Fall 2019

Regulatory Newsletter

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

Titanium dioxide classification

Now that the European Union's Classification, Labelling and Packaging (EU CLP) legislation (EC No. 1272/2008) is subject to a revised legislative process following the implementation of the Treaty of Lisbon, it is likely that the delayed 14th ATP (adaptation to technical progress) with the proposed harmonised classification for titanium dioxide as carcinogenic category 2 via inhalation (spray or dust) will be adopted as a delegated act. It should be noted that the proposed carcinogenic classification would not apply to mixtures where the titanium dioxide particles cannot be inhaled.

The European Commission, which now has more power to adopt such acts, will be advised by the CARACAL expert group, rather than voting in the REACH committee following the opinion from European Chemicals Agency's (ECHA) risk assessment committee (RAC). Discussions are expected to continue during the second half of 2019. Once the commission adopts a delegated act, the European Parliament and the European Council have two months to formulate justified objections, otherwise the delegated act enters into force. Several countries, including the USA, Australia, Mexico, Philippines and Russia, have objected to the WTO notification of the intended reclassification.

TSCA inventory notification (active-inactive) rule

In October 2018, we completed our reporting of materials processed in the U.S. for the 10-year period ending June 21, 2016. This led to publication of a new Toxic Substances Control Act (TSCA) Inventory. Chemical substances are identified as active (i.e., already reported or exempt) or inactive (i.e., not reported or exempt).

Sun Chemical's database of over 15,000 chemicals has been reviewed for status, including contacting those vendors that supply raw materials that contain proprietary information. In the period since June 2016, additional reviews of TSCA status were conducted for various raw materials used in products to be extended to the USA from Europe in order to continue importation of the raw materials in inks imported from the EU.

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As of August 5, 2019, manufacturers and processors are required to notify the EPA before reintroducing into commerce a substance currently identified as inactive on the TSCA inventory. Manufacturers and processors notify the EPA via a Notice of Activity Form B, found in EPA's Central Data Exchange (CDX). Upon receiving such notification, the EPA will change the designation of substances from inactive to active. Per the TSCA Inventory Notification (Active-Inactive) Requirements final rule, inactive designations become effective 90 days after the signing of a memo designating them as such.

In the period of March–August 2019 we submitted nearly 30 NOA Form Bs to change the status of a chemical substance from Inactive to Active.

We expect a new TSCA inventory to be published later this year.

TSCA CDR inventory reporting

We will soon begin preparations for the next reports, for which reporting will begin in June 2020, with 2019 as the principal reporting year. It requires manufacturers (including importers) to provide the EPA with information, including processing and use information, on chemical substances that they manufacture (including import) above threshold production volumes. The scope of the new reporting is not yet known, but the production volume threshold for reporting a chemical substance is generally 25,000 pounds for a specific reporting year. EPA intends to revise the reporting requirements, which may include altering the reporting threshold to 10,000 pounds, among other considerations.

Draft chemical risk evaluation for pigment violet 29 is EPA's first under TSCA reform

EPA's draft risk evaluation for pigment violet 29, or PV29, concludes that occupational exposures to the chemical are limited and that it does not present an unreasonable risk of injury to human health—including workers involved in its manufacture—or the environment. The draft risk evaluation is the first that the agency has published under the recently amended TSCA. As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which was signed into law in June 2016, the TSCA requires the EPA to complete risk evaluations for 10 chemicals, including PV29, by December 2019.

The TSCA Science Advisory Committee on Chemicals (SACC) reviewed the draft risk evaluation for pigment violet 29 on June 18–21, 2019. The agency used scientific advice, information, and recommendations from the SACC, as well as public comments, to inform the final risk evaluation for PV29.

Food contact materials

European Union

The commission's public consultation on the evaluation of the food contact materials (FCM) legislation has finished, and a short summary report is available. The key responses reported are:

- Most citizens trust the safety of FCM to a reasonable (38%) or to a large extent (35%); only 4% of citizens do not trust the safety of FCM sold in the EU.
- 66% of EU citizens believe that the level of safety of food packaging sold in the EU has increased over the last 10 years; only 10% of respondents believe that the safety has decreased.
- A large majority of respondents (94%) indicated that more harmonisation at the EU level is desirable, compared to individual member state legislation.

The overall evaluation is foreseen to be completed in early 2020, including dissemination activities and preparation of a staff working document. Work on the postponed printed food contact materials measure is not expected to commence until after this study is finished.

Meanwhile, the commission has asked member state competent authorities to conduct new sample tests on certain substances migrating from food contact materials and articles, and to report any data generated within the past five years.

This request is to assist the commission in determining the prevalence of substances migrating into food from food packaging and whether further regulatory action may be needed. For example, will additional control measures be needed for substances leaching from plastic FCMs? The information may also contribute to setting priorities for other materials, which currently lack specific EU measures.

The European Food Safety Authority (EFSA) has published guidance on the use of the threshold of toxicological concern (TTC) approach in food safety assessment. The document provides clear step-by-step instructions for use of the TTC approach, which can be used when the chemical structure of the substance is known, the exposure can be estimated, and there are limited chemical-specific toxicity data. The inclusion and exclusion criteria are defined, and the use of the TTC decision tree is explained. If the estimated exposure to a substance is above the relevant TTC value, if the substance under consideration falls into one of the exclusion categories, or if sufficient data are available for a risk assessment, a non-TTC approach is required to reach a conclusion on potentially adverse health effects.

The TTC approach has been adopted by the European Printing Ink Association (EuPIA) and by the Packaging Ink Joint Industry Task Force (PIJITF) as part of the process for safety evaluation of substances which migrate from printed food packaging into food.

The **German** Federation for Food Law and Food Science (BLL) has published a guideline for the assessment of MOSH/MOAH* migration from packaging into food with the aim of minimisation. The guidance is intended to support companies in assessing packaging solutions already in use regarding their food law compliance in terms of mineral oil components.

It also provides answers to the question of whether and, if so, which measures are recommended or necessary to prevent exposure to mineral oil hydrocarbons through other alternative packaging solutions (e.g., barrier layers, inner bags, virgin fibre packaging). The document focuses on understanding migration from packaging materials and quantitative criteria. These guidelines describe not only the basic migration principles, but also step-by-step procedures for checking and effectively developing a packaging/food combination.

Turkey has introduced a new regulation on plastic food contact materials, which will align with those in the European Union. There is a two-year transition period until 2021. The regulation replaces the previous food regulation on plastic FCMs, which has been in place since 2013. Turkey, as a member of the European Union Customs Union, is bringing all its chemical regulations in line with those of the member states.

Latin America

Several of the countries in Latin America have largely harmonised their framework of laws as full members of Mercosur, the largest trade bloc in South America. Largely based on the EU regulatory system, Mercosur's food contact legislation consists of positive lists that limit the use and migration of specific materials in food contact applications.

Regulation of FCMs is generally accomplished through Mercosur resolutions, including a general framework resolution and resolutions applicable to specific material categories. These are then adopted and incorporated into the laws of the member countries. However, individual countries may establish separate registration requirements that apply to packaging materials or articles. The GMC (Grupo Mercado Comun = Common Market Group) resolutions only have the effect of law once transposed into a member state's national legislation.

Mercosur free trade members

All food contact materials, including housewares, must comply with Mercosur's general safety standard, GMC Resolution No. 03/92, which gives the terminology, classification of materials, and general criteria for packaging and articles intended to come into contact with foodstuffs.

This resolution requires all FCMs to be manufactured under good manufacturing practices (GMP), be of suitable purity, not transfer harmful or toxic compounds from the packaging to the food, and not cause an unacceptable change in food composition, taste, or odour.

**Mineral Oil Saturated Hydrocarbons / Mineral Oil Aromatic Hydrocarbons*

Overall migration limits are also specified in this resolution, although the migration test methods are detailed separately in GMC Resolution No. 32/99. In addition to the general safety standard, FCMs are obliged to comply with applicable GMC resolutions addressing specific packaging categories. For example, only substances identified on the relevant positive list may be used in Mercosur to produce plastic and paper FCMs.

GMC Res. No. 02/12 identifies monomers, polymers, and other starting substances that may be used in the manufacture of food contact plastics. GMC Res. No. 32/07 lists additives that may be used in the manufacture of food contact plastics, including antioxidants, foaming agents, lubricants and plasticisers, surfactants, pH buffering agents, and solvents. The resolution does not apply to impurities, intermediates, and aids to polymerisation, such as catalysts, initiators and accelerators.

Both GMC Res. No. 02/12 and 32/07 include limitations pertaining to the use, composition, and specific migration levels (SMLs) of listed substances. GMC Res. No. 32/07 is currently being revised to more closely align it with the EU Plastics Regulation No. 10/2011. GMC Res. No. 02/12 may undergo a similar update.

GMC Res. No. 40/15 (technical regulations on cellulosic materials, containers, and equipment intended to contact food) applies to paper and paperboard FCMs, establishing a positive list of additives used in paper, paperboard, and recycled fibres, and also specifies use, migration, and compositional restrictions. This resolution does not apply to paper used for filtration, infusion, cooking, or microwave applications.

GMC Res. No. 41/15 (technical regulations on cellulosic materials for hot cooking and filtration) includes a positive list for cellulosic materials used to filter aqueous foods. The resolution limits the nitrogen content of total residue from hot water extraction of paper. GMC Res. No. 42/15 (technical regulations on materials, containers, and cellulose equipment intended to be in contact with food during cooking or heating in an oven) contains a positive list for paper and paperboard used for cooking in the oven and microwave, and identifies specific conditions for extraction testing and applicable migration limits.

Polymeric coatings applied to the interior food contact side of metal cans, paper, and other substrates must comply with the positive lists and other requirements provided in GMC Res. No. 02/12 and 32/07. However, coatings applied to the exterior of metal cans are not yet regulated under Mercosur, and the can itself is considered a functional barrier to migration from exterior coating substances.

Bolivia, Colombia, Ecuador, and **Peru** are members of CAN (Comunidad Andina) trade bloc, although the regulation of FCMs is not harmonised amongst CAN member states.

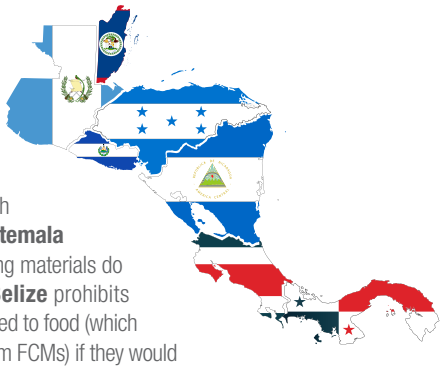
Administrative Resolution No. 019/2003 sets forth Bolivian sanitary requirements for foods and beverages and requires that packaging materials provide adequate protection to foods so that they do not become contaminated or damaged, and packaging materials must be nontoxic.

The Bolivian Institute for Standardisation and Quality has issued standards for FCMs, including plastic containers, but does not define the methods of assessment. Colombian Resolution No. 683 (2012) provides a general FCM safety framework and requires that all FCMs be cleared in the United States, European Union, or Mercosur, otherwise a petition may be submitted to obtain formal clearance.

Executive decree 4114 (1988) establishes general requirements for food packaging in Ecuador, including that it must be safe. Peruvian Ministerial Decree No. 007/1998 requires that packaging must not transfer substances to food and must not contain impurities such as heavy metals and metalloids that can cause damage to the health of consumers. The decree also prohibits certain residual monomers and limits other residual monomers that would damage consumers' health.

Decree No. 977 establishes general standards for FCMs in **Chile,** requiring that all utensils, vessels, containers, packaging, wrappers, and packaging apparatus must not release substances that are toxic or otherwise contaminate or modify the organoleptic or nutritional characteristics of the food. The decree also sets limits on heavy metal impurities in these articles—a combined limit of 0.1% for lead, antimony, copper, zinc, chromium, iron, or tin, and 0.01% for arsenic or other contaminants composed of hazardous metals. Plastics in contact with food may not contain substances that are hazardous to health, and there are limits for residual monomers, such as vinyl chloride, acrylonitrile, and styrene.

Mexico's General Health Law governs the manufacture and sale of food and beverages, prohibits the adulteration or contamination of foods, and addresses specific aspects of the manufacture, transportation and marketing of foods, food additives, and food packaging. Primary packaging (direct contact with food) is required to preserve the physical, chemical, and sanitary integrity of the contents. Food packaging should be sufficient to prevent chemical and microbiological contamination of the product, and should be in a clean and, if necessary, sterilised condition. Packaging for products intended for direct human consumption may not transfer its elements, or substances detrimental to health, to the packaged food in proportions greater than those authorised by any corresponding standard.



Costa Rica requires that materials used to manufacture food packaging do not result in any risk to human health. **Panama** requires that food be packaged with food-grade materials. **Guatemala** requires that food packaging materials do not alter their contents. **Belize** prohibits substances from being added to food (which would include migration from FCMs) if they would make such food injurious to human health or unfit for human consumption. **Mexico, Costa Rica, Panama, Guatemala, Belize,** and **El Salvador** do not have positive lists or specific technical requirements for food contact materials.

While many Latin American countries simply mandate that FCMs be safe for their intended use, Mercosur and CAN member states have specific requirements that should be carefully followed. It is important to consider the legal requirements at both Mercosur and the individual member state level, as these may differ.

India

The Indian Food Safety and Standards (Packaging) Regulations 2018 came into force on July 1, 2019, supported by mandatory Indian standards covering specific materials, replacing the previous requirements from 2011 that mainly used voluntary standards. The primary objective of packaging is to protect the food contents from microbiological, chemical, physical, and atmospheric contamination, as well as preserve the food and thereby protect consumer health.

Good packaging ensures that there is no change in sensory properties or composition of food when packed. Packaging is essential and critical for promoting food safety and extended shelf life, thereby enhancing food security. As well as general and specific requirements relating to packaging materials, the regulations also prescribe overall and specific migration limits for contaminants in plastic packaging materials.

The regulations address concerns identified from previous national surveys on food packaging materials. Packaging material made of recycled plastics, including carry bags for packaging, storing, carrying, or dispensing articles of food, is prohibited, as is the use of newspaper and other such materials for packing or wrapping of food articles.

Among the general requirements, the regulations state that materials shall be of food-grade quality and suitable for the type of product. Printing inks for use on food packages 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, including conformity with the various Indian standards specified in the schedules. Pigments or colourants for use in plastics in contact with food products and drinking water shall conform to IS 9833.

Toys

The European Committee for Standardisation (CEN) has updated EN 71-3 (Safety of Toys Part 3: Migration of Certain Elements) to include new methods for measuring the migration of certain elements. The standard, published on April 10, 2019, sets out a method for determining the migration level of chromium (vi) from scraped-off toy materials. The limit was tightened from 0.2 mg/kg to 0.053 mg/kg by EU Directive 2018/725, which will apply beginning on November 18, 2019. The standard also includes a modified method for testing organic tin compounds, which has an increased extraction yield—improving the detection limit and repeatability. CEN says that other changes include validated methods for filtration that improve the results and simplify filtration work in the laboratory, and the method for pH control ensures that the samples are always tested at the pH intended.

Egypt has proposed an update to its toys standards with new migration limits for 19 substances. The standards cover toys with a reasonable risk of being put into a child's mouth. These include those intended for use close to or inside the mouth, such as cosmetics, writing implements classified as toys, and all toys or parts of toys aimed at children under six years old. The proposed legislation complies with European and ISO standards, but sets even lower migration limits for barium, cadmium, and lead than those in the EU's Toy Safety Directive (2009/48/EC).

Miscellaneous

Following EU regulatory action on tattoo inks under REACH, EuPIA has updated its information note. It emphasises that printing inks manufactured and placed on the market by EuPIA members are not intended for use in tattooing or permanent make-up, and such uses are neither recommended nor supported. Temporary tattoos (transfers applied to the skin using moisture and/or pressure) are not in the scope of the REACH restriction and may be printed with inks supplied by EuPIA members. Such products are considered to be cosmetic products and subject to the provisions of Regulation (EC) No. 1223/2009 on cosmetic products. They may also be classified as toys and fall within the scope of the relevant legislation.

China's Ministry of Industry and Information Technology (MIIT) is drafting a standard—expected to be released before the end of the year—that will set allowable levels of volatile organic compounds (VOCs) in printing inks. The standard, entitled "Limits of volatile organic compounds (VOCs) in printing ink," will cover the basic requirements, technical content, and inspection methods for specifying the limits of VOCs in inks, including offset, gravure, flexographic, and UV-curable inks. In 2018, the State Council launched a three-year action plan on air pollution control, specifically highlighting smog-forming VOCs. Key industries affected include petrochemical, chemical, industrial coating, packaging, and printing. Last year, authorities in several cities in China ordered the industry to replace solvent-based coatings and adhesives with water-based alternatives.

The European Commission has established a new set of Ecolabel criteria for graphic paper and tissue paper products that ban the use of hazardous chemicals and reduce emissions from manufacturing. The new rules forbid the use of substances of very high concern (SVHC) and a range of other chemicals classified under the CLP Regulation (EC No. 1272/2008), and will remain valid until the end of 2024. The criteria also ban metal-based pigments and dyes in paper products. The following categories are covered:

- Graphic paper**: Sheets or reels of not converted, unprinted blank paper or board, whether plain or coloured, made from pulp and fit to be used for writing, printing, or conversion purposes
- Tissue paper: Sheets or reels of not converted tissue paper for conversion into tissue products
- Tissue products: Fit for use for personal hygiene, absorption of liquids or the cleaning of surfaces, or for a combination of those purposes. They include handkerchiefs, toilet tissues, facial tissues, kitchen or household towels, hand towels, table napkins, mats, and industrial wipes.

The European Solvents Industry Group (ESIG), in collaboration with the UK Solvents Industry Association (SIA), has updated its Safe Handling of Solvents video, enabling users of solvents to identify hazards and implement best practice to ensure solvents are managed safely. ESIG has also produced new guidelines for the safe use of gloves for handling solvents. The guidance contains tips for using chemical-resistant gloves, gives information on pictograms and standards, and gives advice on selecting the appropriate gloves.

A series of booklets on assessing workplace risks, published by Germany's Federal Institute for Occupational Safety and Health (BAuA), is now available to download (in German only). The collection contains 12 booklets, which cover different occupational hazards and guidance on how to analyse them. The booklet on hazardous substances covers how to carry out a risk assessment of chemical hazards in the workplace, according to the rules under Germany's Hazardous Substances Ordinance (GefStoffV). Germany's Occupational Health and Safety Act requires every employer to carry out an appropriate risk assessment for their workplace.

***The product group graphic paper is a merger of two previous Ecolabel groups—newsprint paper and copying and graphic paper.*

The **Australian** government's health and safety agency, Safe Work Australia, has released a guide for managing the risks of storing chemicals in the workplace. Aimed at small and medium-sized businesses, the guide explains how to identify hazardous chemicals, and the common health and safety risks associated with storing them. It also outlines how to manage these risks using tools such as a storage checklist and a chart that shows which types of chemicals to separate and by how far.

California's Office of Environmental Health Hazard Assessment (OEHHA) has published a Proposition 65 website with information on styrene. The page includes information on where exposure to styrene may occur and advice for avoiding it. This includes a recommendation to avoid storing or microwaving food in polystyrene-based containers and using a well-ventilated area for printing.

The Association of the European Adhesive and Sealant Industry (FEICA) has announced that they have validated a test method for the accurate measurement of very low contents of free monomeric isocyanate in mixtures. The test method is particularly accurate for the determination of very low content in the range of 0.01% to 0.15% of free diisocyanates, such as MDI, TDI, and IPDI, in a complex mixture.

The accuracy, robustness, and reproducibility of the test method has been confirmed by FEICA members in round robin testing. FEICA indicates that the CURRENTA HPLC-MS/MS test method is the most advanced currently available and should be the preferred method for the measurement of free monomeric isocyanate in adhesives, sealants, and one-component foams.

FEICA has also made available a series of Safe Use of Mixtures Information (SUMI) documents for professional end-users of adhesives and sealants, which provide simplified and tailored information for communication along the supply chain as part of REACH. A SUMI is a communication template, developed by the Downstream Users of Chemicals Co-ordination group (DUCC) to facilitate the information flow downstream to end-users.

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

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