Regulatory Newsletter

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

Industry Associations—Opinions and Positions

Cefic Particle Platform

In February 2023, the Cefic Particle Platform was established. Under the umbrella of this platform, the Cefic (European Chemical Industry Council) sector groups as well as external associations such as Eurometeaux, TDMA (Titanium Dioxide Manufacturers Association) and other national chemical associations are discussing scientific and regulatory developments at the European level on the issues related to particles which exhibit no or very low inherent toxicity, but affect the respiratory tract.

Looking for solutions in view of the regulatory and legislative milestones, such as the Classification, Labelling and Packaging (CLP) regulation and REACH revisions or ECHA's committee for risk assessment's (RAC) mandate to set a generic occupational exposure limit (OEL) for inhalable and respirable dust, the platform aims to join forces to avoid all particles being classified for general particle-related effect. The Particle Platform is already in dialogue with authorities to make them aware of the issue and together find a reasonable way to regulate them.

With regard to the ongoing discussions on particles and particle-related effects, it is worth mentioning that the Council of the European Union adopted the general approach on the CLP regulation and some amendments on the topic of particles with the intention to codify the current practice when it comes to classification of forms of substances. These amendments mean it is possible to classify specific forms or

physical states of a chemical (and subsequently mixtures thereof) unless a substance is subject to harmonized classification without being limited to a specific form or physical state.

Despite there being plastic particles with a size of typically less than 5 mm, microplastics are not covered by this regulatory initiative. The chemical industry is presently engaged in the Cefic Long Range Research program with the aim of supplying information for a thorough risk assessment to assist in analyzing the effects of these particles on the environment and developing a suitable solution.

Cobalt Institute Industry Recommends Higher EU Occupational Exposure Limits for Cobalt

By the end of 2024, the European Commission must propose a limit value for cobalt and its inorganic compounds. To this end, the commission requested the opinion of the ECHA's committee for risk assessment (RAC) on safe levels of occupational exposure to cobalt and other carcinogens. RAC proposed an OEL of 1 µg/m^3 for inhalable and 0.5 µg/m^3 for respirable cobalt, addressing lung inflammation, genotoxicity, carcinogenicity, respiratory and skin sensitization, and reproductive toxicity.

In contrast to the significantly lower levels that RAC set in December, the Cobalt Institute has recommended 5 µg/m^3 for the respirable fraction (< 10 µm for the alveolar fraction) of cobalt and 20 µg/m^3 for the inhalable fraction (> 10 µm) of the compound. These thresholds are magnitudes higher than the original RAC proposals but still a challenge for the industry. According to the socioeconomic impact assessment performed, even an OEL value of 20 µg/m^3 would result in around €400 million in total yearly industry expenses.

Food-Contact Materials

Updated Recommendation XXXVI for Paper and Board by BfR

In April 2023, the German Federal Institute for Risk Assessment (BfR) revised its Recommendation XXXVI on paper and board for food contact. The new version of the recommendation, published on February 1, 2023, showed no changes for colorants or optical brighteners. There must be no migration into foodstuff, and the maximum level for sulfonated stilbene derivates is 0.3%.

Update on the Restriction Proposal for BPA and Related Bisphenols

The European Commission is preparing a proposal to restrict bisphenol A (BPA) in food-contact materials, including plastic and coated packaging, following human health concerns raised by the European Food Safety Authority (EFSA). The group ban is aimed at preventing a "regrettable substitution."

The EU executive said the proposed measure will also address the use of other bisphenols in food-contact materials (FCMs) to avoid replacing BPA with other harmful substances.

In April, EFSA concluded in a final assessment that a 20,000-fold reduction in the safe limit for human ingestion of BPA is warranted based on evidence of immunotoxicity. Consumers of all ages should be concerned about their health if they absorb BPA, according to the FCM panel's findings. This steep reduction will have significant impacts on how much BPA is allowed in food-contact materials. Multiple organizations, including the U.S. FDA and the German Federal Institute for Risk Assessment (BfR), raised concerns about the draft assessment, saying the proposed TDI is not scientifically justified.

The European Commission has started discussing the restriction with member states, and the EU Directorate General for Health and Food Safety (DG Sante) hosted a webinar with stakeholders in July. According to DG Sante, the restriction will enter into force in early 2024 with an 18-month transition period. Extensions for some material uses may yet be granted. The restriction will only apply to "intentionally added" BPA. The term "intentional use" has not yet been fully defined.

India Consults on Revised Standards for PET Packaging for Edible Oils, Food and Drinks

India is consulting on draft revised standards for polyethylene terephthalate (PET) used to make containers and bottles for edible oils, solid and semi-solid food products and alcoholic drinks, respectively. With no discernible color migration, the Bureau of Indian Standards (BIS) amendment provides a migration limit of 60 mg/kg for chemicals traveling from PET packaging to food or drink content.

The updated guidelines additionally include the following migration limits for heavy metals and hazardous substances:

- barium: 1 mg/kg maximum
- cobalt: 0.05 mg/kg maximum
- copper: 5 mg/kg maximum
- iron: 48 mg/kg maximum
- lithium: 0.6 mg/kg maximum
- manganese: 0.6 mg/kg maximum
- zinc: 25 mg/kg maximum
- antimony: 0.04 mg/kg maximum
- phthalic acid, bis(2-ethylhexyl ester) (DEHP): 1.5 mg/kg maximum

A wise way to transform your business.

Count on our knowledge and experience to meet all your sustainability goals.

When you start to peel back the layers, it's easy to see why more and more printers are choosing mono-material packaging. Not only is it easier to recycle, its lighter weight makes it easier to transport—translating into lower carbon emissions. If you're ready to meet sustainability challenges, partner with us and take your business to the next level.

Learn how we can help you redesign your flexible packaging with mono-material solutions at www.sunchemical.com/flexpackaging-transform.

SunChemical®
a member of the DIC group
DIC Color & Comfort

For PET bottles, the revision lays down specific dimensions including wall thickness and tolerance levels for various capacities. It also states that PET bottles must be manufactured with food-grade material conforming to IS 9833 and aligned to the Plastic Waste Management Rules 2016 and all amendments, as notified, until 2021.

In addition, labeling must comply with the Food Safety and Standards (Alcoholic Beverages) Regulations 2018, be made of colored or transparent polypropylene (minimum 50 microns) and use adhesives free of bisphenol A.

The PET solid and semi-solid food containers must be virgin grade. All pigments and colors must comply with IS 9833, while handles and container closures must be made of high-density polyethylene (HDPE) conforming to IS 7328, and polypropylene conforming to IS 13193.

If aluminum foil is used in a PET container, it should conform to standards laid down for food-grade aluminum and coated with food-grade polyethylene.

Brazilian FCM Regulations Updated to Comply with Mercosur Limits on Dye Migration

Brazil has revised its regulations on technical requirements for food-contact materials (FCM) (Resolution 88/2016) related to materials, packaging and cellulosic equipment intended to come into contact with food and other measures. In force since June 2016, the regulations include a list of acceptable ingredients as well as limits on materials, containers and equipment treated with paraffin, waxes, mineral oils and pigments.

The Resolution RDC 88/16 ANVISA was modified by the regulation (RDC 798/2023) incorporating Mercosur Resolution 26/2022, which limits the migration of pigments and dyes in FCMs according to the BS EN 646 standard. This standard uses a grayscale to visually evaluate how much color transfers from one medium to another. Substances must reach a grade 5 on the grayscale in order to guarantee that pigments and dyes do not migrate into food. Currently, only Brazil has put this resolution into practice among the Mercosur members. The measure entered into force on May 19th, and companies must comply with it by November 22, 2023.

FEICA Guidance Evaluates the Potential Migration of Adhesives Containing Mineral Oil Hydrocarbons from Food-Contact Materials

Health concerns were raised after research revealed that consumers could be exposed to mineral oil hydrocarbons (MOH) in meals, with food packaging and additives, processing aids and lubricants being the most likely primary sources. The European Food Safety Authority opinion on mineral oil in 2012 focused on migration from recycled paper, revealing that mineral oil from printing inks was a major source of food contamination. Moreover, the lack of formal analytical methodologies adapted for adhesives together with multi-constituent adhesive raw materials challenge testing for mineral oil hydrocarbons.

In order to help adhesive producers and users comply with the rules on MOH release into food under article 3 of the EU FCM regulation, the Association of the European Adhesive and Sealant Industry (FEICA) has published a guidance document on how to evaluate the potential migration of adhesives containing MOHs from FCMs and, in case testing is needed, how to conduct it and evaluate the results.

Revision of EU Rules on FCMs

In May 2020, the European Commission's committed to revise the FCM legislation to reduce the use of hazardous chemicals and other key strategies as part of its Farm to Fork Strategy to improve food safety and public health.

The starting point for the revision is a roadmap (inception impact assessment). Nonetheless, the European Commission has announced that legislative action on a formal proposal will not begin until 2025 at the earliest, as the procedure does not entail any deadlines. The draft revision regulation will go through the regular legislative procedure, which requires the European Parliament and Council to reach an agreement with the commission. Numerous proposals were made as part of the REACH and CLP updates, and the question of how much these policy options should be considered while working to update the FCM Regulation provides additional difficulties.

The 16th Amendment to Annex I of the Plastics FCM Regulation

Based on recent scientific opinions from the European Food Safety Authority (EFSA), the European Commission (EC) has adopted the 16th amendment to Annex I of the Plastics FCM Regulation.

The amendment revokes the authorization of wood flour and fibers, as well as untreated and salicylic acid, and adds the following substances to the positive list of Annex I:

- FCM 1078 (tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate)
- FCM 1080 (triethanolamine-perchlorate, sodium salt) dimer)

- FCM 1081 (N, N-bis(2-hydroxyethyl) stearylamine partially esterified with saturated C16/C18 fatty acids)
- FCM 1082 (phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate)
- FCM 1083 (benzophenone-3,3',4,4'-tetracarboxylic dianhydride)

Additional modifications to the Plastics Regulation include changing the specified migration levels (SMLs) and/or limitations and requirements for four phthalates, such as:

- phthalic acid, dibutyl ester (DBP)
- phthalic acid, benzyl butyl ester (BBP)
- phthalic acid, bis(2-ethylhexyl) ester (DEHP)
- phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60% C9 (DINP)

In addition, the 16th amendment modifies the restrictions and specifications for poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) (PHBH) and extends the permitted use for diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate and phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester that are used as additives for plastic films and articles.

The 16th amendment entered into force on August 1, 2023.

Europe—Upcoming Chemicals Legislations and Guidance Documents

Reevaluations of Titanium Dioxide

The very contentious harmonized EU classification of titanium dioxide is currently the subject of multiple legal disputes. The European Commission and the French government are challenging a decision by an EU court to overturn the classification.

As the Toy Safety Directive restricts carcinogenic, mutagenic or toxic for reproduction (CMR) substances in toys unless they have been tested and deemed safe by a scientific committee, the European Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) assessed whether the use of titanium dioxide in toys and toy materials can be considered safe in light of the identified exposure and titanium dioxide's classification as carcinogenic category 2 after inhalation.

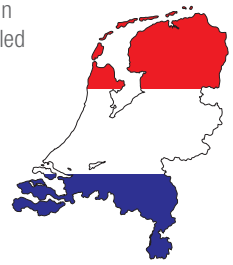
The document was adopted in June 2023. Powdered titanium dioxide is largely used in the toy industry in a variety of materials such as coatings, chalks, paints, clays, polymeric materials, color pencils and wax crayons. SCHEER concluded that toys containing TiO_2 can be used safely when the TiO_2 does not contain ultrafine fractions.

In addition to the Toy Safety Directive, titanium dioxide was scheduled for reevaluation at the 97th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) from October 30th until November 2nd. Governments, interested organizations, producers of these chemicals, and individuals were invited to submit data for the toxicological evaluations, the preparation of specifications for the identity and purity, and estimating the intake of TiO2 until February 28th.

Furthermore, the Titanium Dioxide Manufacturer Association (TDMA) has announced that a new independent study by the Japanese National Institute of Health Sciences (NIHS) was recently published showing no toxic effects from the oral ingestion of titanium dioxide. The study directly addressed the EFSA's concern for genotoxicity and showed that no adverse effects were observed in the liver and other tissues where trace amounts of titanium were detected. The study also showed no adverse effects in the colon.

Harmonized Classification and Labeling for Talc

ECHA is seeking input on the Netherlands' CLH proposal for talc ($Mg_3H_2(SiO_3)_4$). The member state was looking for views by August 18th on carcinogenicity and specific target organ toxicity—repeated exposure.



The conclusions in the CLH report are at least in part in contrast to the IARC classification, which states that inhaled talc (free from asbestos) is not classifiable as to its carcinogenicity (Group 3). In addition, the EPA health assessment indicates that the carcinogenic effects of inhaled talc depend on the presence of contaminants such as asbestos or crystalline silica.

Talc is used in a wide variety of manufacturing processes in different industries, such as as a filling component (bleaching, whitening/filling agent, pharmaceuticals), carrier (coating, dye, paper industry) or separator (rubber), and processing aid (ceramics).

Global Regulations—Upcoming Changes

Per- and Polyfluoroalkyl Substances (PFAS)

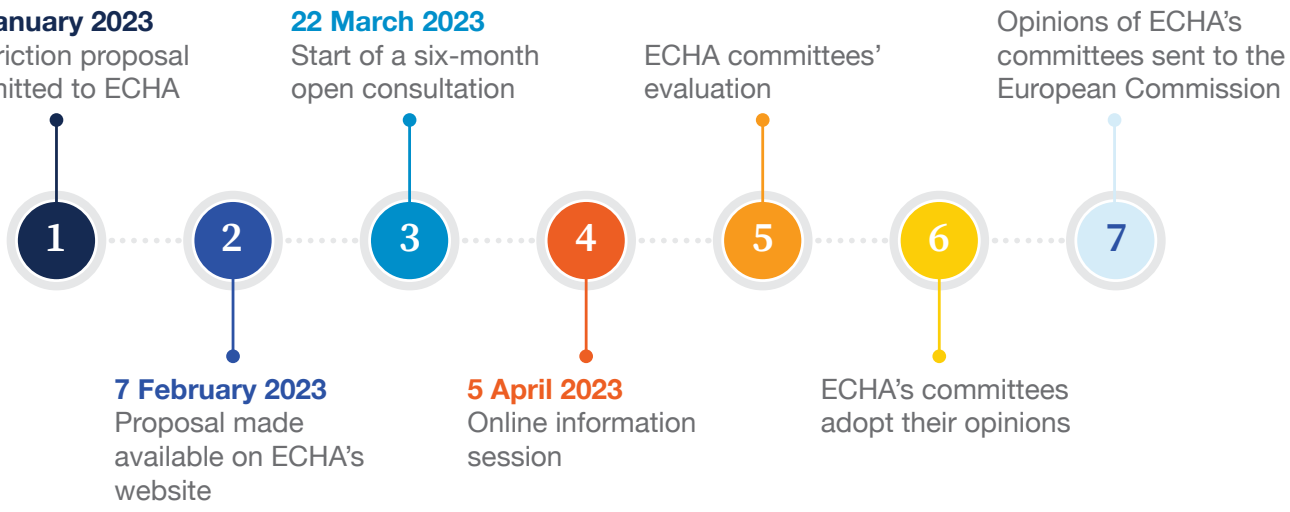
Due to their distinctive and desirable qualities, PFAS are frequently used. Aerospace and defense, automotive, aviation, food-contact materials, textiles, leather, apparel, construction and home goods, electronics, firefighting, food processing and medical items are a few of the key industrial sectors that employ PFAS. The fact that scientists and governments from all over the world initially recognized the negative effects of some PFAS (especially long-chain PFAS) on human health and the environment has caused global manufacturers to start to switch out some PFAS with other PFAS or fluorine-free alternatives during the past few decades.

In the U.S., 12 states (California, Colorado, Connecticut, Hawaii, Maine, Maryland, Minnesota, New York, Oregon, Rhode Island, Vermont and Washington) have passed legislation limiting the use of "intentionally added PFAS" in packaging and food-contact products. PFAS or "intentionally added PFAS" in consumer products are also prohibited in certain states.

In parallel to the various state regulations in the U.S., the European Commission is committed to phasing out all PFAS, allowing their use only when they are shown to be irreplaceable and essential to society. The ban aims to regulate production, trade and import in one go across Europe. After the ECHA Scientific Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) assessed that the proposal meets the legal requirements of REACH in their sessions in March 2023, they subsequently started the scientific evaluation of the proposal. The six-month consultation period ended on September 25, 2023.

While SEAC will form an opinion on the socioeconomic implications, RAC will decide whether the proposed restriction is suitable in decreasing the risks to people's health and the environment. Based on the details in the restriction proposal and the feedback obtained during consultations, both committees will formulate their conclusions. After the opinions are approved, they will be forwarded to the European Commission, which will then decide on the potential restriction along with the EU member states.

- 2024—RAC and SEAC final opinions
- Q4 2024—Public Consultation on Draft SEAC report (participate via associations)
- 2025—European Commission adoption and entry into force
- 2026-27—Restriction becomes applicable



PFAS restriction proposal timeline

Assembly Bill 418 Will Prohibit Use of Some Chemicals in Certain Foods in California

The food safety bill known as AB-418, commencing January 1, 2025, would prohibit a person or entity from manufacturing, selling, delivering, distributing, holding or offering for sale in commerce a food product in California for human consumption that contains red dye No. 3, titanium dioxide, potassium bromate, brominated vegetable oil or propylparaben.

The legislation is based on the model of existing laws in Europe and a 2021 report by the California Environmental Protection Agency assessing the potential effects of seven synthetic food dyes approved by the U.S. Food and Drug Administration, including red dye No. 3, which states that "evidence shows that synthetic food dyes are associated with adverse neurobehavioral outcomes in some children."

The bill, which would go into effect January 1, 2025, would be the first in the United States to ban chemical substances intentionally added to foods as preservatives or additives. The bill went to the State Senate, where it was amended in July and is now still under review.

Linda Birnbaum, former director of the National Institute of Environmental Health Sciences, said, "As California goes, eventually so goes the nation because manufacturers don't want to make things that they can't sell to the fifth largest economy in the world. So, California's actions have major impact not only in the U.S., but worldwide."

For its part, Sun Chemical has developed SUNFOODS™ natural colorants which are designed to replace synthetic colors in specific applications to provide matching color and comparable shelf life.

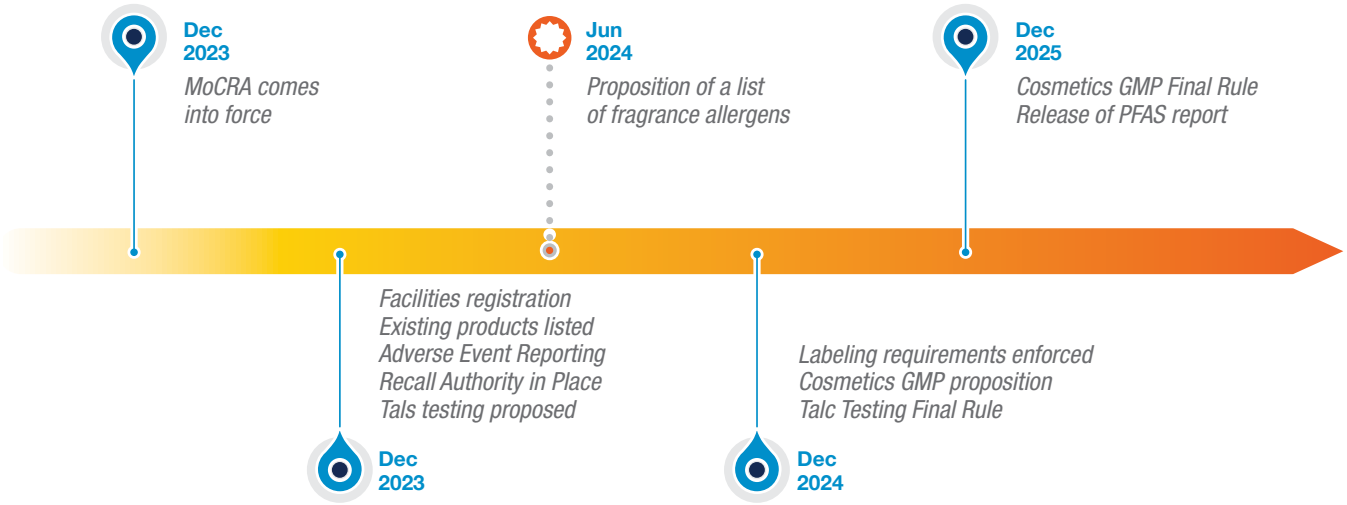
U.S. Cosmetics Regulation Reform

The Modernization of Cosmetics Regulation Act (MoCRA), enacted December 2022, amends the Food, Drug, and Cosmetic Act (FFDCA) and is being enforced gradually in the coming months and years. MoCRA aims to improve oversight of cosmetics in the United States by establishing new requirements for the industry, such as new standards for product listing, adequate safety substantiation, fragrance allergen labeling and good manufacturing practices (GMP) for facilities that manufacture or process cosmetic products to ensure they are not adulterated.

The act also requires that manufacturers register their facilities and products with the FDA and renew their registration every two years. It also requires the responsible person to report serious adverse events within 15 business days after receiving a report of such event.

FDA will also develop regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics. The assessment report of the safety of PFAS in cosmetics will also be released by the FDA by December 29th.

MoCRA includes some exceptions for small businesses and for certain products and facilities subject to drug and device requirements.



Key MoCRA requirements timeline

Environmental Health Advocates Say Sephora Needs Warning Label for TiO_2 in Makeup

The public interest group Environmental Health Advocates (EHA) filed a lawsuit against Sephora and UK-based manufacturer Nails.INC, alleging that the companies failed to adequately warn consumers about exposure to airborne titanium dioxide particles from a powder makeup product.

California´s law allows private entities to take legal action as long as it is demonstrated that the companies failed to warn of exposure to a Prop 65 substance. This lawsuit highlights the growing trend of Prop 65 actions brought by private enforcement groups, as well as the geographical reach of litigation filed under the state's right-to-know statute.

Although only "airborne, unbound particles of respirable size" were recognized as a Proposition 65 carcinogen in California in 2011, thousands of cosmetic products sold in California claimed to include this substance, according to the state's safe cosmetics program database.

EHA is asking the court to compel Sephora and Nails.INC to provide appropriate warnings and pay civil penalties of up to $2,500 per day for each violation. The private enforcer "alleges that damages total a minimum of $1,000,000" for the companies' failure to warn.

Washington State PCB Legislation, Senate Bill SB 5369

In 2022, the Washington State Department of Ecology determined that including paints as a priority product in the Safer Consumer Products Program conflicted with federal PCB limits, and that state regulation is preempted by TSCA. Therefore, the Safer Products recommendation made by the Department of Ecology was for "no regulatory action" against paint and printing inks.

A new bill was then issued in Washington, effective January 1, 2025, that would implement a ban on paint and printing inks that contained "chlorine-based pigments" as a means of getting around the TSCA preemption issue. The prior version of the bill targeted "paints and printing inks with inadvertent PCBs," while the new bill was for a ban on all "chlorine-based pigments."

The Washington state PCBs legislation passed both its House and Senate but had changed significantly. The final version of SB 5369 only directs the Department of Ecology to petition the U.S. EPA, by January 1, 2025, to reassess current TSCA regulations governing PCBs as inadvertent byproducts.

The final bill did not include the following:

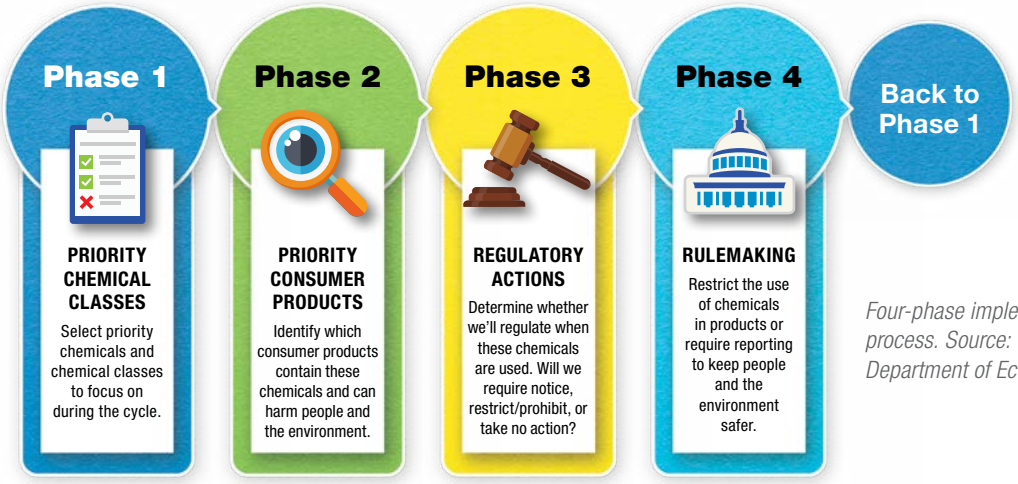
- A ban or restriction on printing inks and coatings that may contain "chlorine" or inadvertently generated contaminants (PCBs)
- A ban on the use of specific pigments containing PCBs (diarylides, phthalocyanines, TiO_2, etc.) for printing inks and coatings
- The authority for the Department of Ecology to designate other products (plastics, packaging, etc.) as priority products and restricting their use in Washington state
- A prohibition on Washington state retailers, wholesalers and distributors from selling printing inks and coatings that may contain inadvertently generated PCBs

Washington State, Priority Listing for Chlorinated Substances

The Safer Products for Washington program, endorsed into regulation in May 2019, is intended to regulate classes of chemicals in consumer products in four stages every five years, reducing the use of toxic chemicals in consumer products. Washington state's Division of Nature is entrusted with (1) focusing on substance classes, (2) focusing on consumer products, (3) deciding expected administrative activities and (4) rulemaking.

The Washington Department of Ecology has begun the second cycle of its Safer Products Program by designating a new set of potential priority chemicals and chemical classes that may be subject to bans or reporting conditions, which include brominated and chlorinated compounds, benzene chemicals, some siloxanes, and formaldehyde releasers. The draft report, which identifies the following substance classes for implicit prioritization ecology, was accepting feedback until July 14th earlier this year:

- brominated and chlorinated substances
- benzene, ethyl benzene, toluene and xylene substances (BTEX)
- cyclic volatile methylsiloxanes (cVMS) like D3, D4, D5 and D6
- formaldehyde and its releasers
- 6PPD
- lead and its compounds
- cadmium and its compounds



Four-phase implementation process. Source: Washington Department of Ecology

The identical four-phase procedure used for Cycle 1 will also be used for Cycle 2. Key deadline highlights for the Cycle 2 compromise include:

- determining which priority consumer products include any new priority chemicals as of June 1, 2025;
- deciding on regulatory measures for the priority chemicals in the priority consumer products by June 1, 2027; and
- adopting regulations that apply the conclusions made as of June 1, 2028.

EPA Releases Draft National Strategy to Tackle Plastic Pollution

EPA extended the public comment period for an additional 45 days through July 31, 2023, to develop a strategy to improve post-consumer materials management and infrastructure to reduce plastic waste and other post-consumer materials in waterways and oceans by focusing on actions to reduce, reuse, collect and capture plastic waste.

By 2040, the United States may stop releasing plastic waste into the environment from land-based sources thanks to voluntary steps outlined in the Draft National Strategy to Prevent Plastic Pollution. Following input from stakeholders, the EPA has chosen three potential goals for the strategy:

- **Goal A**—Reduce pollution during plastic production
- **Goal B**—Improve post-use materials management
- **Goal C**—Prevent trash and microplastics from entering waterways and remove escaped trash from the environment

China: Proposed Lower Migration Limits on Some Substances Used in FCMs

China's National Health Commission proposed changes to the country's main standard regulating FCMs (GB 9685-2016). If approved, the changes would lower the migration limits on several substances, including:

- 4,4'-methylenedianiline—to be amended to 0.002 mg/kg
- 2-ethylhexanol—to be amended to 30 mg/kg
- 1,2,4-benzenetricarboxylic acid—to be amended to 5 mg/kg
- eugenol to be introduced as not detected
- a polysiloxane (CAS156065-00-8) to be introduced as not detected
- m-xylylenediamine to be introduced at 0.05 mg/kg

Other changes the commission proposed include:

- allowing companies to use the additives currently permitted for rubber and silicone rubber use in food contact, as listed in the standard;
- banning the use of C.I. Pigment Blue 15 in polyetherimide (PEI); and
- adding polyvinyl alcohol (PVA) to Annex D.

Singapore: Mandatory Standards Aligned with Seventh GHS

Singapore updated its standards for chemical classifications, labeling and safety data sheets (SDS) to align them with the seventh revision of the UN's Globally Harmonized System (GHS). The changes to Singapore Standard (Part 2: Globally harmonized system of classification and labelling of chemicals—Singapore's adaptations and Part 3: Preparation of safety data sheets (SDS) of the SS 586 series) entered into force on February 6, 2023. They are mandatory for companies manufacturing, importing, supplying, using or that have employees handling hazardous substances, with a transition period of up to 24 months from the release date.

The main highlights are:

- **SS 586—2: 2022**
  - Desensitized explosive adopted as a new physical hazard class
  - Updates to multiple training and labeling requirements
  - New annex, Annex B, which includes examples on small containers
- **SS 586—3: 2022**
  - Updated to align with GHS Rev 7 (requirements for generic toxicity cutoff values and SDS examples)
  - New annex, Annex D, which provides guidance in determining the empirical data for physical and chemical properties of substances or mixtures included in SDS Section 9

Malaysia Creates Voluntary Food Packaging Certification

Malaysia's Ministry of Health (MoH) published revised Food Grade Certification Guidelines on March 14, 2023, originally published in June 2022, to assist stakeholders with the nation's voluntary certification of food-contact products. The guideline specifies the procedures and specifications for all food-grade products used in food preparation, processing, packing, storage, delivery or exposure.

The voluntary certification will allow companies to display the food-grade certification logo on their products that meet the certification requirements for three years. Companies can obtain application forms from the health ministry's Food Safety and Quality Division website or directly from the ministry office. The application form is in Malaysian, although an English version may be available in the future.

The guidelines outline the migration limits, testing requirements and application procedures for chemicals, seven heavy metals, permitted colorants and diluents used in food dyes. Even though the certification is not mandatory, businesses that are interested in selling FCMs in Malaysia probably want to display this food-grade label on their products.

Update of the TSCA Fee Rule

The fees for the administration of the Toxic Substances Control Act (TSCA) rule proposed amendments were announced by the United States Environmental Protection Agency (EPA) on November 16, 2022.

A final rule updating the TSCA fees schedule is expected in November, two months behind the last agenda's timeline. If adopted as proposed, EPA would expect to receive about $45 million in TSCA fees during each of fiscal years (FYs) 2023–2025, or about 25% of its projected $181 million TSCA program expenses in each of those fiscal years. Fiscal year (FY) 2023 ended on September 30th, so the new fee schedule would likely not have taken effect until the beginning of FY 2024 on October 1st. Still, that would provide the EPA with additional resources in the last quarter of calendar 2023.

Under the supplemental proposal, for FYs 2023–2025 the fees for premanufacture notices (PMNs) and significant new use notices (SNUNs) would rise from $19,020 to $45,000 per substance; the fees for low-volume exemption (LVE) applications would increase from $5,590 to $13,200 per substance; and the fees for EPA-initiated risk evaluations (to be shared by all manufacturers of the substance) would increase from $1,605,000 to $5,081,000 per substance. Lower fees would apply to small businesses.

The agency says the proposal would increase resources for the cash-strapped TSCA program, allowing it to chip away at a growing backlog of new chemical reviews and better meet deadlines to evaluate and regulate concerning substances.

California Considers Listing Microplastics

California's Department of Toxic Substances Control (DTSC) has proposed adding microplastics and para-phenylenediamine (PPD) derivatives to its candidate chemicals list (CCL) under its Safer Consumer Products (SCP) program.

State regulators based the proposal on the chemical groups' reported impacts on human health and the environment. Although adding compounds to the CCL does not directly result in the creation of new regulations, it does enable the SCP program to choose consumer goods that include the chemicals for later examination and potential regulation as chemicals of concern in a priority product.

The proposed DTSC definition of microplastics is solid polymeric materials to which chemical additives or other substances may have been added, which are particles having at least three dimensions that are less than 5,000 microns (5 mm).

DTSC expects its priority product listing of 6PPD-containing tires to take effect this July, with priority product notifications (PPNs) due before October. The department formally proposed the listing last May after receiving an industry request for that action in 2021.

Adding the PPD family of chemicals—of which 6PPD is a member—to the CCL "will ensure that manufacturers fully evaluate the trade-offs before switching from 6PPD to another PPD derivative," the DTSC said.

Due to the need for research into the potentially harmful effects of plastic microparticles and nanoparticles on exposed organisms, as well as the enormous difficulty of reliably collecting real plastic microparticles and nanoparticles from the environment for model studies, a team of researchers at the Autonomous University of Barcelona (Spain) created nanoplastic particles that represent real environmental samples for use in animal studies. The team created them by sanding and sieving commercially available white polyethylene terephthalate (PET) plastics, which also contain titanium dioxide.

The study concluded that the particles were taken up by cells in vitro with absorption levels varying depending on cell type. Moreover, the PET and titanium signals were found together, which will aid with particle localization within the test organisms. The plastic particles, on the other hand, do not appear to be poisonous. However, further research using diverse biomarkers is needed to rule out adverse consequences. The study is part of an EU-funded project called PlasticHeal, one of five projects of a European research group to understand the health impacts of microplastics and nanoplastics (CUSP).

Turkey REACH KKDIK—Industry Calls for Extension of Registration Deadline

Cefic has called for a minimum two-year extension to the December 2023 deadline for registrations under Turkey's KKDIK. The industry organization also requested a REACH-like regulation with sequential submission dates based on tonnage band and hazard category.

The organization's proposal to a meeting of trade representatives and government officials came amid concerns that with just a few months until the KKDIK's single submission deadline for all substances, persistent problems with data access and lead registrant nominations continue to affect the registration process.

According to the latest official figures—presented at the meeting in Istanbul in summer this year—only 1,400 chemicals have so far been registered under the Turkish law, with an estimated 7,000 registrations still to materialize.

Cefic's proposal suggests the following KKDIK registration submission deadlines:

- December 31, 2025—substances manufactured or imported in quantities of 1,000 tons or more per year; carcinogenic, mutagenic and reprotoxic substances (CMRs) of one ton per year or more; and substances very toxic to aquatic life of 100 tons or more per year
- December 31, 2027—those between 100–1,000 tons
- December 31, 2029—those between 1–100 tons.

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

Sun Chemical
35 Waterview Blvd #100
Parsippany, NJ 07054
United States
www.sunchemical.com/regulatory-newsletters

Grow your bottom line with data-driven sustainability.

From colors and coatings to inks and pigments, the seeds of environmental stewardship are sown into everything we do. Our data-driven approach provides more transparency through continuous monitoring and reporting—and that kind of data can help your bottom line grow and thrive.

See how in our Sustainability Report. Request your copy at **sunchemical.com/sustainability**.

SunChemical®

a member of the DIC group

DIC Color & Comfort