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New Tool For Categorizing Polymers, Canada Announces Future CMP Activities, OECD, WTO: Top International News in Chemical Policy and Regulation July 12, 2016.

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AUSTRALIA

NICNAS Releases New Tool For Categorizing Polymers: The June 7, 2016, issue of the *NICNAS Bulletin* includes an item announcing a new tool for polymers. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) invites stakeholders to try the new polymer categorization tool, which NICNAS developed to help users understand how the health and environment hazards of polymers would be categorized in Australia under proposed NICNAS reforms. NICNAS states that the reforms "propose a more risk-based and proportionate approach to the regulation of new polymers, which aligns NICNAS requirements more closely with the regulatory schemes of Canada and the United States."

Australia Publishes 18th Tranche of IMAP Assessments: NICNAS published for public comment the 18th tranche of human health and environmental assessments for chemicals identified as part of the Stage One implementation of the Inventory Multi-tiered Assessment and Prioritization (IMAP) Framework. NICNAS states that it seeks comments where information that has the potential to affect the outcome of an assessment has not been considered. Comments provided should be evidence-based and the relevance of submitted information should be highlighted. Comments are due **August 22, 2016**.

BRAZIL

Brazil Publishes Its Industrial Chemicals Regulation (Regulação de Substâncias Químicas Industriais): On June 29, 2016, we published a memorandum providing an overview of the expected Industrial Chemicals Regulation (*Regulação de Substâncias Químicas Industriais*, or *Regulação*) which was then published on June 30, 2016, in the Brazilian Official Gazette, the *Diário Oficial da União*. The *Regulação* is presently in an approximately 45-day comment period. While generally adhering to both industry expectations for the *Regulação* and the criteria of many other national chemical inventories, there are some unique aspects in the proposed *Regulação* that should be noted.

Companies should note that while Article 6 allows for a three-year transition period under the Regulação, Article 15 directs the Executive Branch to "regulate" (promulgate) the law within 180 days of the date of its publication -- **December 27, 2016. Therefore, full compliance will be required as of December 27, 2019**. More information is available in Acta's June 29, 2016, memorandum, "Brazil Moves Closer to National Chemical Inventory," and July 5, 2016, memorandum, "A Critical Review of Brazil's Just-Published Industrial Chemicals Regulation (Regulação de Substâncias Químicas Industriais)."

Article By Bergeson & Campbell, P.C.
ACTA Group
The ACTA Group Regulatory Developments
Biotech, Food, Drug
Environmental, Energy & Resources
Labor & Employment
Global
All International

Brazil Publishes New MERCOSUR Legislation for Food Contact Materials in Diário Oficial Da União: On June 30, 2016, Brazil published the MERCOSUR regulations relating to cellulosic materials in the Official Gazette. These regulations are:

- "Resolução -- RDC nº 88": Approves the technical regulation on materials, packaging and cellulosic equipment intended to come into contact with food and other provisions.
- "Resolução -- RDC nº 89": Approves the technical regulation on cellulosic materials for cooking and hot filtration and other measures.
- "Resolução -- RDC nº 90": Approves the technical regulation on materials, packaging and cellulosic equipment intended to come into contact with food during cooking or heating with an oven and other measures.

As a member of MERCOSUR, countries must transpose such regulations into national law, but are not bound by them until adopted under the national legislative process.

CANADA

Canada Publishes List Of Substances In Next Phase Of The CMP And Two-Year Rolling Risk Assessment Publication Plan: On May 30, 2016, Environment and Climate Change Canada published the list of substances in the next phase of the Chemicals Management Plan (CMP) (**2016-2020**) and two-year rolling risk assessment publication plan. The Risk Assessment Toolbox delineates the various types of approaches that can be considered for assessing a substance or group. The two-year rolling risk management activities and consultations schedule provides a high level summary of risk management activities, including opportunities for stakeholder consultations and engagement, and is a source of information on risk management activities that are scheduled to occur during the next two years for substances managed under the CMP. Canada will periodically publish more detailed notifications as it updates the work plan to specify the substances for which additional information is needed, the associated timelines, and details on how to provide this information.

Canada Announces Future CMP Activities: On June 18, 2016, Canada published a notice in the *Canada Gazette* announcing planned actions to assess and manage, where warranted, the risks posed by certain substances to the health of Canadians and the environment. The current phase of the CMP began in April 2016. It includes steps to address the remaining 1,550 priority substances out of the original 4,300 substances identified as priorities during the categorization exercise. It also includes the ongoing development of risk management actions for additional substances found to present risks that need to be prevented. According to the notice, addressing these remaining priority substances in Canada supports the global goal of achieving the sound management of chemicals throughout their life cycle by **2020**. The notice states that, to support informed decision making, the next Inventory Update, planned for **fall 2016**, will collect information on the commercial status and on exposures for a subset of CMP substances. Other information gathering and research and monitoring activities will also be undertaken to support evidence-based decision making. The Ministers plan to take the following actions to implement the next phase of the CMP:

- Assess all of the substances covered in this notice within five years;
- Provide opportunities for stakeholders to submit information to inform decision making;
- Take into account all relevant information in conducting screening assessments on the substances in a phased manner to determine whether the substances meet one or more of the criteria in Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA);
- Release draft screening assessment reports for a 60-day public comment period;
- Consider comments received on draft screening assessments and on the "measure" proposed prior to the release of final assessments and final recommendations;
- Update the inventory of substances in Canada;
- Identify existing nanomaterials through a Section 71 notice, followed by prioritization for further action;
- Initiate discussions with stakeholders on risk management, where necessary, at the time of the publication of the draft assessment;
- Consult on proposed risk management actions at the same time as the final assessment publication, by outlining actions the government proposes to take to protect Canadians and their environment from risks associated with these substances;

- Develop, implement and enforce risk management actions and measure their effectiveness;
- Conduct targeted research on CMP priority substances to address outstanding questions and knowledge gaps, identify emerging priorities, conduct strategic research to develop tools and approaches to inform future chemicals assessment, and monitor substances of concern in the environment, in foods, and in Canadians to inform decision making;
- Undertake key engagement and outreach activities, such as public comment periods, webinars, publications, meetings, consultations, trade shows, and use social media to streamline communications and to raise visibility and understanding of the CMP with stakeholders and the public.

The ministers also plan to take the following actions under other legislation:

- Continue to re-evaluate food additives, food contaminants, and food packaging material chemicals for which CMP assessments identify potential risks; enhance food research, monitoring, and surveillance activities; continue to conduct special reviews and to re-evaluate older pesticides as required under the Pest Control Products Act; and continue to monitor pesticide health and environmental incidents, and take action as needed.

Health Canada Releases Phase One WHMIS 2015 Technical Guidance On Supplier Requirements: According to the Health Canada web page, "Technical Guidance on the Requirements of the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR) -- WHMIS 2015 Supplier Requirements -- Phase 1," Health Canada intends to release technical guidance in two phases in advance of the **June 2017** deadline for manufacturers and importers to comply with the requirements of the Workplace Hazardous Materials Information System, as amended on February 11, 2015 (WHMIS 2015). Health Canada states that phase one of the technical guidance, which is available upon request, focuses on classification principles, hazard communication, and confidential business information (CBI). The document is intended to provide guidance on HPA and HPR requirements to suppliers of hazardous products destined for Canadian workplaces. This document also provides suppliers with information on the Hazardous Materials Information Review Act (HMIRA), its regulations, and the mechanism to protect CBI. Phase two will focus on physical hazard and health hazard classification and is expected to be released in **fall 2016**.

EUROPEAN UNION (EU)

Stakeholders' Day Video and Presentations Available Online: The European Chemicals Agency (ECHA) held its 11th Stakeholders' Day on May 24-25, 2016. The program featured updates and advice from ECHA and industry on successful Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) registration, ensuring dossier quality, and how the registration information is used. The main focus was on preparing for the **May 31, 2018**, registration deadline, providing a platform for registrants, in particular small- and medium-sized enterprises (SME), to receive advice and guidance. ECHA posted video recordings of and presentations from Stakeholders' Day on its website.

BoA Annuls ECHA's Decision On Diarsenic Trioxide: On May 25, 2016, ECHA's Board of Appeal (BoA) annulled ECHA's decision that diarsenic trioxide used in the production of copper concentrate does not qualify as an intermediate. The BoA stated that the dispute between the Appellant, Nordenhamer Zinkhütte GmbH, and ECHA "revolves around the definition of intermediate under Article 3(15)."

The appellant disputed ECHA's interpretation of REACH Article 3(15), according to which the intermediate status of a substance is defined in relation to the "main aim" driving the process in which the substance is used. Additionally, the appellant contested the conclusion that diarsenic trioxide, as used in its plant, does not qualify as an intermediate under Article 3(15) because the production of copper concentrate is not the "main aim" of the production process in the appellant's plant.

The BoA observed that a literal interpretation of the phrase "in order to be transformed into another substance," which is part of Article 3(15), indicates that incidental transformation into another substance is insufficient for a substance to qualify as an intermediate. In its decision, the BoA states "[t]he transformation into another substance is referred to as 'synthesis' and should be intentional." The BoA "identifies two clear requirements that need to be met cumulatively in order for a substance to qualify as an intermediate: (1) the substance must be manufactured for, and consumed in, a chemical process and (2) there must be an intentional transformation of the substance into another substance in that chemical process." The BoA stated that "the main dispute between the Appellant and [ECHA] concerns the interpretation of the second requirement."

The BoA concluded that ECHA "misinterpreted Article 3(15) ... and erred in law in deciding that diarsenic trioxide is not an intermediate on the premise that the production of copper residue and subsequently copper concentrate does not constitute the 'main aim' of the production process in the Appellant's plant." The BoA noted that, in

accordance with Article 3(15) of REACH, to conclude whether a substance is used by the appellant as an intermediate, it needs to be ascertained whether diarsenic trioxide is transformed into copper residue or copper concentrate or whether instead it simply helps in their production. The BoA observed that ECHA "did not make a thorough assessment of this important issue during the compliance check procedure."

The BoA has requested ECHA to re-evaluate the dossier in light of its decision.

EC Issues Implementing Regulation On BoA Procedures: On May 25, 2016, the European Commission (EC) published Implementing Regulation (EU) 2016/823. The Implementing Regulation addresses changes to procedural rules of ECHA's BoA through amendment of Regulation (EC) No 771/2008.

Implementing Regulation (EU) 2016/823 grants the BoA Chair "managerial and [organizational] powers to give directions to the Registrar on matters relating to the exercise of the functions of the [BoA]." The Implementing Regulation makes several procedural changes relating to intervention, representation, and costs.

Regarding intervention, the Implementing Regulation states "in cases relating to Title VI Chapter 2 of Regulation (EC) No 1907/2006, the Member State whose competent authority has carried out the substance evaluation may intervene without having to establish an interest in the result of that case." This conditional right of involved Member States is granted as an exception to Article 8(1) of Regulation (EC) No 771/2008, which states "[a]ny person establishing an interest in the result of the case submitted to the [BoA] may intervene in the proceedings before the [BoA]."

Additionally, the Implementing Regulation provides Article 1a on "amicable agreement." Under Article 1a, the Chair of the BoA "may invite the parties to reach an amicable agreement ... In the absence of an amicable agreement within [two] months from the decision to allocate the case to a single member, the case shall be referred back to the [BoA]."

More information is available in the Working Group on the BoA's "Review of the structure of the Board of Appeal - 38th meeting of the Management Board."

ECHA Publishes Report On The Implementation Of REACH And CLP: On May 26, 2016, ECHA published its second report on the implementation of REACH and the Classification, Labeling, and Packaging (CLP) regulation. The report describes the main achievements and challenges of REACH and CLP. In its May 26, 2016, press release, "Report confirms safety improvements in Europe," ECHA states that the report's recommendations highlight that companies need to update and improve the quality of the registration data and safety data sheets (SDS). According to ECHA, to date, this has not been done consistently, and ECHA states that "[a]n implementing regulation to clarify the update obligations of companies would help." ECHA notes that companies "need to provide more thorough data on the nanoforms of substances they produce rather than holding back on providing data on nanos." ECHA states that the EC "should soon clarify the legal requirements in REACH about nanomaterials." ECHA recommends a review of the CLP requirements "because companies provide contradictory classifications for substances. ECHA proposes for this regulation to be amended to require companies to share data and agree on the classification." According to ECHA, the interface between REACH and CLP and other legislation should be optimized by making more use of the data generated to comply with other EU chemicals legislation. While companies are required to notify ECHA of substances of very high concern (SVHC) in products, ECHA states that "very few have done this so far." ECHA recommends a review of the notification obligations in the context of the circular economy. ECHA states that it "does not see any imminent need to revise" REACH.

NGOs Want Changes To Proposed Regulation On Mercury: On May 26, 2016, several non-governmental organizations (NGO), including the European Environmental Bureau (EEB), the Health and Environment Alliance (HEAL), Health Care Without Harm Europe, and the World Alliance for Mercury Free Dentistry issued a joint letter to Member State experts on mercury. The NGOs express their opinion that the EC's "mercury package" does not meet the Minamata Convention requirement of "[phasing] down the use of dental amalgam." The letter provides that the EC mercury package proposes to require amalgam separators and encapsulated amalgam. The NGOs state that these two measures fail to phase down European amalgam use because: (1) ensuring that the mercury for dental amalgam is delivered in capsules and implementing end-of-pipeline waste control measures does not lessen the amount of amalgam in use; (2) these measures have already been implemented and have failed to reduce amalgam use; and (3) these measures run the risk of increasing amalgam use in the EU because dentists may believe that capsules and separators make their mercury safe.

The NGOs suggest that the EC mercury package requires amendment with the consequence that amalgam use is phased out in the EU by **2020** with "time limited, specified exemptions." In the interim, the NGOs encourage modification of the EC mercury package with the consequence that: (1) for the first treatment of primary teeth in children and for pregnant patients, alternative materials to amalgam should be the first choice; (2) mercury use in dentistry for children and pregnant women should be phased out as soon as possible, and by **2018** at the latest; and (3) every dental patient and parent learn that: (a) amalgam is 50 percent mercury; (b) the use of amalgam

restorations is not indicated in primary teeth, in patients with mercury allergies, and in persons with chronic kidney diseases with decreased renal clearance; and (c) mercury-free dental fillings are available.

The letter from the NGOs entitled "Phase Out Dental Amalgam Use in the European Union" strongly urges addressees "to support amending the EC proposed mercury regulation, to put the EU on a clear path to phase down and eventually phase out the use of dental amalgam."

Proposed CLH Would Apply To Nanosized Titanium Dioxide: On May 31, 2016, ECHA began a public consultation on a harmonized classification and labeling (CLH) proposal submitted by France for titanium dioxide. The proposed entry in CLP Annex VI is "Carc. 1B, H350i." The CLH report states: "Based on available evidence and information in the registration dossier (*e.g.* mechanism of carcinogenicity, characterization of the particles), the proposed scope for the Annex VI entry is: 'Titanium dioxide in all phases and phase combinations; particles in all sizes/morphologies.'" The entry would apply for both fine particles and nanoparticles of titanium dioxide without any distinction in terms of morphology, crystal phase, and surface treatment. Comments are due **July 15, 2016**. ECHA states that comments can be submitted on general issues, for example on substance identification, physicochemical properties, and data sources. Comments can also be submitted on any unclarities (is "unclarities" grammatically correct?) in the text of the CLH dossier. After the public consultation, ECHA encourages the parties concerned to coordinate their involvement in the Committee for Risk Assessment (RAC) opinion-making process with the regular and sector-specific accredited stakeholder organizations.

ECHA Consults PEGs On Nanomaterial Guidance Documents: ECHA submitted several draft guidance documents concerning nanomaterials to Partner Expert Groups (PEG) for consultation. Following consultation with PEGs, ECHA will consult its committees and/or Forum, where relevant. The final consultation will be with the EC and the relevant Competent Authorities. To ensure that the guidance updating process is transparent and open to participation by relevant partners, ECHA will publish drafts of the texts and feedback from the different consultation steps on its website. According to the website, feedback on ECHA guidance can be provided by any party by using the guidance feedback form.

ECHA submitted the following draft information requirements and chemical safety assessment (IR&CSA) appendices on recommendations for nanomaterials for environmental endpoints to a PEG for consultation:

- *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7a Endpoint specific guidance*;
- *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7b Endpoint specific guidance*; and
- *Appendix R7-2 Recommendations for nanomaterials applicable to Chapter R7c Endpoint specific guidance*.

A different PEG is reviewing *Appendix 4: Recommendations for nanomaterials applicable to the Guidance on Registration*. ECHA developed the draft Appendix to provide advice to registrants preparing their registration dossiers for nanomaterials. The aim of the Appendix is to define the term "nanoform," the minimum criteria for distinguishing between different nanoforms, and the minimum set of parameters that must be reported to characterize a reported nanoform. According to the draft Appendix, a "nanoform" is a form of a substance that meets the requirements of the EC definition of a nanomaterial and always has a specific shape and a specific surface chemistry as additional parameters. The three minimum elements for defining a nanoform are: (1) whether it meets the EC recommendation on the definition of a nanomaterial; (2) its shape; and (3) its surface chemistry. ECHA notes that these are simply the minimum elements necessary to characterize registered nanoforms in a registration dossier. Depending on the substance, additional elements and/or additional refinement of these elements (*i.e.*, specific size ranges, specific shapes, etc.) may need to be reported depending on their impact on properties as determined in the data collected/generated to fulfill information requirements. The draft Appendix states: "Where nanoforms are not reported transparently in the registration dossier for the substance, it is understood as an explicit statement made by the registrants of that substance that nanoforms are not within the scope of their registered substance." The minimum parameters to be reported when nanoforms are registered are: (1) size; (2) shape; and (3) surface chemistry.

A PEG is consulting on *Appendix R.6-1: Recommendations for nanomaterials applicable to the Guidance on QSARs and Grouping*. ECHA intends the document to provide an approach on how to justify the use of hazard data between nanoforms of the same substance, and it is presented as an Appendix to Chapter R.6 of the Guidance on IR&CSA on quantitative structure-activity relationships (QSAR) and grouping "because general concepts on grouping of chemicals are applicable to [nanomaterials]."

A PEG is consulting on *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7a Endpoint specific guidance and Appendix R7-2 Recommendations for nanomaterials applicable to Chapter R7c Endpoint specific guidance*. This document is a proposed amendment to specific extracts only of the following guidance documents: Appendix R7-1 to Chapter R.7a. (section 3 only); and Appendix R7-2 to Chapter R7c (section 2.1.3

only).

EC Urges ECHA To Monitor Synthetic Turf, BPS In Thermal Paper, And Cadmium Content: On June 1, 2016, the EC wrote to ECHA stating "concerns have been raised that the placing on the market and use of recycled rubber granules for use as infill in synthetic turf, and of [Bisphenol S (BPS)] in thermal paper, may pose risks to human health that are not adequately controlled." Therefore, the EC states, ECHA is requested to conduct preliminary evaluations to enable the EC to consider whether, for the purposes of Article 69(1) of REACH, there are such risks that need to be addressed. Additionally, the EC requested ECHA to "carry out an assessment of the current situation and future trends regarding the cadmium content of post-consumer rigid [polyvinyl chloride (PVC)] recyclate and, if appropriate, to prepare an Annex XV restriction dossier, pursuant to [Article 69(1)] of REACH."

Regarding rubber granules used in synthetic turf, the EC requested that ECHA aim to identify any relevant hazardous substances contained in recycled rubber granules that may pose risks to human health in relation to the use of the granulate as infill in synthetic turf. The EC stated "ECHA should [finalize] its preliminary evaluation by **January 2017**."

The EC expressed that during the restriction process for Bisphenol A (BPA) in thermal paper, the RAC noted that according to the submitter of the Annex XV dossier, the most likely substitute for BPA, BPS, may have a similar toxicological profile to BPA and may cause similar adverse health effects. The EC stated that "to avoid the adverse effects of BPA being merely superseded by equivalent adverse effects of BPS, the trend towards substitution of BPA with BPS should be carefully monitored." The EC requested ECHA to launch a survey in **2017** to verify if BPS is used in thermal paper, obtain volumes in this regard as appropriate, and to verify if thermal paper manufacturers are substituting BPA with BPS. The EC requested ECHA to provide the results of the survey by the **end of 2017**.

To review the existing derogation for cadmium and its compounds, as required under Annex XVII of REACH, the EC requested ECHA to: (1) determine, based on the most up-to-date data available, the current quantities and average cadmium content of post-consumer rigid PVC waste, and of recovered PVC obtained from it; and (2) review the hazards associated with cadmium and the risks associated with the use of recovered PVC containing cadmium. The EC stated "[t]he review should be based on the available information from studies conducted in the EU or abroad, including reports from industry." The EC requested ECHA to finalize its evaluation report by **September 1, 2017**.

More information is available in the EC's "Note for the Attention of Mr G. Dancet, Executive Director ECHA."

RAC And SEAC Agree On Draft Opinions For Authorization Applications: During its May 23 - June 3, 2016, meeting, ECHA's RAC agreed on draft opinions for 33 authorization applications. Among these applications, 30 related to uses of chromium VI compounds for a variety of applications (*e.g.*, surface treatment, plating, metals, aerospace, automotive). The three other authorization applications were for arsenic acid, 1,2-dichloroethane, and bis(2-methoxyethyl) ether (diglyme). The draft opinions will be subject to consultation. More information is available in the "Final Agenda - 37th meeting of the Committee for Risk Assessment."

ECHA's Socio-economic Analysis Committee (SEAC) agreed on 29 draft opinions for applications for authorization, for uses of hexavalent chromium compounds, during its May 31 - June 9, 2016, meeting. The uses largely related to the plating and electronics industries. More information is available in the "Final Draft Agenda - 31st Meeting of the Committee for Socio-economic Analysis."

ECHA Provides Instructions On Alternative Test Methods: On June 6, 2016, ECHA announced that "[t]he REACH requirements for skin corrosion/irritation, serious eye damage/eye irritation, acute dermal toxicity and skin [sensitization] are changing, making non-animal testing the default requirement." ECHA's announcement serves as a reminder for compliance with Regulation (EU) 2016/863 of May 31, 2016, which amends Annexes VII and VIII of REACH to address conditions under which animal testing of chemicals is no longer required. The reduction in animal testing that Regulation (EU) 2016/863 is expected to bring has been welcomed by industry.

ECHA provides that the amendments for skin sensitization are expected in **Autumn 2016** and states "[i]n many cases, the information needed under REACH for the classification or risk assessment of a substance will now be obtained through non-animal methods." ECHA states that companies need to take the revised requirements into account when submitting information to ECHA. Since June 21, 2016, along with the launch of the new version of REACH-IT, registrants are required to provide information according to the new legal requirements to pass ECHA's completeness check of registration dossiers.

ECHA states that registrants that have already submitted studies in accordance with the previous requirements do not need to modify their registration dossiers immediately, however, when the dossiers are updated, the new requirements will apply. ECHA states "[t]hose registrants who, for example, met the previous requirements with

an *in vivo* study do not need to carry out additional *in vitro* studies. However, a justification for not submitting the *in vitro* study needs to be included at the time the dossier is updated." ECHA expressed that it will update its guidance on information requirements in **Autumn 2016** and highlighted the usefulness of the IUCLID 6 Validation Assistant in checking dossier completeness prior to submission to ECHA.

Further information is available in ECHA's press release, "REACH annexes amended - registrants to use alternative test methods."

MSC Sends Two SVHC Proposals To EC For Decision-Making: On June 10, 2016, ECHA announced that the majority of the Member State Committee (MSC) supported two proposals to identify substances as SVHCs. The MSC supported identification of Dicyclohexyl phthalate (DCHP) as an SVHC and its inclusion in the Candidate List due to its toxicity for reproduction and its endocrine disrupting effects in humans. The majority of the MSC supported the SVHC proposal for 3-benzylidene camphor due to its "endocrine disruptive effects to the environment."

Sweden and Denmark proposed identification of DCHP as an SVHC. Following MSC discussions, Sweden and Denmark withdrew the part of their proposal relating to identification of DCHP as an SVHC, based on an equivalent level of concern for the environment (REACH Article 57(f)) to generate further information and address issues raised in the public consultation. The MSC unanimously supported the identification of DCHP as an SVHC due to its toxic for reproduction properties. The MSC unanimously acknowledged that there is scientific evidence on the endocrine activity of DCHP and also on the link between this activity and adverse effects on human health. A majority of MSC members supported DCHP's SVHC identification based on its endocrine disrupting properties. A minority of MSC members did not support this proposal, as they considered that the endocrine disrupting properties are already covered by the harmonized classification for reproductive toxicity.

Germany proposed 3-benzylidene camphor and 4-methylbenzylidene camphor for SVHC identification, and withdrew its SVHC proposal for 4-methylbenzylidene camphor to elaborate further on the justification provided. A majority of MSC members supported the proposal to identify 3-benzylidene camphor as an endocrine disrupting chemical (EDC) for the environment and a minority of MSC members requested more conclusive evidence.

ECHA will submit the opinions and the minority positions on the DCHP and 3-benzylidene camphor proposals to the EC for decision-making. More information is available in the Annex XV report submitted by Germany, and in ECHA's press release, "MSC sends two SVHC proposals to the Commission for decision making."

Council Provides Draft Conclusions On Circular Economy: On June 13, 2016, the Council of the EU (Council) provided its draft conclusions on the Circular Economy in a document entitled "Draft Council conclusions on Closing the loop - An EU action plan for the Circular Economy." On June 20, 2016, the Council announced that it has adopted these conclusions. The Council stated "[t]his plan aims to reduce waste and keep the value of products, materials and resources in the economy for as long as possible. The conclusions support this aim and demonstrate commitment to this transition towards a more sustainable model, for instance by cutting resource use, boosting recycling and better managing waste."

The action plan includes sections on "Integrated Policy Approaches," "Product Policies and Resource Efficiency," "Support for Circular Innovation and Business," and "Monitoring, Follow-up and Cooperation."

Regarding integrated policy approaches, the Council states "the transition to a Circular Economy requires long-term commitment and action, in a wide range of policy areas in the EU, and at all levels of government in Member States." The Council encourages Member States to establish and adopt measures and/or strategies to complement and contribute to the EU Action Plan and encourages the EC to integrate fully the Circular Economy in all relevant policies and strategies. The Council "[calls] upon the [EC] to take concrete initiatives to promote sustainable sourcing and supply of raw materials within the EU and in cooperation with third (commodity producing) countries, without creating tariff or non-tariff trade barriers."

The Council makes the following points, among others, regarding product policies and resource efficiency:

- The Council supports the EC's approach in the Action Plan to address the entire lifecycle of products and stresses that such an "integrated, cross-sectoral" approach is essential to "close the loop," leading to an effective Circular Economy.
- Products need to be designed and produced more sustainably, accounting for their "full life cycle" and "[minimizing] negative impact on the environment and on human health."
- The EC should develop and propose a methodology to ensure that environmental claims, including labels, are based on verifiable and transparent information.
- "Well-functioning chemicals legislation" is critical to support the Circular Economy.

The Council emphasizes that research and innovation are vital for developing the necessary sustainable and resource-efficient industrial, economic, and societal processes to stimulate the transition to the Circular Economy. The Council urges the EC to support EU industry in research and innovation, improving cross-cycle and cross-sectoral cooperation, and taking up new technologies and business models.

Regarding monitoring, follow-up, and cooperation, the Council "[stresses] the need for a governance structure at the EU level and a monitoring framework to strengthen and assess the progress towards [a] circular economy, while [minimizing] the administrative burden." The Council calls for consistency in national approaches and standards; exchange of best practices and lessons learned by Member States and stakeholders; and more financial incentives and market-based instruments to promote reuse and the market for secondary raw materials. Lastly in this regard, the Council urges the EC to set up a platform to facilitate more structural exchange of knowledge, technologies, good practices, and policy experiences between Member States and stakeholders at European-level.

EC Issues Scientific Criteria For Identifying EDCs: The EC has issued much anticipated scientific criteria for the identification of EDCs. In its June 15, 2016, press release, "Commission presents scientific criteria to identify endocrine disruptors in the pesticides and biocides areas," the EC states "[t]he scientific criteria endorsed by the [EC] today are based on the [World Health Organization's (WHO)] definition of [EDC], for which there is a wide consensus ... The WHO defines an [EDC] as 'an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.'"

The EC has a legal obligation to specify criteria for the identification of substances with endocrine-disrupting properties under the Biocidal Products Regulation (BPR) and the Plant Protection Products (PPP) Regulation. The obligations arise in Article 5(3) BPR, Article 78(1)(a) of the PPP Regulation, and 3.6.5 of Annex II to the PPP Regulation. In the Judgment in Case T-521/14, Sweden v Commission, the General Court of the EU concluded that the EC, "by failing to adopt delegated acts to specify scientific criteria for the determination of endocrine-disrupting properties, has failed to [fulfill] its obligations under the first subparagraph of Article 5(3) of [BPR]."

The EC's "Communication from the Commission to the [European Parliament (EP)] and the Council on Endocrine Disruptors and the Draft Commission Acts Setting Out Scientific Criteria for their Determination in the Context of EU Legislation on [PPPs] and Biocidal Products" provides a background on the EDC definition debate and discusses management of EDCs under BPR, the PPP Regulation, and the REACH Regulation. The EC's Communication was accompanied by an Impact Assessment and draft measures setting out scientific criteria for the determination of endocrine-disrupting properties in biocides and PPPs.

The EC's Communication provides that, relying on WHO's definition of EDC, "the draft scientific criteria now being presented aim to introduce in legal form this concept of the 'endocrine mode of action' as one of the elements to consider when determining what is an endocrine disruptor for the two product areas concerned ... More specifically, the criteria set out that an endocrine mode of action is 'the inherent ability of a substance to interact or interfere with one or more components of an endocrine system.'"

Regarding the "adverse effect" element of the criteria for EDCs, the EC states in its Communication that it will rely on the definition provided by the International Program on Chemical Safety. This is 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." For causality, the EC favored the adoption of a reasonable evidence or "biological plausibility" approach over one that requires "conclusive evidence."

In the EC's opinion, "establishing different categories of what may be an endocrine disruptor does not help to define what is an endocrine disruptor in the context of biocides and pesticides." For this reason, along with concerns over "certainty for regulators and stakeholders," a category approach has not been proposed by the EC. Although the concept of safe thresholds "is used by regulators worldwide," the EC considered that "answering the question of whether a threshold exists is neither necessary nor appropriate when defining scientific criteria for determining what is an [EDC]."

The EC concluded that considerations of potency were not relevant for the specific purpose of setting scientific criteria for EDCs. In its Communication, the EC states "[p]otency is a question to be asked only once it has been established that a substance is an [EDC] at all." In its press release, the EC states that identification of an EDC should be conducted by making use of all relevant scientific evidence, by using a weight of evidence-based approach, and by applying a robust systematic review. The scientific criteria provided by the EC apply only for biocidal products and PPPs, and do not have a direct legal consequence in other areas of EU law. The EC states "[t]he adoption of criteria to identify [EDCs] will [fulfill] the legal obligations under the [PPP] and biocides legislation. Once adopted, the EU regulatory system will be the first regulatory system worldwide to define scientific criteria for [EDCs] in legislation."

The EC requested the European Food Safety Authority (EFSA) and ECHA to start looking at whether approved individual substances that show indications of being EDCs can be identified as EDCs according to the draft texts presented. The draft legal texts containing the criteria require adoption by the EC under the relevant procedures. For the PPP Regulation, the draft legal text will be voted on by Member States. In the context of the BPR, the draft measure will be discussed in a group of experts of Member States prior to adoption by the EC. Both measures involve the EP and the Council. The EC stated that "to ensure coherence between the two acts, the EC will present both texts simultaneously to the EP and the Council for them to exercise their functions." Important progress is expected on the draft measures in July 2016.

HEAL, the Danish Environment and Food Ministry, the European Chemical Industry Council (Cefic), the European Crop Protection Association (ECPA), and Plastics Europe have issued statements highlighting a number of concerns related to the scientific criteria proposed by the EC. Some of these concerns relate to the lack of consideration given to potency in development of scientific criteria for EDCs; the potential of the proposed criteria to ban "crop protection products with the same endocrine disrupting properties found in everyday products like coffee"; and the burden of proof for EDCs being too high with the consequence that there will be "years of harm to health" before their removal from the European market.

On June 20, 2016, environment ministers from Sweden (Karolina Skog), Denmark (Esben Lunde Larsen), and France (Ségolène Royal) issued a joint letter to Vytenis Andriukaitis, European Commissioner for Health and Food Safety, and EC President Jean-Claude Juncker, stating "[w]hile we welcome the fact that the [EC] refers to WHO definitions of [EDCs] and dispenses with potency among the proposed criteria, this project remains unacceptable."

The letter provides that "two provisions raise deep concerns." The first issue addressed in the letter is that only substances that are known to cause adverse effects relevant for human health or non-target organisms can be identified as EDCs "for the implementation of these regulations." The ministers state that since "the scientific validation process is very long and comes after irreparable damage to human health and the environment has appeared," the precautionary principle should be applied to decide on prohibitions "as soon as environmental impacts are proven or even when endocrine disruption suspicions appear."

The second issue addressed is that from the ministers' standpoint "[t]he draft modification of the regulation on [PPPs] does not fulfill the need to ensure the highest level of human protection." The ministers also highlight and urge consideration of the health costs of EDC use, which are estimated in the letter at € 160 billion within the EU. The ministers invited amendment of the EC's proposal on EDCs to provide greater protection for EU citizens' health, "for now and for future generations."

EDCs were discussed during the Environment Council's June 20, 2016, meeting at France's request. The "Outcome of the Council Meeting - 3476th Council Meeting" states "[s]ome ministers expressed strong concerns about the [EC's] approach, based only on evidence, and asked the [EC] to respect the precautionary principle and address also the suspected [EDCs] for which no evidence is yet available."

EU Announces Agreement Intended To Reduce Trade In Conflict Minerals: The EC announced on June 16, 2016, that after negotiations between the EC, Council of the EU, and EP, the EU agreed on a framework for a regulation intended to stop financing armed groups through trade in conflict minerals. The EU approach will build upon the Organization for Economic Cooperation and Development (OECD) *Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas*. Under the agreed framework, there will be clear obligations for the upstream part of the conflict minerals supply chain, including smelters and refiners, to source responsibly. According to the EC, the vast majority of metals and minerals imported to the EU will be covered, while exempting small volume importers from these obligations. In addition, the EC will carry out other measures, including the development of reporting tools, to boost further supply chain due diligence by both large and smaller EU downstream companies. The EC states that the agreement "sets the Regulation on track for technical work and final adoption in the coming months." The EP's June 16, 2016, press release states that the framework will include mandatory due diligence rules for importers; exemptions for the smallest importers (*e.g.*, for dentistry), recycled metals, existing EU stocks, and by-products; disclosure requirements for big EU manufacturers and sellers; and a requirement that the EC review and report to the EP and Council on the effectiveness of the new law. The EP press release states that the technical details of the legislation still need to be worked out. According to the press release, the Dutch Presidency of the Council pledged to conclude the informal legislative negotiations with the MEPs before its term ended on July 1, 2016. Further political trilogues under the Slovak presidency may be needed to seal the final text of the legislation before it is approved by the EP in plenary session.

Council And EP Agree On Medical Devices Regulations: The Council's Permanent Representatives Committee and the EP's Committee on Environment, Public Health and Food Safety (ENVI) endorsed agreed texts of two proposed Regulations on medical devices. The EC's "Revisions of Medical Device Directives" webpage provides that the aims of the revisions are to ensure: (1) "a consistently high level of health and safety protection for EU

citizens using these products"; (2) "the free and fair trade of the products throughout the EU"; and (3) "that EU legislation is adapted to the significant technological and scientific progress in this sector over the last 20 years."

The proposed Regulations address medical devices and *in vitro* diagnostic medical devices (IVD). In its June 15, 2016, press release, the Council states "[i]f the agreement is confirmed by the [EP's] ENVI committee, the Council will approve the agreement at ministers' level. This is planned for [**September 2016**], once the draft regulations have been translated into all official languages. Following their legal-linguistic review the two draft regulations will be adopted by the Council and the [EP], probably at the **end of the year**. The new rules will apply three years after publication as regards medical devices and five years after publication as regards [IVDs]."

The revisions impact a variety of medical devices, including pacemakers, hip replacements, x-ray machines, and pregnancy tests. The proposed Regulation on medical devices provides labeling requirements for devices intended: "to be invasive devices [that] come into contact with the body of the patient for short- or long-term"; "to (re)administer medicines, body liquids or other substances, including gases, to/from the body"; or "to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body." The proposed Regulation states that where these devices contain, in a concentration of 0.1 percent or more by mass of the plasticized material, phthalates that are classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) under Category 1A or 1B, they "shall be [labeled] on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates."

Additional information is available in the EC's Citizens' Summary, the EC's 2012 press release entitled "Safer, more effective and innovative medical devices," and the Executive Summary of the Impact Assessment on the Revision of the Regulatory Framework for Medical Devices.

EC Issues Draft Authorizations For Lead Pigments: The EC has issued a draft Implementing Decision granting authorization for two lead pigments, sulfochromate yellow and chromate molybdate sulfate red.

Both lead pigments were granted authorization by the EC for distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use; industrial application of paints on metal surfaces; professional, non-consumer application of paints on metal surfaces; distribution and mixing of pigment powder in an industrial environment into liquid or solid premix to color plastic/plasticized articles for non-consumer use; industrial use of solid or liquid color premixes and pre-compounds containing pigment to color plastic or plasticized articles for non-consumer use; and professional use of solid or liquid color premixes and pre-compounds containing pigment in the application of hot melt road marking.

Under REACH Article 60(9)(e), the review period granted to Dominion Color Corporation (DCC), the applicant, expires on **May 21, 2022**. The EC granted the authorizations subject to conditions, which include:

- The risk management measures and operational conditions for the respective use, which are described in the Chemical Safety Report, shall be applied fully;
- DCC and the Downstream Users (DU) must implement a program for selection, appropriate use, and maintenance of personal protective equipment;
- DCC and the DUs must implement an employee training program for all uses of the two substances;
- Lead sulfochromate yellow cannot be "placed on the market" at over 2,100 metric tons per annum, and lead chromate molybdate sulfate red cannot be placed on the market at over 900 metric tons per annum; and
- By **December 31, 2017**, DCC must submit a report on the "status of the suitability and availability of alternatives for his [DUs], justifying the need to use lead sulfochromate yellow or lead chromate molybdate sulphate red."

DCC "[acknowledged] and [welcomed]" the EC's draft decision, stating "[this] is a positive development for our EU coatings and plastics customers who continue to require these two pigments for limited and controlled uses. The EC decision confirms and supports the positive opinions previously issued by [ECHA] on the basis of the reports by the [RAC] and [SEAC]."

BPC Adopts 14 Opinions On 12 Active Substances: On June 17, 2016, ECHA announced that the Biocidal Products Committee (BPC) supported the approval of four active substances for use in "insecticides, preservatives, slimicides and for veterinary hygiene."

The BPC approved the following active substance and product type combinations:

- Peracetic acid for product types 11 and 12;

- Cyanamide for product types 3 and 18;
- Piperonylbutoxide (PBO) for product type 18; and
- Epsilon-momfluorothrin for product type 18.

ECHA's BPC also adopted opinions supporting renewal of approvals for the following eight substances used in anticoagulant rodenticide products (product type 14):

- Chlorophacinone;
- Coumatetralyl;
- Warfarin;
- Bromadiolone;
- Difenacoum;
- Brodifacoum;
- Difethialone; and
- Flocoumafen.

More information is available in ECHA's press release, "Biocidal Products Committee adopts 14 opinions on 12 active substances," and in the related Annex.

ECHA Adds SVHC To Candidate List: On June 20, 2016, ECHA announced that it has added one new substance, Benzo[def]chrysene, to the Candidate List of SVHCs for authorization due to its CMR, persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) properties. ECHA cites REACH Articles 57(a)-(e) as the reasons for inclusion in the Candidate List and provides that the substance is "[n]ormally not manufactured intentionally but may occur as a constituent or impurity in other substances."

The Candidate List of SVHCs now contains 169 substances. ECHA states "[c]ompanies may have legal obligations resulting from the inclusion of the substance in the Candidate List. These obligations may apply to the listed substance on its own, in mixtures or in articles. In particular, any supplier of articles containing a Candidate List substance above a concentration of [0.1 percent] (weight by weight) has communication obligations towards customers down the supply chain and consumers. In addition, importers and producers of articles containing the substance have six months from the date of its inclusion in the Candidate List (20 June 2016) to notify ECHA."

More information is available in ECHA's press release, "A new substance of very high concern added to the Candidate List."

Enforcement Projects Indicate Non-Compliance: On June 21, 2016, ECHA announced that the "Results of two enforcement projects [are] available," and that "Many consumer products with hazardous chemicals are not child-resistant." The enforcement projects were coordinated by ECHA's Forum for Exchange of Information on Enforcement.

The "Forum Pilot Project on Child-resistant fastenings," a combined effort of 15 Member States and countries within the European Economic Area (EEA), which aimed to check the level of safe packaging of consumer products containing hazardous chemicals, resulted in 411 legal actions and enforcement measures. Twenty four products were prohibited from being placed on the market and a further 24 products were withdrawn from the market. Most of the legal actions were in the form of verbal or written advice and administrative orders. In several cases, companies were willing to take voluntary actions to comply with the legislation.

A total of 797 products with hazardous chemicals were inspected. Among these, 230 products did not meet the requirements of the CLP Regulation, resulting in an overall non-compliance rate of 29 percent. ECHA stated that the majority of the inspected products were disinfectants, bleaches, and "different kinds of cleaners for drains, toilets, ovens and windows." Although all actors in the supply chain were inspected, the majority were distributors, and particularly retailers.

In 32 cases, inspectors proved that products containing hazardous chemicals were "not adequate to prevent children from opening them," and that consequently the products did not meet the legal requirements for child-resistant fastening. The inspectors frequently encountered unreliable certificates and certificates without clear reference to packaging. For 77 products, either the required "tactile warning of danger" was not on the packaging, or it was not placed correctly. The classification and labeling relating to child-resistant fastening

requirements was incorrect in 66 cases. ECHA stated that "[in] a small number of cases, products were found to be designed in a way that could attract the curiosity of children and therefore were not compliant with the CLP Regulation."

Another enforcement project on CMR substances and skin sensitizers caused inspectors to investigate eight cases of potential non-compliance with the duty to apply harmonized classification and labeling in registration dossiers under Article 4(3) of the CLP Regulation. Four of the eight cases were found to be non-compliant with the duty to apply harmonized classification and labeling, and legal action was taken in three of these cases. All of the registrants updated their dossiers following the inspectors' actions. In seven cases, the updates resulted in compliant dossiers. The project report is expected to be adopted and published in **Summer 2016**.

ECHA stated "[t]he main objective of the [CMR substances and skin sensitizers] project was to test a specific type of institutional interlink - the provision of information by ECHA to national enforcement authorities, to facilitate targeting of controls. Related to this, the [Forum for Exchange of Information on Enforcement finalized] a guide on interlinks describing the cooperation between ECHA and national enforcement authorities on 13 types of ECHA decisions, for example, those on dossier evaluation. This process works well and ECHA reliably receives information about enforcement actions in a reasonable time to complete its own dossier evaluation activities."

EC Issues Decision On DEHP Use In Recycled Plastic: On June 22, 2016, the EC published its decision authorizing the use of Bis(2-ethylhexyl)phthalate (DEHP) in recycled PVC by Vinyloop Ferrara, Stena Recycling, and Plastic Planet.

The authorization is for:

- Formulation of recycled soft PVC containing DEHP in compounds and dry blends; and
- Industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression, and injection molding to produce PVC articles.

The authorization is granted with exceptions, which include toys and childcare articles; erasers; household articles smaller than ten centimeters that children can suck or chew on; consumer textiles/clothing intended to be worn against bare skin; and cosmetics and food contact materials regulated under "sector-specific Union legislation."

The reason provided for the decision is that "[i]n accordance with Article 60(4) of [REACH], the socioeconomic benefits outweigh the risk to human health arising from the use of the substance and there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicants and some of their [DUs]."

The review period for the authorization expires on **February 21, 2019**.

NETHERLANDS

RIVM Issues Report On Work-Related Cancer: The Dutch National Institute for Public Health and the Environment (RIVM) published a report on work-related cancer in the EU. Chapters in the report include "Introduction to the legislative frameworks"; "The burden of work-related cancer caused by carcinogenic substances in the EU"; and the "View of stakeholders and experts involved in the policy on carcinogens at the EU level."

The report provides that "[d]espite many protective measures workers can be exposed to carcinogenic substances at work. Additional policy interventions are needed to reduce the future burden of work-related cancer in the EU." RIVM estimates that, in 2012, 122,600 persons in the EU were newly diagnosed with cancer caused by past exposure to carcinogenic substances at work. In total, RIVM estimates that "almost 1.2 (0.8 - 1.6) million years of life were lost due to premature death caused by past exposure to carcinogenic substances at work in the EU-population."

RIVM's report suggests that the consequences of work-related cancer extend further than mortality and morbidity figures, providing that "reduction in the quality of life" and "productivity losses" also merit consideration. The report states "[h]ealth care expenditure and productivity losses are estimated to cost between €4-7 billion annually for the EU. When welfare losses of premature deaths and diagnosis with cancer are added, the total annual economic representation of the societal impact is estimated to be in an order of magnitude of €334 (242 - 440) billion."

The report indicates that several measures can be taken to reduce the negative impact of work-related cancer in the EU. Some of these efforts, the report suggests, can include identification and monitoring of the most relevant carcinogens based on exposure data; substitution of carcinogenic agents/factors with less harmful ones; prohibition of exposure to carcinogens at work as a general rule; and medical supervision of the workforce

exposed to carcinogenic factors.

More information is available in RIVM's report, "Work-related cancer in the European Union - Size, impact and options for further prevention."

OECD

OECD Seeks Comment On Draft Actions For Companies To Identify And Address The Worst Forms Of Child Labor In The Minerals Supply Chain: OECD is seeking comment on draft *Practical Actions for Companies to Identify and Address the Worst Forms of Child Labour in the Minerals Supply Chain*. The Practical Actions would be for use by all companies in the minerals supply chain to identify, mitigate, and account for the risks of child labor in their mineral supply chains, in accordance with the due diligence framework of the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas. The Practical Actions draw on publications by OECD, the United Nations (UN), the International Labor Organization (ILO), International Organization of Employers (IOE), and United Nations Children's Fund (UNICEF) to help companies integrate due diligence of the risk of the worst forms of child labor into their supply chain operations. OECD seeks input from companies, industry associations, local and international civil societies, child rights experts, and government stakeholders active in the minerals supply chain. Comments are due **July 15, 2016**.

PAKISTAN

Pakistan Announces Plans To Employ 6th Edition Of The "Purple Book" For Hazardous Substances Labeling: The Environmental Protection Agency has issued the draft "Handling, Manufacture, Storage, Import of hazardous waste and hazardous substances Rules, 2016." The draft regulation directs that hazardous substances which are imported into the country must bear labels and classification(s) conforming to the 6th edition of GHS. The legislation may be found (in English) online.

SOUTH KOREA

MOE Notifies WTO Of Revisions To K-REACH Enforcement Decree And Rules: On May 26, 2016, the Ministry of Environment (MOE) notified the World Trade Organization (WTO) of proposed revisions to the revised enforcement decree and enforcement rules for the Act for the Registration and Evaluation of Chemicals (K-REACH). According to the notification, the proposed revisions:

- Specify measures to manage the Chemical Substance Evaluation Committee;
- Expand exclusion from reporting obligations such as manufacturing;
- Broaden application of alternative tests;
- Identify details of government supports for SMEs;
- Revise regulations regarding approvals from authorities for using hazard assessment results and their cancellation;
- Ensure the grace period of 14 days, for confirming that a chemical substance imported for research or study is exempted from registration obligation; and
- Build a legal ground for supporting operation of joint registration consultative group.

The WTO notification states that the proposed date of adoption and entry into force is **July 31, 2016**.

UNITED KINGDOM (UK)

Brexit Vote Presents Questions For Industry And Action By ECHA: On June 24, 2016, the results of the UK's referendum on whether to leave or remain in the EU were announced, with a result in favor of leaving the EU (52 percent to 48 percent). The form that the "Brexit" will take is uncertain and it will be some time before the terms of the UK's future relationship with the EU are known.

Article 50 of the Treaty on EU (TEU) provides the mechanism for leaving the EU. Under Article 50, notice of the UK's intention to leave the EU must be given to the European Council. Once this notice is given, negotiations for a withdrawal agreement will commence. The agreement will take into account the framework for the UK's future relationship with the EU. The UK will stop being an EU Member State on the earlier of a withdrawal agreement being concluded or two years from the date of notice. The two-year timeframe can be increased if the "European Council, in agreement with the Member State concerned, unanimously decides to extend this period." A

withdrawal agreement will need to be agreed by the EP, the European Council, and the UK Parliament.

While the UK can trigger Article 50 of TEU at any time, there is no tool for the EU to compel the UK to do so. Until the UK leaves the EU, the UK and companies operating within the UK must maintain compliance with EU laws. Free movement of goods, persons, services, and capital will continue during this transition period. Changes within the Conservative Party, the possibility of a "Scottish block," and European politics are some of the factors that may interplay to affect the terms and timing of the UK's departure from the EU.

A number of business groups and NGOs including the European Association of Craft, Small and Medium-sized Enterprises (UEAPME), BusinessEurope, EEB, the Chemical Business Association (CBA), the Chemical Industries Association (CIA), the National Federation of Self Employed and Small Businesses (FSB), and the Confederation of British Industry (CBI) have issued statements on the impact of the Brexit vote.

Steve Elliott, Chief Executive of CIA, stated "[t]his is democracy in action - both in terms of the result and the level of participation. It is not the decision that our sector wanted, but we fully respect the wish of the people for change. Whilst business craves certainty, it is also used to operating in challenging and changing circumstances; this is what companies and their representative bodies do wherever they operate. We now have to look to the future and I am confident that an important and resilient industry such as ours can prosper in this new situation .... This morning I am calling on the Government to work hard on securing the best exit plan for the UK and then establishing the new trading arrangements. Whilst we need to progress both these negotiations as soon as we can to limit uncertainty, we also need an immediate period of calm reflection to [minimize] instability. As an Association we will do everything we can to help our members through any period of uncertainty and to be influential in the Government's negotiations, both here in the UK and with our partners in Brussels. Our sector looks forward to playing its part in helping to carve out a new role for our country, [maximizing] UK chemical and pharmaceutical competitiveness and jobs in the global economy."

In similar spirit, CBA's press release concluded with the phrase "[t]he industry's pragmatism has always been one of its major strengths - so, for the time being, it's business as usual." UEAPME stated "[t]hings need to change, especially in order to create a more business friendly environment for our SMEs. Not only do we need Europe to be less bureaucratic, we also need the necessary reforms to create the right framework conditions for our SMEs to start a business and to successfully make it grow."

ECHA has appointed Andreas Herdina, Head of its Communications and Outreach Directorate, as its contact point for British companies and ECHA's British staff. Mr. Herdina's task is to ensure that ECHA maintains a single consolidated position towards British companies and staff, and to serve as the reference point on issues related to the Brexit. ECHA noted that countries outside the EU that are members of the EEA participate in ECHA's work, and that third countries may be invited to do so subject to the agreement of ECHA's Management Board.

VIETNAM

Ministry Of Health Publishes Draft Decree Regulating The Management Of Chemicals, Insecticides, And Disinfectants Used In Households And For Health Purposes: The Vietnamese Ministry of Health has signaled its intent to regulate several types of chemicals which are used in and around the home, as well as for health purposes. The Draft "Decree for the management of chemicals, insecticides and disinfectants used in households and medical, including production conditions; marketing authorization and export and import of chemicals, insecticides and disinfectants" entered into force on July 1, 2016, subject to any delays.

The draft Decree, among multiple other requirements, mandates that the labelling, packaging and transportation of chemicals, insecticides, and disinfectants shall satisfy specific requirements relating to labeling (Article 28), packaging (Article 29), and transportation (Article 30). The Decree (in Vietnamese) can be obtained online.

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