Regulatory Newsletter

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

Food-Contact Materials (FCM)

German Printing Ink Ordinance

The German Bundesrat has now passed the 21st Ordinance amending the German Consumer Goods Ordinance, otherwise known as the German "Printing Ink Ordinance" ("Druckfarbenverordnung"). The ordinance amends the German consumer goods regulation by introducing a list of substances permitted to be used in the manufacture of printing inks for food-contact materials, together with their specific migration limits, covering all printed food-contact materials.

The ordinance does not regulate printing inks as such, but printed food-contact materials for which a transfer of substances from the printing ink layer to the food cannot be excluded.

The provisions are only applicable after a transitional period of four years, from January 1, 2026.

The core of the German Ink Ordinance is a positive list of substances (Annex 14, Tables 1 and 2), which may be used for the manufacture of printing inks for food-contact materials. In addition, there is a dynamic reference to the positive list of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.

It should be noted that this reference to the EU Plastics Regulation only applies to substances which are listed therein without group restrictions and without restrictions and specifications. In the positive list, specific migration limits, group limits or restrictions are partially laid down and must be observed. If no migration limit or other restrictions are defined, the global migration limit of 60 mg/kg of the foodstuff applies.

Inks for printing food-contact materials where the print does not come into direct contact with food may be manufactured from substances

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other than those listed, provided these substances are not classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under chemical legislation (CLP Regulation (EC) No. 1272/2008), and their migration from the printed packaging is not detectable (with a detection limit of 0.01 mg/kg food or 10 ppb).

Transient food-contact applications, where the print may come into direct contact with food during normal or foreseeable use, such as printed napkins, are considered to be direct food-contact applications. Consistent with EU legislation, unintentionally added substances (NIAS) must be evaluated in accordance with internationally recognized scientific principles on risk assessment.

Trade Associations—Opinions and Positions

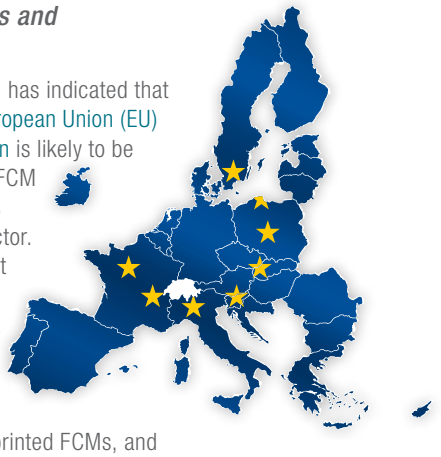
The German Ink Manufacturers Association (VdL) has published an information note indicating that the positive list is still incomplete and missing essential substances, and stating that there is currently no basis for requesting confirmations of compliance with the requirements of the ordinance. In addition to the composition of the printing ink, compliance with the migration limits depends on various factors such as the layer thickness, the packaging design and the packaging material, and is thus subject to the compliance work of the manufacturer of the final food-contact material.

The VdL and the entire food-packaging chain strongly believe that only a European regulation can satisfy the functioning of the European internal market and ensure a uniform level of consumer protection. This view is also shared by the Bundesrat.

In an accompanying resolution, the Bundesrat calls on the federal government to support the European Commission in its review of the EU legal framework and to strongly advocate the development of a uniform European regulation. The federal states conclude that the "established concepts of the European Printing Ink Association (EuPIA) ensure the safety of printed packaging" and thus confirm the successful EuPIA concepts for safe food packaging. In principle, the German federal government also recognizes the priority of a European regulation, and an extension of the transitional period is envisaged should the EU Commission present a corresponding specific measure on printed food-contact materials within this period.

Intergraf (the European graphic industry trade association) and FTA Europe (representing the flexo printing industry) have come together to produce a Guide to Applying Food-Contact Materials Legislation for printing and converting companies that make printed food-contact materials. Concern about harmful chemical migration means that strict rules are in place which must be applied by printers and converters. The document is a guide to the applicable legislation and the basic legal requirements for food-packaging printers. The aim is to help printers demonstrate they are legally compliant. The guide should be viewed as the basic best-practice advice that all printers should follow and brings together all legal requirements in the current absence of a clear legal framework. A supporting webinar is also available to watch.

Europe—Upcoming Legislations and Guidance Documents



Meanwhile, the European Commission has indicated that the ongoing review and revision of European Union (EU) food-contact material (FCM) legislation is likely to be delayed until early 2023. Linking the FCM rules with the upcoming EU chemicals strategy legislation is an important factor. The EuPIA and the Packaging Ink Joint Industry Task Force (PIJITF) have provided feedback to the consultation, emphasizing that the priority should be on the timely development of further specific measures for nonharmonized materials, especially printed FCMs, and such specific measures should incorporate industry risk assessment for nonlisted substances.

The Council of Europe's European Directorate for the Quality of Medicines & Health Care (EDQM) has published a technical guide entitled Paper and board used in food-contact materials and articles, following the adoption of Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food. The publication incorporates the resolution and its guiding principles and provides technical guidance relating to the requirements, compliance testing and supporting documentation for paper and board materials. The guidance document is expected to improve the protection of consumers against contaminants (metals, antioxidants, stabilizers, colorants, plasticizers, etc.) potentially released by materials in contact with food (packaging, containers, plates, cups, straws, baking and filter papers, napkins, etc.). It also aims to support the harmonization of regulatory approaches to consumer health protection across Europe.

Titanium Dioxide—E 171

The European Commission has published Regulation (EU) 2022/63 (amending Regulation (EC) No. 1333/2008 on food additives) in which titanium dioxide (E 171) is no longer authorized for use as a food additive after August 7, 2022. This follows the European Food Safety Authority's (EFSA) opinion of May 2021, which concluded that a concern for genotoxicity could not be ruled out based on the available data. Also, due to the many uncertainties and following a precautionary approach, E 171 could no longer be considered as safe when used as a food additive.

This latest opinion diverges from previous opinions in 2016, 2018 and 2019, which concluded that the use of titanium dioxide as a food additive did not raise a genotoxic concern. The discrepancy seems to be linked to gaps in the toxicity data available for, and relevance of extrapolation from, different particle size distributions. EFSA highlighted the need for more research to fill the data gaps.

Interestingly, although it is no longer authorized for use in food, titanium dioxide is still listed in Regulation (EC) No. 1333/2008 to allow continued use in medicinal products according to Directive 2009/35/EC. Furthermore, EFSA stated that their evaluation is related to the risks of titanium dioxide used as a food additive and not to other uses.

The EuPIA has issued a statement which confirms that neither the EFSA opinion nor Regulation (EU) No. 2022/63 affects the legal status of the use of titanium dioxide in printing inks for food-contact materials, neither under EU legislation for food-contact materials nor under the Swiss Consumer Goods Ordinance (SR 817.023.21), and concludes that titanium dioxide can continue to be used in printing inks for food-contact applications, without risk for the consumer.

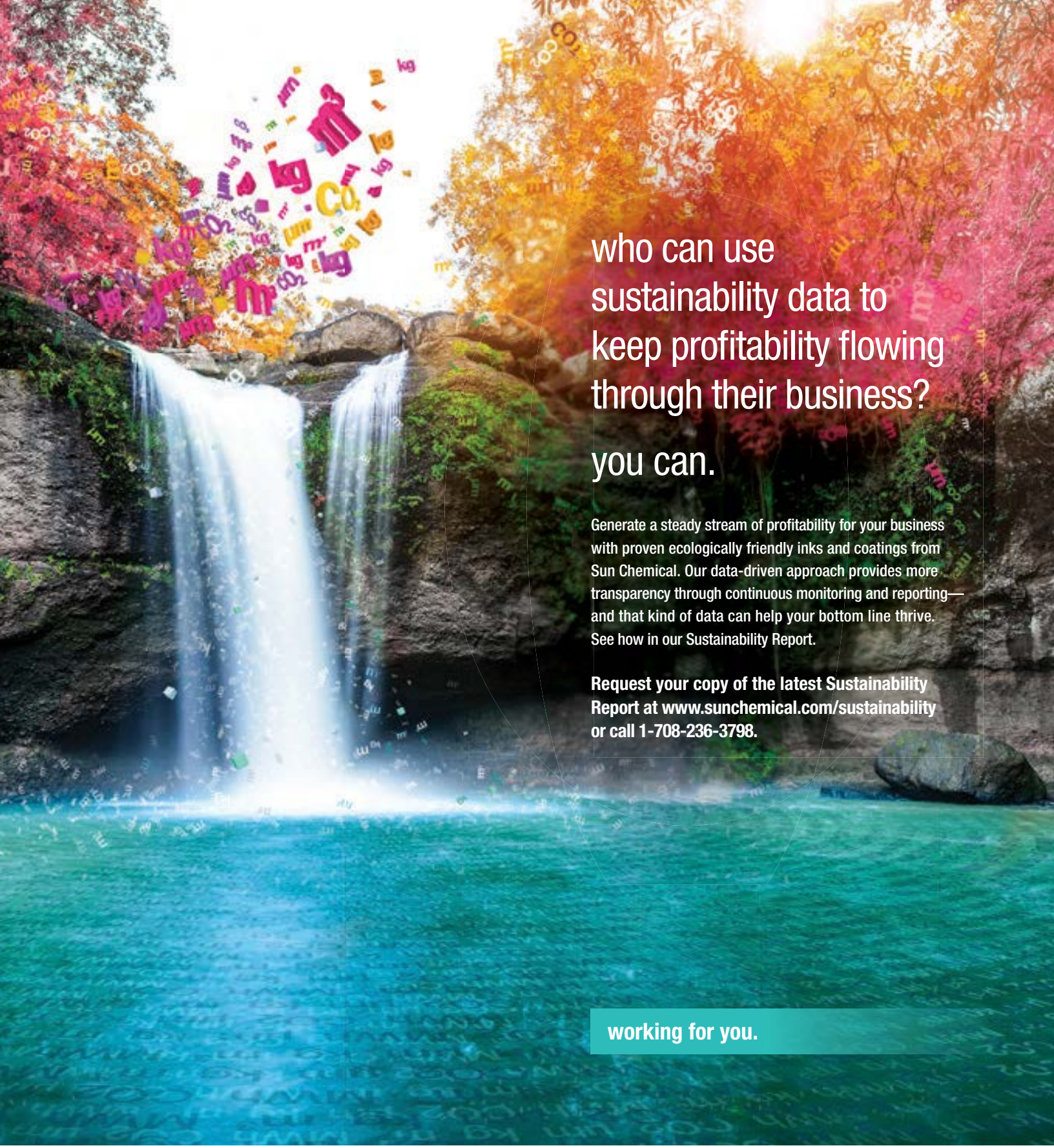
Global Regulations—Upcoming Changes

India has overturned a regulation from 2018 by an amendment to the rules on plastic waste management, which now allows the use of recycled plastic in food-contact materials. It supersedes a Food Safety and Standards Authority of India (FSSAI) ban on the use of recycled plastic as a FCM introduced via the Food Safety and Standards (Packaging) regulation. This required all-virgin plastic to be used as a food-contact material, a total (overall) migration limit of 60 mg/kg of food and no visible migration of color, together with maximum migration limits.

Metal	Limit (mg/kg)	Metal	Limit (mg/kg)
Barium	1	Iron	48
Cobalt	0.05	Lithium	0.6
Copper	5	Manganese	0.6

The Mercosur trade bloc has approved measures to amend its food-contact materials and articles resolution. The Mercosur countries (Argentina, Brazil, Paraguay and Uruguay) had until April 2022 to transpose these measures into their national law. Resolution No. 19/21 modifies Resolution No. 02/12 and sets specific migration requirements for different metals used in food-contact substances (see table). In addition, a more stringent migration limit of 0.05 mg/kg food is set for bisphenol A (BPA), and the substance is prohibited for use in feeding bottles and similar articles for infants and children up to three years old. A further 19 substances have been added to the positive list of substances allowed for use in the manufacture of food-contact materials.

Metal	Limit (mg/kg)	Metal	Limit (mg/kg)
Aluminum	1	Lithium	0.6
Barium	1	Manganese	0.6
Cobalt	0.05	Nickel	0.02
Copper	5	Zinc	5
Iron	48		



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Colombia's Ministry of Health and Social Protection technical regulation (Resolution No. 1440/2021) on tableware and articles of glass, ceramic or glass-ceramic that are intended to come into contact with food, as well as ceramic cookware, came into force in March 2022. It sets out the standards and migration requirements for lead and cadmium according to NTC ISO 6486 Parts 1 and 2, NTC ISO 7086 Parts 1 and 2, and NTC ISO 8391 Parts 1 and 2.

Scope	Lead	Cadmium
Permissible release limits in ceramic, glass ceramic and glass dinnerware in contact with food (NTC ISO 6486-1)	(NTC ISO 6486-2)	
Flatware	0.8 mg/dm²	0.07 mg/dm²
Small hollowware (< 1.1 L)	2.0 mg/L	0.5 mg/L
Large hollowware (≥ 1.1 L)	1.0 mg/L	0.25 mg/L
Cups and mugs	0.5 mg/L	0.25 mg/L
Storage hollowware (≥ 3 L)	0.5 mg/L	0.25 mg/L
Cookingware	0.5 mg/L	0.05 mg/L
Permissible release limits in glass hollowware in contact with food (NTC ISO 7086-1)	(NTC ISO 7086-2)	
Small glass hollowware (< 600 ml)	1.5 mg/L	0.5 mg/L
Large glass hollowware (≥ 600 ml)	0.75 mg/L	0.25 mg/L
Storage glass hollowware (≥ 3 L)	0.5 mg/L	0.25 mg/L
Permissible release limits in ceramic articles for cooking (NTC ISO 8391-1)	(NTC ISO 8391-2)	
Small glass hollowware (< 600 ml)	5 mg/L	0.5 mg/L
Cookingware	5 mg/L	0.5 mg/L

Adhesives

Primary Aromatic Amines (PAAs) in Adhesives

The Association of the European Adhesive and Sealant Industry (FEICA) has published a recommendation to adhesive suppliers and users on the assessment of primary aromatic amines (PAAs) in polyurethane adhesives intended to be used in food packaging. PAAs are not intentionally added components in food-packaging materials, but may be present as non-intentionally added substances (NIAS) mainly associated with azo pigments or polyurethane adhesives used in materials for packaging. Although polyurethane adhesives do not contain PAAs, they can be formed by the reaction of residual monomeric aromatic diisocyanates from the not fully cured adhesive layer of a laminate in contact with moisture present in the food. As long as monomeric aromatic diisocyanates are present in the polyurethane adhesive, migration through the film separating the not fully cured adhesive from the food can happen, and PAAs will be formed. Consequently, the adhesive user has to be made aware of the potential formation of PAAs.

Due to the toxicological concerns about PAAs (some of them are carcinogens, while others are suspected carcinogens), they are subject to legal restrictions, such as low specific migration limits in food-contact materials. Previously, a photometric sum method was sufficient to prove compliance with legislation. However, this method is no longer recommended due to sensitivity limitations. Most of the methods now use liquid chromatographic separation of the PAAs in the migration solution via high-performance liquid chromatography (HPLC), followed by detection of the separated PAAs via mass spectrometry (MS) or diode array detectors (DAD) to achieve a detection limit of 0.002 mg/kg food or simulant. A concentration step, e.g. via solid phase extraction, can be a helpful option to establish the required limit of detection.

Considering the limits for PAAs in Regulation (EU) 2020/1245 (15th Amendment to the EU Plastic Food-Contact Materials Regulation), FEICA makes the following recommendations to adhesive users:

1. When using polyurethane adhesives with aromatic diisocyanates, contact your adhesive supplier and ask which possible PAAs might be formed. Also contact the supplier of the other materials used in packaging (e.g., ink producers) to determine whether other components are present which might possibly form or contain PAAs. Collect a list of all PAAs that might be present in the final packaging.
2. Provide all information about possible PAAs to the laboratory that has to verify compliance of the final packaging according to the limits in the legislation.

Restriction of Diisocyanates under EU REACH

Regulation (EU) No. 2020/1149 on diisocyanates was adopted under the EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) legislation targeting respiratory and dermal sensitization potentially caused by diisocyanates. After a three-year transition phase, by August 24, 2023, all users of diisocyanates must be trained and certified prior to use. This will apply to all professional and industrial users of products with a total monomeric diisocyanate concentration of ≥ 0.1%. Since February 24, 2022, such products have had to carry a phrase on the label indicating the requirement for user training. FEICA has issued an information leaflet relating to the safe use of polyurethane and isocyanate-based adhesives and the impact of the regulatory requirements. The isocyanate manufacturers and principal using industries have also provided more detail about the scope of the diisocyanates restriction and the training requirements. In addition, they have established an online training platform with teaching materials developed and provided for specific sectorial uses and applications of diisocyanates, to offer a joint industry approach for access to appropriate training.

Cosmetics

United Kingdom

The UK's Health and Safety Executive (HSE) has published guidance for companies seeking to make cosmetic products available to consumers in Great Britain. Since leaving the EU, the UK has been implementing its own regulatory framework for cosmetics. This is a direct copy of the EU cosmetic products regulation, and the provisions for placing products on the market in England, Scotland and Wales remain largely the same as they are in the EU. The guide does not cover making cosmetic products available in Northern Ireland, for which the responsible person must be established there, or in the EU (separate technical guidance is available).

South Korea

Revisions to South Korea's Cosmetics Act, introduced in February 2022, set strict limits on the distribution and sale of cosmetics or cosmetic ingredients developed using animal testing, and also apply to new animal testing. However, there are certain exemptions that allow the sale and distribution of products and ingredients that are tested on animals:

- Ingredients developed and tested under other laws such as K-REACH
- Preservatives, colorants or sun-protection agents that require a risk assessment
- Raw materials that have potential public health concerns
- Products or ingredients where no alternative non-animal testing is available
- Products or ingredients where the Ministry of Food and Drug Safety (MFDS) has decided animal testing is too difficult to replace
- Exports to or imports from countries where their laws require animal testing

The act also prohibits cosmetics that imitate foods which consumers, especially children and the elderly, could consume by mistake. This includes products that mimic the form, smell, color, size, containers or packaging of foods.

Brazil

Brazil's National Health Surveillance Agency (Anvisa) has published a list of 36 UV filters it will allow for use in cosmetics, personal hygiene products and perfumes. Resolution RDC No. 600 sets maximum concentration limits for the substances, which include titanium dioxide, zinc oxide and benzophenone-3 (oxybenzone). The regulation incorporates Mercosur Resolution No. 44/2015 (as amended by Resolution No. 14/2021), which sets out a list of permitted UV filters for use in products such as sunscreens in the four Mercosur countries (Argentina, Brazil, Paraguay and Uruguay). The Mercosur regulation closely mirrors the chemical restrictions of the EU Cosmetics Regulation.

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

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