

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

European Union

Despite the fact that the European Commission announced plans to introduce a European Union (EU) measure on printed food contact materials in 2018, it appears to have made little progress. The European Commission has decided to give priority to an evaluation of the food contact materials legislation to address what it considers to be potential inefficiencies in the present regulatory model (e.g., functioning of positive lists, information in the supply chain, and enforcement issues relating to legal certainty, lack of resources and missing analytical methods). Work on the printed food contact materials (FCM) measure is not expected until after completion of the evaluation study, scheduled for early 2020.

Meanwhile, the Packaging Ink Joint Industry Task Force (PIJITF) has been very active, producing a proposal for the regulation of printed food contact materials, supported by the supply chain, which addresses the potential inefficiencies identified by the European Commission. Whilst we push for progress on the printed FCM measure and continue to promote it and discuss with Member States, the ball is very much with the European Commission, for which this appears to be less of a priority.

This is particularly relevant since Germany suspended work on its draft printing inks ordinance, following the announcement that the European Commission would bring in an EU harmonised measure. The longer the European Commission delays, the greater the fear that Germany will recommence work on the national measure. Fortunately, Germany would still have to address the adverse comments submitted by other Member States during the consultation phase to bring a revised proposal, and the European Commission has indicated that it will maintain contact to learn about how the national measure is intended to be progressed, with the aim to limit the impact on the internal market. We continue to monitor developments closely.

The European Commission has published an amending [regulation](#) (EU) No 2018/213 on the use of bisphenol A, setting a revised specific migration limit (SML) of 0.05 mg/kg of food, which applies from 6th September 2018. Sun Chemical does not intentionally use bisphenol A, and our products placed on the European market intended for food packaging and other sensitive applications will meet this new limit.

working for you.

China

The organisation CIRS has provided some [details](#) of the Chinese food contact materials and articles regulation system. The most important are GB 4806.1-2016, General Safety Requirements for Food Contact Materials and Articles, and GB 9685-2016, Standard for the Uses of Additives in Food Contact Materials and Articles, which came into force in October 2017. GB 4806.1 is a new standard which applies to all FCM, specifying the basic requirements, restrictions, compliance principle, test methods, traceability, and product information for FCM.

It refers to other GB standards, including those for good manufacturing practice and migration testing, as well as for specific materials. Interestingly, it also sets a migration limit of 0.01 mg/kg of food (10 ppb) for unapproved substances (substances not listed in the corresponding GB standards).

The Chinese authorities are working on a specific standard for packaging inks, to which the European Printing Ink Association (EuPIA) has had some input, which is expected in 2019. GB 9685-2016 is an update of GB 9685-2008, and includes 1294 approved food contact additives. It specifies the principles for uses of additives in FCMs, approved additive categories, application scope, maximum permitted level, specific migration limit or maximum residue limit, total specific migration limit, and other restrictions in FCMs.

Unfortunately, it is not possible to formulate a packaging ink based solely on the additives listed in GB 9685; hence, until the new ink-specific standard is published, if compliance is required, then it must be based on the no-migration principle (below 0.01 mg/kg, as specified in GB 4806.1).

India

The Food Safety and Standards Authority of India has [prepared](#) new food safety and standards (packaging) regulations, supported by 17 Indian standards covering specific materials. Amongst the general requirements, it states that materials shall be of food-grade quality, printing inks for use on food packaging shall conform to IS 15495, and the printed surface of packaging shall not come into direct contact with food products.

Specific requirements relate to paper and board materials, glass containers, metal and metal alloys, and plastic materials, supported by various Indian standards. Pigments or colourants for use in plastics in contact with food products and drinking water shall conform to IS 9833. Following notification to the World Trade Organization (WTO), only the EU [submitted](#) comments regarding the proposed measure.



South Korea

The organisation ChemSafetyPro has provided helpful articles on how to comply with food-contact regulations in different countries. In [Korea](#), there is no official positive list of substances or additives that are permitted for use in manufacturing food contact materials or articles. However, the Ministry of Food and Drug Safety (MFDS) has established standards and specifications for various food-contact materials and their raw materials.

Some hazardous substances are restricted or banned depending on the type of food contact materials and intended applications. Article 8 of the Korean Food Sanitation Act prohibits the manufacture, import, or sale of food-related apparatus, containers, or packages that contain poisonous or harmful materials that are likely to cause harm to humans. The act also authorises MFDS to enforce the law and establish regulations, standards, and specifications for food-related products such as food additives, food packaging materials, and food containers.

The most important standard for food contact materials is Standards and Specifications for Food Utensils, Containers and Packages, which consists of three main parts. *Common standards and specifications* describe general requirements for apparatus, food containers and packaging, and their material. In particular, the standard states that the food contact surface shall not be printed in the manufacture of utensils, containers, and packages, and only colourants permitted as food additives, or where there is no possibility of migration into foods, shall be used.

Specifications for individual materials include limits on residue content, hazardous substance migration, and testing methods that can be used to demonstrate compliance. *Testing methods* are aimed at ensuring the finished food contact materials meet various specifications, such as migration of hazardous substances and heavy metal content. The testing conditions (solvent, time/temperature, etc.) are based on the intended application of the packaging material.

Canada

In [Canada](#), there is no official positive list of substances or additives that are permitted for use in manufacturing food contact materials or articles, and there is no mandatory food contact notification or testing requirement.

If you place food contact materials on the Canadian market, you will need to assure your customers that they are compliant with relevant food contact regulations. Food packaging materials are governed by Section B.23.001 of the Canadian Food and Drugs Act and Regulations.



Under this legislation, it is the responsibility of the food seller (manufacturer, distributor) to ensure the safety of packaging material and compliance with Section B.23.001. Manufacturers and suppliers of food packaging materials or additives do not have direct compliance responsibility. However, they can request, on a voluntary basis, a pre-market assessment of their products from Health Canada and get a letter of no objection (LONO) to show compliance. It should be noted that there is a mandatory requirement for Health Canada to review food contact materials used to package infant formula, foods for special dietary use, and novel foods.

In order to apply for the pre-market assessment, suppliers of a formulated product or a finished packaging article shall submit [information](#) on the product identity and proposed usage, including dimensions, surface-area-to-weight/volume ratio, time/temperature conditions, etc. More data is required for assessment of specific constituents, including simulated migration testing and toxicological data. The request for pre-market assessment and the letter of no objection are submitted on a voluntary basis. It is not necessary if you are confident that the food contact material is safe for its intended use. Health Canada maintains positive lists of polymers for which letters of no objection have been issued for use in food packaging and other food contact applications. Suppliers do not need the letter of no objection for listed polymers if they can demonstrate equivalence.

The article also indicates that compliance with the Canadian food contact regulations can be demonstrated by reference to authorisations for use in specific FCMs in the EU or USA, and advises food packaging or food companies to request adequate product information from the supplier of the FCMs, including a declaration of compliance (DoC), and to conduct migration testing to verify compliance if necessary.

Australia & New Zealand



Food Standards Australia New Zealand (FSANZ) has decided to [abandon](#) the proposed regulation of food packaging materials following publication of a final food safety study report. FSANZ concluded that food packaging materials pose no health risk at current exposure levels,

and exposure estimates for substances analysed in food were well below levels of concern. Since many businesses marketing packaged food in Australia also do business in the U.S. and the EU, it is thought that compliance with international regulations contributed to the survey findings.

FSANZ decided that any kind of prescriptive approach or positive/negative list was not warranted following assessment of the risks. However, FSANZ plans to develop guidance to provide a comprehensive source of information for industry, address the gaps in awareness and knowledge for SMEs, provide general information on safety issues with chemical migration from packaging into food for consumers, and describe the obligations on food businesses to use safe packaging materials.

United States

A [bill](#), entitled *Protect Our Food from Phthalate Contamination Act*, has been introduced in the U.S. Senate to ban the use of ortho-phthalate chemicals in food contact substances. The bill is expected to reduce exposure to phthalates from food and will provide companies with a two-year period to phase out phthalates and find safe alternatives. Although some of these phthalates are considered safe for the intended use as specified in the indirect food additives by the U.S. FDA, Sun Chemical stopped using phthalates in food packaging inks and coatings many years ago.



The Food Safety Alliance for Packaging (FSAP), a technical committee of the Institute of Packaging Professionals (IoPP), has published a [document](#) entitled *Food Packaging Product Stewardship Considerations* to provide guidelines to suppliers of food packaging. This consists of a voluntary set of considerations that a supplier or food producer can use (in whole or in part) as a roadmap for awareness on quality issues and minimising or eliminating chemicals of concern from food packaging. The document is the output of a food brand owners' working group, based on many different lists of chemicals of concern and quality considerations, and goes beyond regulatory requirements.

FSAP considers that the nonbinding list can be used as a best practice for the formulation of food packaging for consumer products. Listed items are grouped by packaging part and substance, and fall into two categories:



1. Should not use intentionally:
Listed items should be replaced where a safe and technically suitable alternative exists; or
2. Minimise use: Should use as much as necessary to achieve a technical effect, but no more.

Inclusion of an item on the list does not indicate that the members of the working group consider said item to pose a risk to food safety or public health. They also note that:

- applicable regulations must be followed in order to support the intended conditions of use for any food contact material;
- more extensive risk assessments should be considered for special package types, including but not limited to baby food packaging, thermally processed packaging, and microwaveable/ovenable packaging; and
- additional requirements may be necessary to fulfil the standards of a given food manufacturer or customer.

Other

As foreseen in the previous newsletter, Turkey has now published new legislation aligning its rules on food contact materials with those of the EU. These two regulations correspond to the 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.



Brazil's regulations on technical requirements for food contact cellulosic materials have now entered into force, following a two-year transition period. The regulations list the substances that may be used in the manufacture of cellulosic materials in contact with food, as well as restrictions on materials, containers, and equipment treated with paraffin, waxes, mineral oils, and pigments. The regulations also include the permitted migration levels for other substances that may constitute part of cellulose containers and packaging, including those for various phthalates, cadmium, lead, mercury, and antimony.



The rules are adoptions of those drawn up by Mercosur, the South American trade bloc. Argentina and Uruguay have also recently incorporated Mercosur resolutions on FCMs and cellulosic materials into their own national legislation, with implementation dates of 30 December 2018 and 7 June 2023, respectively.

Issue 8 of the BRC Global Standard for Food Safety is now available, with the first audits to be conducted from February 2019. Companies that work to the standard need to be aware of the changes and start to prepare to meet them now. One of the most obvious changes to Issue 8 is the addition of sections on production risk zones and traded goods. New requirements for food safety and quality culture, food defence, and environmental monitoring will need to be implemented. Updates to existing sections include validating cooking instructions and shelf life, training on labelling, cybersecurity, understanding laboratory results, traceability procedures, and defining root cause analysis. A short [video](#) describing these changes has been prepared by Campden BRI.



ChemSafetyPro has also prepared a short [article](#) on *How to Use Toxtree to Determine Cramer Class and Estimate Toxic Hazard*. Toxtree is a free (Q)SAR tool that can be used to determine the Cramer Class of a chemical substance and estimate its relative toxic hazard. The Cramer classification scheme is the best-known approach to estimate the threshold of toxicological concern (TTC) for a chemical substance based on its structure. There are three different Cramer Classes, each representing a different level of daily exposure to a chemical which is considered to be of negligible concern. This approach may be used to assess the risks from exposure to low-level contaminants migrating from food packaging, as described in the [EuPIA guidance document](#) on risk assessment of NIAS or non-listed substances, or as part of the process for evaluating food additives as used by EFSA.

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

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