Regulatory Newsletter

This newsletter is intended to provide an information update on important regulatory issues and developments of interest to Sun Chemical customers.

European Union General Court Annuls Titanium Dioxide Carcinogen Classification

The European Union's (EU) General Court has annulled the European Commission's 2020 decision that classified titanium dioxide as a carcinogen (Carc. 2 for powder containing >1% particles with an aerodynamic diameter below 10 µm). In its ruling, the court said the commission made an error in its assessment of the acceptability and reliability of a scientific study on which the classification was based. The commission also infringed criteria that classification can relate only to a substance that has the intrinsic property to cause cancer, a condition that was not met for titanium dioxide, the court said.

Regarding the second point of the ruling, that carcinogenicity was not an intrinsic property of the substance, the court said that although the concept does not appear in the Classification, Labelling and Packaging (CLP) regulation, "it must be interpreted in its literal sense as referring to the 'properties which a substance has in and of itself.'" Essentially, the court said that the hazard is situational in that it only arises through a specific set of conditions. This statement makes it hard for regulators to argue for classification of a solid substance on the basis of particle size, something that could be significant for the regulation of nanomaterials and poorly soluble, low-toxicity substances (PSLTs), such as pigments or carbon black, in the EU.

On February 8, 2023, France lodged an appeal against the ruling of the European Court of Justice. According to a press release, France is challenging the ruling because the court "exceeded the limits of its judicial review by carrying out its own evaluation and interpretation of the scientific data," adding that the court's decision is "also a setback in terms of protecting the health of European citizens and workers who handle this substance."

This means that the harmonized classification, as well as the additional warning H-statements for solid and liquid mixtures, will continue to apply

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until the conclusion of the new proceedings and, if the Court of First Instance upholds the decision, the judgment would only take effect from the date of dismissal of the appeal.

According to initial estimates from the law firms involved in the case, it will take approximately two to three years to come to a decision on whether this appeal will be granted or dismissed.

The decision of the court, as well as the appeal, affects only the classification of TiO_2 as a chemical and has no direct impact on titanium dioxide as a food additive or as an ingredient in cosmetics. However, TiO_2 as a food additive will be reevaluated by the FAO / WHO expert committee in November 2023, creating a chance for regulatory changes.

Industry Associations—Opinions and Positions

Revision of EU Rules on Food-Contact Materials

On May 20, 2020, the European Commission published a communication on a Farm to Fork Strategy, in which it commits to revise the EU legislation on food-contact materials (FCMs). Specifically, it aims to improve food safety and public health, support the use of innovative and sustainable packaging solutions using environmentally friendly, reusable and recyclable materials, and contribute to food waste reduction.

Public consultations held from October 5, 2022, until January 11, 2023, aimed to collect views of citizens and stakeholders. The industry associations VdMI and Eurocolour had already published a position paper in April 2022 on the introduction of a generic approach to risk management (GRA), pointing out that a GRA is in contradiction with the precautionary principle. GRA targets chemicals for regulatory action based on the substances' hazardous properties and general considerations of their exposure, no matter what use, conditions and risk-management measures are in place. As a result, professional users may, e.g., not be allowed to work with paints which contain substances with skin-sensitizing properties.

In this public consultation, the associations noted furthermore that the additionally requested information on identity and properties of substances is of limited use, as the focus for FCMs is on substances potentially migrating from the product rather than on all possible raw materials and intermediates used within the supply chain. A corresponding regulation for disclosure of chemicals used in FCM intermediates may represent a competitive disadvantage for the European producer.

In addition, the Packaging Inks Joint Industry Task Force (PIJITF) has proposed a blueprint for printed food-contact materials and articles (pFCM), which may be used to produce harmonized measures for all materials or as a general approach outlined in the framework regulation. The strategy is founded on the notion of industry self-evaluation and process management to assure final product conformance and facilitate the transition to sustainable food systems.

Food-Contact Materials

EFSA Final Assessment of BPA Delayed until Fall 2023

The European Food Safety Authority (EFSA) published its final assessment of bisphenol A (BPA) in April 2023, confirming that the authority will move forward with a 20,000-fold reduction in the tolerable daily intake (TDI) of BPA which is now 0.2 nanograms per day. In its draft assessment in 2021, the agency proposed the steep reduction, which would have significant impacts on how much BPA is allowed in food-contact materials. Meanwhile, bisphenol A is facing a general concentration limit under a REACH restriction.

Europe—Upcoming Legislations and Guidance Documents

CLP Revision—Implications for the Use of Chemicals in the EU

In December 2022, the European Commission published its final proposal to revise the CLP Regulation to add new hazard classes for endocrine disruptors and other harmful substances. The revision of CLP is an important part of the Chemicals Strategy for Sustainability (CSS), which is a key building block of the European Green Deal. The CLP revision process just finished in March.

The new hazard classes are:

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

The delegated act will have far-reaching implications for the use of chemicals in a wide range of value chains. Given the potential extension of the Generic Approach to Risk Management, as well as product regulation, assigning new hazard classes to chemicals will result in automatic limitations and restrictions under REACH. This is one of the concerns of Cefic, the European Chemical Industry Council.

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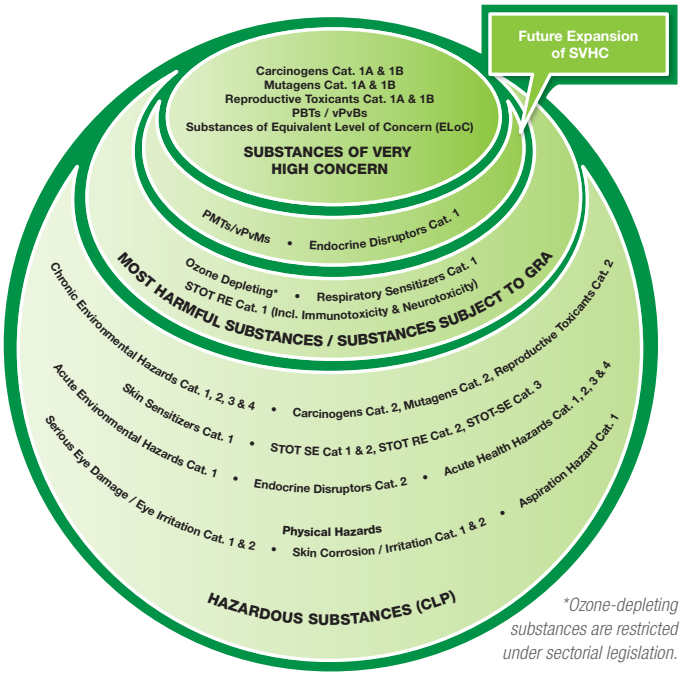

**Ozone-depleting substances are restricted under sectorial legislation.*

The future implications of the expansion of substances of very high concern

Cefic also expressed concerns about the lack of alignment between CLP and the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS). EU CLP is based on the UN GHS and, therefore, adding new hazard classes to CLP ahead of the GHS process undermines confidence in the proper functioning of the global system.

The commission has maintained its proposal for a 24-month transition period for new substances and 36 months for mixtures. It has also put forward a timeline of 42 months for substances on the market (before the entry-into-force date) and 60 months for mixtures already on the market.

At one of the recent CARACAL meetings, ECHA announced that the work on the guidance documents would be initiated in the first quarter of 2023 and published by mid-2024. These documents are crucial for industry to implement the revised regulation and be compliant within the given deadlines. The European Chemical Industry Council seeks to provide timely input, even if the draft legal acts are not published yet.

RAC Proposal for Occupational Exposure Limits (OELs) for Cobalt and Its Inorganic Compounds

ECHA's risk assessment committee (RAC) adopted opinions on occupational exposure limits (OELs) for cobalt compounds during its December meeting. The committee is proposing an OEL of 1 microgram per cubic meter (µg/m³) over eight hours for the inhalable fraction of cobalt, and 0.5 µg co/m³ for the respirable fraction of the compound.

Cobalt is used widely to manufacture chemicals, catalysts, batteries, feed-grade materials and biogas. Some cobalt compounds are already on REACH's candidate list, because of their carcinogenic, mutagenic and reprotoxic (CMR) properties. The cobalt compounds were due for restriction under REACH, before the commission decided that a binding OEL under Occupational Safety and Health (OSH) legislation was the better option for protecting workers.

While the industry welcomed the commission's decision to manage cobalt via OELs, rather than through a restriction, it has reacted to RAC's proposal with trepidation. One trade association, the Cobalt Institute, said that the OEL values proposed are "disproportionately low" and misleading on the safety of using the ferromagnetic element in the EU. However, the next steps of the OEL process may balance out RAC's approach.

Global Regulations—Upcoming Changes

Restriction for Per- and Polyfluoroalkyl Substances in the EU and USA

The national authorities of Denmark, Germany, the Netherlands, Norway and Sweden have submitted a proposal to ECHA to restrict per- and polyfluoroalkyl substances (PFASs) under REACH.

PFASs are known to be highly persistent in the environment, contaminating surface water, groundwater and soil, and causing harmful consequences in human health, such as cancer and reproductive and developmental impairment. Some PFASs may potentially interfere with the human endocrine hormonal system.

According to the Restriction Process, ECHA's scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) were to check the proposed restriction in their meetings in March 2023.

In February 2020, the United States' Environmental Protection Agency (EPA) provided an update to their action plan listing steps to address and mitigate the chemicals in the environment. The federal agency is moving forward with the development of a national drinking water regulation for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) under the Clean Water Act. The EPA issued a proposal ensuring that certain chemicals within the class cannot be manufactured or imported without notification and review under the Toxic Substances Control Act (TSCA), and initiated the regulatory process for listing PFOA and PFOS as CERCLA hazardous substances.

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The table below summarizes the U.S. state laws with references to state legislation impacting food packaging containing PFASs. PTFE wax, used in some printing inks, is considered a PFAS according to most definitions.

State	Date	Type of Packaging	Only Direct Food Contact	Intentionally Added?	Alternative Required Prior to Ban
New York	Dec. 31, 2022	Paper/plant fiber	Yes	Yes	No
California	Jan. 1, 2023	Paper/plant fiber	No	Yes or NIAS >100 ppm	No—but must be least toxic alternative
Vermont	Jul. 1, 2023	Any	Yes	Yes	No
Connecticut	Dec. 31, 2023	Any	Yes	Yes	No—but replacement cannot create a worse hazard
Minnesota[1]	Jan. 1, 2024	Any	No	Yes	No
Maine[2]	Jan. 1, 2023	Any	Yes	Yes	Yes
Washington	Jan. 1, 2022[3]	Paper/plant fiber	Yes	Yes	Yes
Maryland	Jan. 1, 2024	Paper/plant fiber	Yes	Yes	No
Colorado	Jan. 1, 2024	Paper/plant fiber	Yes	Yes	No
Rhode Island	Jan. 1, 2024	Any	Yes	Yes	No—but replacement cannot create a worse hazard
Hawaii[4]	Dec. 31, 2024	Paper/plant fiber	Yes	Yes	No

[1]Inks are specified in the regulations (Section 105).

[2]Initial reporting requirement; no ban yet on food packaging.

[3]Effective date applies if the report required under Law 70A.222.070 finds that safer alternatives are available for specific food-packaging applications.

[4]The prohibition under this section shall apply to wraps and liners, plates, food boats and pizza boxes.

Uncertain Status of UK REACH

The uncertainty surrounding UK chemicals policy is hurting businesses and deterring investment into the country, industry representatives have said, and urged the government to "move on faster" and provide clarity on REACH requirements. The biggest concerns for companies are potential duplicate data costs for registration, repeat animal testing and the unavailability of certain substances on the UK market. The majority of the industry welcomed a three-year extension of data submission deadlines, but many complained that this took a year to decide while a new registration model is still being worked on.

In a webinar held by CEPE and the British Coatings Federation in January 2023, two options on how to proceed were presented. The first one is reregistration with full dossiers. Though, according to CEPE, it makes no sense to start from zero in the UK and referred to the low capacities of the authorities to check all the dossiers. The second option focuses more on the hazard and risk profile and the specific use of the chemical in the UK. This plan B also did not convince the industry, as it raises costs, is considered time consuming and uses data

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specifically in the UK that is most likely scarce. Producers and importers still favor the Swiss Model, which is like the EU REACH regulation with minor specific adaptations. Finally, there is still no way forward and the pattern remains as it is.

K-REACH Amendment

Reduced costs are a top priority for small and medium-sized enterprise (SME) subsidy programs run by the South Korean government to help industries pay for their K-REACH registration expenses.

South Korea's National Institute of Environmental Research (NIER) has therefore proposed an amendment to the K-REACH rule on registration dossier and risk assessment review procedures with the aim of reducing vertebrate animal testing for registrations. It appears to be less expensive and time consuming, and it will support maintaining consistency in dossiers, categorization and labeling between the EU and South Korea. According to the amendment, registration dossiers may include nontesting data such as quantitative structure-activity relationship (QSAR), read-across and weight of evidence (WoE).

Concerns about the authorities possibly rejecting submissions still exist. The registrant will be asked to submit test data if non-animal testing information is deemed to be inadequate by the NIER evaluation and, consequently, may give rise to additional charges.

Additionally, the K-REACH amendment has updated the reporting requirements for importers and manufacturers of products containing priority control substances. At this time, there are 699 priority control substances listed under K-REACH.

California Proposition 65 Lists Glycidyl Methacrylate as a Carcinogen, Excludes BPA from List

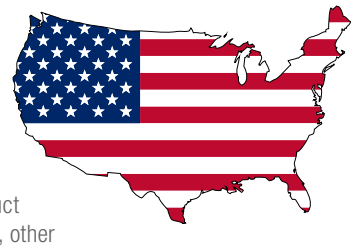
In accordance with the state's Proposition 65 right-to-know scheme, the Office of Environmental Health Hazard Assessment (OEHHA) of California has declared its intention to list glycidyl methacrylate as a carcinogen.

If the proposed classification were adopted, companies would be required to give warnings whenever they exposed the public to any of the compounds above possible "safe harbor" levels.

On the other hand, OEHHA has stated that it will not add bisphenol A (BPA) as a carcinogen under Proposition 65. The decision has no bearing on BPA's current Prop 65 classification as a female reproductive and developmental toxicant. However, the decision implies that businesses won't need to mention an additional cancer risk when issuing warnings for substance exposures.

Cosmetic Regulatory Reform in the USA

In order to improve the Food and Drug Administration's (FDA) supervision of the personal care products industry, the U.S. Congress has enacted a number of wide regulations, including ingredient notification requirements and mandatory recall authority.



The revision would bring about some of the first changes to U.S. cosmetics regulations since the passage of the federal Food, Drug and Cosmetic (FD&C) Act of 1938. The revisions, known as the Modernization of Cosmetics Regulation Act (MCRA), would require companies that make personal care products to list each product yearly, including its scents, flavors, colors, other components and other information. They would also need to maintain safety-related records for all products, register all production facilities within a year, renew registration every two years, and withdraw a product from the market if the FDA determines there is a "reasonable chance" that it is contaminated and its use or exposure might have a major negative impact on health or cause death.

A legislative suggestion to phase out the majority of animal testing on personal-care products is also included in the law.

Israel Updates Toy Migration Limits for 19 Substances

To bring its standards in line with the most recent update on toy safety from the EU, the Israeli government changed the permitted migration limits in toys.

The standard is in accordance with the EU's EN 71-3:2019, *Safety of Toys—Part 3: Migration of Some Elements,* from April 2019. It was released in the nation's official gazette on November 17, 2022, with a transition period until April 16, 2023. This contains the specifications and test procedures for the migration of 19 elements, including zinc, antimony, arsenic, barium, boron, cadmium, copper, lead, manganese, mercury, nickel, selenium, strontium, tin and organic tin.

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China Updates the Inventory of Existing Chemical Substances of China (IECSC) with 42 New Chemicals

The Ministry of Ecology and Environment (MEE) has added 42 new compounds to China's Inventory of Existing Chemical Substances (IECSC). There will no longer be a registration or notification need for these chemicals. New compounds that are not included on the IECSC are subject to particular MEE Order 12 obligations, such as registration and notice.

Canada Publishes New Version of Guidance for New Substance Notifications

For the purpose of assisting companies in adhering to Canada's New Substances Notification (NSN) regulations for chemicals and polymers, Environment and Climate Change Canada (ECCC) has revised its guidelines.

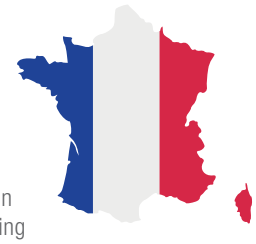
The document is divided into 10 sections and is meant to assist notifiers in determining if a material is subject to the standards and explaining what information must be provided. The concept of nanomaterials and the notification guidelines for chemicals produced at the nanoscale are included in the new guidance document. The paper also outlines the procedures for adding and removing chemicals from the non-domestic-substances list (NDSL). Additionally, the agency provides a summary of received comments and program responses.

Brazil Launches Public Consultation on Proposed Regulations for Metals in Food-Contact Materials

The National Health Surveillance Agency (ANVISA) of Brazil is looking for feedback from the general public about a plan to modernize the technical specifications for the use of raw metals in metallic packaging, coatings and equipment that come into contact with food. Submissions were accepted through March 6, 2023. Draft Resolution 1334, which was released in late December 2022, aims to amend RDC 20/2007 and RDC 498/2021.

French Mineral Oil Decree

Article 112 of the French Decree No. 2020-1725 on the "Fight Against Waste and the Circular Economy" regulates the use of mineral oil on packaging and free advertising. The article prohibits mineral oil–containing substances that interfere with waste recycling and provides the following definitions:



- MOH = Mineral Oil Hydrocarbons
- MOAH = Mineral Oil Aromatic Hydrocarbons consisting of 1 to 7 aromatic cycles
- MOSH = Mineral Oil Saturated Hydrocarbons consisting of 16 to 35 carbon atoms

The first restrictions began January 1, 2023, and run until January 1, 2025, wherein printing inks containing more than 1% MOAH are banned. Then from January 1, 2025, printing inks containing more than 0.1% MOAH (1 to 7 aromatic cycles) or more than 1 ppm of MOAH (3 to 7 aromatic cycles) or more than 0.1% MOSH (C16 to C35) are banned.

These limits, especially the very low limits specified in 2025, will have a particular impact on certain printing technologies.

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

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United States
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