

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

Despite the lack of enthusiasm from the European Commission to introduce legislation for **nonplastic food contact materials**, interest continues to grow. The [European Parliament](#) has this on its radar and is calling for urgent action to tackle shortcomings in implementation and enforcement.

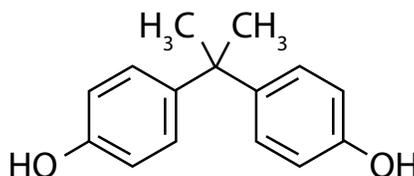
Controls differ greatly across EU member states, with few authorities carrying out regular monitoring or having the necessary trained staff to deal with the process efficiently. A single EU standard for analytical testing is recommended, and nonintentionally added substances (NIAS) are highlighted as a major challenge for risk assessment.

In addition, harmonised rules for nonplastic food contact materials currently without specific legislation, particularly paper and board, inks, coatings and adhesives, are called for. This corresponds with the views of industry and NGOs, which believe that EU measures will create a level playing field, increased certainty and safety, and avoid market fragmentation caused by different national requirements.

At the same time, the European Commission's Joint Research Centre is investigating the current status of national controls for nonharmonised food contact materials, with a view to assessing the need for measures at the EU level.

Meanwhile, there is no progress to report regarding the draft **German printing inks Ordinance**—it is possible that activity has been suspended pending the outcome of EU initiatives.

Following the publication of a [roadmap](#) setting out regulatory options for **bisphenol A (BPA)**, the European Commission has notified the World Trade Organization (WTO) of a [draft regulation](#) covering BPA in food contact materials. The specific migration limit (SML) will be reduced from 0.6 mg/kg food to 0.05 mg/kg food, and will apply to varnishes and coatings in addition to plastic food contact materials.



The chemical structure of bisphenol A.

working for you.

It is expected that the provisions will apply from Q1 2017, although articles lawfully placed on the market before this time will be allowed until stocks are exhausted. The proposal has been welcomed as a first step to restore the internal EU market and avoid distortion from unilateral national measures.

The European Food Safety Authority (EFSA) and the World Health Organisation (WHO) have published a report on the [Threshold of Toxicological Concern \(TTC\)](#), following a three-day expert workshop. The TTC approach is fit for purpose as a screening tool to assess low-dose chemical exposures and to identify those for which further data are necessary to assess the human health risk.



The report considers that the TTC approach is a valid, science-based tool for prioritising chemicals that lack toxicity data, and more extensive use could yield significant benefits in terms of reduced animal testing.

The TTC was developed for substances with low human exposures and fills gaps using data from structurally related chemicals to establish exposure levels below which there is unlikely to be a safety concern. TTC is a particularly useful tool for risk assessment of nonintentionally added substances (NIAS) and is often used within Sun Chemical for safety assessment of printed food packaging, where appropriate.

EFSA has also published an [opinion](#) on recent developments in the **risk assessment** of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. In particular, more focus on the actual substances migrating from finished materials and articles and on estimating consumer exposure is called for.

It is important to evaluate the safety of all migrating substances and not just the starting substances. The amount of toxicity data needed should be related to the level of human exposure, and three threshold levels are proposed as triggers for additional toxicity data. The European Commission and the member state authorities will consider the opinion and provide feedback with regard to how the developments might be incorporated into the guidance for evaluation of substances to be used as food contact materials.

FoodDrinkEurope has recently updated its [guidelines](#) on the safe use of **paper and board made from recycled fibres** for food contact use. The document is intended to illustrate best practice in relation to the use and selection of recycled paper and board for food contact packaging. It is aimed at individuals who have responsibility for ensuring the compliance of paper and board packaging items with food contact legislation.



The purpose of the document is to encourage a risk evaluation to assess the suitability of a given item or recycled paper packaging, for use with a specific food product in a packaging format, and also to encourage an appropriate dialogue between food producers and the packaging suppliers. The document includes sections on general requirements for risk evaluation, functional barriers, specific (groups of) substances to be considered, microbiological and quality considerations, and legislative and other references.

The Chemical Inspection & Regulation Service (CIRS) has published a [short comparison](#) of differences in **food contact migration testing** between Europe and China. The Chinese Standard GB 31604.1-2015 *General rules for migration test of food contact materials and articles* is similar to the requirements specified by the Plastics Regulation (EU) No. 10/2011, but small differences could result in confusion. The Chinese Standard applies to all types of food contact materials and articles that directly or indirectly come into contact with food, including plastic, rubber, metal and paper used as food packaging, containers, kitchen utensils, or in production process food contact facilities, as well as coatings, inks and adhesives used in food packaging, containers, and kitchen utensils.



The Plastics Regulation applies to materials and articles consisting exclusively of plastic, and plastic multilayer materials and articles held together by adhesives, whether coated or printed or not, as well as plastic layers in multilayered multilayer materials and articles. Polyphenylene oxide (Tenax®) is the simulant for dried solid food according to the Plastics Regulation, whereas the Chinese Standard has no simulant for dried solid food, and the migration test may be exempted due to the lower migration risk.

The Chinese Standard also specifies that when the food contact material is already in contact with food, the migration shall be tested in food, and that the surface area to volume of the food or food simulant should be calculated based on the most demanding use condition. GB31604.1-2015 gives details on how to select the appropriate food simulant, how to conduct screening tests, conditions for migration testing and calculation algorithms to be used.



Our Sun Chemical colleague Dr. Gregory Pace gave a presentation on printing inks for **low migration packaging** to Pack Expo in Chicago entitled *Concept to consumer: Design of inks and coatings for safe and sustainable packaging*. A [video recording](#) of the presentation is now available, which covers subjects such as customer requirements, mechanisms of migration, testing and regulatory requirements.

The **U.S. Food and Drug Administration** (FDA) has issued a [final rule](#) which includes food contact substances (FCS) in the Foreign Supplier Verification Program (FSVP) for importers of food for humans and animals. The FSVP regulation requires importers to verify the safety of the food that they import into the USA, under the same requirements as domestic producers, based on hazard analysis and risk-based preventative controls and standards of the Federal Food, Drug and Cosmetic Act.

In the final rule the FDA did not exclude food contact substances, which would include indirect food additives from the components of materials in the food packaging. Therefore, any chemical in the food packaging which migrated to the food would be regulated as a food contact substance, including those chemicals from non-direct food contact packaging inks and coatings.

Public comment from industry stated there would be a low risk to food safety; however, the FDA declined to exempt importers of FCS from the FSVP rule. Manufacturers of food contact materials and packaging articles would need to ensure no chemicals migrate to the food, including those from non-direct food contact packaging inks, coatings and adhesives. Compliance with the rule will be mandatory from July 2017.

The **U.S. FDA** is also considering a food additive petition submitted by several NGOs to revoke the regulations that allow the use of **ortho-phthalates** in food contact materials. A number of dialkyl phthalates are listed as permitted indirect food additives in various sections of Chapter 21 of the Code of Federal Regulations. The [petition](#) raises safety concerns about the use of these ortho-phthalates, citing evidence of various reproductive, developmental and endocrine health effects. Sun Chemical does not use ortho-phthalates in its printing inks.

California Proposition 65

California's Office of Environmental Health Hazard Assessment (OEHHA) has launched a [Proposition 65 warning website](#). It is intended to provide information regarding exposure to chemicals that require warning disclosure under Proposition 65 to the public. Proposition 65 requires businesses to provide clear and reasonable warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive

harm. These chemicals can be in the products that Californians purchase, in their homes or workplaces, or that are released into the environment.

By requiring that this information be provided, Proposition 65 enables consumers to make informed decisions about their exposures to these chemicals. Some concerns have been expressed regarding the accuracy of the information on the website and the potential for confusing or alarming consumers; however, OEHHA has said it would welcome feedback, particularly regarding inaccuracies.

OEHHA has listed **styrene** on Proposition 65 as a substance known to the State of California to cause cancer. The listing follows the designation of styrene as reasonably anticipated to be a human carcinogen in the National Toxicology Program's (NTP) 12th Report on Carcinogens. The listing took effect April 22, 2016, and businesses will have to provide a warning for exposure to styrene one year from that date.



Within the European Union, styrene is not classified as carcinogenic. OEHHA is proposing a No Significant Risk Level (NSRL) of 27 µg per day for styrene; this represents the safe harbour level below which a warning is not required under Proposition 65. Styrene is commonly used as a monomer in the manufacture of polymers that find widespread use in waterborne products, including water-based printing inks and coatings. Although these polymers may contain low levels of residual styrene monomer, consumer exposure to styrene from printing inks or printed articles is not considered to be a cause for concern.

OEHHA has also issued a proposed [emergency regulation](#) under Proposition 65 regarding exposure to **bisphenol A** (BPA) from canned and bottled foods and beverages. BPA is a chemical known to the State of California to cause harm to the female reproductive system. The regulation would promote the use of a temporary, uniform, point of sale warning for BPA exposure, to avoid a potential misperception on the part of the public that the canned and bottled food supply poses an imminent health threat.

Cans, lids on jars and caps on bottles may have epoxy linings used to avoid microbial contamination and to extend shelf life; some of these linings can leach small amounts of BPA into the food or beverage. The emergency action is needed because widespread warning labels could cause consumers to avoid purchasing canned and bottled fruits and vegetables, to the detriment of their health, and to avoid retailers removing all canned and bottled food products from shelves due to a lack of knowledge as to which may or may not contain bisphenol A.

Perfluorinated chemicals

The U.S. Food and Drug Administration (FDA) has [prohibited](#) the use of three classes of long-chain perfluorinated compounds in food contact materials. The FDA considered that there is no longer a reasonable certainty of no harm from food contact use, based on new toxicity data for substances with similar structures. The amendment to the food additive regulation no longer allows these substances to be used as oil and water repellents in paper and paperboard products, such as pizza boxes and microwave popcorn packaging.

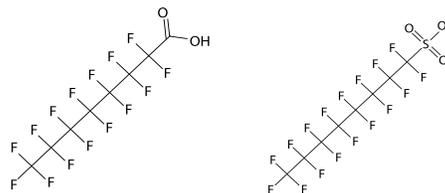


In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has [recommended](#) that industry phase out the use of per- and polyfluorinated alkyl substances (PFASs), also known as per- and polyfluorinated chemicals (PFCs). Such chemicals are used as ingredients and intermediates in specialty products that provide resistance to heat, abrasion and other chemicals, and can also be used as dispersion, wetting or surface treatment agents. PFASs and their derivatives have been used in the manufacture of nonstick cookware, to protect garments and textiles (e.g., Scotchgard™), in metal plating and in some types of fire-fighting foam.



The two main types of perfluorinated chemicals used in industry are perfluoroalkyl sulphonic acids (PFASs), such as perfluorooctyl sulphonic acid (PFOS), and perfluorocarboxylic acids (PFCAs), such as perfluorooctanoic acid (PFOA). PFASs are highly persistent in the environment, can undergo long-range transport and can bioaccumulate in animals and food chains.

NICNAS recommends that PFOS, PFOA and other related chemicals should continue to be restricted to essential uses where less hazardous alternatives are not available, and industry should actively seek alternatives to, and phase out, PFASs and related substances of concern. In addition, PFOS-based fire-fighting foams should only be used in essential applications, and stocks disposed of responsibly on expiry. Finally, up-to-date information on handling and safe use should be provided on labels and safety data sheets.



Examples of the chemical structure for perfluorinated compounds.

The Organisation for Economic Co-operation and Development (OECD) has signalled [concerns](#) about global emissions of PFCAs, and highlighted that, although production and emissions have almost been eliminated in the U.S., Western Europe and Japan, transfer of production to countries such as China, India and Russia has completely offset these reductions. The U.S. Environmental Protection Agency (U.S. EPA) has restricted the use of PFOS and other long-chain PFASs to low amounts and only where no safer alternative is available. Canada has prohibited the manufacture, use, import and sale of PFOS and related substances, and is currently considering a similar proposal to prohibit PFOA and related substances. In the European Union, PFOS is restricted to a small number of uses, such as in electroplating, and PFOA and related substances will be subject to additional controls under REACH.

Sun Chemical does not use such perfluorinated chemicals. A number of printing inks and varnishes can contain low levels (< 1%) of polytetrafluorethylene (PTFE) wax to adjust the slip properties, but these materials have not been included in discussions about restrictions or control of perfluoro compounds.

Miscellaneous

The U.S. National Toxicology Program (NTP) has published its [monograph](#) on **cobalt** and cobalt compounds that release cobalt ions *in vivo*, and finds that these substances are reasonably anticipated to be human carcinogens. Cobalt carboxylates, such as cobalt acetate or cobalt octoate, can be used as catalysts (driers) to enhance oxidation drying of products such as oil-based gloss paints and conventional sheetfed offset printing inks. Sun Chemical does not use cobalt driers in its manufacture of printing inks.



The long-awaited, and much debated, legislative reform to the U.S. Toxic Substances Control Act (TSCA) has finally been agreed upon. There will be changes to the evaluation and regulation of chemicals, and the Environmental Protection Agency (U.S. EPA) will have more authority to obtain data and be required to prioritise, assess the risks and restrict where necessary, the use of chemicals in commerce. The EPA has published a TSCA Work Plan which contains the "Top 100" chemicals to be addressed first. More details will be available in the next edition of this newsletter.

A [report](#) published only in Japanese on behalf of the Japanese Ministry of Health, Labour and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Environment (MoE) has upheld the 50 parts per million (ppm) limit for **polychlorinated biphenyls** (PCBs) in manufactured or imported organic pigments. PCBs are known to be persistent and toxic to human health and the environment, and can be formed unintentionally during the manufacture of certain organic pigments. The 50 ppm limit corresponds to that established by the Stockholm Convention on persistent organic pollutants (POPs). The report recommends that companies should use best available technology and make efforts to further decrease the level of PCBs below 50 ppm. Pigments manufactured or imported by Sun Chemical contain less than 50 ppm of PCBs.



The Japanese MHLW has also made an [amendment](#) to the act on control of household products containing harmful substances, designating **azo compounds** containing any of 24 listed aromatic amines as harmful substances as of April 1, 2016. The scope of the regulation covers textile products with azo dyes (including diapers, underwear, sleepwear, bedding, floor coverings, tablecloths, towels, handkerchiefs and related products), and leather or fur products with azo dyes (including underwear, gloves, clothing and floor coverings). Any of the specified 24 aromatic amines must be less than 30 µg/g (parts per million, or ppm) when tested using gas chromatography coupled with mass spectrometry. This is remarkably similar to the existing European restriction on azo dyes in the REACH Regulation Annex XVII.



Hong Kong has announced that companies that manufacture or import **toys** in Hong Kong must comply with the international toy safety standard ISO 8124-5: 2015 as of October 1, 2016. The standard specifies the total allowable concentration of seven heavy metals in toys manufactured from materials including coatings, paints, varnishes, printing inks and polymers, and in packaging materials that form part of the toy or have intended play value.

China's Ministry of Industry and Information Technology (MIIT) has [published](#) the final administrative measures for the restriction and use of hazardous substances in electrical and electronic products (**RoHS2**), which will come into force on July 1, 2016. Concentration limits for cadmium, mercury, lead, hexavalent chromium, polychlorinated biphenyls and polybrominated diphenyl ethers in electrical and electronic products and parts are set by Standard GB/T 26572. (The limits correspond to those in the European RoHS Directive). Compared with the original Chinese RoHS regulation, RoHS2 extends the scope from electrical information products to electrical and electronic

products, excluding power generation, transmission and distribution equipment, and expands the labelling and information disclosure requirements. MIIT has also published a [frequently asked questions](#) document (in Chinese only) on RoHS2, explaining which products are excluded from scope, the transitional period for implementation and responsibilities for noncompliant products. The European Commission is also [looking](#) at amending its RoHS legislation, in particular to deal with resale and refurbishment of equipment, and provision of spare parts, ahead of the 2019 deadline.



China has adopted voluntary industry [guidelines](#) on responsible mineral supply chains. The Chinese due diligence guidance for responsible mineral supply chains has been drawn up by the Chinese Chamber of Commerce for Metals, Minerals and Chemicals and was adopted at an OECD meeting in December. The guidelines apply to all Chinese companies extracting or using mineral resources and their related products; companies can be certified against the guidance. The OECD has been instrumental in developing a framework on which international efforts to tackle **conflict minerals** have been based. The aim is to reduce the money going from mining of key minerals—tin, tantalum, tungsten and gold—to armed groups in areas of conflict.

Classification, labelling and safety data sheets

Taiwan's Occupational Safety and Health Administration has issued advisory GHS classifications for around 6,000 hazardous substances. Most (but not all) are consistent with the European CLP Regulation classification. Two main sources were used for the classification list—the European Chemicals Agency CLP classification and labelling inventory together with the REACH registered substances database, and recommended classifications based on available data from major international databases. The revised mandatory GHS standard, CNS 15030: *Classification and labelling of chemicals*, came into force on January 1, and applies to all companies manufacturing, handling and using hazardous chemicals in the workplace.



South Korea is proposing to amend its standards for classification and labelling of chemical substances and material safety data sheets to align with international standards, and to bring them into line with the fifth edition of the UN GHS.





European Union member states have agreed to amend the REACH Annex testing requirements for skin corrosion / irritation and for serious eye damage / eye irritation. The standard information required will no longer specify an *in vivo* study: the amendments remove the need for animal tests for these endpoints, and results from alternative test methods will be sufficient. Proposals to also replace the *in vivo* murine local lymph node assay (LLNA) for skin sensitisation with an integrated approach using nonanimal alternatives were not agreed to, and further work was considered to be necessary.



Sun Chemical has a policy to minimise animal testing as far as possible, and makes use of data already generated from suppliers and recognised organisations. We already take advantage of *in vitro* tests where we can to generate information, and in those circumstances where we are legally obliged to make some tests using animals, animal welfare is a key consideration.

The European Chemical Agency (ECHA) has added [information](#) aimed at downstream users dealing with [safety data sheets](#) from suppliers, including tips and examples, and links to other information sources. ECHA has also published a searchable [list](#) which contains the harmonised classification and labelling of hazardous substances (as per Annex VI of the CLP Regulation).

Customers are 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 on-line 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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