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COSMETICS REGULATORY INTELLIGENCE

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Cosmetics Regulatory Intelligence – Europe

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ECHA provides advice on new hazard classes for substances and mixtures.

(Publication date 20 April 2023)

The European Commission has updated the Classification, Labelling and Packaging Regulation with the following hazard classes:

- endocrine disruptors (ED) for human health or the environment;
- persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); and
- persistent, mobile, and toxic (PMT); very persistent and very mobile (vPvM).

Companies and Member State authorities can use current guidance on identifying endocrine disruptors and on PBT (persistence, bioaccumulation, toxicity) assessment until the guidance on applying the CLP criteria has been updated. It is expected to be ready in 2024.

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REACH committee votes to restrict intentional microplastics

(Publication date 27 April 2023)

The Commission welcomes the positive vote of the EU countries on the REACH committee for its proposal to restrict microplastics that are intentionally added to products.

The Preliminary Opinion is open for comments: The proposal will now be subject to a 3-month scrutiny.

Readmore

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

(Publication date 16 May 2023)

In the SCCS/1633/21 Opinion, the Committee concluded that Methyl Salicylate in toothpaste is safe for children under 6 years of age when used up to the maximum concentration of 2.52%. 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. For toothpaste up to a maximum concentration of 2.52% methyl salicylate is considered safe.

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SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation - 12th revision

(Publication date 16 May 2023)

MAIN CHANGES IN 12TH REVISION OF THE SCCS NOTES OF GUIDANCE (NOG)

The NoG have been revised and updated with emphasis on the following:

- Importance of systematic literature review
- Updating of animal-free alternative methods: NAM (New Approach Methodology), changes introduced for acute inhalation, skin irritation testing, eye irritation testing with DAL (Defined Approach for eye irritation, Liquid), DASS (Defined Approaches for Skin Sensitisation), new in vitro methods for genotoxicity testing (3D skin Comet; in vitro micronucleus)

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EU to Amend the Use Requirements for 13 Nanomaterials in Cosmetics

(Publication date 26 May 2023)

On May 23, 2023, EU notified WTO of a draft Commission Regulation which proposed to revise the prohibited and restricted ingredient lists in Regulation (EC) No 1223/2009 (Cosmetics Regulation). This draft measure was previously notified under EU/TBT/872, but is modified now to newly include the prohibition of Colloidal Silver (nano) and the restriction of Hydroxyapatite (nano).

The Preliminary Opinion is open for comments: Deadline for comments: July 22, 2023

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ECHA adds two hazardous chemicals to Candidate List

(Publication date 14 June 2023)

ECHA has added two new chemicals to the Candidate List. One is toxic for reproduction and the other has very persistent and very bioaccumulative hazardous properties. They are used, for example, in inks and toners and in the production of plastic products.

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New EU chemicals enforcement project to focus on products sold online

(Publication date 20 June 2023)

ECHA's Enforcement Forum agreed to launch an EU-wide project to check that products sold online comply with REACH restrictions and the requirements of the Classification, Labelling and Packaging (CLP) Regulation. Its subgroup on Biocidal Products Regulation, BPRS, agreed to launch a project on labelling of biocidal products.

Inspections in this REACH-EN-FORCE (REF)-13 project will take place in 2025. The objective is to check that products, such as toys, common household goods or chemicals, sold online comply with REACH restrictions. Inspectors will also check that mixtures are classified, labelled, and packaged in line with CLP and that online offers include the required information about the hazards of the mixture. Inspectors may also check compliance with restrictions under the Persistent Organic Pollutants (POPs) Regulation and the Restriction of Hazardous Substances (RoHS) Directive.

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EU to Revise the Cosmetics Regulation (EC) No 1223/2009

(Publication date Jun 28, 2023)

On June 8, 2023, the European Union issued a notification G/TBT/N/EU/986 to the World Trade Organization (WTO), proposing to revise the following appendices of the EU Cosmetics Regulation (EC) No 1223/2009:

- List of Substances Prohibited in Cosmetic Products (Appendix II);
- List of Substances Restricted in Cosmetic Products (Appendix III);
- List of Preservatives Allowed in Cosmetic Products (Appendix V); and
- List of UV Filters Allowed in Cosmetic Products (Appendix VI).

Preliminary Opinion open for comments: Deadline for comments: August 7, 2023

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EU SCCS Finalizes the Opinion as to Salicylic Acid

(Publication date 09 June 2023)

On December 15, 2022, EU Scientific Committee on Consumer Safety (SCCS) initiated a two-month public consultation on the preliminary opinion on Salicylic Acid (CAS No. 69-72-7). considering into account the feedback received, SCCS published the final opinion on June 9, 2023.

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EU SCCS Releases the Preliminary Opinion on Benzyl Salicylate

(Publication date 13 June 2023)

On June 13, 2023, EU Scientific Committee on Consumer Safety (SCCS) published the preliminary opinion on the use of Benzyl Salicylate (CAS No. 118-58-1) in cosmetics.

Benzyl Salicylate commonly serves a perfuming function in cosmetics. As an established contact allergen in humans, it is a restricted ingredient currently regulated under Regulation (EC) No 1223/2009 (Cosmetics Regulation), and subject to individual labelling requirement. To comply with this requirement, its presence shall be indicated in the ingredients list on product packaging when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.

Preliminary Opinion open for comments: Deadline for comments: August 24, 2023

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EU to Implement a Union-wide Ban on PFHxA in Cosmetics

(Publication date 21 June 2023)

On June 19, 2023, the EU notified WTO of a draft regulation aiming at amending the Annex XVII to Regulation (EC) No 1907/2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This draft proposes to prohibit the use of Undecafluorohexanoic Acid (PFHxA), its salts, and related substances in various applications, including cosmetics.

Preliminary Opinion open for comments: Deadline for comments: August 18, 2023

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EU Proposes Amendments to Use Restrictions on D4, D5, D6 in Cosmetics

(Publication date 27 June 2023)

On June 22, 2023, EU introduced new amendments to the Annex XVII to Regulation (EC) No 1907/2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) through a draft regulation notified to WTO. This draft proposes to further restrict the use of Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), and Dodecamethylcyclohexasiloxane (D6) in cosmetics as well as other consumer and professional products.

Preliminary Opinion open for comments: Deadline for comments: August 21, 2023

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Health Canada Consults On Fragrance Labelling Regulations

(Publication date 11 Apr 2023)

Health Canada has launched a consultation on its proposal to mandate the disclosure of fragrance-based allergens on cosmetics labels, according to a report published by Lexology. The consultation is open to the industry, stakeholders,

Preliminary Opinion open for comments: Deadline for comments: April 22, 2023

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Canada Introduces Legislation to Ban Cosmetic Animal Testing and Trade

(Publication date 26 April 2023)

In the Budget, the government proposes to amend the Food and Drugs Act to ban cosmetic testing on animals. The proposed amendments would prohibit:

- testing cosmetics on animals in Canada.
- selling cosmetics that rely on animal testing data to prove the product's safety, with some exceptions.
- false or misleading labelling related to the testing of cosmetics on animals.

The proposed policy will align with the animal testing ban in the EU, as well as fit and be workable within the Canadian regulatory framework.

Preliminary Opinion open for comments: Deadline for comments: August, 2023

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California DTSC Plans To Add Microplastics To Candidate Chemicals List

(Publication date 03 May 2023)

California's Department of Toxic Substances Control proposes adding microplastics to its list of Candidate Chemicals, which would not have a regulatory impact at first but could lead to Priority Product selections, alternatives analyses, and regulatory responses to reduce or eliminate adverse impacts to public health and the environment. Microplastic-containing cosmetics are among products in the DTSC's line of sight.

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How The US FDA Is Checking For Adequate Controls Against DEG/EG Ingredient Substitution

(Publication date 18 May 2023)

Agency has increased its efforts to protect the US market from the diethylene glycol and ethylene glycol adulteration linked to hundreds of deaths in seven countries with testing, remote records requests, inspections, import alerts and more. Manufacturing quality compliance director Francis Godwin stresses importance of testing every container, while sharing tips for simplifying the task.

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US FTC Pushed For Environmental Reg Harmonization, Organic Definition – 'Green Guides' Comments

(Publication date 22 May 2023)

Cosmetics industry stakeholders agree the US Federal Trade Commission's "Green Guides" are ripe for an update. Issues old and new need to be addressed and state-level laws and regulations considered along with national and international programs and standards, say leading companies, trade associations, and consumer advocacy groups in comments to the agency.

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Minnesota Introduces Comprehensive Ban on PFAS and Regulates Heavy Metals in Cosmetics

(Publication date 02 Jun 2023)

The US state of Minnesota has approved measures to regulate PFAS and heavy metals in a wide variety of products. The provisions relating to PFAS will be implemented in phases, starting January 1, 2025.

On May 24, 2023, the governor of Minnesota signed HF 2310 (Chapter 60, 2023) into law. As an omnibus environment and natural resources bill, it sets budget appropriations to related agencies and a wide array of provisions regarding environmental matters. Specific sections of the law regulate perfluoroalkyl and polyfluoroalkyl substances (PFAS) and two heavy metals (lead and cadmium) in a wide range of products

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Eight Technical Guidelines for the Testing of Cosmetic Products and New Cosmetic Ingredients

(Publication date 06 May 2023)

China National Institutes for Food and Drug Control (NIFDC) started a public feedback process for the draft Technical Guidelines for Skin Sensitization Test. Consisting of five parts, the draft introduces the basic test principles and contents, and gives instructions on result analysis and evaluation.

Preliminary Opinion open for comments: Deadline for comments: May 20, 2023

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China Consults on Guidelines for Submitting Information through the Cosmetic Ingredient Safety Information Submission Platform

(Publication date 17 May 2023)

The objective of developing the Guidelines is to provide guidance to ingredient manufacturers on the correct use of the Ingredient Safety Information Submission Platform (the Platform) and standardize the submission of ingredient safety information. The Guidelines consists of 12 Articles, including the basis, purpose, application scope, submitting entity, submission content, the generation and use of ingredient submission codes, etc.

Preliminary Opinion open for comments: Deadline for comments: May 31, 2023

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Thailand to Ban PFAS in Cosmetic Products

(Publication date 17 May 2023)

Thailand will soon issue an updated list of prohibited cosmetic ingredients that includes 13 kinds of PFAS and their derivatives.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are synthetic chemicals widely used in consumer and industrial products. In cosmetic applications, they are sometimes used to condition and smooth the skin to make it appear shiny and used to improve product spreadability. However, they do not readily degrade and will accumulate in the environment and in living organisms, posing potential health risks.

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China Issues the First License for Cosmetic Personalized Service

(Publication date 24 May 2023)

On April 26, 2023, the SkinCeuticals store located in Shanghai Pudong New Area was granted a cosmetic production license for on-site personalized service by the Shanghai Municipal Medical Products Administration (MPA). This license allows the enterprise to provide consumers with personalized services that involve direct contact with cosmetic contents at the store, akin to bringing the factory to the store and producing custom-made products. As the first license of its kind in China, it marks a major achievement and a milestone in the development of the personalized cosmetics industry in both Shanghai and nationwide.

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China Consults on Technical Guidelines for Filling in and Submitting Cosmetic Formula

(Publication date May 4, 2023)

NIFDC released the draft Technical Guidelines for Filling in and Submitting Cosmetic Formula for public consultation. The draft provides instructions for enterprises seeking to register or notify special/general cosmetics and outlines the requirements for completing the cosmetic formula table.

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China Proposes Technical Guidance on Ingredient Safety Information Filling and Submission

(Publication date 09 May 2023)

NIFDC initiated a public consultation on the Technical Guidelines for Filling in and Submitting Safety Information of Cosmetic Ingredients (the Guidelines). Consisting of 11 parts, the Guidelines systematically outlines the vital points and technical principles for filling in and submitting the ingredient safety information, covering aspects of ingredient's basic information, brief descriptions of ingredient's production technique, necessary quality control requirements, limitation requirements for risk substances, etc.

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Taiwan Region Proposes Changes to Particulars of Specific Purpose Cosmetics That May Be Voluntarily Modified

(Publication date 26 May 2023)

Subject to Cosmetic Hygiene and Safety Act, the pre-market registration requirement for specific purpose cosmetics will be replaced with notification and the establishment of a product information file (PIF) starting on July 1, 2024. In line with this transition, on May 19, 2023, Taiwan Food and Drug Administration (TFDA) proposed to revise Particulars of Specific Purpose Cosmetics That May Be Voluntarily Modified. Once the amendment takes effect, cosmetic enterprises will be allowed to delete the separately listed specific purpose ingredients from product labels at their discretion.

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ASEAN Updates Cosmetic Ingredient Annexes for ACD: 42 New Ingredients Added and 10 Revised

(Publication date 31 May 2023)

In January 2023, ASEAN introduced the latest amendments to the ingredient annexes to ASEAN Cosmetic Directive (ACD). These amendments were approved in the 36th ASEAN Cosmetic Scientific Body (ACSB) meeting.

The main amendments include:

1. adding 42 prohibited ingredients, and revising the requirements for 1 prohibited ingredient;
2. revising the requirements for 4 restricted ingredients;
3. revising the requirements for 1 permitted colorant;
4. revising the requirements for 3 permitted preservatives;
5. revising the requirements for 1 permitted UV-filter.

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