

Regulatory Newsletter

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

EU REACH registration deadline, minor changes considered

The second REACH registration deadline for substances manufactured or imported into the EU at more than 100 tonnes per annum was 31 May. As with the first deadline (2010), Sun Chemical submitted registration dossiers of those substances for which it has a registration obligation (EU-manufactured pigments and some imported materials).

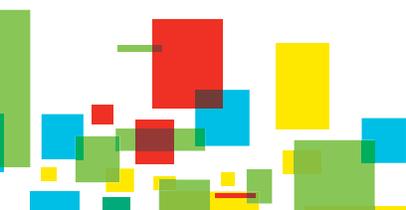
We have also received inquiries about the published list of some 400 substances which appear to have no lead registrant. This is not a cause for concern, as there are several reasons why no lead registrant has come forward; this was also seen in advance of the 2010 deadline. In those cases we have checked, we found that some substances will only have one registrant (therefore a lead registrant is not required), and for others the actual volume for registration is below 100 tonnes per annum (deadline 2018).

The European Commission recently published its review of the REACH Regulation. Although the report identifies a need for some adjustments to the legislation, the Commission wants to ensure legislative stability and predictability for European businesses. No changes to REACH's main terms are proposed at present. It believes that REACH is generally working well, although the impact on Small & Medium-sized Enterprises (administration and costs) should be reduced. There is insufficient information to judge whether innovation and competitiveness have been affected. Phaseout of Substances of Very High Concern (SVHC) should be encouraged, and nanomaterials should be able to be covered by the existing REACH framework. The Commission believes harmonized enforcement is a challenge and needs to be improved. Several Sun Chemical sites have been successfully inspected as part of the REACH ENFORCE programme.

An update of the Community Rolling Action Plan (CoRAP) for substance evaluation has been published. A small number of substances used in printing inks are included (mainly monomers used in the manufacture of polymers or binders). Inclusion in this list indicates that the substance will be assessed by a Member State; it does not imply that the substance will be prohibited from use. Sun Chemical will work with suppliers to provide additional information where necessary to assist with the evaluation process.



working for you.



OSHA helping companies comply with HazCom 2012 and GHS

The U.S. Occupational Safety and Health Administration (OSHA) is preparing guidance to help companies prepare for compliance with the HazCom 2012 standard, which aligns the U.S. with the Globally Harmonized System (GHS) of classification and labelling of chemicals for workers. The agency has also put together a [factsheet](#) on how employers must train their workers on elements such as [pictograms](#) and the 16-section format for safety data sheets. The deadline for employee training is 1 December 2013.



BPA update

The controversy surrounding Bisphenol A (BPA) continues. In 2012 the U.S. Food and Drug Administration (FDA) amended its food additive regulations to disallow the use of BPA in baby bottles and children's sippy cups on the grounds that these uses of BPA have been discontinued. The FDA rule does not cover BPA used in any food and beverage packaging or other reusable food containers and does not address BPA safety. Fourteen U.S. states are considering bills that would bar the use

of BPA in various products, including food and beverage containers, cash register receipt papers and children's products.

France has introduced legislation which would prohibit the use of Bisphenol A in food packaging from 2015, including substances and polymers manufactured from BPA, even if all the BPA is completely reacted. The European Food Safety Authority (EFSA) is undertaking another comprehensive review of the safety of Bisphenol A, and a public consultation is expected shortly. The European Commission has indicated that it will not decide upon the validity of the French national initiative with respect to the functioning of the internal market until EFSA delivers its opinion.

With the exception of some specialty thermochromic inks, Sun Chemical does not use BPA. However certain raw materials (such as some epoxy resins) do use BPA as a starting material earlier in the supply chain. We are working to replace these materials in our products.

Food packaging ink legislation

A new version of Annex 6 to the [Swiss packaging inks Ordinance](#) SR817.023.21 took effect 1st April 2013. Printing inks and varnishes applied to the non-food contact surface of food packaging may only be manufactured from the substances listed in Annex 6 (or Annex 1). In addition, the stipulated migration limits must not be exceeded. Sun Chemical's European packaging inks are formulated in accordance with the Swiss requirements and will allow printed food packaging to comply with this Ordinance when used as directed and in accordance with good manufacturing practice.



A third draft of the proposed German printing ink Ordinance has been released to stakeholders. The concept is similar to the Swiss Ordinance with a positive list of substances; however, it will be possible to use other substances which appear on a separate inventory list (similar to the Swiss Part B list). There are still a number of issues with the latest proposals, and the industry is lobbying to achieve a workable outcome. Sun Chemical is working with suppliers to ensure that key raw materials are evaluated and included in the positive list.

Mineral oil use being examined

The German Ministry of Food, Agriculture and Consumer Protection (BMELV) has released a second draft of the Mineral Oil Ordinance in response to concerns about the presence of mineral oil hydrocarbons in recycled paper and board used for food packaging. A key difference compared with the first draft is that the restrictions are now limited to mineral oil aromatic hydrocarbons (MOAH), rather than MOAH and mineral oil saturated hydrocarbons (MOSH) as previously proposed. The Ordinance will prohibit the transfer to food of MOAH with carbon numbers between C10 and C25 from food contact materials produced using recycled paper/pulp. Mineral oils are not used in Sun Chemical's low migration inks and coatings.

A [recent publication](#) reports on the effect of storage time and the barrier performance of different internal wrappers on migration of various components from recycled paperboard, including mineral oil.

France enacts nanomaterials reporting law

New French legislation has established a mandatory reporting scheme for the use of nanomaterials throughout the production chain, requiring annual declarations to be submitted every year before 1 May for nanomaterials manufactured in France or placed on the French market the previous year. Decree 2012-232 defines the framework for the mandatory reporting scheme. This applies to “substances at the nanoscale,” defined as those containing particles in an unbound state or as an aggregate or agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm. However, the French definition only applies to substances intentionally manufactured at the nanoscale, whereas the EU definition applies to natural, incidental and manufactured materials.

The Decree imposes a reporting obligation on any manufacturer, distributor or importer of substances at the nanoscale, by themselves, as part of an unbound mixture, or in articles intended to release such substances under normal or reasonably foreseeable conditions of use, with a threshold of 100 g/year. The scheme does not apply to articles containing substances at the nanoscale if they are not intended to be released. A unique identification number is assigned to each declaration and provided to the declarer. This declaration number must be communicated by the declarer to professional users and distributors upon transfer of ownership of the substances.

There is still considerable debate and uncertainty about whether traditional pigments and extenders are “intentionally manufactured at the nanoscale” and whether particles dispersed in a resin or binder, as found in a (wet) ink or coating, are bound or unbound. The position of the French Association of Printing Ink Manufacturers (AFEI) is that the dispersed particles in inks and coatings are considered to be bound and therefore not covered by the reporting requirement. Further clarity on the definitions and reporting obligations is being sought.

For more information on these regulatory issues, please contact the Regulatory Affairs team in [North America](#) or [Europe](#).



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