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

The draft of the **German "Printing Ink Ordinance"** was, after much anticipation, notified to the European Commission on July 5, 2016, as part of the TRIS[1] procedure. This process allows the commission and EU member states to object if they believe that it would create barriers to the operation of the internal market. The ordinance would amend the German consumer goods regulation by introducing a positive list of substances permitted to be used in the manufacture of printing inks for food contact materials, together with their specific migration limits.

The food packaging supply chain and other stakeholders are in favour of EU-wide legislation rather than a piecemeal of individual national regulations. During the consultation period, eight EU member states provided detailed opinions about the impact of the proposal on the EU market. This requires Germany to modify the proposal to take these opinions into account. It is also understood that the Federal Ministries themselves have not yet reached agreement on the final text.

It is acknowledged that the current positive list of substances is still incomplete and will continually be updated until the ordinance takes effect. For these reasons, the European Printing Ink Association (EuPIA) has issued an information note indicating that requests for "compliance" with the German Printing Ink Ordinance are premature. Current indications are that the ordinance requirements will not apply before 2019 at the earliest.

Meanwhile, the European Parliament has passed a nonbinding resolution calling on the European Commission to introduce EU-wide legislation for more **food contact materials.** The current regulation allows for arrangements concerning 17 types of materials, but only four of these (plastics, ceramics, regenerated cellulose and active and intelligent materials) are harmonised at the EU level.

The lack of harmonised rules causes problems for consumers, companies and authorities, and it means that there is no single market; some countries have high standards and others have low standards. Members of the European Parliament believe that the commission should prioritise specific EU measures for paper and board, printing inks, coatings and adhesives. This corresponds with the views of industry and nongovernment organizations (NGOs), which believe that EU measures will create a level playing field, increase certainty and safety, and avoid market fragmentation caused by different national requirements.

[1]The Technical Regulation Information System notification procedure allows the European Commission and the Member States to examine the technical regulations intended for introduction before their adoption. The aim is to ensure that these texts are compatible with EU law and the internal market principles, and prevent technical barriers to trade.

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In response to the consultation on the draft German Printing Ink Ordinance (and in consideration of the Resolution of the European Parliament), the European Commission has indicated that it will begin work on new union legislation on printed food contact materials, including printing inks. The commissioner has invited Germany to postpone the adoption of its draft legislation.

On September 25, 2016, **Belgium** passed a royal decree on varnishes and coatings intended to come into contact with foodstuffs, which entered into force on January 1, 2017. The decree allows substances listed in the EU Plastics Regulation (EU No 10/2011) or approved by another member state or the European Food Safety Authority to be used intentionally to manufacture food contact coatings. Individual substances should not migrate above their specific migration limits, or if unavailable, should not exceed the generic limit of 60 mg/kg of food. Substances that do not migrate to a detectable amount in food, are not classified as carcinogenic, mutagenic or toxic to reproduction (CMR), and are not in nanoform, are also permitted. Coatings and varnishes intended for food contact are requested to be accompanied by a compliance statement.

The **U.S. Food and Drug Administration (FDA)** has published a final rule detailing the criteria for concluding that the use of a substance in human or animal food is generally recognized as safe (GRAS). This GRAS rule may also be applied to certain substances present in food contact materials that may become indirect additives in food. The final rule specifies the types of scientific evidence that can be used to demonstrate safety and details the voluntary GRAS notification procedure. Although GRAS substances do not require pre-market approval, the FDA encourages companies to follow the notification procedure and inform the agency of GRAS conclusions to aid the FDA's food safety monitoring efforts. NGOs continue to press the FDA to address the nontransparency of manufacturers claiming GRAS.

China's National Health and Family Planning Commission has revised, consolidated and published 53 mandatory standards for food contact materials and additives (in Chinese). GB 4806.1 on general requirements includes a revised definition of "unintentionally added" and introduces a new requirement for a declaration of compliance and labelling. GB 9685 on additives includes a revised definition of the specific total migration limit, and the list of additives has been increased from 958 to 1294. Other important standards are listed in the table. A separate standard for printing inks is still under development.

Standard	Subject matter
GB 4806.1	General safety requirements for food contact materials and additives
GB 4806.6	Plastic resins for food contact use
GB 4806.7	Plastic materials and articles for food contact use
GB 4806.8	Paper and board materials for food contact use
GB 4806.9	Metallic materials and articles for food contact use
GB 4806.10	Paints and coatings for food contact use
GB 5009.156	General principles of pre-treatment methods for migration testing of food contact materials and products
GB 9685	Use of additives for food contact materials and products

China's new food safety standards.

Food Standards Australia New Zealand (FSANZ) has published a peer-reviewed report on the use of nanotechnology in food additives and packaging. The report reviewed the evidence on nano-scale silicon dioxide, titanium dioxide and silver in food. It was concluded that the weight of evidence does not support claims of significant health risks for food-grade materials. From the case studies on the use of nano-clay and nano-silver in packaging, the report concludes that there is no evidence of migration into food from packaging.

The nano-scale nature of nano-silver (whether used in packaging or food) is also not likely to be dangerous to consumers' health. Titanium dioxide and silicon dioxide are used internationally in a range of food products and have been used safely for many years. They are approved food additives in Australia and New Zealand. Silver is also an approved food additive in Australia and New Zealand, but is permitted in very few foods.

Overall, the findings of the report are consistent with recently published information in the Organisation for Economic Co-operation and Development's Working Party on Manufactured Nanomaterials Sponsorship Programme for the Testing of Manufactured Nanomaterials toxicological dossiers on silicon dioxide, titanium dioxide and silver. There is no direct evidence to suggest novel nanomaterials are currently being used in food packaging applications in Australia or New Zealand.

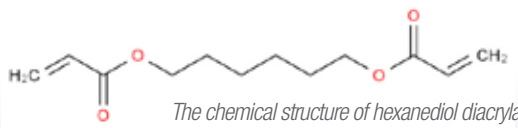
In anticipation of the German Printing Ink Ordinance and with increased emphasis on direct food contact applications, **EuPIA** has released a new, updated version of its Good Manufacturing Practice (GMP) document. This latest edition of the GMP guide has been fully updated and expanded to cover the manufacture of all varnishes, coatings and inks intended to be printed onto food contact materials (FCM), including all nonfood contact and food contact surfaces of packaging and containers.

This version of the GMP is likely to require significant change and process improvements in several areas, and full implementation may take several months. The 47-page document includes references to EU regulations and opinions of the European Food Safety Authority (EFSA), as well as national regulations such as the Swiss Ordinance on printing inks for food packaging. It also provides a comprehensive reference document which clearly outlines all steps required to ensure compliance in relation to food packaging and safeguard against potential hazards.

EuPIA has revised its exclusion list for printing inks and related materials. This has now evolved into an "Exclusion Policy." With increasing reclassification of substances under EU chemicals legislation, such as the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the hazard-based approach of the exclusion list could have negative impacts on printing processes.

The Exclusion Policy is a preemptive step by EuPIA in advance of official controls on hazardous chemicals under REACH, and it demonstrates the self-regulatory nature of the industry in its desire to achieve the highest possible standards of health and safety for its members and their downstream partners. The new Exclusion Policy preserves the clarity of the previous exclusion list, while taking the intended uses and exposure scenarios of the chemicals into account. This enables impacts on the downstream supply chain to be mitigated where immediate substitution is not an option, and safety in use can be adequately demonstrated.

We are pleased to report that the EU REACH Committee has rejected a proposal that **Hexanediol Diacrylate (HDDA),** used in the manufacture of industrial UV-curing inks and coatings, should be added to the candidate list of substances of very high concern (SVHC). Sweden had proposed that HDDA's skin-sensitising properties should be considered as of a level of concern equivalent to Category 1 carcinogens, mutagens or reproductive toxicants (CMRs). The irreversibility and seriousness of the effect were important considerations in the discussions. While the acquisition of skin sensitisation (allergic response by the immune system) itself is not reversible once acquired, the symptoms are completely reversible following cessation of exposure. Data gathered from within the industry found that the few reported incidences of sensitisation to HDDA were due to poor handling or inadequate use of personal protective equipment, and patients quickly and fully recovered once they had been removed from exposure.



The chemical structure of hexanediol diacrylate.

Titanium dioxide is also on the EU radar for further control following the French proposal for a harmonised classification as a Category 1B carcinogen by inhalation. The French agency for Food, Environmental and Occupational Health and Safety (Anses) cites experimental animal studies in rats, which found lung tumours after inhalation of high doses of titanium dioxide, and believes that these are relevant for humans, and in particular to workers' exposure to high dust concentrations.

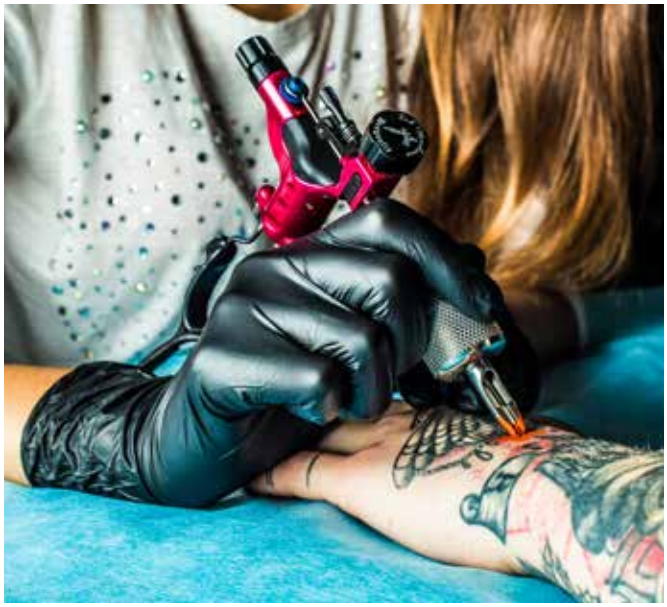
The proposal received a large number of highly critical comments during the public consultation process. The main arguments against classification are that the animal results were obtained under conditions of lung overload, whereby the normal clearance mechanism for particles in the lung was completely overwhelmed in a species that is particularly susceptible. Hence these results are not relevant for human exposures or for classification and labelling purposes.

This is backed up by epidemiological studies of workers in titanium dioxide manufacturing plants, and among using industries, which show no adverse health effects. In addition, there were comments on the socioeconomic importance of titanium dioxide, which is used in a large number of products, including food, cosmetics, plastics, paint and printing inks, and for which there are no available alternatives. In many of these products, the titanium dioxide is embedded in a liquid or solid matrix, and there is no potential for exposure by inhalation. The next step should be a discussion of the proposal and the consultation responses (expected in June 2017), with an opinion being formulated 12 to 24 months later.

The U.S. Department of Health and Human Services has included **cobalt and cobalt compounds** as reasonably anticipated to be a human carcinogen in its 14th Report on Carcinogens. Vitamin B12 is not included in the listing, since it does not release cobalt ions in the body. This follows publication of the U.S. National Toxicology Program (NTP) monograph on cobalt and cobalt compounds that release cobalt ions in vivo, which found 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.

Tattoo inks

The European Commission's Joint Research Centre (JRC) has published a technical report on **tattoos and permanent make-up,** looking at use and ingredients as well as potential health problems. More than 100 pigments were identified, and these are not generally produced for such an application. Hence, there is no risk assessment which takes account of their injection and permanence in the human body. The majority of the risks indicated in recent alerts were due to hazardous chemicals or impurities, although there was also some concern about microbiological risks, mainly due to lack of sterility of the tattoo inks.



It is estimated that around 12% of the whole European population are tattooed, and more than 20% in the United States. Higher prevalence was reported in the young population, including adolescents. While traditionally men were more tattooed than women, this is changing, particularly in young generations.

Most of the tattoo inks used in Europe are imported from the United States. Denmark has called for EU regulation of tattoo colours, and wants to see better information to highlight potential exposure to possible allergenic and carcinogenic substances in tattoo inks. The Australian National Chemicals Notification and Assessment Scheme (NICNAS) has also published a report on the use and composition of tattoo inks, finding that inks not intended for tattooing are used, and impurities associated with some of the pigments are a potential concern. The report is accompanied by Frequently Asked Questions on tattoo inks.

For many years, Sun Chemical has received inquiries on this subject. At issue is the use of Sun Chemical's inks and organic pigments in tattoo applications. These requests have included a variety of questions, such as suitability for subdermal and topical applications.

Sun Chemical's Performance Pigments Group has a longstanding policy that specifically prohibits intentionally selling pigment products or trading with companies involved in these types of applications.

The European Printing Ink Manufacturers trade association (EuPIA) has issued an information note on tattoo inks, stating that members' printing inks are not suitable and not recommended for use in tattooing or permanent make-up. It also indicates that temporary transfer tattoos (transfers applied to the skin using moisture and/or pressure) may be printed using inks supplied by EuPIA members, and that these should be regarded as cosmetics products and subject to the scope of the Cosmetics Regulation (EC) No 1223/2009. They may also be classified as toys and fall under toy-specific standards and legislation.

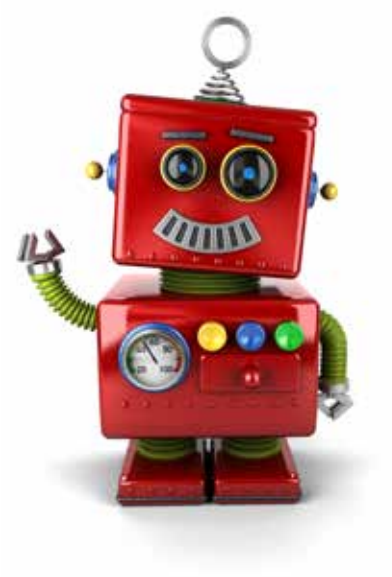
Endocrine disruptors

Two legal act drafts setting the criteria to identify **endocrine disruptors** were presented by the European Commission in June 2016 as required under the Biocidal Products and Plant Protection Products Regulations. Following criticisms from several member states and NGOs, revised proposals have been presented which clarify the scope of the definition, the burden of proof, and the kind of scientific evidence that can be used to identify endocrine disruptors.

The scientific criteria are based on the World Health Organisation's (WHO) definition requiring that the substance shows adverse effects in humans or nontarget organisms because of an endocrine mode of action. An adverse effect is described as a change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences. Criteria are provided for the data and assessment requirements to identify substances with endocrine-disrupting properties. Further details can be found on the European Commission's website.

Toy safety

ASTM International, a standards organization in the United States, has introduced a significant revision to the **toy safety standard,** ASTM F963. Since 2009, all toys in the United States must meet the safety requirements of F963, as specified by the Consumer Product Safety Improvement Act (CPSIA) of 2008. In particular, the updated standard clarifies the requirements for heavy metals in toy substrate materials and introduces new requirements related to microbiological safety, as well as clarifying some of the aspects relating to physical and electrical safety.



Turkey has announced a revised regulation on toy safety, which is an exact copy of the EU Toy Safety Directive (2009/48/EC). Compared with the previous version, there is a large reduction in the permissible content of metals in toys, as well as an increase in number from eight to 19. Fifty-five allergenic fragrances are also banned in toys, and nitrosamines and nitrosatable substances are prohibited.

Hong Kong has announced that companies which 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.

Electronic materials

Singapore has published a regulation prohibiting the use of six hazardous substances in electrical and electronic products, which will take effect on June 1, 2017. The regulation has been adapted from the EU Restriction of Hazardous Substances (RoHS) Directive, and restricts the use of cadmium, hexavalent chromium, lead and mercury and their compounds, together with polybrominated biphenyls and diphenyl ethers.

The requirements apply to mobile phones, laptop computers, televisions, washing machines, refrigerators and air conditioning, batteries and accumulators. Products designed for industrial use only are exempted, as are second-hand goods. Manufacturers and importers of electrical and electronic products will be required to submit a declaration of conformity before selling products in Singapore.

Sun Chemical safety data sheets

Customers are encouraged to sign up for the 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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