SunChemical®
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Color & Comfort

Regulatory Newsletter

Winter 2015

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

FOOD CONTACT MATERIALS

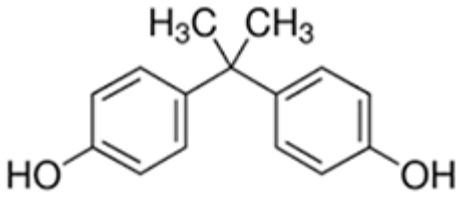
The German NGO Foodwatch made national media headlines in Germany, France and the Netherlands, following publication of its findings from laboratory testing of dry foods with long shelf-lives packaged in paper or board (e.g. rice, pasta, cereals, etc.). The research found that **mineral oil** had migrated into the food, with high levels of contamination in certain samples, and positive results from many other cartons. Foodwatch has launched a petition to demand immediate action, requiring effective barriers on all food packaging and the setting of specific limits for harmful substances, and for mineral oils in particular. Whilst these findings have been publicised in a rather alarming manner, they are not particularly new, since they reinforce the findings of earlier studies in Germany and Switzerland, indicating that recycled carton board can be a significant source of mineral oil hydrocarbons. It is interesting to note that the actions demanded by Foodwatch are precisely the same as those requested by the European Printing Ink Association (EuPIA) in their statements on the use of recycled materials for food packaging.

Despite the fact that the German Federal Ministry for Food and Agriculture (BMEL) already prepared a draft Ordinance to restrict the level of mineral oil hydrocarbons in recycled paper and board used for food packaging, progress seems to have stalled, with the latest draft being that of July 2014. The Foodwatch campaign may prompt a re-initiation of the project. Similarly, no visible progress has been seen regarding the

draft **German printing inks Ordinance** – the version of July 2014 is still the latest public draft. We understand that discussions between the different Ministries continue with concerns about the potential costs, competitiveness and impact on the German market.

The European Commission's DG Health and Food Safety indicated its views on the harmonisation of food contact materials at a stakeholder conference on **food contact materials** hosted by the Luxembourg presidency of the EU on 30th September. The Director of the Safety of the Food Chain Directorate stated that the focus should be on improving mutual recognition of national packaging rules, so that what can be sold in one EU country can be sold in the others, rather than pan-European regulations. Currently, only plastic materials are substantially harmonised across the EU, and this represents the limit of what the Commission has the resources to achieve. To harmonise rules for non-plastic food contact materials would require extending evaluations and authorisations from the current 1,000 substances for plastics to more than 10,000. The Commission has fewer and fewer resources every year, and hence the priority is to improve mutual recognition, which is the pillar of the single market, rather than engage in further harmonisation.

The French Constitutional Court has lifted the national ban on the manufacture and export of food contact materials containing **bisphenol A**, by annulling parts of the law adopted in December 2012. The Court ruledthat stopping the production and export of product poses an unjustifiable restriction of trade, because it is disproportionate with rules in other EU member states. However, the Court ruled that the rest of the law remains valid, upholding the restrictions on placing bisphenol A based food contact materials on the French market. Interestingly, the Court stated that it did not have the scientific competence to assess the law itself, or its benefits to human health, and it did not assess the compatibility of the French law with existing EU law.Plastics Europe will continue legal proceedings, both nationally and at EU level, arguing that the law should be completely revoked, based on the European Food Safety Authority (EFSA) opinion published earlier this year, indicating that the levels to which consumers are exposed are well below the recommended safety threshold. Plastics Europe also filed a complaint with the European Commission in 2013 and is waiting for a decision on a formal infringement procedure against France.



Meanwhile, the European Commission has published a roadmap setting out 5 options for regulation of**bisphenol A** following the EFSA opinion. It recognises that some member states have introduced different national bans on the use of bisphenol A, which makes it difficult for companies to understand which products that use or contain bisphenol A can be placed on the market. Amongst the options is a proposal to extend the scope from plastics to all food contact materials, which would bring printing inks and varnishes into scope. This should have the benefit of clarifying the status with regard to the French national ban on bisphenol A. The roadmap suggests that there could be difficulties for the paper and board sector, due to bisphenol A coming from the recycling of thermal paper (e.g. till receipts).

Denmark has announced an advisory limit – designed to act as a ban – on the use of **perfluorinated chemicals** in paper and cardboard food packaging. The Environment Minister stated that consumer safety was paramount, and there should not be harmful fluorinated substances in the paper and paperboard in contact with our foods. It is intended as a signal that a ban might be around the corner, and to help stop the use of perfluorinated chemicals. Perfluoro-octanoic acid (PFOA) and related substances are already under discussion for REACH Restrictions. Such substances are not used by Sun Chemical within the EU. A number of printing

inks and varnishes can contain low levels (< 1%) of polytetrafluorethylene (PTFE) wax to adjust the slip properties, but these materials are normally not included in discussions about perfluoro compounds.

The **US Food and Drug Administration** (FDA) has issued a final rule which includes food contact substances in foreign supplier verification programmes (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.

In **China**, an amended Food Safety Law, with significantly expanded scope, took effect on 1st October 2015. This includes improved regulatory supervision of special foods, including health foods, formula foods for special medical purposes and baby and infant formulas, improved supervision of online food transactions and imported food, strengthened enforcement and improved supervision of food safety. Chapter 6 of the amended law refers to GB 9685, the national food safety standard on uses of additives in food contact materials and products. It specifies the basic requirements for manufacturers and importers of food contact materials and products, including testing methods, traceability and product information. The standard has been renamed the 'Food Safety Standard – uses of additives in food contact materials and products', and the revisions are intended to make it easier for companies which import food contact materials and products into China. It contains a positive list of 1,316 substances, and provides new total specific migration limits, along with revised terms and definitions; 204 substances on the positive list have had restrictions on their range and amount of use extended.

Revised testing methods for substances in food utensils, containers and packages have been issued by the Ministry of Health and Welfare in **Taiwan**. These relate to plastic uncoated paper products, polylactic acid plastic products, polycarbonate plastic products and polyethylene terephthalate plastic products; the limits are indicated in the table:

Substance	Threshold limit (ppm)
Lactic acid	5
Lead	5
Cadmium	0.5
Germanium	0.001
Antimony	0.001
Bisphenol A	0.0005

Mercosur, the South American trading bloc, which comprises **Argentina, Brazil, Paraguay, Uruguay, Venezuela** and **Bolivia**, regulates its food contact materials market though governmental resolutions which apply across the bloc. Mercosur is reviewing its positive list of additives used in plastic food contact materials, following the publication of a new version of the positive list of monomers and polymers, based on US and EU food contact legislation. Several specific migration limits and concentration limits from the EU rules for plastic monomers, and the EU ban on the use of bisphenol A in baby bottles, have been included. The general reuse of plastic food contact materials is forbidden in Mercosur, but several resolutions have authorised the use of PET bottles for beverages and foodstuffs, according to good manufacturing practices and a quality assurance system. Mercosur associate, **Chile**, is also aligning its emerging plastic food contact material regulation to the

EU rules. Mercosur rules covering cellulose-based materials, such as paper, paperboard and cardboard, include a positive list of components and migration methods.

Brazil has notified the World Trade Organization (WTO) of a technical resolution establishing Good Manufacturing Practices (GMP) for companies which manufacture direct food contact packaging. GMP is a fundamental part of the EU rules to protect consumer health and prevent food contamination from food contact materials. Brazil has announced its own requirements, which include: design of buildings and facilities, pest control, cleaning, waste, selection of raw materials, measures to avoid contamination, hygiene, training, standard operating procedures and documentation.

THE UNITED NATIONS' GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

The **United States** Occupational Safety and Health Administration (OSHA) will update its chemicals Hazard Communication Standard (HCS) 29 CFR 1910.1200 (HazCom 2012), which implements the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS), to align it with the 6th revised edition of GHS. This includes criteria for aerosols and desensitised explosives. The **US** and **Canada** are continuing to collaborate on GHS implementation to avoid variances where possible. The majority of labelling and Safety Data Sheet requirements are aligned, but some differences have been maintained to ensure continued worker protection, such as bilingual labels for Canada and the combustible dust hazard for the US.

OSHA has launched an interactive, on-line, game-based training tool which is intended to teach small business owners and their workers the process for finding hazards in their workplace, and to raise awareness on the types of information and resources about workplace hazards available on OSHA's website. After using the tool, users will be able to better understand the process to identify hazards in their own workplace.

Mexico enacted and published a new official mandatory standard (NOM-018-STPS-2015) in October 2015, adopting the fifth revised edition of GHS. The standard has a transitional period of three years, and follows closely to the previous voluntary standard. It includes a uniform hazard communication for chemical products, labelling requirements and Safety Data Sheets, and applies to all places of work where hazardous chemicals are handled (excluding pharmaceuticals, food additives, cosmetics, pesticide residues in food and hazardous waste).

Argentina has delayed its implementation of GHS as a consequence of discussions with the chemical industry and small and medium sized enterprises, advising of difficulties in complying with the GHS labelling requirement in such a short transitional period (180 days). Implementation of GHS in the workplace will now be enforced from 15 April 2016 for substances and 1 January 2017 for mixtures.

In May, **Brazil** published another modification to Regulation ABNT NRB 14725, which implemented GHS in 2009. This modification extends the deadline for labelling of mixtures from 1 June to 1 December 2015. Until 30 November, compliance with the labelling of mixtures provision is optional, and hazardous chemical products already labelled before this date will be valid until the expiry date on the label. More recently, **Chile** has updated its standard on Safety Data Sheets for chemical products to align it with GHS.

GHS is implemented in 11 Asia Pacific countries, and pending in three more, but the implementation and enforcement varies depending upon the jurisdiction. Each country often has its own set of regulations, making the compliance requirements particular to the specific country. For example, **China** has implemented GHS classification standards from different revisions (2nd and 4th editions). **Japan** is in the process of consolidating its SDS and labelling standards into a single standard (JIS Z7253), with an expected entry into force of January 2017. In **South Korea**, classification and labelling of mixtures according to GHS has been mandatory since July 2013, and more recently the 3rd revised edition has been adopted. **Taiwan's** implementation is based on the 2nd edition of GHS, but with four different phase-in deadlines, concluding in January 2017.

Australia implemented the 3rd edition of GHS, effective from January 2012, with a transition period which expires 31 December 2016; however, as a workplace regulation, the scope is limited to the workplace, and environmental hazards are not included. In **New Zealand**, one of the first countries to adopt GHS, it applies to all products, industrial and consumer. The regulations will be shortly updated to align with the 5th revised edition of GHS.

In **Indonesia**, GHS is aligned with the 4th edition and compliance for substances has been mandatory since March 2010, with a deadline of December 2016 for mixtures. **Singapore** is also now aligned with the 4th edition (previously 2nd edition), with the deadline for mixtures of July 2016. **Thailand** has implemented the 3rd revised edition of GHS, and requires all labels and SDS to be in Thai. **Vietnam** also implemented the 3rd edition in March 2012, with a two year transitional period for substances and four years for mixtures (to March 2016). Similarly, **Malaysia** adopted the 3rd revised edition, but in 2013, and required compliance by April 2015 for both substances and mixtures; in addition, labels and SDS must be in both English and Malaysian.

All of these differing national requirements and implementations is the principal reason why SDS harmonisation in Asia is not possible. Countries have different rules in terms of language, composition, ingredients and confidential information. Classification lists are provided for reference only in some countries, but can be mandatory in others. For language, **Malaysia** requires SDS in both Malaysian and English, whereas **Singapore**requires just English. **China** uses simplified Chinese characters, whereas **Hong Kong** and **Taiwan** use traditional characters. **Malaysia** also requires that temperatures are listed in both Celsius and Fahrenheit.

So although GHS is a supposedly global and harmonised system, there are still significant differences to be aware of, and it will be some considerable time yet before we truly have global harmonisation. In addition to the various differences described above, GHS also allows flexibility in the implementation of classification thresholds, so that the same product may be classified differently, depending upon which country the product is destined. An example of this can be seen in the table, where USA and Brazil have adopted similar (low) concentration thresholds, whereas China and the EU have similar, but much higher thresholds for classification. Sun Chemical will continue monitoring the different legislative requirements and ensure that it meets its obligations and legal requirements when supplying products to different countries.

Hazard Class Category Concentration thresholds for classification of mixtures				
Country	US	Brazil	Europe	China
Repiratory sensitisation Category 1	0.1%	0.1%	1%	1%
Skin sensitization Category 1	0.1%	0.1%	1%	1%
Carcinogenicity Category 2	0.1%	0.1%	1%	1%
Reproductive toxicity Category 1	0.1%	0.1%	0.3%	0.3%
Reproductive toxicity Category 2	0.1%	0.1%	3%	3%
STOT single exposure Category 1	1%	1%	10% (Cat 2 @ 1%)	10% (Cat 2@ 1%)
STOT single exposure Category 2	1%	1%	10%	10%
STOT repeat exposure Category 1	1%	1%	10% (Cat 2 @ 1%)	10% (Cat 2@ 1%)
STOT repeat exposure Category 2	1%	1%	10%	10%

REACH & CLP

The French authorities have submitted a proposal to have a harmonised EU classification for titanium dioxide as a category 1B carcinogen. At the time of writing, the details of the proposal and justification for a 1B classification were not available, and so it is difficult to comment on the validity of the proposal or its chances of success. It has been known for some years that inhalation of inert particles in high doses can result in tumours in rats, but this is recognised to be a consequence of overloading the lung clearance mechanism in rodents, and is considered as not relevant for humans. The Titanium Dioxide Manufacturers Association (TDMA) hasstated that the classification was assessed as part of the REACH registration, and no classification is required for any end point. This is supported by epidemiological studies amongst 20,000 workers at 15 titanium dioxide manufacturing plants over several decades, which showed no adverse health effects. Titanium dioxide is a very common white pigment, and finds use in a myriad of applications, from paint and ink, to cosmetics, sunscreens, toothpaste and food additives; a category 1B carcinogen classification would have a huge impact. The TDMA is convinced of the non-hazardous status and safety of titanium dioxide, and will provide detailed scientific data to the consultation and classification process to support this position.

The European Chemicals Agency (ECHA) has launched a public consultation on a draft 7th recommendation to add 11 new substances to REACH Annex XIV, which is the first stage of the REACH Authorisation process. This latest draft includes 2 anhydride respiratory sensitisers, 2 perborate compounds, 2 phthalates, trixylyl phosphate and 4 lead compounds: none of these substances is used by Sun Chemical.

Germany is working on a proposal to include di-isocyanates in REACH Annex XVII (Restrictions), which is expected to be submitted by July 2016. Many low molecular weight di-isocyanates are classified as respiratory sensitisers, and have been shown to cause occupational asthma. The proposal is expected to restrict the use of di-isocyanates, on their own, or as a constituent in other substances or mixtures, for industrial or professional use, unless the concentration is below 0.1%, and measurements show that only an acceptable residual risk is present. In addition, users of di-isocyanates will be required to undergo certified training to ensure that the materials are handled safely.

The European Court of Justice (ECJ) has made an important ruling as regards the 0.1% threshold for Substances of Very High Concern (SVHC) in Articles. Previously, the ECHA guidance considered that a complex product, such as an imported car, was itself an article, and the 0.1% limit applied to the complete item. However, the ECJ, in response to a legal action from a number of Member States, has now said that “each of the articles,

incorporated as a component of a complex product, is covered by the relevant duties to notify and provide information, when they contain an SVHC in a concentration above 0.1% of their mass", i.e. once an article, always an article. ECHA has indicated that it will update its guidance on requirements for substances in articles to align with the ECJ judgement. Although this ruling is likely to have a major impact in some sectors, it is of very limited relevance to Sun Chemical products, which are used in the manufacture of articles rather than being component articles in their own right, and normally constitute only a very small proportion by weight of the completed article.

The issue of lower classification limits for skin and eye irritation as a consequence of the change to GHS/CLP for mixtures was highlighted in the previous Newsletter. EuPIA has now issued a customer information note on this subject, which provides additional information.

Since 1st September 2015, the Biocidal Products Regulation specifies that biocidal products cannot be marketed in the EU unless either the active substance supplier or the biocidal product supplier is included on the ECHA Article 95 list, for the relevant product type. Sun Chemical complies with this requirement and only uses biocides and other biocidal products in the EU that come from Article 95 listed suppliers.

Environment Canada has published Frequently Asked Questions with regard to the Significant New Activity (SNAc) provisions under the Canadian Environmental Protection Act, to provide basic information for businesses and citizens. These include the purpose and key elements of the provisions, business impact and where to get more information.

A Danish NanoDEN project, investigating the environmental risk of engineered nanomaterials, has found that there is currently no cause for concern. Ten substances were selected, including titanium dioxide, zinc oxide, silver, carbon nanotubes and carbon black, since they were expected to be environmentally relevant. The final report, entitled Environmental assessment of nanomaterial use in Denmark, states that no causes for significant environmental concerns regarding nanomaterials in the Danish environment have been identified.

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