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Color & Comfort

Regulatory Newsletter
Spring 2025

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

Industry Associations – Opinions And Positions

Titanium Dioxide - Final Judgement of the High Court regarding the appeal of France and the European Commission

The General Court of Justice of the European Union (ECJ) ruled that the ECHA Committee for Risk Assessment (RAC) committed a manifest error of assessment and annulled the Carc. 2 classification for Titanium Dioxide (TiO2) in November 2022. Two principal grounds for annulment were made: an error in the assessment of the reliability and acceptability of the (Heinrich) study on which the classification was based. And that a classification can only apply to a substance that has the intrinsic property to cause cancer. The Court concluded furthermore that also the European Commission (EC) committed the same manifest error of assessment in basing its decision on the conclusions of the RAC.

Member State France and EC appealed to the ECJ arguing with the precautionary principle and that the Heinrich study was only weight of evidence.

An oral hearing took place in November 2024 and the Advocate General delivered her opinion on 6 February 2025. According to the Advocate General the Court exceeded the limit of its power of judicial review "by going further than simply judging whether the administration was aware of and had assessed all the aspects that current scientific knowledge required it to take into consideration". She proposed that the ECJ overturns the judgment under appeal and refer the case back to the General Court for resolution of the remaining pleas in law. The ECJ is not bound by the opinion but follows in 80% of the cases. Which would implicate for TiO2 that the Carc. 2 classification and labelling for TiO2 remains and other insoluble, particulate materials could be classified accordingly. The final binding judgment of the Court is expected in May 2025.

In parallel to the proposed classification for chemicals, the Titanium Dioxide Manufacturer Association (TDMA) seeks to push EFSA to release a revised opinion on the food colorant E171. In the latest EFSA opinion on E171 published in May 2021 EFSA concluded that it no longer considers E171 safe as a food additive because concerns for genotoxicity could not be ruled out. Consequently, the European Commission withdrew the approval for the use of E171 in food in the EU on 18 January 2022. On the contrary, other organizations and authorities such as WHO and US FDA in 2023 confirmed the safety of TiO2 used as food colorant.

EU Packaging and Packaging Waste Regulation (PPWR)

Eurocolour informs that the text of the PPWR and the corresponding translations have been published in the Official Journal of the EU on 22.01.2025. According to Article 71 of the text, the regulation will enter into force 20 days after its publication in the Official Journal, on 11 February 2025, and will apply from 12 August 2026. Due to the scope, the broad application, the innovations and the still open regulations, the Commission had presented the PPWR in detail and given the opportunity to ask questions during a webinar in December 2024. Overall, the regulation aims to reduce packaging waste and promotes its recycling as well as refill-systems. By end of 2030 all packaging should be recyclable and 40% reuseable by 2040 70% reuseable packaging is anticipated. From 2030 single-use plastic packaging shall be banned. Furthermore, binding quotas for the proportion of recycled plastic in new plastic packaging are included.

The slides of the event were published by the Commission afterwards. The Commission has announced that it will publish an FAQ document incorporating the questions raised during the webinar and that it will start talks with the member states in preparation for implementation soon.

Industry associations such as FoodDrink Europe as well as CEFLEX attended the webinar and produced an extract of the key points discussed . They stated that relevant technical details as well as definitions and criteria were clarified during the webinar. However, the verbal answers provided were not fully clear in all cases e.g. the term “single-use plastic packaging” requires further explanation. The Commission will publish a written FAQ document in January which should provide some further clarification on key questions.

Eurocolour elects new Presidential Board

Eurocolour, the European umbrella organisation for manufacturers of pigments, dyes, fillers, and ceramic decoration products, welcomes four new members to its Presidential Board. During its General Assembly held in Madrid on 29 January 2025, the members elected Emmanuel Auer (Evonik Operations GmbH) as new President with Ulrich Veith (Sun Chemical), Wolfgang Oehlert (Lanxess Deutschland GmbH) and Julian Hohberger (Bruchsaler Farbenfabrik GmbH & Co. KG) joining as new board members.

Eurocolour’s activities are currently focused on the regulation and risk assessment of particles, the regulation of food contact materials such as plastics and ceramics and other issues related to chemicals legislation. Of course, the association is keeping a close eye on what the EU Commission’s ‘Clean Industrial Deal’ and ‘Chemicals Industry Package’ will entail. The members are concerned about the challenges posed by the current crises and the continuing flood of regulation in the EU. “The professional scientific and technical work of our expert groups will remain as a ‘must-have’ of Eurocolour” emphasised President Emmanuel Auer, “while an intensive dialogue with regulators on a science-based, transparent regulatory environment for industrial production must target the best for end-consumers, secure workplaces, and protection of natural resources.”

Food Contact Materials

European Commission adopts BPA ban in food contact materials

The European Commission has confirmed a ban on the use of bisphenol A (BPA) in food contact materials (FCMs), due to its potentially harmful health impact. The ban, which was adopted on 19 December 2024, targets the use of BPA and other bisphenols in plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers in FCMs, and will enter into force in 2026.

The regulation sets out an 18-month transition period for most uses, including coatings and varnishes on the interior of cans. However, the Commission proposed a longer 36-month transition period for applications that maintain food safety that will take manufacturers longer to replace with alternatives, it says.

The European Printing Ink Association (EuPIA) emphasized that BPA as such is not used in printing inks but can only occur as a component or impurity in certain raw materials. For food contact materials, typically only raw materials, which are not based on BPA or its derivatives are used.

7th edition of the EuPIA Exclusion Policy

The EuPIA Exclusion Policy has been updated already in March to take into account the new hazards class of “Endocrine Disruptors Category 1 for human health (EUH380)”. In November 2024 the 7th edition was released including a new annex on substances with occupational concern when it comes to inhalation exposure & poorly soluble particles.

The European sector group of the printing ink industry took over existing national stewardship initiatives to create the Exclusion List for Printing Inks and Related Products in 1996. It applied stricter rules to the manufacture and marketing of inks than the existing legal regulations would have required. Since 2003, the European printing ink industry is represented by the European Printing Ink Association (EuPIA) and its Technical Committee has amended and adapted the Exclusion List over the years.

PFAS restrictions in EU food packaging to apply from 2026 under the Packaging and Packaging Waste Regulation

Restrictions on the use of PFAS in food packaging will come into force in 2026, following the EU Council of Ministers’ approval of the packaging and packaging waste regulation (PPWR) on 16 December 2024. The rules will restrict the placing on the market of food contact packaging containing per- and polyfluoroalkyl substances if they exceed the following thresholds:

- 25ppb for a single PFAS;
- 250ppb for a group of PFAS measured as a targeted sum; and
- 50ppm for all PFAS, including polymeric PFAS.

These thresholds are the same as those proposed under the broader EU-wide REACH restriction. To avoid overlap with restrictions under other EU legislation, such as the PFAS REACH restriction, the final text requires the European Commission to carry out an evaluation to assess the need to amend or repeal these provisions within five and a half years.

The regulation will be published in the EU Official Journal in the first quarter of 2025 and enter into force 20 days later, with restrictions applying after a transition period of 18 months. When in force, the PPWR will repeal the existing packaging and packaging waste directive (PPWD).

MERCOSUR adds two substances to FCM positive list

The MERCOSUR trade bloc has added two additives to its 'positive list' of substances approved for use in food contact materials (FCMs).

Resolution 28/2024, published on 4 December 2024, adds Tetramethyl bisphenol F diglycidyl ether (TMBPF-DGE) for use in dispersions of macromolecular substances in water used in can coating for beverages; and Polyamide-imide 2 (PAI-2) for use as a binding agent for producing high temperature resistant coatings on kitchen utensils.

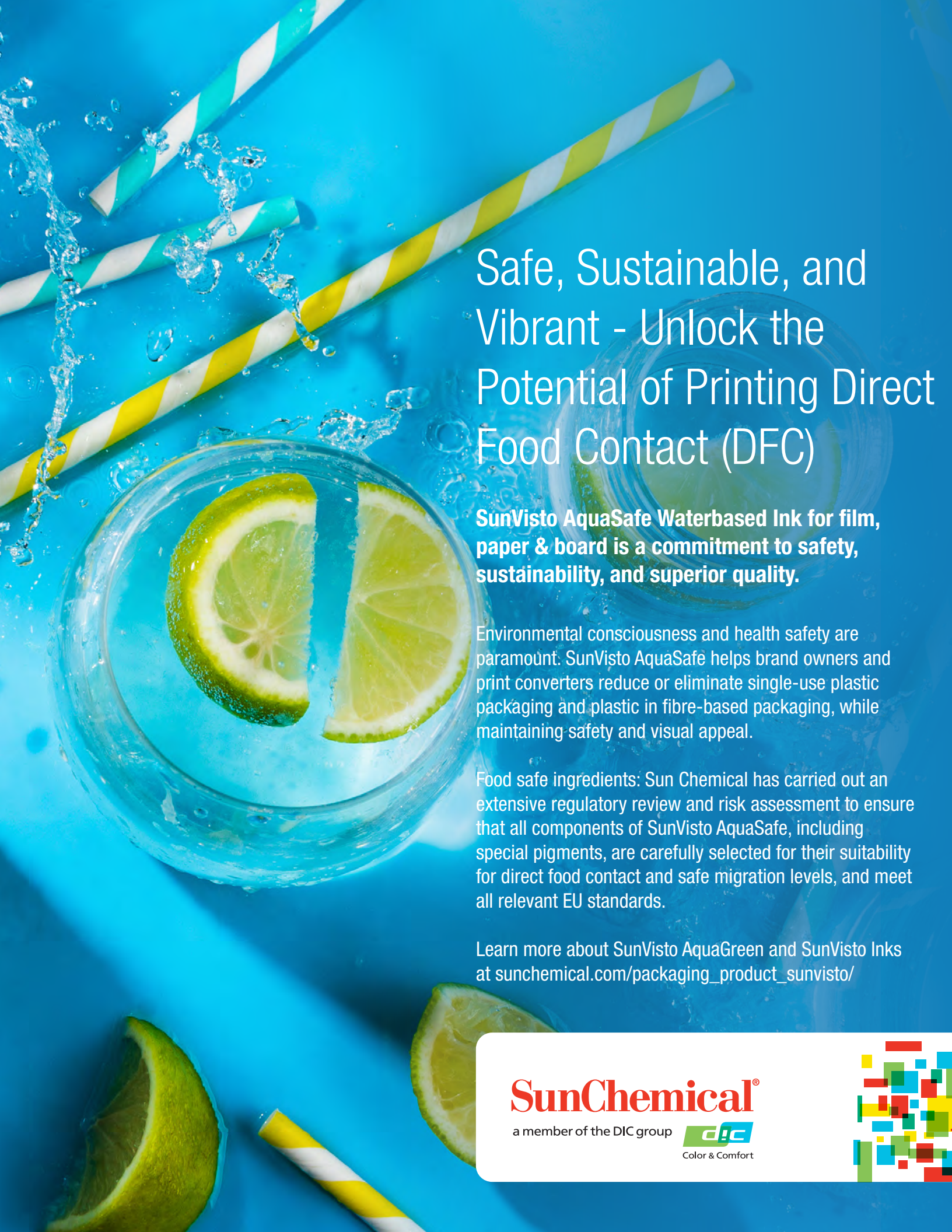
MERCOSUR members, comprising Argentina, Bolivia, Brazil, Paraguay and Uruguay, must now incorporate the resolution into their own national legislation.

Europe – Upcoming Chemicals Legislations And Guidance Documents

Reclassification for Pigment Red 53:1

In 2020, Germany added Pigment Red 53:1 (CAS 5160-02-1) onto the CoRAP (Community Rolling Action Plan) list and end of 2021, it was concluded that should be classified and labelled as a Carc. 2 (suspected of causing cancer, H351). After the confirmation of the RAC committee the draft 23rd ATP of the CLP regulation has been notified to the WTO. The adoption of the 23rd ATP was anticipated for end of 2024, with an entry into force 20 days after publication in the official journal which is approximately 2 months after adoption. The classification will apply 18 months after the entry onto force which should be around August - September 2026. Until release of this newsletter no information on the delay or a new due date was published.

With this reclassification as a carcinogen category 2, any mixtures containing 1% of more of this pigment in the EU would also need to be classified and labelled as carcinogen category 2.



Safe, Sustainable, and Vibrant - Unlock the Potential of Printing Direct Food Contact (DFC)

SunVisto AquaSafe Waterbased Ink for film, paper & board is a commitment to safety, sustainability, and superior quality.

Environmental consciousness and health safety are paramount. SunVisto AquaSafe helps brand owners and print converters reduce or eliminate single-use plastic packaging and plastic in fibre-based packaging, while maintaining safety and visual appeal.

Food safe ingredients: Sun Chemical has carried out an extensive regulatory review and risk assessment to ensure that all components of SunVisto AquaSafe, including special pigments, are carefully selected for their suitability for direct food contact and safe migration levels, and meet all relevant EU standards.

Learn more about SunVisto AquaGreen and SunVisto Inks at sunchemical.com/packaging_product_sunvisto/

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Publication of the revised CLP regulation and of ECHA`s new CLP guidance series

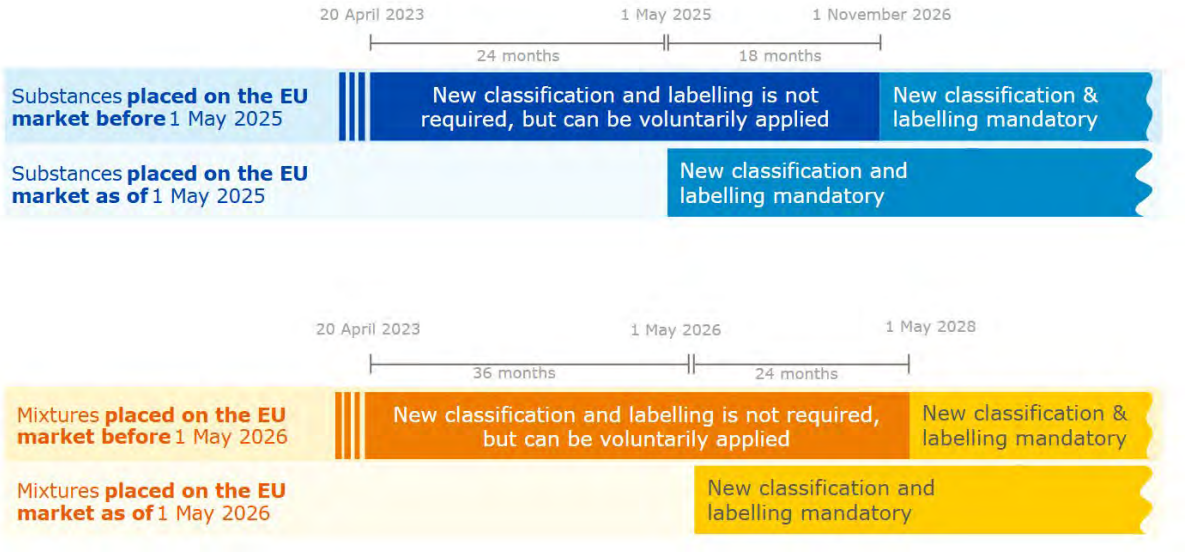
The revision of the main text of the CLP Regulation was published in the Official Journal on 20 November 2024 and entered into force 20 days later (December 10th). The main changes include in brief the introduction of new hazard classes, new classification rules for substances with more than one component (MOCS), the promotion of group classifications in the CLH process, new formatting rules for labels and the introduction of digital labelling and the promotion of folded labels.
The table as well as the chart below summarize the most relevant changes and deadlines.

New hazard classes	The new hazard classes include endocrine disruptors for human health and the environment as well as substances that are persistent (P), bioaccumulative (B), mobile (M) and toxic (T). PBT and vPvB substances are already known from the REACH Regulation and ED substances from the Biocide Regulation. Only the PMT and vPvM substances represent a completely new approach and hazard class.
New classification rules for substances containing more than one constituent (MOCS)	The approach for classifying MOCS is similar to the procedure for mixtures. It only applies to CMR and the new hazard classes. Exemptions can be requested to the EU Commission if evidence is provided that the approach is not suitable. While the MOCS approach as such was adopted there was no agreement on the definition for MOCS during the trilogue discussions and is being re-viewed in five years.
Digital label	Safety relevant information must continue to be present on the physical label. The digital label can therefore only be used for additional information.
Classification and labelling inventory	The date of the last update and the identity of the notifier are to be added in the future. In addition, the reason for a deviation from the highest classification should be given, as well as the reason for a higher classification (Article 40).
Transitional periods for MOCS and label-update	An 18-month transition period applies for the MOCS concept as well for the label-update and digital labels. A 24-month transition period applies for labelling changes regarding font size, spacing, symbol size etc.
Transitional periods for New hazard classes	From 1st May 2025 onwards, all new substances placed on the market must be labelled according to the new hazard classes. For substances that were previously available, a sale-off period applies until 1st November 2026. Please see also the chart below. From 1st May 2025 onwards, all new substances placed on the market must be labelled according to the new hazard classes. For substances that were previously available, a sale-off period applies until 1st November 2026. Please see also the chart below. Similar to substances, there are two cut-off dates for mixtures: 1st May 2026 for mixtures newly placed on the market and 1st May 2028 for previously available mixtures.

New requirements for labelling and fixed deadline for updating

Container size	**Dimension label (mm)**	**Dimension pictograms (mm)**	**Minimum font size (x-height in mm)**
≤ 3 l	If possible, min. 52 x74	Not smaller than 10 x 10 If possible, min. 16x16	Container < 0.5l: 1.2 Container 0.5-3l: 1.4
3 – 50 l	min. 74 x 105	min. 23 x 23	1.8
50 – 500 l	min. 105 x 148	min. 32 x 32	2.0
> 500 l	min. 148 x 210	min. 46 x 46	2.0

In parallel ECHA published its new guidance series on the application of the CLP criteria. The guidance is split in four separate documents for ease of use. Part 1 is an overview document explaining the general principles for classification and labelling. Parts 2-3 refer to physical hazards, health hazards and environmental hazards, respectively.



New hazard classes 2023 - ECHA. (n.d.). https://echa.europa.eu/new-hazard-classes-2023

European Commission to launch evaluation of cosmetics regulation

The European Commission (EC) will launch its official evaluation of the EU cosmetic products regulation (CPR) in a process that could kick-start the delayed revision of the 15-year-old law. An overhaul of the cosmetic products regulation has been expected since its inclusion in the chemical strategy for sustainability (CSS). October 2024 DG Grow announced that the Commission is "launching the evaluation now" and hopes to conclude it "during the first half of 2026".
Even though there is no proposal for a revision of the law so far, an inception impact assessment showed that it will likely include:

- an extension of the generic risk assessment (GRA) to hazard classes other than carcinogenic, mutagenic and reprotoxic (CMR) chemicals;
- new measures to account for combination effects from exposure to chemicals from different sources;
- digital labelling rules;
- a review of the definition of nanomaterials; and
- integrating the Scientific Committee on Consumer Safety (SCCS) into ECHA

Especially the update of the definition of nanomaterials (NM) raises concern within cosmetics industry. The alignment with the EU Commission`s recommendation for a NM definition might result in a loss of specific, currently used criteria such as "intentionality manufactured" or "insoluble" and to enlarged perimeter of ingredients considered as NM e.g. colorants. Being prepared for the upcoming revision industry seeks to bring potential NM on the CPR Annex IV to guarantee the continuity of its use in cosmetics. Though before a substance is going to included in the annexes of the regulation it needs to be reviewed by the Scientific Committee on Consumer Safety (SCCS). The ever-postponed revision of the CPR entails therefore not only a lot of uncertainty but also tremendous workload for both, industry and Committee.

Proposed change of EC number format

ECHA proposed during the last ECHA-Industry-Meeting in December 2024 to change the EC number format. The EC numbers serve as substance identifier within the EU; for every new substance a new list number is created by the agency in the format 123-456-7. Due to the high consumption rate list numbers are running out now. Therefore, a new format was under discussion.

ECHA proposed two options to extend the EC numbers: either to keep the current format and length of the EC numbers, but allow the use of alphanumerical characters, e.g. 2XP-6AZ-7. Or to extend the format and length of the current EC numbers, but maintain the numbers-only-structure, e.g. 123-200-001-5.

An aligned reply by industry was sent to ECHA in January: more than 70% voted for the alphanumerical option. ECHA considers to update the list number format around early summer 2025. EC numbers assigned before the format change will stay as they are and will not be affected by the new format

Clearing up the online C&L inventory

As of July 2025, ECHA will change the status of active Classification & Labelling (C&L) notifications, submitted on behalf of a group of manufacturers or importers (group of MIs), to 'annulled' if the lead notifier has successfully registered the same substance under the REACH Regulation.

If notifiers would like to avoid annulment, they have to contact the other notifiers in the group of MIs to identify a new lead notifier to take over the lead role. The notification can be transferred free of charge to the new lead any time before July 2025 by using the legal entity change functionality in REACH-IT.

This decision will impact the C&L inventory entries listed under the source option "Notified C&L" and aims to reduce duplicates and to clear up the inventory.

Global Regulations – Upcoming Changes

Vietnam's National Assembly reviews amended draft of Law on Chemicals

Vietnam's Minister of Industry and Trade (MOIT) has said that the country's draft Law on Chemicals, currently under review in the National Assembly, aims to balance regulation with fostering creativity. Nguyen Hong Dien said there was a need to "liberate all productive forces and resolutely abandon the mindset of 'If you can't manage, then ban'".

The draft Law on Chemicals, the country's overarching legislation on chemicals management, introduces stricter control measures for toxic chemicals, enhanced sanctions for violations, and digital tracking systems to monitor regulated chemicals. New provisions regulate imports, production, trading and transport of chemicals, covering the entire lifecycle, with varying levels of oversight. Companies using controlled chemicals must register their purposes in a centralised database, aiding inspection and preventing misuse. Also, production and storage facilities for toxic chemicals must be located away from residential areas and adhere to strict safety measures.

The draft reduces administrative procedures by eliminating nine groups of procedures while adding four new ones, streamlining the total to 12 groups. The MOIT will consider the discussion points raised during the review to finalise the draft for submission at the next National Assembly session. Vietnam intends to adopt the final version of the draft amendment to the law on 1 May 2025, with entry into force on 1 May 2026.

China consults on limits for heavy metals in inks

China's Ministry of Industry and Information Technology (MIIT) has invited public comments on drafts of four mandatory national standards pertaining to chemicals management from November 2024 until January 2025. Three of the drafts cover the safety technical requirements for natural and synthetic stone, limits on harmful metals in wall materials and harmful elements in graphite and in fluorite. The fourth draft specifies the maximum permissible limits for heavy metals in printing inks and ink products:

- elemental lead, cadmium, mercury, hexavalent chromium – total content ≤100mg/kg;
- soluble antimony – ≤60mg/kg;
- soluble arsenic – ≤25mg/kg;
- soluble barium – ≤1,000mg/kg;
- soluble cadmium – ≤75mg/kg;
- soluble chromium – ≤60mg/kg;
- soluble lead – ≤90mg/kg;
- soluble mercury – ≤60mg/kg; and
- soluble selenium – ≤500mg/kg.

Brazil to form working group for national chemicals law

Brazil's National Commission on Chemical Safety (CONASQ) is expected to work on a proposed set of rules to help set the government's new chemicals management law into motion. The influential panel plans to create a specific working group to develop the regulation draft for the law.

Brazil's newly enacted "REACH-inspired" chemicals management law will establish a national inventory of chemicals and a framework for assessing and controlling the risk of substances that companies make, use or import.

The government, which has a maximum of three years to create the online registration platform for the inventory, is also in the process of contracting with a company that will develop the IT platform.

Japan published Weight of Evidence methodology draft for evaluation of degradability of chemicals

Japan is proposing to implement a weight of evidence (WoE) framework that will help to assess a chemical's potential for degradation in the natural environment.

Currently, under Japan's Chemical Substances Control Law (CSCL), prior to the manufacture or import of new chemical substances, a preliminary review is conducted based on test results submitted by businesses according to statutory testing methods. After manufacturing or import, risk assessments are carried out using the actual quantity reports and toxicity information submitted by the businesses.

The tests that are performed are equivalent to OECD 301C and 301F, and following an assessment, a substance is classified as either readily degradable or difficult to degrade.

However, the test substance concentration in the degradability test, which is usually 100mg/l, is susceptible to microbial toxicity. In addition, poorly water-soluble substances are not dissolved in the test solution, resulting in poor bioavailability. As such, the current testing regime is not always suitable.

To verify the effectiveness of the draft manual, METI conducted a trial evaluation using two chemicals and sought opinions on the use of WoE methodology from experts and business operators.

India consults on revised standards for poster colors

India's Bureau of Indian Standards (BIS) is consulting on the first revision of its standard for poster colors. The standard stipulates that poster colors shall not contain more than 10 ppm of lead when tested, as per the laid down methods. The standard also gives instruction on the packaging and container labelling of the colors. It refers to the following 26 colors: magenta, turquoise green, carmine, mauve, dark green, pink, cobalt blue, permanent yellow, burnt sienna, Prussian blue, lemon yellow, burnt umber, cerulean blue, yellow ochre, Vandyke brown, ultramarine blue, orange, grey, light green, crimson lake, black, medium green, scarlet lake, white, deep green and vermilion.

Washington state initiates rulemaking to 'potentially' raise allowable lead in cosmetics

Washington State's Department of Ecology (Ecology) has initiated a new rulemaking to "potentially" adjust the 1ppm allowable limit on lead impurities in cosmetic products, set to take effect on 1 January as part of the state's 2023 Toxic-Free Cosmetics Act (TFCA).

In a 19 December announcement, Ecology said the goal of the rulemaking is for "potentially adopting a different limit on lead impurities" other than the TFCA's 1ppm restriction. The department said it aims to better understand compliance challenges related to the 1ppm restriction about which manufacturers had previously raised alarms, and to "determine the lowest feasible limit the manufacturers can achieve" in cosmetic products "that is also protective of people and the environment". The department plans to take informal comment on a preliminary draft rule in early 2025, according to an overview of Ecology's rulemaking plan. A formal proposal and consultation is expected in summer 2026, with a final rule anticipated in "winter 2026". Ecology said it will consider federal regulations from the US EPA and the Food and Drug Administration (FDA), as well as regulations from other states, "and will coordinate with these agencies if necessary".

In the meantime, Ecology also adopted an interim policy on lead limits in cosmetic products to provide temporary relief for manufacturers unable to meet the law's 1ppm restriction. In the interim policy, the department conceded that the 1ppm limit on lead in cosmetic products "can be difficult, if not impossible" to achieve. Going forward, Ecology said it "will not enforce strict compliance" with the 1ppm limit where manufacturers meet one of two 'safe harbour' options. In the first option, two criteria must be met:

- the lead concentration is 2ppm or below for general cosmetics (including lotions and cleansers) or 5ppm or below in colour cosmetics (including blushes and eye shadows) and clay masks; and
- the manufacturer has notified Ecology of its plan to meet these limits for products sold in Washington.

The second option requires three criteria to be met:

- the lead concentration of a colour cosmetic or clay mask is between 5ppm and 10ppm;
- the manufacturer has notified Ecology of its plans to meet these limits for products sold in Washington; and
- the manufacturer is monitoring lead in each batch of the product and retaining lead concentration data and information.

Regarding the second option, Ecology said manufacturers may measure lead concentrations by testing raw ingredients, testing final products or tracking amounts based on certificates of analyses. Testing must be completed by a third-party laboratory.

Industry groups had previously been critical of Ecology's 1ppm lead limit in cosmetics. Earlier this year, Ecology denied three industry petitions seeking to raise the allowable lead limit to 10ppm. The Personal Care Products Council (PCPC), which had previously called the 1ppm lead limit "unrealistic and unreasonable", praised the department's action. Ecology's "commitment to take interim policy action and open rulemaking are positive steps forward on this matter", PCPC spokeswoman Tesia Williams told Chemical Watch News & Insight.

The interim policy takes effect on 1 January 2025 and will remain in effect until either a new rule is adopted or the policy is repealed, or until 31 December 2026 – whichever occurs first. The department also said it may extend the interim policy beyond 2026, if necessary. Manufacturers planning to use one of the safe harbour provisions in the interim policy must notify Ecology of their intentions via the department's online submission form.

US EPA proposes TSCA risk management rule for PV29

The US EPA has proposed a TSCA rule for pigment violet 29 (PV29) that would impose workplace requirements only where the substance is used in dry powder form. The agency said it expects the rule would affect 22 companies, potentially avoiding impacts on the roughly 50,000 companies that use the colorant as part of a formulated product in downstream applications.

Issued in pre-publication form in December 2024, the proposed TSCA section 6(a) rule addresses the identified concerns and proposes respiratory protection and cleaning plans in workplaces where PV29 is used in dry powder form. The agency did not propose to regulate the substance once it is incorporated into a mixture, like plastic, paint or ink. Comments on the proposal will be due 45 days following its formal publication in the Federal Register.

The Color Pigments Manufacturers Association (CPMA) criticized the proposal. The association plans to submit comments and to facilitate a meeting with new EPA appointees as soon as they are confirmed.

Australia adds seven industrial chemicals to national inventory in January

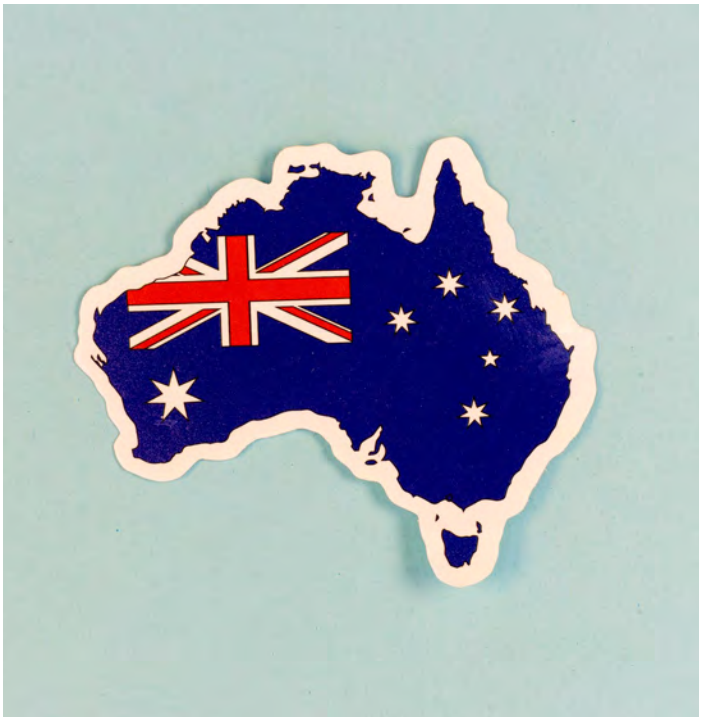
The Australian Industrial Chemicals Introduction Scheme (AICIS) has added six industrial chemicals to the Australian Inventory of Industrial Chemicals (AIIC), with importers and manufacturers still required to report relevant information to the regulator. The newly listed industrial chemicals are CAS 1197818-14-6; CAS 2209052-54-8; CAS 86830-15-1; CAS 163069-69-0; CAS 918887-41-9 and CAS 1311393-70-0 and CAS 1392276-61-7. Furthermore eight evaluations about the human health and environmental risks associated with the use of certain chemicals on the Inventory were published, amongst other Bisphenol A (BPA).

Australia proposed standards for chemicals of concern

In October 2024, the Australian Government initiated a public consultation on proposed limits for recognized chemicals of concern, including PCBs at 2ppm and HCB at 5ppm. Under the proposal, the chemicals will be listed on schedule 7 of the Industrial Chemicals Environmental Management Standard (IChEMS) register and prohibited from manufacture. The Department of Climate Change, Energy, the Environment and Water (DCCEEW) said that these measures “are not expected to disrupt industry or trade” because information indicates that PCBs and PCTs have never been commercially manufactured in Australia. Similarly, HCB has no current industrial use in the country, “so a lengthy adjustment period is not required for entities to adapt to the standard”.

ETAD, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers, submitted comments requesting a specific limit of 10 ppm for both substances. In December 2024, a revised proposal was published, which now explicitly includes an exemption for pigments and dyes in the case of PCBs (50 mg/kg) and establishes an overall new limit for HCB (10 mg/kg).

Sun Chemical`s Heliogen phthalocyanine pigments are produced by use of a unique process preventing formation of harmful by-products. So has e.g. HELIOGEN Green a significantly lower HCB level than the limit.



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Turkish Ministry opens consultation on the KKDIK Draft of Procedures and Principles

The Ministry of Environment, Urbanization, and Climate Change has published the draft of the "Procedures and Principles for the Implementation of the Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals (KKDIK)" and is asking for feedback. Stakeholders were expected to review the draft and submit their opinions by end of January.

Key points of the new obligations proposed are:

- Deadlines for Pre-registration for all potential registrants of a Substance Information Exchange Forum (SIEF).
- Deadlines for selecting the lead company for substances placed on the market.
- It has been clarified that dossiers can still be submitted individually if not accepted as a lead or joint registrant.
- Preliminary registration deadlines for lead companies have been defined (December 31, 2025). And deadlines for member companies to complete their registrations after preliminary registration have also been set. Preliminary Registrations must be performed by the Only Representative (OR), and certificates must be uploaded to the system.
- Safety Data Sheets prepared in compliance with the regulation must be registered in the Ministry's IT infrastructure, along with the certification of the relevant OR.

All relevant information and deadlines are summarized in the table below. Information on adoption and implementation of the draft has not yet published.

Pre-registration periods	The deadline for pre-SIEF registrations is 30/06/2025. Substances that are manufactured and/or imported for the first time after 30/06/2025 should be pre-registered within the below-stated deadlines: a) 100-1000 t/y: 31/12/2027 b) 1-100 t/y: 31/12/2029.
Lead Registrant (LR) Determination	For substances placed on the market before 31/12/2030, LRs must be determined by 30/09/2025 For substances whose LR was determined before the publication of this amendment but whose registration dossier has not been submitted yet, the LR selection will be repeated according to these principles and procedures: a) If more than 70% of SIEF members approve the candidate LR, it is confirmed as the LR b) If more than 30% of SIEF members disapprove, the candidate must inform all SIEF members of this outcome and withdraw from the LR role. The process for selecting a new LR will then restart. The determination of lead companies is based on voluntary participation. In the absence of volunteers, the Ministry and TOBB (TOBB - The Union of Chambers and Commodity Exchanges of Türkiye) will cooperate to designate a lead company from among companies with the largest tonnage, the most data, and the largest scale.
Provisional registration (dossier that contains only Physical and Chemical Properties)	All LRs shall complete the Provisional Registration by 31/12/2025 in accordance with the requirements specified in Annex I of the draft Principles and Procedures. After the LR completes the provisional registration, member companies shall submit their member registrations by 30/06/2026. Companies that will register individually complete their provisional registration by 31/12/2025.

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