

## REGULATORY NEWSLETTER

Jul 2023 - Sep 2023

GLOBAL COSMETICS REGULATORY INTELLIGENCE



## Cosmetics Regulatory Intelligence - Europe

### **EU REACH to Restrict Intentionally-added Microplastics in Cosmetics**

(Publication date Sep 25, 2023)

European Commission (EC) has adopted measures restricting microplastics intentionally added to products under the EU chemical legislation Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This restriction will come into force later this week once it is published in the Official Journal of the EU. The ban uses a broad definition of microplastics – it covers all synthetic polymer particles below five millimeters that are organic, insoluble and resist degradation. Cosmetics where microplastics are used for multiple purposes, such as exfoliation (microbeads) or obtaining a specific texture, fragrance, or color, will no longer be allowed.

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## EU Cosmetic Regulation Update: Enhanced Labeling from 24 to 80 Allergens

(Publication date Aug 02, 2023)

The EU has introduced a crucial amendment to its Cosmetic Regulation that focuses on the labeling of fragrance allergens in cosmetic products. Commission Regulation (EU)2023/1545, which was introduced on July 26, 2023, amends Regulation (EC) No 1223/2009 of the European Parliament. The committee identified 56 new fragrance allergens, which have been known to cause allergies in humans but currently lack individual labelling requirements. Considering the SCCS opinion and the potential risk to human health associated with these additional fragrance allergens, the EU deemed it necessary to inform consumers about their presence in cosmetic products. Consequently, Commission Regulation (EU) 2023/1545 introduces an obligation to individually label these fragrance allergens when their concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.

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### PFHxS are now officially part of persistent organic pollutants

(Publication date Aug 08, 2023)

On 8th August 2023, the European Commission published Delegated Regulation (EU)2023/1608 of 30 May 2023, which amend Annex I to Regulation (EU) 2019/1021 of 30 May 2023. This relates to persistent organic pollutants (POP), which updates specially concerning perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds, which have been adopted in the new version published. The amendment adds the substance Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS related compounds to Part A of Annex I to Regulation (EU) 2019/1021 (POP), which lists substances prohibited to be used for manufacturing, placing on the European market, and use.



### Ingredients in the spotlight: Cannabidiol (CBD)

(Publication date September 15, 2023)

There is an ongoing call for data on the safety of Cannabidiol (CBD) in cosmetic products. On June 1, 2023, the European Commission invited all interested parties to submit any scientific information about the use of CBD in cosmetics. The consultation will remain open until September 30, 2024. The data collected will be the basis for mandating the Scientific Committee on Consumer Safety (SCCS) to assess the safety of CBD in cosmetics as well as the safe trace level of Tetrahydrocannabinol (THC).

This process aims at harmonising the rules at the EU level on the use of CBD in cosmetic products. Indeed, in recent years, several EU Member States have raised concerns about the potential risk of CBD for consumers' health and, at the moment, there are some national discrepancies.

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### EU Amends the Ecolabel Criteria for Cosmetic Products

(Publication date July 26, 2023)

EU released the Commission Decision (EU) 2023/1540 to amend the Ecolabel criteria for cosmetic products. These amendments primarily pertain to the wording of provisions within the criteria, and came into force upon their release.1

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### EU to Ban 30 More CMR Substances in Cosmetics from December 2023 (Publication date July 21, 2023)

The European Commission (EC) is banning several cosmetic ingredients identified as carcinogenic, mutagenic and toxic for reproduction (CMR). The governing body has listed the chemicals in the amendment of Annexes II of the Cosmetics Regulation (EC) No 1223/2009. Starting December 2023, beauty and personal care products containing any CMR substances will be prohibited from being made available or commercialized in the EU.

The updated regulation is part of the EC Omnibus Act VI, formally EU Regulation 2023/1490. The ingredients used in cosmetics formulations that have been added to the banned ingredient list include ammonium bromide, benzophenone, tellurium dioxide and 27 others.

## SCCS Issued a Preliminary Opinion on Water-soluble Zinc Salts Used in Oral Hygiene Products

(Publication date July 04, 2023)

The European Union Scientific Committee on Consumer Safety (SCCS) published the preliminary opinion on water-soluble zinc salts (SCCS/1657/23). The deadline for comments is set for September 8, 2023.

The SCCS has calculated aggregate exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% and from diet and concluded that the use of zinc in toothpaste is safe per se except for children under the age of one because the intake exceeds the upper limit level. For children up to the age of one, the SCCS recommends a safe concentration of 0.72% for soluble zinc salts (as zinc) in toothpaste. The inclusion of zinc in mouthwash at 0.1% is considered safe across all age groups.

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## SCCS Scientific Advice – children exposure on Methyl salicylate (methyl 2-hydroxybenzoate)

(Publication date 22 September 2023)

In view of the conclusions of SCCS/1633/21 and the aggregate exposure, the SCCS considers the use of Methyl Salicylate as safe in cosmetic products intended for children of age 0.5-3 years when used up to a maximum concentration of 0.02% in shower gel, hand soap, shampoo, body lotion, face cream, hand cream, lip products and hair conditioner. For toothpaste up to a maximum concentration of 2.52% methyl salicylate is considered safe.

As no specific data were provided by the applicant for children below 6 months, the SCCS has not considered this age category in this safety assessment.

## Cosmetics Regulatory Intelligence - North America

### FDA Issues Draft Guidance for Registration and Listing of Cosmetic Product Facilities and Products

(Publication date August 07, 2023)

The U.S. Food and Drug Administration issued a draft guidance which, once finalized, will assist cosmetics companies submitting cosmetic product facility registrations and cosmetic product listings, including ingredients, to the FDA. This includes a wide range of products such as makeup products, nail polishes, shaving creams and other grooming products, perfumes, face and body cleansers, haircare products, moisturizers, and other skincare products.

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### Canada Proposes to Amend Cosmetic Ingredient Use Requirements (Publication date July 13, 2023)

Health Canada released a notice concerning the review of several amendments to the Cosmetic Ingredient Hotlist. Companies are welcome to contact Health Canada (cosmetics@hc-sc.gc.ca) before October 11, 2023 to provide safety information or other considerations about the proposed ingredients, which may further inform Health Canada's decisions. Information that are recommended to be provided includes:

- · Additions to the Hotlist;
- Changes to the existing requirements in the Hotlist;
- Proposal to include additional ingredient identifiers or make minor corrections.

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### Modernization of Cosmetics Regulation Act of 2022

(Publication date September 18, 2023)

Most American consumers use cosmetic products every day. On average people use 6 to 12 cosmetics products daily. Examples of some of these products include makeup, nail polishes, shaving cream and other grooming products, perfumes, face and body cleansers, haircare products, moisturizers, and other skincare products.

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938. This new law will help ensure the safety of cosmetic products many consumers use daily

## Cosmetics Regulatory Intelligence - APAC

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## ASEAN Introduces Amendments to the Ingredient Lists of ASEAN Cosmetic Directive

(Publication date Jul 11, 2023)

The 37th ASEAN Cosmetic Scientific Body (ACSB) meeting was held on May 8-9, 2023, during which new amendments to the ingredient annexes to ASEAN Cosmetic Directive (ACD) were approved. These amendments will officially take effect on May 8, 2025.

- 1. The 37th ASEAN Cosmetic Scientific Body (ACSB) meeting adopted new changes to cosmetic ingredient annexes:
  - List of prohibited ingredients: 19 entries added
- 2. List of restricted ingredients: 2 entries added
- 3. List of permitted preservatives: 1 entry revised
- 4. List of permitted UV filters: 2 entries revised

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### NIFDC Notice on the Undertaking Units of the Project for the Revision of the Technical Specification for the Safety of Cosmetics

(Publication date August 18, 2023)

NIFDC aims to revise the Technical Specification for the Safety of Cosmetics, expanding the scope of application of existing inspection methods to toothpaste, and adding physical and chemical inspection methods for toothpaste. The deadline for project application is August 27, 2023.

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## NIFDC Notice on the Undertaking Units of the Project for the Formulation of Toothpaste Efficacy Evaluation Standards

(Publication date August 08, 2023)

In order to do a good job in formulating standards related to toothpaste, the China Institute for Food and Drug Control, in accordance with the "Cosmetics Supervision and Administration Regulations" and related work arrangements, publicly solicited units responsible for the toothpaste efficacy evaluation standard formulation project.

NIFDC aims to formulate the following toothpaste efficacy evaluation standards:

- Efficacy Evaluation of Toothpaste: General Principles
- Efficacy Evaluation of Toothpaste: Anti-caries
- Efficacy Evaluation of Toothpaste: Control of Dental Plaque
- Efficacy Evaluation of Toothpaste: Anti-dentin Hypersensitivity
- Efficacy Evaluation of Toothpaste: Gum Problems Alleviatio



## Comprehensive Guide to Cosmetic Notification Requirements for Market Entry in Vietnam

(Publication date September 14, 2023)

Under Vietnamese regulations, introducing cosmetics to the market requires prior notification to the authorities, which must be fulfilled for imported cosmetic products before the products cross the Customs Gate. Consequently, to allow sufficient time for the requisite cosmetic notification procedure, thorough preplanning is imperative for enterprises intending to launch new products.

Furthermore, cosmetic notification in Vietnam is valid for five years from the date of issuance. Noteworthy alterations to the products may mandate a fresh cosmetic notification. Therefore, importers must ensure the utilization of accurate and valid cosmetic notifications for their imported cosmetic products.

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