

# Regulatory Newsletter

This newsletter provides updates on important regulatory issues and developments of interest to Sun Chemical customers.



## INDUSTRY ASSOCIATIONS – OPINIONS AND POSITIONS

### Industry ECHA Meeting 2024

The annual Industry ECHA (European Chemicals Agency) Meeting held on June 17-18 covered various topics ranging from the release of the latest versions of the IUCLID software and CHESAR tool, the launch of the new ECHA CHEM platform, the forthcoming new submission portal that aims to integrate different regulatory frameworks, and the release of the third edition of the OECD (Organisation for Economic Co-operation and Development) guidance on the grouping of chemicals (GD 194).

In addition to these technical topics, the industry (Cefic/Eurometaux/CONCAWE) raised their concerns regarding the ARN (Assessment of Regulatory Needs) reports. Cefic presented the industry's position on the ARNs activities as streamlined in the position paper submitted to ECHA at the end of 2023 and expressed the disappointment that in some cases ARN grouping is not based on a solid/robust assessment.



ECHA insisted, however, that the industry failed to provide relevant information about why grouping is not appropriate. Instead, they argue why the specific classification would not be relevant or not applicable, respectively. At least the new submission portal aims to facilitate the feedback submission process, allowing companies to reply to ARN communications and enhance the export of relevant (additional) data in various formats.

Furthermore, the Board of Appeal (BoA) case on 'cease of manufacturing/tonnage downgrade' was discussed. The Board of Appeal's decision in November 2021 (joined cases A-006-2020 and A-007-2020), clarified that tonnage band downgrades after receiving a draft compliance check decision could constitute new significant information and should be taken into account by ECHA.

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These downgrades may be scrutinized for abuse without objective industrial or commercial considerations. Thus, ECHA accepts downgrades made after the submission of a draft decision if the registrant informs ECHA and updates the dossier accordingly; however, if the downgrade appears to be a tactic to avoid compliance requirements without objective reasons, it may be scrutinized and possibly rejected.

The industry also addressed the dilemma of older (animal) studies that may not be in compliance with current OECD guidelines (and REACH Standard Information requirements) which might have an impact on the tests' acceptance of the read-across validity and on mutual acceptance of data (MAD).

ECHA pointed out that the agency is legally not bound by the MAD system since the EU has not acceded to the OECD convention. The industry proposed that studies performed according to guidelines valid at the moment of the registration submission could be accepted by default. ECHA instead stated that any new study should comply with the latest version of OECD guidelines or the EU Test Methods Regulation.

## UPCOMING GLOBAL CHANGES AND REGULATIONS

### Follow-up to Amendment of the European POP Regulation by New PCB Limit Values

The amendment of the Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs) regarding the introduction of an Unintentional Trace Concentration (UTC) limit for polychlorinated biphenyls (PCBs), was discussed again during the 30th Competent Authorities meeting held in June 2024.

The latest proposal (29th meeting in November 2023) was a UTC limit value of 0.1 ppm for all chemicals and a derogation for organic pigments that foresees 25 ppm upon entry into force, then 10 ppm three years after entry into force and finally 0.1 ppm six years after entry into force.

After the 29th POP meeting, several comments were received from member states (MS) as well as industry associations. While some MS expressed concerns regarding suitable analytical methods or the inability of the EU pigment industry to meet the limits for many necessary colors, others claimed that the limits would be too generous, and industry would have had sufficient time to adapt.

The industry commented that 0.1 ppm is technically not feasible for the vast majority of the chlorinated organic pigments and that by-product PCBs cannot be simply extracted out of the final pigment. They pointed out that downstream industries would likely be severely affected including the automotive sector, aviation, building and construction, textiles, publications, and printed packaging, and that the limit would drive pigment, mixture and finished article production to third countries, outside of the EU.

Finally, the Commission sees support for the approach of a default UTC limit value of 0.1 ppm and an exemption for organic pigments. Based on the information received from the industry, a limit value of 0.1 ppm appears to be technically not feasible. A limit value of 10 ppm did not seem to be contested much, however. Furthermore, the Commission understands that it is of importance to specify an analytical method, and that the derogation wording should also cover the downstream users of organic pigments. The resulting proposal is therefore as follows:

- Identification: CAS = 1336-36-3 and others; EC = 215-648-1 and others, as is currently the case in Annex I and Annex IV to the POPs Regulation,
- UTC limit value: 0.1 ppm,
- Derogation for organic pigments and mixtures and articles containing organic pigments: 25 ppm upon entry into force; 10 ppm three years after entry into force,
- Concentration determination methods: specification in legal text: ISO 787—28/2019.

Member states are now invited to comment on the proposal and the Commission envisages to proceed with the adoption of the delegated act, assuming that all comments are now appropriately reflected in the draft measure.



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### Upcoming IARC Classification for Acrylonitrile

Acrylonitrile was evaluated by the International Agency for Research on Cancer (IARC). In its [press release](#) in June, IARC announced that acrylonitrile is now classified as carcinogenic to humans (Group 1). The strongest evidence came from a large cohort study of workers in different industries producing or using acrylonitrile. In this study, workers with higher exposure to acrylonitrile had a higher rate of lung cancer mortality compared with workers with lower exposures.

Acrylonitrile is a volatile organic compound that is mainly used in the production of polymers. Uses of these polymers include fibers for clothing, carpets, and other textiles, as well as plastics for consumer products. Occupational exposure may occur during the production of acrylonitrile and its use in polymer production.

### Washington State Toxic Free Cosmetics Act



In May 2023, Washington State adopted the [Toxic Free Cosmetics Act](#) that aims to ban certain chemicals from personal care products within two years. The measure (HB 1047) is the “strongest” legislation in the US regulating chemicals in cosmetics, according to the nongovernmental organization, Toxic-Free Future (TFF).

Beginning January 1, 2025, it will prohibit several intentionally added substances in cosmetic products such as ortho-phthalates, formaldehyde or per- and polyfluoroalkyl substances (PFAS). In June 2024, the Department of Ecology announced during a [webinar](#) that formaldehyde releasing agents will be added to the list for the first set of restrictions.

Washington State’s legislation also prohibits lead or lead compounds at 1ppm or above, which raised concerns in the industry. The Personal Care Product Council (PCPC) said the legislation “is not consistent with California law and federal guidance in addressing unavoidable traces of elements found naturally in the environment, such as in soil and water.” The trade association said that it supports limits on the heavy metal, consistent with guidance developed by the U.S. Food and Drug Administration (FDA). The HB 1047, however, would establish an unrealistic and unreasonable requirement for personal care product development and production. PCPC filed a formal appeal of Washington Ecology’s denial of their petition to conduct rulemaking to set a higher limit for lead impurities in cosmetics.

Retailers will have until 2026 to sell existing stocks of non-compliant products.

A [preliminary draft](#) of the rule was published in July, offering a blueprint for the implementation of future cosmetics restrictions in the state. Comments were due by the 13th of August. The agency anticipates launching another consultation on a formal draft rule in November, followed by public hearings in December and final rule adoption next summer.



### FOOD CONTACT MATERIALS

#### Ban of Bisphenol A in Food Contact Materials



An EU member states expert committee has backed a [European Commission proposal](#) to ban bisphenol A (BPA) and other bisphenols in food contact materials (FCMs), moving the proposal one step

closer to adoption. The draft regulation, released in February, proposes a ban on the use of BPA and other bisphenols in plastics, printing inks, adhesives and rubbers in FCMs, and is set to enter into force in 2026. The draft proposes an 18-month transition period for most uses. However, the Commission proposes a longer 36-month transition period for applications that will take manufacturers longer to replace with alternatives that maintain food safety.

The proposal follows an [opinion](#) from the European Food Safety Authority (EFSA), which said a 20,000-fold reduction in the safe limit for human ingestion of BPA is necessary based on evidence of immunotoxicity. The European Parliament and Council of Ministers will assess the proposal. If there is no opposition, the ban could be adopted by the end of 2024.

#### 18th Amendment to the Plastics Regulation EC 10/2011

In March, the European Commission has published a draft regulation proposing additional requirements for the use of plastics in food contact materials (FCM). The 18th amendment to the [plastics FCMs regulation](#) (Regulation (EU) No 10/2011) aims to align with the Regulation on Recycled Plastics and the Biocidal Products (Regulation (EU) 2022/1616).

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The proposal includes the introduction of purity criteria (Articles 3 and 8) for all substances used in the production of plastic materials and articles, including those obtained from waste or from natural origin. According to some industry associations, there are concerns that these proposed stringent quality requirements may create significant obstacles to the continued use of plastics in FCMs in the EU.

The draft amendment would also impact the migration testing of multi-layer materials, namely the application of migration limits when a plastic layer is in direct contact with food. A review of the tests and labeling for articles intended for repeated use is also expected. The adoption of the new regulation is scheduled for the second quarter of 2024, including an 18-month transition period.

The DG Sante stakeholder event in June informed on the overall expected regulatory changes summarizing the ban on BPA, the quality amendment to regulation (EU) No. 10/2011 (Plastics Regulation) and possible amendments to regulation (EU) No. 2022/1616 (Recycled Plastics).

### Mineral Oil Hydrocarbons in Packaging, Inks and Food

Some mineral oil hydrocarbons pose a health concern in foods, according to an updated risk assessment by the European Food Safety Authority (EFSA). Mineral oil saturated hydrocarbons (MOSHs) and mineral oil aromatic hydrocarbons (MOAHs) can migrate into foods from a variety of sources, including food contact materials (FCM), processing aids and lubricants for machinery. In particular, FCMs can be contaminated via mineral oils and the hydrocarbons can also migrate from recycled paper and cardboard.



The European Commission foresees an amendment of Regulation (EC) No 333/2007 regarding the analysis of inorganic arsenic, lead and polycyclic

aromatic hydrocarbons in foodstuffs and certain performance criteria for analysis. Following the publication of the draft proposals (Rev2) and a stakeholder forum held in January, many stakeholders sent further written comments to DG SANTE. These comments and also the stakeholder data

have been studied and a first discussion about them took place in the Working Group on Industrial and Environmental Contaminants in Food in June followed by the publication of an FAQ document. The commodity specific comments and data were further discussed in order to come to a revised draft of the proposal. A third revision of this draft was circulated to the stakeholders in July. In view of the ongoing discussions, a possible vote on the proposals will be scheduled at the earliest in Q1 2025. Challenging from an analytical point of view, according to EuPIA and EFSA, method IP 346 is not considered appropriate to ensure the absence of MOAH. An alternative method was not mentioned or recommended.

In addition to the work of the European Commission regarding mineral oils in foodstuff, France foresees a ban on mineral oil hydrocarbons in packaging and inks that is not limited to sensitive applications or FCMs. In 2021, France published Decree No. 2020-105 on the 'Fight Against Waste and the Circular Economy.' Important for the packaging industry is Article 112 as it prohibits mineral oils on packaging and for printing. Decree No. 2020-1725 'Various Adaptation Provisions Relating to Extended Producer Responsibility' and articles D.543-45-1 and D.543-213, respectively, describe various adjustment provisions related to extended producer responsibility and the conditions for prohibiting mineral oils in packaging and printing inks intended for the public.

France's Ministry for Ecological Transition issued a corresponding Order in 2022 to specify the requirements on the regulation of mineral oils and the implementation timeline. The Order became effective on January 1, 2023, and contains important limits, provisions and definitions.



In Article 2, the substances of concern are specified (MOAH with 1 to 7 aromatic rings; MOSH with 16 to 35 carbon atoms), and restriction limits and deadlines are defined (until December 31, 2024, the ban on the use of mineral oils applies when the MOAH concentration by mass in the ink is > 1%. From January 1, 2025, the mass concentration of MOAHs in the ink shall not exceed 0.1% or the mass concentration in the ink of compounds with 3 to 7 aromatic rings shall not exceed 1 ppm. For MOSH, the mass concentration in the ink shall not be greater than 0.1%.

According to EuPIA, the stipulated limit values mean that any ink formulations containing intentionally added mineral oils can be considered to not meet the French law thresholds and should therefore not be used. The limits in the French Order are low enough that unintentionally added trace mineral oils could result in findings above limit values. In the absence of a harmonized analytical method for the quantification of MOSH/MOAH, general declarations of "mineral oil free" inks down to ppm levels should be considered with caution. Therefore, EuPIA strongly recommends that for the time being, compliance work should rely on a best practice approach, focusing on open discussions with the printing ink manufacturers and accompanied by fact-based regulatory statements.

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## EUROPE—UPCOMING CHEMICALS LEGISLATIONS AND GUIDANCE DOCUMENTS

### CLH Proposal for Silica (STOT RE 1)

On June 10, 2024 ECHA published a [proposal for a harmonized classification and labeling](#) in the hazard class specific target organ toxicity-repeated exposure 1 (STOT RE 1) for silica. The public consultation closed in August. Several industry associations and consortia, such as ASASP, SASforREACH or Eurocolour, sent their comments, pointing out that silicon dioxide has no intrinsic toxicity and that the guidance limits provided in the CLP are therefore not applicable (as tailored for chemicals with intrinsic toxicity). ASASP considered furthermore that silica is safe as placed on the market due to their particle size and the low probability for respiration. The deadline for adoption of the RAC opinion is November 2025.



### EU PFAS Restriction Proposal Not Coming in 2025

The European Commission is now “pretty sure” it will not be able to publish its universal PFAS restriction in 2025 as originally foreseen, an official for the executive has said. It is the first time a delay to the heavily anticipated and

controversial proposal has been voiced officially by the Commission.

ECHA’s risk assessment committee (RAC) is currently assessing a record number of comments received in a public consultation, using a sector-by-sector approach. The five countries that submitted the initial dossier are also in the process of updating their document with information from the comments.

Meanwhile, two EU member states, France and Denmark, are pressing ahead with PFAS bans at a national level.

### EU Commission Restriction Roadmap



The European Commission has finalized its update of the REACH restrictions roadmap, further delaying the timelines for upcoming bans on some substance groups and refining them for others. It published the final version of the revised roadmap seven months after starting discussions on the amendments with member state authorities.

With the REACH revision delayed and facing increased uncertainty due to political pressures and the upcoming new EU parliament after the

elections, campaign groups are intensifying their efforts to pressure the Commission to efficiently implement the restrictions outlined in the roadmap. NGOs had complained about the update of the roadmap when it was circulated in November, saying it must include “precise and ambitious” timelines for chemical bans and the Commission should be transparent on the reasons for any delays in the decision-making process. The final version, published on July 1, clarifies some of the timeline delays.

A major addition in the draft update of the roadmap was a potential ban on a large group of hydrocarbyl siloxanes due to their persistent and bioaccumulative properties damaging the environment. The final version does not change the timing of the ban. It says ECHA, member states and the Commission are currently assessing the need for further regulatory management measures and the formal restriction process will not begin before 2025.

On carcinogenic, mutagenic or toxic for reproduction (CMR) substances in childcare articles, it says the first discussion in the REACH committee is planned for October 2024, following ECHA’s investigation report last October.

The timelines for restrictions on other major substance groups, including bisphenols, lead chromates, substances in thermal paper and chromium VI compounds, were unchanged from predictions made in the draft roadmap.

### EU Occupational Health Body Lists Nine Candidates for Urgent Action

The European Commission’s main advisory body for occupational health (ACSH) has outlined nine chemicals and chemical groups that it says should be considered immediately for binding occupational exposure limits (OELs).

The ‘immediate priority’ substances are titanium dioxide, zinc oxide and poorly soluble low toxicity particulates (PSLTs), including aluminum, graphite, carbon black and talc. The committee says a scoping study should help clearly define the term PSLT and the widespread exposure across many employment sectors.

The European Commission has historically followed the ACSH’s advice when mandating ECHA to carry out the scientific assessments that will underpin future OELs. The committee’s latest list, however, vastly exceeds the EU’s capacity to evaluate limit values: ECHA can be directed to prepare a maximum of five scientific opinions and/or scoping studies for OELs a year. Since scientific assessment is a prerequisite for OEL setting, this has created a “major bottleneck”. The ACSH said it “continues to express its concern about this situation and urges the Commission to urgently find a solution that would allow for an increase in the capacity of preparing scientific opinions for priority chemicals.”



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The SunChemical logo features the brand name in a bold, red, sans-serif font. To the right of the text is a colorful, abstract graphic composed of small squares in various colors (red, yellow, green, blue, purple) arranged in a grid-like pattern.

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The DIC logo consists of the letters 'DIC' in a stylized, green, sans-serif font, with a white outline. Below the letters, the tagline 'Color & Comfort' is written in a smaller, black, sans-serif font.

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A close-up of a brown paper coffee cup with a white lid. The cup features a wavy, abstract pattern in shades of brown and tan. Steam is rising from the cup. The background is a stylized landscape with a wavy river in shades of blue and purple, a rainbow in the sky, and several green trees.

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## GLOBAL REGULATIONS – UPCOMING CHANGES

### Progress in the proposed registration model for UK REACH

The UK published full details of its Alternative Transitional Registration model (ATRM) for UK REACH on May 16. The aim of the ATRM is to reduce costs to companies by “reducing duplication and speeding up decision-making,” according to the Department for Environment, Food and Rural Affairs (Defra).



The proposal on the subject of registration-related requirements incorporates three areas. First, a plan to “significantly reduce” the hazard information provided in registrations for transitional substances, which has been proposed “in light of a greater focus on use and exposure information.” These revised hazard requirements will apply to all registrations of substances that were on the market before the end of the Brexit implementation period. Full hazard information requirements will continue to apply to registrations of new substances that enter the market after that date. Second, a proposal to enhance what information on ‘use and exposure’ registrants in Great Britain need to provide in their registrations.

Lastly, a plan for reduced hazard requirements in Chemical Safety Reports (CSRs) conducted by all registrants of a transitional substance manufactured or imported in quantities of over 10 tonnes a year.

The proposal was welcomed by the industry, which has frequently raised concerns about the high costs of registration, particularly those associated with using existing hazard data owned by companies operating in the EU. UK REACH – a ‘copy-and-paste’ version of the EU regulation – currently requires companies operating in the UK to submit data for registrations following Brexit, with no allowance for information already submitted in the EU.

But the nongovernmental organization, CHEM Trust, accused the government of prioritizing lower industry costs “at the expense of chemical safety” by placing more responsibility on the regulator to chase registrants for information. Another issue is that the Defra proposal allows UK REACH registrants to simply copy the required hazard information from the ECHA database, which is publicly available online, and drop it into their UK REACH registrations. The underlying implication is that this action would not trigger an obligation to pay the data owner. Also, the dependence on the EU REACH dossiers raise concerns as these dossiers are living documents and regularly updated. Consequently, classifications, DNELs and PNECs might change, and Defra’s consultation document does not indicate what measures, if any, UK registrants would be obliged to take into account for this possibility.

Meanwhile a UK industry association has urged the newly elected Labour government to find a “pragmatic and workable solution” to UK REACH issues and collaborate with the EU through an improved relationship. Tim Doggett, chief executive of the Chemical Business Association (CBA), said the government must make UK REACH “a top priority” as the uncertainty around the legislation continues to stifle investment and harm UK industry. It remains, however, unclear whether the Labour government will maintain the course proposed by Defra.

### California Evaluates Paints Under the Safer Consumer Products Program

California has proposed scrutinizing paints and microplastic releasers under its Safer Consumer Products (SCP) program, alongside ongoing evaluations of several other product categories. Released on May 16, California’s draft 2024-2026 priority product work plan outlines goods that its Department of Toxic Substances Control (DTSC) wants to study during that timeframe to identify priority products for possible regulation under the state’s green chemistry scheme.



The agency said it has started screening research on paints due to concerns that these widely used goods could expose children, workers, and the public, as well as aquatic and terrestrial biota, to candidate chemicals like formaldehyde or benzene.

Additionally, the DTSC intends to expand prior efforts on food packaging and motor vehicle types by looking at food contact articles and motor vehicle items more broadly.

### Ukraine Adopts CLP Regulation and REACH Regulation

In May, the Ukraine government has formally approved its draft classification, labeling and packaging of substances and mixtures (CLP) regulation. The regulation entered into force on June 29. The country has been pressing ahead on its path towards EU membership by aligning national chemicals legislation with the trade bloc.



Furthermore, the government has formally approved the technical regulation for the safety of chemical products—Ukraine REACH—aligning its national system for managing chemicals with that of the EU. The technical regulation implements EU REACH with a key requirement to register all chemicals produced, imported, and supplied in Ukraine in volumes of more than one tonne per year, according to the Ministry of Environmental Protection and Natural Resources on July 23.

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The official publication of the regulation text and the decree on its approval are still pending. But according to a draft resolution, published in March, it would enter into force six months after the date of approval—January 23, 2025. Registration deadlines were extended following a two-month public consultation on the draft resolution, with the following proposed:

- more than 1,000 tonnes, CMR 1A and 1B more than one tonne and substances very toxic to aquatic organisms more than 100 tonnes—1 October 2026;
- between 100 and 1,000 tonnes—1 June 2028; and
- between 1 and 100 tonnes—1 March 2030

The deadlines were extended from between June 2025 and June 2027 as initially foreseen in the draft resolution. Pre-registrations are expected to start from the entry into force of the regulation and last for a year. The new deadlines provide some relief for companies selling into Ukraine, given that many of them are also addressing similar deadlines for K-REACH, Turkey's KKDİK and UK REACH.

### Swedish Database PRIO Includes “New” Hazardous Chemicals



The Swedish Chemicals Agency (KEMI) has expanded its PRIO searchable database of hazardous substances by 5,000 after adding those that are affected by new EU CLP hazard classes (PMT, vPvM and suspected endocrine disruptors). Around 30 substances with PMT or vPvM assessment are added to the list. KEMI has also updated three existing hazard classes for PBT/vPvB substances, potential PBT and vPvB substances, and EDCs.

Jessica Norrgran Engdahl, administrator of the PRIO tool at the Swedish agency, said that the updates are important because “users should be able to trust that PRIO is based on current knowledge and is at the forefront,” according to a press release. PRIO is used, among others, by companies and municipalities that want to phase out the use of substances that are hazardous, but not yet banned or restricted by legislation.

### China Issues Finalized Chemical Classification and Labeling Standard

China's Ministry of Industry and Information Technology (MIIT) has issued a final standard for the classification and labeling of chemicals following a public consultation earlier this year. The standard, GB 30000.1, Rules for classification and labeling of chemicals—Part 1: General specifications, will enter into force on August 1, 2025. It replaces GB 13690-2009, General rules for classification and hazard communication of chemicals, which generally follows GHS 4.




It is the country's first step to align with the eighth edition of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS 8). Based on the draft issued in March, changes include adding a hazard category for desensitized explosives, as well as specifying terms, definitions, and abbreviations from GHS 8. Appendix A, B and C have been removed. The full text of the new standard is expected to be released in the next month.

For more information on these regulatory issues, please contact the Regulatory Affairs team in [North America](#), [Latin America](#) or [Europe](#).

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