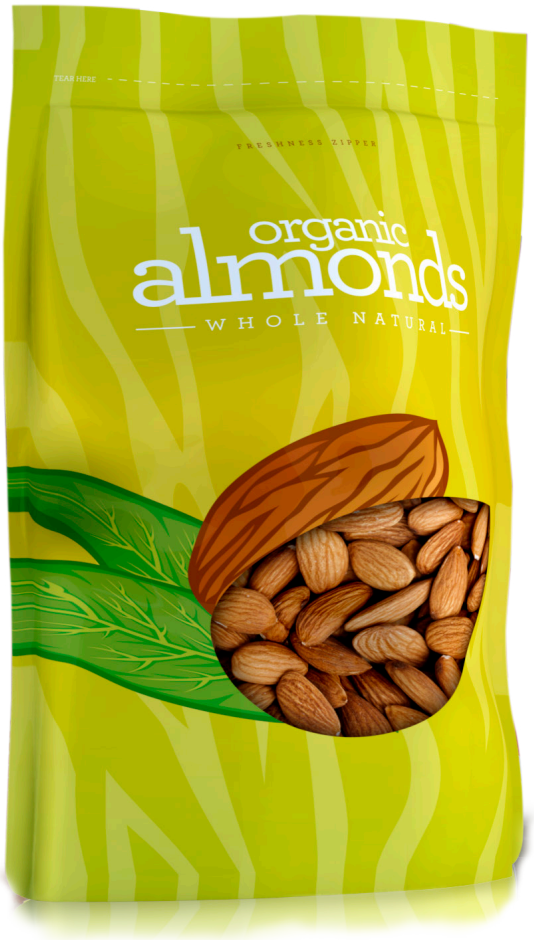
Regulatory Newsletter

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



Food contact materials

As indicated in the previous newsletter, the European Commission has announced that it plans to introduce a Union measure on printed food contact materials in 2018. This follows the notification of the proposed German Ordinance on printing inks last year and pressure coming from the European Parliament for more food contact materials to be included in harmonised EU legislation.

The commission's health directorate, DG SANTE, has asked interested stakeholders to participate in a study on information in the supply chain, compliance and demonstration of safety as part of this exercise. Sun Chemical has submitted extensive information and documentation to illustrate how the processes of communication and establishing safety operate with regard to printing inks and printed articles.

Sun Chemical is also extensively involved in the European Printing Ink Association (EuPIA) activities and proposal for our preferred approach and content of the new Union measure on printed food contact materials. We have discussed our proposal with other partners in the supply chain, national authorities and DG SANTE, and believe that it offers a workable solution.

DG SANTE recognises the limitations of having and managing a positive list of substances and appears open to alternative approaches. Our EuPIA proposal is to have a database of substances that have been fully evaluated by a competent authority with their restrictions (tolerable daily intakes or specific migration limits), together with either a database of screened substances, or a specified screening process, for those substances not yet fully evaluated.

The proposed criteria for screening and establishing a migration or exposure limit involves an assessment for genotoxicity, using (quantitative) structure activity relationships (QSAR modelling) in the absence of complete genotoxicity data, and then using the chemical structure to determine the Cramer Class and applying the appropriate threshold of toxicological concern (TTC).

The Joint Research Centre of the European Commission (JRC) published its baseline study of non-harmonised food contact materials in the EU and found several shortcomings. The study examined materials which are not currently covered by specific EU legislation, such as adhesives, coatings, printing inks, paper and board, etc., for which Member States can set national provisions.

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A lack of common standards and guidelines for, and transparency of, risk assessment and authorisation requirements across Member States, together with inconsistent measures for good manufacturing practice (GMP) and food safety requirements, were highlighted. In addition, significant differences between national lists of authorised substances (different substances, different restrictions and limits) and a lack of testing methods for enforcement and to demonstrate compliance, make it difficult to ensure food safety. The fragmented regulatory landscape creates a number of difficulties, particularly for mutual recognition between Member States.

The organisation ChemSafetyPro has provided a helpful overview of the national legislation on food contact materials in the EU, largely based on the JRC baseline study report, together with links to specific legislative texts.

Meanwhile, the Belgian and Dutch authorities are reported to be working on aligning their national legislation on food contact coatings. The Belgian royal decree on varnishes and coatings intended to come into contact with foodstuffs came into force at the beginning of the year. The Netherlands is currently revising its Commodities Act (Packaging and Consumer Articles Regulation), which includes the section on coatings.

Both countries specify migration testing according to the EU Plastics Regulation and the commission's migration guidelines, but there are concerns that these methods will be applied inappropriately to non-plastic food contact materials, such as coatings and printing inks. Trade associations covering non-plastic sectors are working to develop their own migration testing guidelines and demonstrate where the approach specified for food contact plastic is not suitable.

The Swiss Federal Department of Home Affairs (FDHA) has published a new national food law, which incorporates a revised version of the Ordinance on food contact materials (SR 817.023.21). It came into force on May 1, 2017, and updates three annexes of authorised substances: plastics (Annex 2), silicones (Annex 9) and printing inks (Annex 10). Section 12 sets out the provisions relating to printing inks applied to the non-food contact surface, and Article 35 specifies that only authorised substances should be used in their manufacture. Changes are mostly minor as compared with the previous version of the Swiss Packaging Inks Ordinance, although there are several newly authorised substances, and a variety of individual substances covered by a generic group entry have been removed. EuPIA has updated its Questions & Answers on the Swiss Ordinance document to reflect the latest changes.

The German Federal Ministry of Food and Agriculture (BMEL) has published a new draft text (only available in German) for mineral oil aromatic hydrocarbons (MOAH) in food contact materials (draft 22nd amendment to the Commodities Regulation). A migration limit of 0.5 mg per kg of food or food simulant is proposed to protect consumers from MOAH leaching into food from paper or carton board packaging, and functional barriers are recommended to reduce migration from recycled paper and board. In contrast to previous proposals, a corresponding limit for mineral oil saturated hydrocarbons (MOSH) has been removed from this latest draft.

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has issued an opinion on the migration of mineral oil compounds into food from recycled paper and cardboard packaging. The agency recommends validation of a specific and robust analytical method for determining the composition of mineral oil mixtures, since better compositional knowledge is a prerequisite for making toxicological recommendations.

Additional toxicity studies on representative mixtures of mineral oil hydrocarbons to which the consumer is exposed should be carried out, and additional data on food contamination from mineral oil hydrocarbons coming from recycled paper and cardboard packaging is required. ANSES recommends limiting consumer exposure to mineral oil hydrocarbons, and to MOAH in particular, by the use of MOAH-free printing inks, adhesives, additives and processing aids in the manufacturing process for paper and cardboard packaging.

In addition, ANSES recommends the use of migration barriers to limit the transfer of mineral oil hydrocarbons from packaging into foods; the application of various barrier coatings directly to the paper and cardboard packaging is one potential solution.

Meanwhile, the European Commission has adopted a recommendation on the monitoring of mineral oil hydrocarbons in food and food contact materials. Member States should monitor the presence of mineral oil hydrocarbons in food during 2017 and 2018. The monitoring

should cover bread and rolls, breakfast cereals, confectionery, grains and pulses, oilseeds, pasta, vegetable oils, fish and meat, as well as the food contact materials used for these products. Where mineral oil hydrocarbons are detected, further investigations should be carried out to determine possible sources, including checking of documentation and good manufacturing practice for food contact materials.

The European Commission has published an amendment to the Plastics Regulation (EU) No 10/2011. Commission Regulation (EU) No 2017/752 makes a number of changes and corrections to Annexes I, II, III and IV, and incorporates several new substances into the Union list following a favourable EFSA opinion. Of particular note is a new migration limit for nickel of 0.02 mg/kg food, based on an allocation factor of 10% applied to the tolerable daily intake (TDI). The amendment entered into force on May 19, 2017, although plastic materials and articles which complied with the regulation applicable before this date may be placed on the market until May 19, 2018, and may remain on the market until the exhaustion of stocks.

EFSA has issued new administrative guidance for applicants seeking to authorise substances for use in plastic food contact materials. The procedures, from submission of the application to adoption and publication of the scientific opinion, are described together with instructions on how to prepare a dossier for safety evaluation.

EFSA has also announced the launch of a new database, OpenFoodTox, which provides instant access to a wealth of information from over 1650 EFSA scientific outputs about the toxicity of chemicals found in the food and feed chain. This is part of EFSA's effort to increase transparency and open its data for others to explore and reuse. It provides quick and easy access to the summary of toxicological information used by EFSA in its risk assessments since 2002, covering over 4,000 substances, and identifying their critical effects and safe levels, such as acceptable or tolerable daily intakes as set by EFSA.

The European Commission Joint Research Centre (JRC) has released an updated version of the FACET software (version 3.0.2), which is available for download. The FACET tool enables estimates of exposure to be derived for new and existing substances used in food contact materials, new packaging structures containing new or existing substances, and non-intentionally added substances (NIAS) associated with substances or materials. In addition, data from different food surveys, age groups, genders, EU country and packaging loyal customers can be selected and used.

EuPIA has published a guidance document outlining the process of risk assessment for non-intentionally added substances (NIAS) and non-listed substances (NLS) in printing inks used for printing food contact materials. This process can be used to establish compliance with the general food contact materials safety requirement *'not to transfer components in quantities which could endanger human health,'* for migrating components that have not been assessed or listed by official bodies. The EuPIA proposal for the new Union measure on printed food contact materials mentioned earlier is largely based on this methodology and approach.

Turkey has notified the World Trade Organisation (WTO) of two food contact regulations: (1) a regulation to determine the general rules for food contact materials and articles and setting the procedure for the authorisation of the substances that are used in them; and (2) a regulation to determine the rules for active and intelligent materials and articles in contact with food. The proposed date of entry into force is the end of August 2017, with a transitional period of one year. These two regulations are considered to be the enactment of the corresponding EU Framework and Active and Intelligent Food Contact Material Regulations (EC No 1935/2004 and EC No 450/2009) as part of Turkey's ongoing EU accession process.

The United States' Food and Drug Administration (FDA) has published a draft guidance for the industry on the preparation of food contact notifications (FCNs) for food contact substances (FCS) in contact with infant formula or human milk. It is based on the rationale that infant dietary exposure is much higher compared to adult exposure, due to the facts that formula may account for 100% of infant nutrition in the first six months and the body mass to food intake ratio for adults used in FDA toxicological assessments differs significantly from that for infants. Once finalised, this will outline the agency's latest thinking on this topic.

The guidance contains recommendations regarding how the scientific information in FCNs for infant food uses should demonstrate that the FCS is safe for the specific intended use. There has been increased scientific interest in the role of human life stages when evaluating the safety of chemicals. Advances in toxicology and developmental biology suggest that different life stages involve fundamental biological differences that may influence responses to chemical exposures, particularly for infants, who have different nutritional requirements and whose metabolic processes may not be fully developed.

The National Association of Printing Ink Manufacturers (NAPIM) Food Packaging Safety Committee has prepared lists of commonly used printing ink formulation chemical components. These lists provide recommendations for both suitable and unsuitable ink formulation components appropriate for, and applicable to, non-direct food contact applications. This is not a comprehensive listing, and other requirements may apply. Direct communication with the converter/brand owner is essential to ensure that the appropriate ink system is provided. Additional guidance is provided in the NAPIM Guidelines for Inks on Food Packaging.

Taiwan's FDA has produced new guidelines for nanomaterials used in food packaging materials. In Taiwan, food packaging materials that contain nanomaterials must undergo safety assessment and pre-market approval. Information to be submitted for approval includes composition, manufacturing process and physico-chemical properties of the nanomaterial, toxicology, migration testing, microbiological properties, intended use, and international approval status for food contact use.

Titanium dioxide

Following the French proposal for a harmonised classification as a Category 1B carcinogen by inhalation, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) has agreed that titanium dioxide should be classified as a suspected carcinogen (Category 2).

ECHA will now send the RAC Opinion to the European Commission, which will decide what (if any) regulatory measures should be taken. The industry has been highly critical of the classification proposal, which is largely based on experimental studies in rats at extremely high doses, whereby the normal clearance mechanism for particles in the rat lung was completely overwhelmed, and which are not relevant for human exposures or for classification and labelling purposes.

Epidemiological studies of workers in titanium dioxide manufacturing plants, and among using industries, show no adverse health effects. The industry believes that titanium dioxide should not be classified for carcinogenicity, and it remains safe for use in applications such as paints, coatings and printing inks. Once titanium dioxide is incorporated into paint or ink, the risk of inhalation of particles of titanium dioxide is no longer present.

Under current labelling rules, even where titanium dioxide is no longer in its powder form, products would have to be labelled as *suspected of causing cancer* by inhalation of the powder. In view of the lack of evidence of any risk to any user or consumer of paints, coatings, printing inks and other finished products containing titanium dioxide, a number of trade associations are challenging this requirement of the legislation.

Chemical controls

The European Commission has added 12 substances of very high concern (SVHC) to REACH Annex XIV—the list of 43 substances subject to authorisation. Eight of the substances are toxic for reproduction Category 1B, with a sunset date (the deadline by which non-authorised uses are prohibited) of July 4, 2020 (bromopropane and seven phthalate esters). Two are carcinogenic Category 1B and PBT/vPvB with a sunset date of October 4, 2020 (anthracene oil and coal tar pitch), and two have endocrine-disrupting properties with a sunset date of January 4, 2021 (ethoxylated octylphenol and ethoxylated nonylphenol).

The ECHA has produced an interactive guide on safety data sheets (SDS) and exposure scenarios, to help suppliers and recipients of SDSs to compile and easily understand substance and use information. The built-in navigation elements enable users to move around and find the information they need.

The guide includes examples of SDS and exposure scenarios, descriptions of what information is contained in each section of the SDS and exposure scenario, advice on what to do to promote safe use and regulatory compliance, and tips for recipients on actions they may need to take based on the information received. ECHA also has published guidance specifically to support downstream users, explaining their role and responsibilities under REACH and how to deal with information received from their suppliers to ensure safe use.

Turkey has at last published its version of REACH (KKDIK), which will come into force on December 23, 2017. The regulation will bring various Turkish chemical legislation under one law by replacing three existing regulations. The law sets a registration deadline of December 31, 2023, and a preregistration deadline of December 31, 2020, in order to give businesses time to prepare. The legislation has been significantly delayed as a consequence of changes in personnel and ministerial reshuffles, and following the failed coup last year. This law is the last step in Turkey's aim to align its chemicals legislation with the EU as part of the accession negotiations. One key difference is KKDIK requires that only trained and qualified experts sign off registrations and notifications; other than that, there are no major differences between Turkey's KKDIK regulation and EU REACH.

The U.S. Environmental Protection Agency (EPA) has published two rules as part of the revised Toxic Substances Control Act (TSCA) framework. The final rules direct how risk assessments will be conducted and how chemical substances will be prioritised for risk assessment. These framework regulations impact manufacturers, importers, processors and users of chemical substances.

The risk evaluation process includes identification of the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider, and covers hazard assessment, risk assessment, risk characterisation, and peer review. The prioritisation rule establishes a risk-based screening process and criteria to designate existing chemical substances as either high priority (requiring comprehensive risk evaluation) or low priority (not warranting additional risk evaluation).

As part of this process, Pigment Violet 29 has been identified in the first group of 10 substances requiring evaluation. Sun Chemical has been working jointly with the Society of Chemical Manufacturers and Affiliates (SOCMA) to provide details regarding the conditions of use of interest (hazard, exposure, potentially exposed or susceptible subpopulations) as well as other information to allow the EPA to conduct the risk evaluation.

New amendments to California's Proposition 65 are expected to take effect on August 30, 2018. These significant changes will update the requirements for chemical warning labels, especially concerning the issue of what constitutes clear and reasonable warnings. The Proposition 65 list of chemicals contains a wide range of naturally occurring and synthetic chemicals that include additives or ingredients in pesticides, common household products, food, drugs, dyes or solvents.

Listed chemicals may also be used in manufacturing and construction, or they may be byproducts of chemical processes, such as motor vehicle exhaust. Changes to the content and design of the warning labels include:

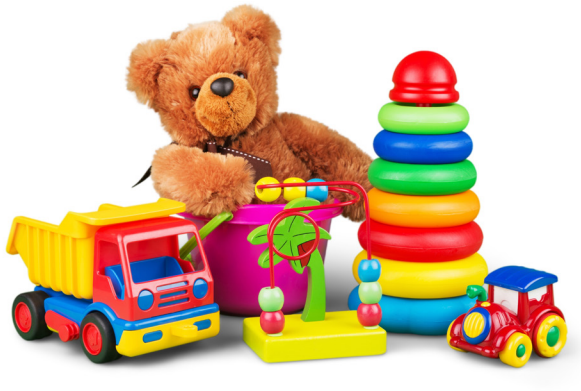
- Increased information about the listed chemical present in the product
- Requiring the P65Warnings.ca.gov web address
- Addition of a yellow triangle with a black exclamation mark pictogram

The new amendments will require businesses to review their current Prop 65 warnings and update their labels as necessary to comply with the expanded requirements.

Toys

Turkey has amended its recently adopted regulation on toy safety to provide an exemption for nickel used in toys, or their components, made of stainless steel that are intended to conduct an electric current. The regulation, which came into effect on April 4, 2017, is the Turkish implementation of the EU Toy Safety Directive (2009/49/EC). In addition, there are new limits on certain flame retardants and a migration limit of 0.1 mg/l for bisphenol A, together with content limits for the isothiazolinone biocides BIT (5 mg/kg), MIT (0.25 mg/kg), CMIT (0.75 mg/kg) and CMIT/MIT (3:1) (1 mg/kg).

Meanwhile the EU Council of Ministers has issued Council Directive (EU) No 2017/738, which amends the Toy Safety Directive (2009/48/EC) by significantly reducing the limits for lead in toys. The limits for lead in dry, liquid and scraped-off toy material are reduced from 13.5 mg/kg, 3.4 mg/kg and 160 mg/kg to 2.0 mg/kg, 0.5 mg/kg and 23 mg/kg respectively, applicable from October 28, 2018.



Malaysia has amended its consumer protection laws on toys to incorporate 13 international safety standards, including EN 71 and ISO 8124. With the changes, toys available on the Malaysian market will have to be tested for phthalates and for maximum acceptable levels of migration of elements such as antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and parts, especially those with oral contact.

Miscellaneous

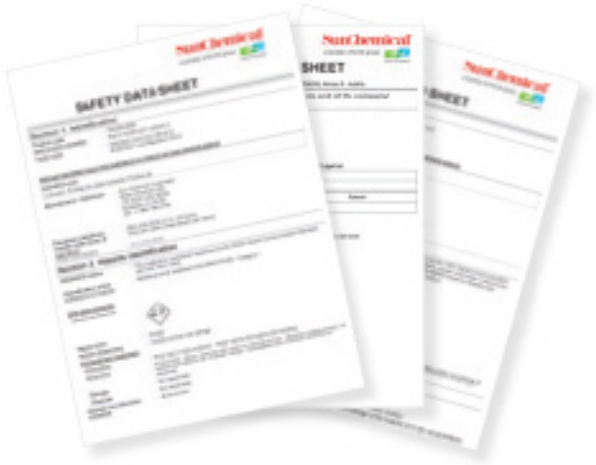
Canada has concluded that cobalt and soluble cobalt compounds are harmful to organisms in the environment and should be subject to regulatory risk management. Solubility is a crucial factor in the environmental risk posed by cobalt containing substances. They can harm the survival, growth and reproduction of water-, soil- and sediment-dwelling organisms.

The final screening assessment focussed on the cobalt moiety rather than specific compounds, considering elemental cobalt, cobalt-containing substances and cobalt released in dissolved, solid or particulate form. It concluded that cobalt and soluble cobalt compounds should be added to the Canadian Environmental Protection Act (CEPA) list of toxic substances.

An article entitled *Reducing the Environmental Impact of Packaging with Eco-Friendly Inks,* written by Sun Chemical colleagues, was recently published in Flexible Packaging Magazine. The article explores ways to reduce the environmental impact of packaging and the role ink suppliers can play in helping printers, brands and consumers meet the eco-efficiency standards and expectations that have been set in the industry by regulators and non-governmental organisations.

Customers are still encouraged to sign up for email distribution of **Sun Chemical Safety Data Sheets.** This will ensure that information is rapidly available to users purchasing new products, or when updates are required, rather than waiting for delivery via surface mail.

Customers registering for this service will also be able to access and download Safety Data Sheets via our online repository, which has been found to be of immense assistance in advance of an official inspection. Please contact your local account manager for details on how to register for this service.



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

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