conditions including the submission of an SCCS dossier at the latest 6 months after the adoption of the RAC opinion.

This dossier, although based on the p-cymene, would not defend the direct use of p-cymene as a cosmetic ingredient, but its natural presence in the hundreds of NCS containing p-cymene.

→ **Without this dossier submission, not only p-cymene would be banned** but also, **as a consequence of the constituent ban, all NCS containing p-cymene** (neroli oil, thyme oil, lemon oil, cumin oil, lavender oil, etc.) **could no longer be used in cosmetics**.

3. *The way forward: a workable application of Article 15.2 of CPR for constituents of NCS*

Building on this concrete p-cymene case, for which RAC opinion is expected in mid 2024, Cosmetics Europe and IFRA are therefore **seeking a workable application of Article 15.2 of CPR for constituents of NCS.** To note: This application for derogation under Article 15.2 would not target use as such of the substance(s) as cosmetic ingredient(s) but only their natural presence in NCS used in cosmetics.

The specificities of NCS constituents are particularly relevant for the first two conditions to be fulfilled:

a) comply with food safety requirements &

b) no suitable alternatives

[3] Proposed by Sweden as dossier submitter: Harmonized classification and labelling previous consultations - ECHA (europa.eu)

The application to be given to the two last conditions (i.e. c) the application for a particular use with a known exposure; and d) evaluated and found safe by the SCCS) do not raise any particular questions with regard to constituents of a NCS. Indeed, as regards criterion c) there are already examples on how 'particular uses with known exposure' can be addressed in the Annexes of the CPR (see Annex below). As regards criterion d), there is no doubt that the fundamental basis for any derogation from the CMR-ban is a positive safety conclusion by the SCCS.

a) Comply with food safety requirements

The **wide occurrence of the constituent in plants and spices used for human (food) consumption** to be a sufficient justification to conclude on the compliance with food safety requirements.

The criterion should be considered as fulfilled by **demonstration of single/few examples of natural presence of the constituent in food ingredients.**

b) no suitable alternatives

Contrary to what can be done for single ingredients, when applied to constituents of NCS this criterion does not apply to the direct substitution of one natural ingredient in a finished product by another ingredient. Rather, it needs to be considered as the possibility of substitution of the classified constituent in all NCS containing it. Additionally:

- The **olfactive properties of the NCS require the totality of its constituents**.
- Substituting a constituent in NCS will inevitably create a different substance which not only will have different properties and may even no longer qualify as an NCS.
- The widespread natural presence of the constituent in hundreds of very different NCS from different botanical families would require an **unmanageable number of assessment of alternatives** to be carried out.

→ Taking into account these considerations, the non-availability of suitable alternatives should be the by-default conclusion for constituents of NCS.

4. Call for action.

An agreement in the CPWG on how to approach the classification of p-cymene needs to be found as a matter of urgency, given the advanced stage of the CLH process in ECHA/RAC.

However, ultimately and similarly to the "*Practical guidelines on the procedural steps to enforce the ban or possible exemptions to the ban of CMR substances in cosmetic products (February 2020) (Working document of the Working Group on Cosmetic Products)*", Cosmetics Europe and IFRA would also call for more detailed guidelines to be developed for the application of the Article 15.2 of CPR, not only for constituents of NCS but for any substance subjected to the CMR Cat 1 derogation process. Such guidelines, laying down the responsibilities and deadlines for both industry and Member States will provide **transparency on the decision-making process and consequently** legal clarity and certainty for all stakeholders involved in the Article 15.2 derogation process.

5. Annex: Precedence for constituents of NCS under the CPR

There are **two examples** under the CPR **where the SCCS**, in the context of CMR substances, **recommended different regulatory approach for direct use of a substance and its presence as constituent of NCS:**

- **Methyl eugenol (Annex III)**
  - **Genotoxicity and Carcinogenicity concerns**
    - Banned if intentionally added.
    - When fragrance compounds containing methyleugenol naturally present in essential oils are used as components in cosmetic products, the highest concentration of methyleugenol in the finished products must not exceed 0.01% in fine fragrance, 0.004% in eau de toilette, 0.002% in a fragrance cream, 0.0002% in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products.

- **Safrole (Annex II)**
  - **Harmonised classification as Carcinogenic 1B**
    - Banned as such.
    - Except for normal content in the natural essences used and provided that the concentration does not exceed: 100 ppm in the finished cosmetic product, 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children.

***

Joint webinar Cosmetics Europe - IFRA

The anticipated increase of harmonized classification proposals with a cascading impact on the continued use of natural complex substances (NCS) in cosmetic products

Managing constituents of NCS under the Cosmetic products Regulation (CPR)

16 February 2024

The International Fragrance Association

Cosmetics Europe

Introduction

The International Fragrance Association

Cosmetics Europe

Thyme oil

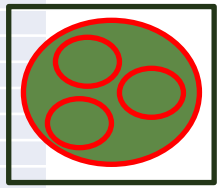
Constituents	Typical concentration (%)
1-Methyl-3-methoxy-4-isopropylbenzene	0,25
1-Octen-3-ol	0,3
3,7,10-Humulatriene	0,2
3-Octanone	0,2
4-Carvomenthenol	1,3
4-Isopropyl-2-methoxy-1-methylbenzene	0,3
alpha-Pinene	0,7
alpha-Terpineol	0,4
alpha-Terpineol acetate	0,4
alpha-Thujene	0,6
beta-Caryophyllene	1,4
beta-Pinene	0,4
Borneol	1,2
Bornyl acetate	0,1
Camphene	0,7
Carvacrol	3
Carvacrol acetate	0,1
Caryophyllene oxide	0,2
cis-Sabinene hydrate	0,2
delta-Cadinene	0,2
Eucalyptol	0,2
Eugenol	0,1
Geraniol	0,1
Linalool	3,2
Limonene	0,7
Myrcene	1,3
p-Cymene	20
p-Mentha-1,3-diene	1,1
p-Mentha-1,4-diene	10
Sabinene	0,2
Terpinolene	0,1
Thymol	50

CLP revision – classification of Natural Complex Substances (NCS) (= More than One Constituent Substances (MOCS))

Positive outcome to maintain the current rules

Case-by-case assessment to **self-classify NCSs** using available data:

- On the **NCS** itself (“*on the substance*”)
- On the **individual constituents** (CLP mixture rules).



→ This achievement addresses the classification of NCSs...

Cosmetics Europe

Thyme oil

Constituents	Typical concentration (%)
1-Methyl-3-methoxy-4-isopropylbenzene	0,25
1-Octen-3-ol	0,3
3,7,10-Humulatriene	0,2
3-Octanone	0,2
4-Carvomenthenol	1,3
4-Isopropyl-2-methoxy-1-methylbenzene	0,3
alpha-Pinene	0,7
alpha-Terpineol	0,4
alpha-Terpineol acetate	0,4
alpha-Thujene	0,6
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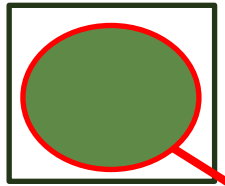
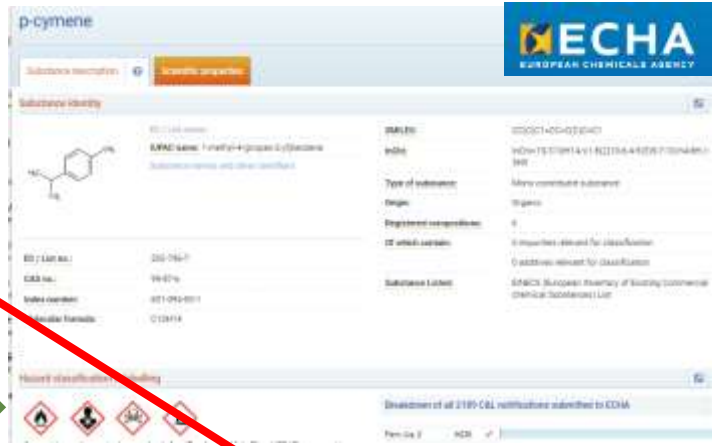
Borneol	1,2
Bornyl acetate	0,1
Camphene	0,7
Carvacrol	3
Carvacrol acetate	0,1
Caryophyllene oxide	0,2
cis-Sabinene hydrate	0,2
delta-Cadinene	0,2
Eucalyptol	0,2
Eugenol	0,1
Geraniol	0,1
Linalool	3,2
Limonene	0,7
Myrcene	1,3
p-Cymene	**20**
p-Mentha-1,3-diene	1,1
p-Mentha-1,4-diene	10
Sabinene	0,2
Terpinolene	0,1
Thymol	50

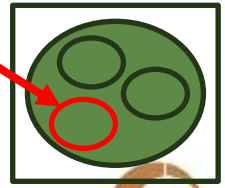
….. but not the consequences coming from substances with a harmonized classification as CMRs 1 which are constituents of NCSs

p-Cymene



Starting point: Classification of the single substance





Impact: Issue when this substance is a constituent of (a) NCS(s)

Cosmetics Europe

Thyme oil

Constituents	Typical concentration (%)
1-Methyl-3-methoxy-4-isopropylbenzene	0,25
1-Octen-3-ol	0,3
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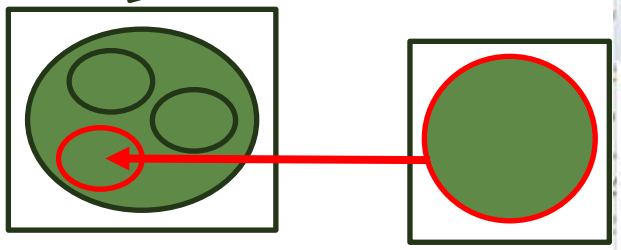
p-Mentha-1,3-diene	1,1
p-Mentha-1,4-diene	10
Sabinene	0,2
Terpinolene	0,1
Thymol	50

Objective of the discussion:
→ Address the consequences under the Cosmetic Products Regulation (CPR) resulting from the classification of chemical substances that are constituents of NCS



p-Cymene

The issue

The International Fragrance Association

Cosmetics Europe

Article 15.2 of CPR bans substances with a harmonised classification as CMR Category 1 unless a derogation is granted

Prohibition

CLP classifies a substance as CMR category 1A or 1B (harmonised classification)

Implementation: COM amends CPR Annex II => substance is prohibited in cosmetics

Derogation process

May be used where **all of the following conditions are fulfilled**:

(a) comply with food safety requirements;

(b) no suitable alternatives;

(c) the application for a particular use with a known exposure; and

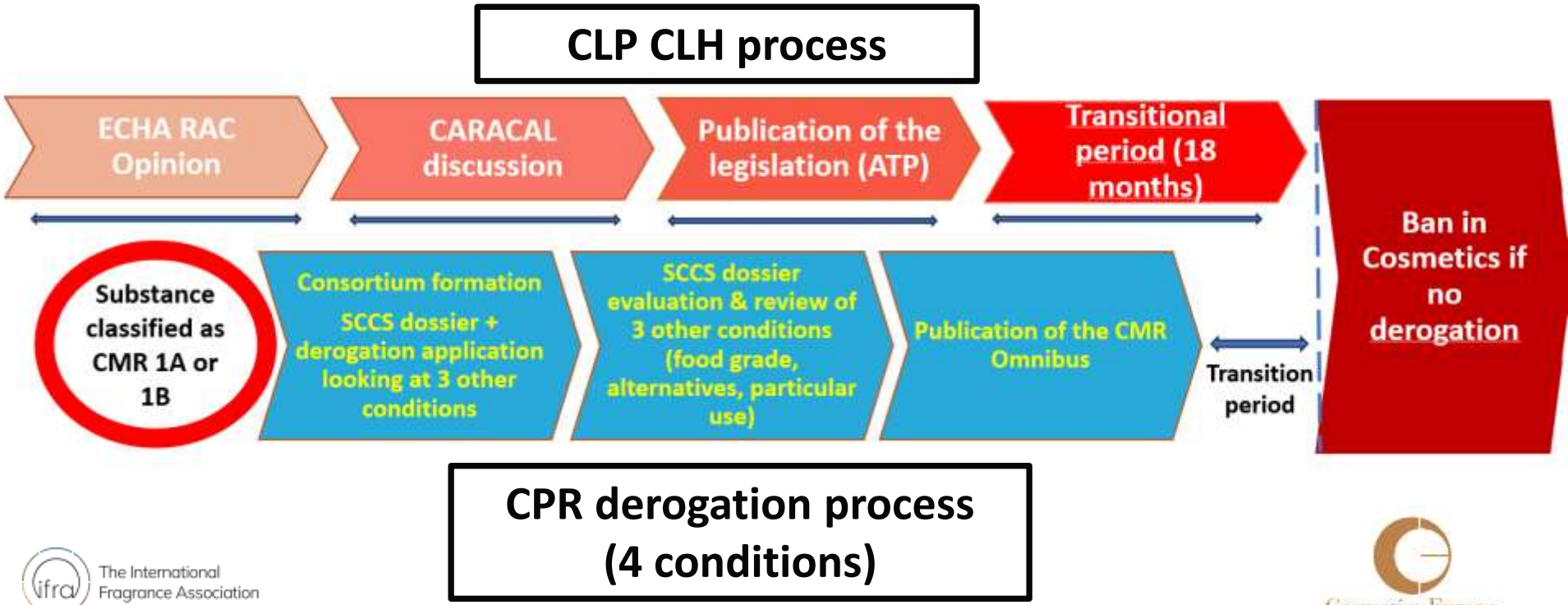
(d) evaluated and found safe by the SCCS.

Application

There is no precedent for such a derogation for a substance classified as CMR Cat. 1.

Two cases of single chemical substances where industry submitted a dossier the SCCS supported the safety of use but Member States concluded that there were suitable alternatives to the substance.

The adoption of an opinion on the harmonized classification (CLH) of a chemical substance by ECHA is the starting point for the possible ban of CMR substances in cosmetic products



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An increased number of fragrance substances can be anticipated for classification, due to a convergence of 2 factors

Today:

1) "Case-by-case"
(majority: individual substance classification)

2) Dossiers initiated by Member States & Industry

Tomorrow:

1) "Grouping" (becoming the norm)
(classification by group(s) of chemicals)

2) Dossiers initiated by Member States, Industry, ECHA and EFSA

The International Fragrance Association

Cosmetics Europe

Thyme oil

Constituents	Typical concentration (%)
1-Methyl-3-methoxy-4-isopropylbenzene	0,25
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Borneol	
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Sabinene	0,2
Terpinolene	0,1
Thymol	50

The situation is more complex and has further-reaching consequences for substances that are also constituents of NCS

The resulting ban of a CMR 1 would cover the use of:

- The substance as such as a cosmetic ingredient
- **All NCS containing the constituent (around 350 NCS containing in the case of p-cymene)**

p-Cymene

Cosmetics Europe

- Article 15.2 was designed for **single substances** – however NCS constituents have their own specificities
- SCCS in its original opinion on CMR substances recommended **different regulatory approach for direct use of a substance** and its presence as constituent of NCS

- There are **2 cases** in which substances are prohibited, but not when these substances are constituents of NCS

Methyl eugenol (Annex III) Genotoxicity and Carcinogenicity concerns	Safrole (Annex II) Harmonised classification as Carcinogenic 1B
• Banned if intentionally added. • *When fragrance compounds containing methyleugenol naturally present in essential oils are used as components in cosmetic products, the highest concentration of methyleugenol in the finished products must not exceed ……*	• Banned as such • *Except for normal content in the natural essences used and provided that the concentration does not exceed……..*

Cosmetics Europe and IFRA call for a workable application of Article 15.2 of the CPR for constituents of NCS

→ **A specific 'common-sense' reading and applying Art 15** is necessary for constituents of NCS to avoid unwanted and disproportionate impact

→ Most of these constituents **are present in food**

→ NCS constituents **cannot be substituted**

→ **A SCCS dossier for NCS constituent should be sufficient**

→ p-Cymene is one example, but **many more constituents of naturals will be concerned**

The International Fragrance Association

Cosmetics Europe