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GLOBAL COSMETICS REGULATORY INTELLIGENCE

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Regulatory Intelligence of Cosmetics – EMEA

New QSAR assessment framework supports alternatives to animal testing. (Publication date October 10, 2023)

The framework helps regulators to assess quantitative-structure activity relationships (QSAR) studies, used as an animal-free method to gain data on chemicals.

The Organisation for Economic Cooperation and Development (OECD) has published the framework for assessing QSARs, developed by an expert group led by ECHA and the Italian National Institute of Health, ISS. It guides regulators in evaluating computational results and enhances confidence in accepting alternative methods for chemical hazard assessment. This helps build confidence in the use of QSARs and reducing reliance on animal testing. Read More

ECHA to prepare restriction proposal on chromium (VI) substances. (Publication date October 11, 2023)

The European Commission has requested ECHA to prepare a REACH restriction proposal on certain chromium (VI) substances currently on the Authorisation List of substances of very high concern.

ECHA has received a mandate from the European Commission to prepare an Annex XV report for possible restriction of at least the chromium (VI) substances that are currently in entries 16 and 17 of the REACH Authorisation List (Annex XIV). ECHA will submit the proposal by 4 October 2024.The restriction proposal aims to address the challenges posed by the current and possible future workload both for ECHA and the Commission. This workload stems from the high number of applications for authorisation to use these substances, already submitted or potentially coming from hundreds of companies. For ECHA, evaluating the applications and concluding opinions on them would go beyond the available resources of the committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) and would affect their work in regulating other hazardous chemicals. Read More

ECHA recommends more transparency in the trade of hazardous chemicals. (Publication date October 25, 2023)

The European Chemicals Agency (ECHA), with the aim of improving the EU's implementation of the Prior Informed Consent (PIC) Regulation, that governs the export and import of hazardous chemicals and pesticides, is making recommendations for changes to the legal text.

ECHA's third report on the operation of the Prior Informed Consent (PIC) Regulation shows that the overall workload of implementing the regulation, despite a slight decrease of export notifications, has continued to increase due to the constant addition of new chemicals subject to PIC and the increase in substances subject to explicit consent from non-EU importing countries prior to export. Read More

Water-soluble zinc salts used in oral hygiene products - Submission II (Publication date November 6, 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 1 year because the intake exceeds the upper limit level. For children between 6 months and 1 year of age, 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% Zn is considered safe across all age groups above 6 years.

Read More

EU SCCS Releases the Preliminary Opinion on Benzophenone-4 (Publication date 15 December 2023)

EU Scientific Committee on Consumer Safety (SCCS) issued a preliminary opinion on the use of Benzophenone-4 (CAS No. 4065-45-6) in cosmetics. The opinion is open for comments until February 16, 2024.

Currently, Benzophenone-4 is regulated under Regulation (EC) No 1223/2009 (Cosmetics Regulation) as a UV-filter in sunscreen products, with a permitted concentration of up to 5%. In CosIng, it is also reported with the functions of UV-stabiliser and UV-absorber, protecting cosmetic formulations against sunlight. In response to concerns regarding its endocrine disrupting properties, the European Commission launched a call for data on Benzophenone-4 in 2021. Based on the scientific evidence provided by stakeholders, SCCS has assessed its use in cosmetics and prepared this opinion.

Considering assessment results, SCCS is of the opinion that Benzophenone-4 is safe when used as a UV filter up to a concentration of 5% in sunscreen, face and hand creams, lipstick, sunscreen propellant spray, and pump spray, either used separately or in combination. Read More

SCCS - Preliminary Opinion open for comments on the safety of aluminium in cosmetic products - Submission IV (Deadline for comments: 16 February 2024) (Publication date 15 December 2023)

In light of the new data provided, does the SCCS consider Aluminium compounds safe when used in cosmetic products? In the event that the estimated exposure to Aluminium from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for each category and product type. Read More

SCCS - Final Opinion on Methylparaben (Publication date 15 December 2023)

In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Methylparaben, does the SCCS consider Methylparaben safe when used as a preservative in cosmetic products up to a maximum concentration of 0.4% (as acid) when used on its own and up to 0.8% (as acid) for mixtures of esters as indicated in entry 12 of Annex V to the Cosmetics Regulation? On the basis of the safety assessment considering all available data and the concerns related to endocrine activity, the SCCS is of the opinion that the use of Methylparaben as a preservative in cosmetic products at concentrations of up to 0.4% (expressed as acid) is safe. Read More

SCCS - Final Opinion on Silver Zinc Zeolite (Publication date 22 December 2023)

In light of the data provided and taking under consideration the classification as Toxic for reproduction Cat. 2, does the SCCS consider Silver Zinc Zeolite safe when used as a preservative in cosmetic products according to the specifications and concentration limits provided in the dossier submission? The SCCS considers that Silver Zinc Zeolite (CAS No. 130328-20-0) incorporating a maximum silver content of 2.5% is safe in spray deodorant and powder foundation when used at the proposed concentration of 1%. Read More

SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation - 12th revision: Corrigendum adopted on 21 December 2023 (Publication date 22 December 2023)

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)
- Updating of in silico prediction possibilities
- Exposure of children to different cosmetic product categories according to age
- Sun protection by sunscreen products: rationale behind exposure data
- Human biomonitoring (HBM) and differences with SCCS approach for risk assessment
- CMRs reporting requirements. Read More

EU and Greenland sign strategic partnership on sustainable raw materials value chains (Publication Date: 30 November 2023)

EU signed a Memorandum of Understanding (MoU) with the Government of Greenland for a strategic partnership to develop sustainable raw materials value chains.

Executive Vice-President for the European Green Deal, Interinstitutional Relations and Foresight of the European Commission, Maroš Šefčovič, signed the MoU with the Government of Greenland, Minister of Business, Trade, Mineral Resources, Justice and Gender Equality, Naaja H. Nathanielsen.

Greenland's extensive natural riches are a major asset for reaping the benefits of global value chains, as it seeks to diversify its economy in a sustainable way. 25 of the 34 critical raw materials identified by the Commission as strategically important for Europe's industry and the green transition can be found in Greenland. Read More

Commission welcomes provisional agreement on improving classification, labelling and

packaging of hazardous chemicals (Publication Date: 5 December 2023)

The Commission welcomes the provisional agreement reached today between the European Parliament and the Council on the revision of the regulation on the classification, labelling and packaging of chemicals (CLP). While improving the functioning of the EU market regarding products containing hazardous chemicals, the new measures will better protect consumers, workers, and the environment. The revised text will also accelerate the identification of hazardous substances and mixtures at EU level. The revision will improve communication about hazardous chemicals including for chemicals sold online. It also lays down rules on refill sales and provides more flexibility on how to use the labels. Read More

Commission welcomes political agreement on the Critical Raw Materials Act (Publication Date: 13 November 2023)

The Commission welcomes the political agreement reached today between the European Parliament and the Council on the Critical Raw Materials Act (CRMA). The Act sets out a series of comprehensive actions to ensure the EU's access to a secure, diversified, affordable and sustainable supply of critical raw materials. This is essential for the competitiveness of Europe, including for green and digital industries as well as defence and aerospace.

The new rules help to increase domestic capacities for critical raw materials along the supply chain, complementing initiatives to diversify their supply through international partnerships supported by the Global Gateway facility. The agreed benchmarks specify that the EU should have the capacity to extract 10%*, process 40%, and recycle 25% of its annual consumption of strategic raw materials by 2030. Read More

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FDA Issues Final Guidance on Registration and Listing of Cosmetic Product Facilities and Products (Publication date December 18, 2023)

The U.S. Food and Drug Administration, issued a final guidance for industry on cosmetic product facility registrations and product listings, as mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

The guidance assists stakeholders with cosmetic product facility registration and product listing submissions to FDA, by describing who is responsible for making the registration and listing submissions, what information to include, how to submit, when to submit, and certain exemptions to the registration and listing requirements. Read More

FDA Announces Launch of Cosmetics Direct for Electronic Registration and Listing of Cosmetic Product Facilities and Products (Publication date December 18, 2023)

The U.S. Food and Drug Administration (FDA) announced the launch of its Cosmetics Direct electronic submission portal for registration and listing of cosmetic product facilities and products, mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

Cosmetics Direct is an FDA Structured Product Labeling (SPL) authoring tool, for cosmetic product facility registration and cosmetic product listing, with user-friendly data entry forms that creates, validates, saves, submits, processes, and automatically transmits the SPL submission to FDA for internal processing without having to use the Electronic Submissions Gateway (ESG). Read More

FDA Issues Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing (Publication date November 8, 2023)

The U.S. Food and Drug Administration (FDA) issued guidance on its intent to delay enforcement of the requirements for cosmetic product facility registration and cosmetic product listing requirements under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) for six months to help ensure that industry has sufficient time to submit such facility registration and product listing information.

MoCRA provided new authorities to FDA including:

- Facility Registration: Cosmetic product manufacturers and processors must register their facilities with FDA, update content within 60 days of any changes, and renew their registration every two years.
- Product Listing: A responsible person must list each marketed cosmetic product with FDA, including product ingredients, and provide any updates annually. Read More

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FDA Publishes Structured Product Labeling (SPL) Implementation Guide with Validation Procedures for Cosmetic Product Facility Registrations and Product Listings (Publication date November 14, 2023)

The U.S. Food and Drug Administration published an updated Structured Product Labeling (SPL) Implementation Guide with Validation Procedures today, November 14, 2023. The guide includes updates to the cosmetics product facility registrations and product listings that are included within the SPL framework. Read More

FDA Issues Updated Instructions for Serious Adverse Event Reporting for Cosmetic Products (Publication date December 14, 2023)

The U.S. Food and Drug Administration (FDA) is providing an update on ongoing activities related to serious adverse event reporting mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which are enforceable starting December 29, 2023.

A responsible person is required to report serious adverse events associated with the use of cosmetic products in the United States to FDA within 15 business days. The responsible person must include a copy of the label on or within the retail packaging of such cosmetic product. If the responsible person receives medical or other information about the adverse event within 1 year of the initial report to FDA, they must submit this new information to FDA within 15 business days. Read more

FDA Issues Update on Cosmetic Product Facility Registration and Cosmetic Product Listing (Publication date November 1, 2023)

The U.S. Food and Drug Administration (FDA) is providing an update on ongoing activities related to the new cosmetic product facility registration and cosmetic product listing mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

In August 2023, FDA issued draft guidance on cosmetic product facility registrations and product listings. FDA received more than 40 comments on the draft guidance and is in the process of evaluating the comments. Read More

EPA Begins Process to Prioritize Five Chemicals for Risk Evaluation Under Toxic Substances Control Act (Publication date December 14, 2023)

The U.S. Environmental Protection Agency (EPA) announced that it is beginning the process to prioritize five additional toxic chemicals for risk evaluation under the nation's premier chemical safety law. If, during the 12-month long statutory process, EPA designates these five chemicals as High Priority Substances, EPA will then begin risk evaluations for these chemicals.

EPA plans to prioritize the following chemicals for risk evaluation under the Toxic Substances Control Act (TSCA):

- Acetaldehyde (CASRN 75-07-0),
- Acrylonitrile (CASRN 107-13-1),
- Benzenamine (CASRN 62-53-3),

- 4,4'-Methylene bis(2-chloroaniline) (MBOCA) (CASRN 101-14-4), and
- Vinyl Chloride (CASRN 75-01-4). Read More

cVMS in Hair Care Products Pose Threats to the Environment (Publication date November 16, 2023)

A recent study reveals that hair care products release significant amounts of cyclic volatile methyl siloxanes (cVMS) in both indoors and outdoors. cVMS not only pollutes indoor air but also affects the external environment. Moreover, its long exposure may be bio accumulative and has the potential to cause harm to the environment. Read More

EPA Takes Action to Protect People from PFAS that Leach from Plastic Containers into Pesticides and Other Products (Publication date December 1, 2023)

The U.S. Environmental Protection Agency (EPA) issued orders to Inhance Technologies LLC (Inhance) directing it not to produce per- and polyfluoroalkyl substances (PFAS), chemicals that are created in the production of its fluorinated high-density polyethylene (HDPE) plastic containers. This action, taken under the authority of the Toxic Substances Control Act (TSCA), will help protect the public from exposure to dangerous PFAS chemicals in containers used for a variety of household consumer, pesticide, fuel, automotive and other industrial products. Read More

EPA Proposes Stronger Rules to Protect People from Persistent, Bioaccumulative, and Toxic Chemical Exposures (Publication date November 20, 2023)

The U.S. Environmental Protection Agency (EPA) released a proposed rule to further protect people from exposure to two chemicals that are toxic, remain in the environment for long periods of time, and accumulate in the body. Both decabromodiphenyl ether (decaBDE) and phenol, isopropylated phosphate (3:1) (PIP (3:1)) are persistent, bioaccumulative and toxic (PBT) chemicals that were subject to risk management rules under the Toxic Substances Control Act (TSCA).

EPA's proposed rule would impose workplace safety protections and restrict water releases. It would also address broader implementation issues affecting the supply chains of various industry sectors including the nuclear energy sector, transportation, construction, agriculture, forestry, mining, life sciences, and semiconductor production. Read More

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China NIFDC Details Principles for Determining and Researching New Cosmetic Ingredients (NCIs) (Publication date December 1, 2023)

NIFDC released the second draft of the Technical Guidelines for Determination and Research of New Cosmetic Ingredients (NCIs). The purpose of the Guidelines is to establish standardized guiding principles for the identification and research of New Cosmetic Ingredients. It offers comprehensive information on NCI categorization, as well as the research content of and naming requirements for NCIs. Read More

Notice on the release of the "Working Mechanism for Communication and Exchange of New Cosmetic Raw Materials (Trial)" (Publication date December 1, 2023)

In order to encourage and support the research and innovation of new cosmetic raw materials, and standardize the communication between registrants and filers of new cosmetic raw materials and cosmetics technical review departments, in accordance with the "Cosmetics Supervision and Administration Regulations" and the "State Food and Drug Administration's Regulation on Encouraging New Cosmetic Raw Materials" According to the relevant requirements of the "Announcement on Matters Related to Innovation and Standardized Management" (No. 143 of 2023), our institute has formulated the "Working Mechanism for Communication and Exchange of New Cosmetic Raw Materials (Trial)", which is now released. Registrants and filers of new cosmetic raw materials can apply for communication and exchange on important technical issues through the cosmetics smart application review system before applying for registration or filing. Read More

Notice on publicly soliciting opinions on the "Technical Guiding Principles for Definition and Research of New Cosmetic Raw Materials (Draft for Comments)" (Publication date December 1, 2023)

In order to standardize and guide the definition and research of new cosmetic raw materials, in accordance with the relevant requirements of the "Cosmetic Supervision and Administration Regulations" and the "State Food and Drug Administration Announcement on Matters Concerning Encouraging Innovation and Standardizing the Management of New Cosmetic Raw Materials (2023 No. 143)", The Cosmetics Supervision and Administration Department of the State Medical Products Administration once again organized the National Medical Products Administration to draft the "Technical Guiding Principles for Definition and Research of New Cosmetic Raw Materials (Draft for Comments)" and Drafting Instructions , which are now publicly soliciting opinions from the public. Read More

MFDS becomes the first to be WHO-Listed Regulatory Authority (Publication date: November 08, 2023)

Korea's outstanding regulatory system and capabilities have been internationally recognized- The WLA's status is expected to grant Korea favourable conditions for international procurement of pharmaceuticals and correspondingly expand exports.

The Ministry of Food and Drug Safety (Minister Oh Yu-Kyoung), Republic of Korea officially stated on November 1st (KST) that WHO announced that MFDS has been listed as WHO-Listed Authority (as of October 26, 2023) on October 31, 2023 (local time in Geneva). Read more

Announcement of the State Food and Drug Administration on matters related to encouraging innovation and standardizing management of new cosmetic raw materials (2023 No. 143)

(Publication date: November 10, 2023)

In order to encourage and support the research and innovation of new raw materials for cosmetics, standardize the research and development, use and registration and filing management of new raw materials, ensure the quality and safety of raw materials and products, protect the health of consumers, and promote the healthy development of the cosmetics industry, in accordance with the "Regulations on the Supervision and Administration of Cosmetics" (hereinafter referred to as the "Regulations") "), "Measures for the Administration of Registration and Filing of Cosmetics" (hereinafter referred to as the "Measures") and other laws and regulations, the matters related to strengthening the management of new raw materials for cosmetics are hereby announced as follows. Read more

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