

Argentina's MERCOSUR Regulation, Australia's Industrial Chemicals Reform, Greenpeace China: Top International News in Chemical Policy and Regulation October 2016

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ARGENTINA

Argentina Incorporates "MERCOSUR Technical Regulations For Products Disinfectants (Pesticides)" Into National Law: On August 31, 2016, Argentina incorporated the Annex to ANMAT No. 7292/981, the MERCOSUR GMC Resolution No. 18/10 (the Regulation), into their national legal system. Similar to the European Union (EU), where Directives must be incorporated into a country's national law by implementing legislation, MERCOSUR countries must formally integrate them into the country's legislation.

This Regulation covers disinfectant products for home application and related common areas, such as in interiors, in public or collective buildings and related environments, to control insects, rodents, and other harmful to health pests. The products at issue may be either direct to the consumer or restricted to institutions' or companies' specialized service providers (similar to the Certified Applicators provision of the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), codified at 40 C.F.R. Section 171 *et seq*).

AUSTRALIA

NICNAS Releases Fourth Consultation Paper On Implementing Reforms: On October 4, 2016, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) released the [fourth consultation paper](#) on implementing reforms to NICNAS. The consultation paper outlines the overarching framework for the reforms that NICNAS proposes be set out in new legislation. The implementation detail described in the consultation paper will be included in primary legislation, delegated legislation, and in guidance material. According to the paper, the details to be described in delegated legislation will be the subject of further consultation once the government has considered the proposal for the primary legislation. The proposed framework includes the following key features:

- Any person who introduces an industrial chemical in Australia, either by importing or manufacturing the chemical, would continue to be required to be registered with NICNAS;
- NICNAS would continue to maintain the Australian Inventory of Chemical Substances (AICS), which will list existing industrial chemicals that any registered person may introduce in

accordance with the defined scope of assessment and any conditions of introduction, if specified;

- A registered person who wishes to introduce a new industrial chemical, or to introduce an existing industrial chemical outside the scope of assessment on AICS would determine the indicative risk of their proposed chemical introduction by considering the chemical's hazard and the degree to which people or the environment may be exposed to the chemical as a result of its introduction;
- Registered introducers would be expected to know how a new chemical is proposed to be used in Australia, and to hold information on its intrinsic hazards. Introducers are most likely to obtain this information from international sources, and must have the legal right to use any intellectual property associated with this information;

The legislation would establish three categories of new industrial chemical introductions: exempted; reported; and assessed. Chemical introductions would be categorized separately for human health and environmental risks. The regulatory treatment of the chemical introduction would correspond to the highest category (health or environment), and the assessment would focus on the issues of particular concern:

- Exempted chemical introductions would be very low risk based on the intrinsic lack of hazard and/or their low exposure to humans or the environment. A registered introducer could import or manufacture an industrial chemical under the exempted chemical introduction category without any other interaction with NICNAS prior to introduction, but must maintain records as to the basis on which the introducer categorized the chemical introduction as exempted, and must declare to NICNAS as part of annual registration that they are an introducer under this category;
- Reported chemical introductions would be low risk based on their hazard and/or exposure, or because they have been assessed for the same introduction and use by a trusted international regulator. A registered introducer would be required to: report this chemical introduction to NICNAS prior to commencing import or manufacture; maintain records as to the basis on which the chemical introduction was categorized as reported; and submit an annual declaration to confirm that the chemical introduction continues to meet the criteria for a reported chemical introduction; and
- Assessed chemical introductions would be medium to high risk chemical introductions based on the chemical hazard and/or exposure. A registered introducer must submit information to NICNAS for a risk assessment, and must not introduce the chemical until an assessment certificate has been granted. The assessment will focus on issues of particular concern for human health and/or the environment. To increase transparency, an assessment statement will be published at the time the certificate is granted and linked to the AICS listing at the expiry of the certificate period or earlier on request.
- NICNAS could, on its own motion, initiate an assessment of any new or existing chemical, or group of chemicals, tailored to address issues of concern. NICNAS would maintain the ability to call for information on chemicals subject to assessment, either on a voluntary or mandatory basis;
- NICNAS would have broader monitoring and compliance powers, comparable to those of other regulators, because the reduction in the pre-market assessment of lower risk chemical introductions would be balanced by increased post-market monitoring, to ensure that human health and environmental protections are maintained.

The legislation would continue to allow introducers to apply for protection of CBI that is required to be provided to NICNAS. Such protection would continue to be subject to a public interest test, to be

reviewed every five years.

According to the consultation paper, subject to government agreement and Parliamentary consideration, the reforms would take effect from **July 2018**. Comments are due **November 4, 2016**.

CANADA

Canada Determines 612 Substances Do Not Meet CEPA Section 64 Criteria: The August 27, 2016, issue of the *Canada Gazette* includes a [notice](#) publishing the final decision of the Department of the Environment and the Department of Health after screening assessment of 612 substances specified on the Domestic Substances List (DSL). According to the notice, the 612 substances do not meet any of the criteria set out in Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA), as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Health Canada Creates Public Database Of Pest Control Registrant Inspections: Health Canada announced on September 30, 2016, the availability of the [Pest Control Registrant Inspections Database](#). According to Health Canada, it created the online database to help Canadians make informed decisions about the pest control products they buy and use. The database includes specific inspection findings, as well as summary report cards from inspections and information about companies' history of compliance with the Pest Control Products Act and its regulations. More information is available in Health Canada's press release, "[Health Canada Launches New Inspections Database for Pesticide Companies](#)."

Health Canada Begins Public Comment Period On TTC-Based Approach For Certain Substances: On September 30, 2016, Health Canada published a Science Approach Document entitled [Threshold of Toxicological Concern \(TTC\)-based Approach for Certain Substances](#). Health Canada identified a group of 237 candidate substances from the approximately 1,500 remaining priority substances to be addressed in the third phase of the Chemicals Management Plan (CMP). According to Health Canada, the aim was to identify those substances that were not evaluated using previous rapid screening approaches but for which exposure to the general population was expected to be limited. Health Canada then assessed the candidates via a TTC-based approach. The TTC-based approach identified 89 substances that are unlikely to pose a risk to human health, based on current levels of exposure. The Chemical Abstracts Service (CAS) Numbers of the 89 substances [are provided](#) in the Science Approach Document. For each candidate, Health Canada compared exposure estimates to assigned TTC values. Based on information presented in the Science Approach Document, the 89 substances identified had exposure estimates below assigned TTC values and thus were considered to be of low concern for human health, based on current levels of exposure. The remaining 148 substances of the 237 candidates were either excluded or had exposure estimates that exceeded the TTC values; these substances will undergo further assessment under separate initiatives. Health Canada states that it will conduct an assessment of the 89 substances under CEPA Sections 68 and/or 74, and will publish it at a later date. Comments are due **November 30, 2016**.

CHINA

Greenpeace East Asia Publishes Spatial Distribution Mapping Of China's Chemicals Industry: On September 21, 2016, Greenpeace East Asia (Greenpeace) posted a blog item, "[Why we're mapping China's hazardous chemicals facilities](#)." Greenpeace states that, to address the lack

of transparency concerning China's chemicals industry, it used publicly accessible information to tally the separate accidents that occurred in China in 2016 to date and mapped the locations of chemicals facilities across China. Greenpeace claims that "China has averaged 29 chemical accidents a month in the first 8 months of 2016 alone causing the deaths of 199 people and 400 injuries." The causes of the accidents included chemical leaks (43 percent), fires (27 percent), and explosions (16 percent). Just over half the accidents, 52 percent, happened while the chemicals were being transported, while 27 percent occurred during production. Excluding the accidents that occurred in transit, for which there was no location data available, most of the accidents happened in densely populated and industry-heavy areas, such as eastern Jiangsu Province, where 21 percent of the accidents occurred. Greenpeace announced that it is creating a user-generated mapping system to allow the public to contribute and review information on the locations of chemical facilities in their areas. In its [media briefing document](#), Greenpeace recommends:

1. In the restructuring of the chemical industry, the structural and unknown risks of chemicals being currently manufactured and used must be recognized, and future chemicals management policy must be based on the intrinsic hazards of chemicals;
2. Coherent industrial and environmental policies must be developed to enable the sound management of chemicals and the sustainable growth of chemistry in China without harm to human health and the environment. Hazardous chemical facilities should be moved away from densely populated urban and environmentally sensitive areas, and their sites must be cleaned up with caution. Current and newly developed "chemical parks" must operate a precautionary and transparent chemicals management system, and be kept a safe distance away from areas of potential environmental and human risk;
3. In conjunction with other departments, the Ministry of Environmental Protection (MEP) and the State Administration of Work Safety (SAWS) must work to improve transparency in the chemicals industry. The MEP should "publicly and proactively" publish hazard-related information, including the location of chemical enterprises, information on chemical substances, risk prevention, and control in environmental management of chemicals;
4. Both the Ministry of Industry and Information Technology (MIIT) and MEP should promote the transformation and upgrading of the chemical industry, including downstream chemical users, to eliminate or substitute hazardous chemicals with "non-regrettable alternatives"; and
5. China should play a leadership role in the use and production of chemicals in ways that lead to the minimization of adverse effects on human health and the environment. By **2020** (the end of the 13th Five-Year Plan period), China should show progress on this front in line with the sound chemicals management goal committed to in the 2002 Johannesburg Plan of Implementation of the World Summit on Sustainable Development.

COLOMBIA

Colombia Proposes Bills To Require Assessment of Raw Materials and Substances, Including Potential Restrictions And Bans: The Colombian House and Senate have each proposed a bill that would require the competent authority, the *Ministerio de Salud y Protección Social* (Ministry of Health and Social Protection, *Ministerio*), to assess substances that may pose a risk to human health and, critically, with an eye toward possible restrictions on sale and/or use, as well as complete bans, on such substances.

The House legislation, [*Proyecto De Ley Número 085 de 2016 Cámara*](#), (Draft Law Number 085 of 2016, House), would create the “National System Monitoring of Hazardous Substances” (SNSN), which would be managed cooperatively by the National Institutes of Health, the Institute of National Food and Drug Monitoring, and the Superintendency of Industry and Commerce. Specifically, under Article 3, these authorities will conduct periodic studies and/or research on products or raw materials that may be dangerous or harmful to health, prioritized based on their toxicity, frequency of use, and likelihood of exposure by workers or the general population. Article 6 requires the *Ministerio* to report the findings to Congress on July 20th of each year, as well as to detail the progress of investigations and studies that are in process.

The parallel Senate legislation, *Proyecto De Ley Número 058 de 2016 Senado* (Draft Law Number 085 of 2016, Senate), is largely similar in its content. Article 4 directs “the national government through the Ministry of Health and Social Protection [to] adopt decisions designed to regulate, limit, restrict and or prohibit the use, sale and/or any form of distribution of a substance or raw material if it considers that they represent collective harmfulness to public health.” Perhaps interestingly, Article 4(d) specifically provides for “guarantees of compensation, rehabilitation and counseling relocation of workers and replacement of business or industry . . . [as well as] social and economic measures to compensate the territories, employers and workers” who suffer loss of employment or commercial activity as the result of such actions by the *Ministerio*.

DENMARK

Danish EPA Conducts Survey On Allergens In Children’s Products And Cosmetics: The Danish Environmental Protection Agency (Danish EPA) has issued a report entitled “[Survey of Allergenic Substances in Products Targeted Children – Toys and Cosmetic Products](#).” The Danish EPA focused “on allergenic substances from four overall groups”: (1) fragrances; (2) preservatives; (3) colorants; and (4) ultraviolet (UV) filters.

A “gross list” of allergenic substances found in cosmetic products for children and toys was prepared by making a preliminary list of allowed colorants, preservatives, UV filters, and fragrances in cosmetic products. The substances in the preliminary list were assessed for their potentially allergenic properties based on opinions of the Scientific Committee on Consumer Safety (SCCS), harmonized classifications, and other relevant knowledge. Substances without allergenic properties were eliminated and the remaining substances were included in the gross list.

Based on the gross list, a survey was conducted to analyze which substances are used in toys and cosmetic products for children on the Danish market. The survey was carried out through visits in shops; close reading of lists of ingredients on products in shops; literature searches; Internet searches; and contact with industry.

Among its findings, the report states “[a]n essential conclusion from the survey is that it is possible to find cosmetic products for children in the Danish shops without potentially allergenic substances (127 out of 157 investigated products are without a content of potentially allergenic substances from the established gross list) . . . The overall picture from the survey of toys is that alternative products without allergenic substances (based on the gross list) are found on the Danish shop market and that part of the Danish toy sector who responded to the inquiry is aware of the problem and in general tries to avoid allergenic substances.”

Danish EPA To Publish New Chemicals Package: On August 28, 2016, the Danish EPA [announced](#), in Danish, that it will develop a new chemistry package with a special focus on five

areas. The Danish chemicals package will include: (1) information on combination effects of chemicals; (2) information on better EU regulation of chemicals; (3) a list of endocrine disrupting chemicals (EDC); (4) information on fluorinated chemicals; and (5) support for EU-level regulation of tattoo ink. The new chemicals package is intended to support a more comprehensive approach towards regulation of chemicals in food, consumer products, and the environment.

More information is available, in Danish, in the Danish EPA's document entitled "[Særlig kemiindsats over for hormonforstyrrende stoffer m.v.](#)"

European Union

EC's JRC Issues Report On Safety Of Tattoos And Permanent Make-up: The European Commission's (EC) Joint Research Committee issued a report entitled "Safety of Tattoos and Permanent Make-up – Final Report." The report addresses "the issue of the safety of tattoo/[permanent make-up (PMU)] products and practices with a view to contribute to consumers' health protection, and states "there are chemicals which are banned in consumer products that get into direct contact with the skin under different EU legislations, like the Cosmetic Product Regulation or [the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation], but not in tattoo inks."

The report contains several sections, including "Legislative framework in the EU/[European Free Trade Association] countries and other jurisdictions," "Statistical data related to tattoo and PMU practices," "Ingredients of tattoo and PMU inks," "Allergic/hypersensitivity and auto-immune type reactions," and "Conclusions."

The report identified the following data gaps and research needs: (1) development and harmonization of analytical methods to assess the possible presence of impurities and/or banned ingredients; (2) guidelines for risk assessment of tattoo/PMU products, including toxicological studies on ingredients, and exposure data from use of tattoo/PMU inks; (3) the fate of colorants in human skin and body after tattoo application or removal and their toxicokinetics; and (4) prospective epidemiological studies to ascertain the risk of carcinogenicity from tattoo inks' constituents, including their degradation products.

The report recommends that, in addition to addressing the aforementioned research needs, harmonized hygiene guidelines for tattoo/PMU professionals should be developed and further enforced. In conclusion, the report emphasizes the importance of eradication of "clandestine tattooing" and states that "[r]isk communication campaigns should be encouraged" and "[a harmonized] curriculum and training at EU level for tattooists and a register for professional tattooists would be both welcome."

EU Informs WTO Of Changes To CLP Regulation: On August 22, 2016, the EU [notified](#) the World Trade Organization (WTO) of a draft proposal to amend the Classification, Labelling, and Packaging (CLP) Regulation. The notification states that the purpose of the draft proposal is to amend Table 3.1 to Annex VI of the CLP Regulation by introducing new and revised entries for the harmonized classification and labelling of 37 substances and the Acute Toxicity Estimates (ATE) for nicotine.

Additionally, the proposal amends Annex VI to the CLP Regulation by adding a provision on ATE, replacing references to Table 3.1 with references to Table 3, and by deleting references to Table 3.2, the Dangerous Substances Directive, and the Dangerous Preparations Directive.

The notification, which was provided to WTO with a proposed Regulation and Annex, states that its “[objectives] and rationale” are: (1) ensuring the proper functioning of the EU internal market; (2) protection of human health or safety; and (3) protection of the environment. The proposed date for adoption of the proposal is the **first quarter of 2017**, and the proposed date for entry into force is 20 days after publication in the *Official Journal of the EU*.

BoA Adopts First BPR Data Sharing Decision: On August 23, 2016, the European Chemicals Agency’s (ECHA) Board of Appeal (BoA) adopted its [first decision](#) on a data sharing dispute under the Biocidal Products Regulation (BPR).

Thor GmbH (Thor) lodged the appeal in 2015 after ECHA granted permission to a company to cite studies owned by Thor for the substance reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (CIT/MIT). According to ECHA, Thor had insisted on a technical equivalence assessment of its substance with the other company’s active substance to check if the companies’ substances had similar chemical composition and hazard profiles. ECHA stated this was not required under BPR and data owners “do not have the right to demand any form of similarity check as a prerequisite for getting a letter of access.”

The BoA ruled in favor of Thor, which raised five pleas in law, as the companies had mutually agreed to perform a technical equivalence assessment before sharing data. The BoA concluded that while ECHA “might be correct” in concluding that the technical equivalence assessment is not a legal requirement for data sharing under BPR, “this legal observation cannot constitute an assessment of the parties’ efforts to reach an agreement within the meaning of Article 63.”

The BoA stated “it is part of the Appellant’s and the prospective applicant’s contractual freedom to insert a clause relating to a technical equivalence assessment in the data sharing agreement.” The BoA also reviewed the negotiations between the parties to determine whether the parties made every effort to reach an agreement, and found that ECHA “did not consider all the relevant facts in a balanced manner when assessing whether every effort had been made by the Appellant and the prospective applicant under Article 63.”

Consequently, the BoA concluded that Thor had made every effort to reach an agreement with the other company and ECHA had failed to consider all the facts of the case.

EC Issues Report On Benefits Of Chemicals Legislation: The EC issued a report entitled “[Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment – Development of a System of Indicators](#).” The study is part of the EC’s Regulatory Fitness (REFIT) program and “will inform the general report on the operation of the REACH) Regulation and, more in general, of the chemical legislative framework, expected in **2017**.”

The objective of the study was to develop a system of indicators that can establish and measure the links between chemical substances and their impacts on human health and the environment, and measure the role that chemicals legislation has had in reducing such impacts. The report states that its “ultimate aim is to indicate the benefits of EU chemicals legislation over the period 2004-2013.”

The report focuses primarily on REACH and the CLP Regulation, which the report refers to as the “[recognized] cornerstones of the chemicals acquis.” The report provides three types of indicators: (1) output (*i.e.*, expectations from legislation); (2) result (*i.e.*, immediate effects of legislation on direct recipients); and (3) impact (*i.e.*, ultimate consequences of the legislation beyond its direct interaction with recipients).

The report indicates that “the two main challenges” in developing a system of indicators for the assessment of benefits of chemicals legislation are:

- The availability of historic data on trends in exposures to chemical substances and on the impacts attributable to the chemicals exposures; and
- The extent to which any change in trends can be attributable to the action of chemicals legislation, as opposed to technical or economic factors.

EC’s Report Addresses CAs And Enforcement: The EC issued a report entitled “[Service Contract for Technical Assistance to Review the Existing Member State Reporting Questionnaire under Article 117 REACH, Including the Evaluation and Configuration of an Appropriate IT Tool for the Reporting – Final Report.](#)”

The report provides a comparative analysis of Member States’ reporting questionnaires under REACH Article 117(1) and Article 46 of the CLP Regulation. The report states “[Competent Authorities (CA)] are generally satisfied with their level of technical resources, while they consider their financial and human resources insufficient or limited, which impedes the achievement of all activities required under REACH ... CAs generally expressed a high level of satisfaction with the cooperation between CAs at EU and national levels and with the cooperation with ECHA and the [EC].”

The report indicates that CAs expressed a high level of satisfaction towards the REACH Committee, the Member States Committee, the Risk Assessment Committee (RAC), and the Helpnet Committee. The Socio-Economic Assessment Committee (SEAC), the CAs for REACH and CLP (CARACAL), and the Risk Communication Network “gathered less positive feedback.” Frequent comments on the committees related to organizational issues, working methods, workload, and availability of experts and resources.

The report states that the majority of European Economic Area (EEA) countries indicated that enforcement strategies are in place within their jurisdictions. A number of CAs indicated that their priorities are aligned with those defined in the REACH-EN-FORCE projects. Additionally, CAs considered enforcement projects and pilot projects as the “most effective cooperation activities.”

All CAs provided data on the number of official controls, including inspections, investigations, monitoring, or other enforcement measures related to REACH and the CLP Regulation. The report states “[t]here is, in both cases, a large degree of variation between countries. Some of the variation may be attributed to the different interpretations of which enforcement measures should be included or different ways of collecting data. In general, data provided by CAs were often incomplete and not consistent.”

France Proposes BPA For SVHC Candidate List: On August 30, 2016, France submitted a proposal, in the form of an [Annex XV Report](#), for inclusion of Bisphenol A (BPA) on the Candidate List of Substances of Very High Concern (SVHC). France previously submitted a proposal for classification of BPA as a Category 1B substance toxic for reproduction, which was approved by EU Member States and the EC, and enters into force in **2018**.

France’s proposal states that uses of BPA listed in registration dossiers that should be subject to the Authorization procedure include:

- Industrial or professional repackaging of BPA;

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- Industrial use of BPA for manufacturing thermal paper;
 - Manufacture and blending of polycarbonate; and
 - Industrial use of BPA for manufacturing polymers.

Several uses of BPA as an intermediate are not proposed by France to be subject to the Authorization procedure (e.g., use of BPA in the manufacture of epoxy resins and coating materials). The deadline for submitting comments on the proposal is **October 21, 2016**.

Biocides Stakeholders' Day Addresses Important Issues: The fourth Biocides Stakeholders' Day took place on September 1, 2016, at ECHA's headquarters in Helsinki, Finland. The event provided biocides stakeholders with information on the Biocidal Products Regulation and the tools and support available. The focus was on experiences from companies, ECHA, and the EC. ECHA stated "[t]he objective was to equip companies with information about their roles and obligations to meet the legal requirements for biocides."

The [program](#) for the event included three plenary sessions. Plenary Session 1, "[Challenges and Opportunities](#)," was commenced by ECHA's Executive Director, Geert Dancet. Topics discussed in Plenary Session 1 included a "[r]egulatory update from the [EC]," "[a]ctivities in 2016," and "Union [Authorization] in Practice." Plenary Session 2 focused on "[IT Tools and Dossier Preparation](#)," and included discussions on IUCLID 6 and R4BP. Plenary Session 3 on the "[Enforcement of Biocidal Products](#)" consisted of discussions on enforcement by the EC and Member States, and closed with a case study on "Enforcement from an Industry Perspective."

The Plenary Sessions were followed by Questions and Answers, closing remarks from Jack De Bruun, ECHA's Director of Risk Management, and an opportunity for attendees to meet the ECHA staff.

Study Finds More Action Needed To Substitute Hazardous Chemicals: ECHA [announced](#) on September 5, 2016, the availability of a study conducted by the Lowell Center for Sustainable Production entitled [Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH](#). According to the study, regulations are critical drivers for industry to substitute hazardous chemicals in the EU. The biggest hindrances are limited staff and other resources focusing on substitution, ignorance on safer alternatives, and limited information in the supply chains. To accelerate identifying very hazardous substances and substituting them with safer alternatives, the report recommends improving the analysis of safer alternatives and education on substitution, as well as stimulating collaboration within supply chains. This all requires more dedicated staff and other resources in ECHA, Member States, and industry. ECHA states that more government facilitated innovation research, public-private partnership, more detailed guidance, and technical support will also be needed to ensure successful substitution. These investments need to be coupled with enhanced inter-authority and stakeholder collaboration on substitution and the development of expert networks that can support industry and authorities.

ECHA Consults On Identification Of Six Substances As SVHCs: On September 6, 2016, ECHA [opened consultation](#) on the identification of the following substances as SVHCs:

- BPA, proposed by France, and reported in more detail above;
- 4-heptylphenol, branched and linear, proposed by Austria;
- 4-tert-butylphenol, proposed by Germany;
- Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride), proposed by

Netherlands;

- Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts, proposed by Sweden; and
- P-(1,1-dimethylpropyl)phenol, proposed by Germany.

The deadline for submitting comments on ECHA's consultation is **October 21, 2016**.

Scientists Want Potency Considerations In EC's EDC Criteria: [Numerous scientists](#) agreed upon and supported an editorial entitled "[Endocrine disruptors: science is more potent than politics](#)" and an appeal to the EC regarding its proposed criteria for identifying EDCs. The editorial states "[b]y relying entirely on the [World Health Organization's International Program on Chemical Safety] definition, a key element that would allow practical implementation of the [EC's] proposed criteria has been omitted: potency ... By evaluating the strength of a chemical's interaction with the endocrine system, it can be determined with great accuracy whether the chemical could produce any effect – either beneficial or adverse – in humans."

The editorial highlights the importance of inclusion of potency as a consideration in identifying EDCs and provides a historic overview of EDC regulation. The editorial concludes by suggesting that the EC should "make only a small change in its second criterion for a chemical to be considered an EDC: (2) "it acts through an endocrine mode of action with sufficient potency to alter human endocrine function, as established by potency comparisons to human hormones or human pharmaceuticals."

The editorial states that it is time to "suspend political posturing" and suggests that making the aforementioned change would provide for reliable identification of EDCs without requiring direct human data on each chemical or "unnecessary, expansive studies in laboratory animals."

EU General Court Rules On Three SME Cases: On September 15, 2016, the European General Court ruled on three cases lodged by Italian chemical companies against ECHA. The cases concerned contested decisions by ECHA that the companies are not small- and medium-sized enterprises (SME) eligible for reduced fees.

The General Court dismissed the case filed by [Marchi Industriale SpA \(Marchi\)](#) under Article 263 of the Treaty on the Functioning of the EU (TFEU) and ordered Marchi to pay the costs. Marchi raised two pleas in law in support of its action. The first plea alleged a failure to state reasons for the contested decision, and the second plea alleged an error of assessment of the facts of the case. At the hearing, Marchi withdrew its head of claim seeking annulment of the invoices pursuant to the contested decision.

The General Court annulled the relevant contested decisions in cases filed by [Crosfield Italia Srl \(Crosfield\)](#) and [K Chimica Srl](#). Crosfield was requested by ECHA to supply certain documents to verify the declaration by which it had indicated it was a small enterprise. Following exchanges of documents and e-mails, ECHA found in its contested decision that Crosfield should be regarded as a large enterprise and pay the appropriate fee. Under Articles 91 and 92 of the REACH Regulation, Crosfield filed an appeal against the contested decision before ECHA's BoA. The BoA decided to suspend the procedure before it, pending a decision from the General Court.

ECHA contended that the BoA does not have jurisdiction in the Crosfield dispute. Crosfield alleged that the contested decision does not specify the reasons for regarding it as a large enterprise. Key issues in the case included the definition of an SME, and whether turnover of Marchi and Esseco

Group Srl should have been accounted for in determining the size of Crosfield for regulatory purposes. The General Court ordered each party to bear its own costs.

SumOfUs' Public Petition Urges Governments To Reject EC's EDC Criteria: [SumOfUs](#), an international corporate watchdog, has issued a [public petition](#) to encourage European governments to reject the EC's "disastrous draft proposal on [EDCs] to protect public health and the environment."

SumOfUs states "[EDCs] should be banned – but instead the EU is poised to give the chemical industry the gift they've always wanted ... The draft rules are designed to protect corporate profits, not public health." SumOfUs quotes Dr. Lisette van Vliet of EDC-Free Europe, who stated "the standard of proof is so high that we have to wait for years of damage to our health before withdrawing from the market."

SumOfUs suggests that while Member States beyond Sweden, Denmark, and France may take a stand against the EC's proposed criteria, "it's very difficult to tell with these nontransparent Brussels meetings." In conclusion, SumOfUs states "No to [EDCs] – Tell European Governments to reject the [EC's] draft proposal on [EDCs]."

EC Amends REACH Skin Sensitization Provisions: On September 20, 2016, [Commission Regulation \(EU\) 2016/1688](#) was published in the *Official Journal of the EU*. The Regulation, which enters into force 20 days after its publication in the *Official Journal of the EU*, amends REACH Annex VII. Commission Regulation (EU) 2016/1688 states "[t]o reduce animal testing, point 8.3 of Annex VII to [REACH] should be amended to allow the use of these alternative methods, where adequate information can be obtained through this approach and where the available test methods are applicable for the substance to be tested."

Commission Regulation (EU) 2016/1688 expands upon and modifies Point 8.3 of REACH Annex VII substantively, with the consequence that skin sensitization tests do not need to be carried out if the relevant substance is:

- Classified as skin corrosion (category 1); or
- A strong acid (pH ? 2,0) or base (pH ? 11,5); or
- Spontaneously flammable in air or in contact with water or moisture at room temperature.

In vitro/in chemico tests are not needed if:

- An *in vivo* study is available; or
- The available *in vitro/in chemico* test methods are not applicable for the substance or are not adequate for classification and risk assessment.

The Regulation states "[t]he murine local lymph node assay (LLNA) is the first-choice method for *in vivo* testing. Only in exceptional circumstances should another test be used. Justification for the use of another *in vivo* test shall be provided."

Cefic Suggests Revised Data Sharing Guidance Is Critical To Avoid Uncertainty: On September 22, 2016, the European Chemical Industry Council (Cefic) issued a [press release](#) that states it is important that there is legal certainty in the matter of data sharing under REACH. Cefic stated "[t]his is important in order to avoid duplication of work, cut unnecessary costs and reduce animal testing." Cefic stated that an important step in this regard will be an update of ECHA's

guidance to incorporate the provisions of [Commission Implementing Regulation \(EU\) 2016/9](#). Cefic and other stakeholders “have worked with ECHA in the run up to the release of this Guidance,” and Cefic will in parallel update its support template agreements to reflect Implementing Regulation 2016/9 (e.g., a section helping companies to itemize costs and data). Cefic stated “[t]his will give companies – particularly SMEs – a needed 18 month period to digest and prepare for the **2018** deadline.”

ECHA's [draft version of its updated "Guidance on data-sharing"](#) includes a number of modifications, including revisions to “reflect the new clarifications in [Implementing Regulation 2016/9].” The draft guidance contains the following updates: (1) integration of key principles from Implementing Regulation 2016/9; (2) “[s]hift of the burden of the data-sharing activities from the Lead Registrant to the co-registrants in general”; (3) introduction of the need to agree on a cost sharing mechanism that includes a reimbursement mechanism; (4) clarification on itemization requirements of Implementing Regulation 2016/9; and (5) additional detail on Competition Law requirements.

A final version of ECHA's revised guidance is expected in **late 2016-early 2017**.

Stakeholder Consultation Begins As Part Of Study To Review Possible Restriction Of SBAA's Under RoHS:

The Danish EPA commissioned Oeko-Institut e.V and COWI A/S to perform a preliminary review of a possible restriction of small brominated alkyl alcohols (SBAA) under the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive. On September 23, 2016, a six-week [stakeholder consultation](#) was launched to collect further input. The consultation is targeted at the following groups: electrical and electronic equipment (EEE) industry; EEE industry federations; consultancies; research institutions and universities; non-governmental organizations (NGO); and public administrations. Information shall be reviewed and, if relevant, prepared in a dossier format to be submitted by the Danish EPA to the EC for further review as to the need to restrict the group in the future. A [background document](#) and a [questionnaire](#) for collecting further input are available. Comments are due **November 4, 2016**.

CAs' 66th Meeting On Implementation Of BPR Considers Enforcement: At the 66th meeting of CAs on the implementation of BPR, the CAs explored options for managing enforcement related to biocides. The meeting paper on the “[Future Settlement of \[Biocides Enforcement Group \(BEG\)\]](#)” addresses three options for managing enforcement of biocides: (1) BPR enforcement is integrated fully in ECHA's Enforcement Forum; (2) BPR enforcement coordination is handled by a Subgroup of the Forum; and (3) BEG remains as a separate entity. The paper explores these options and describes their respective advantages and disadvantages.

Regarding Option 2, which received unanimous support from Member States, the paper includes the following as advantages:

- BPR coordination will become part of an existing body that has good experience and efficient practices in coordinating enforcement;
- ECHA will provide the Secretariat for the operation of the Forum;
- As “[c]ross-cutting issues exist” between enforcement of BPR and other chemicals legislation, this option would be useful in optimizing synergies for enforcement of chemicals legislation;
- BPR enforcement will be fully independent from REACH enforcement coordination; and
- The BPR representatives in the BPR Subgroup can elect their own chair (i.e., BPR Subgroup Vice-Chair).

Until ECHA and the EC decide on the most effective method for implementing the Subgroup, BEG will continue to operate as a separate group.

ECHA Publishes List Of Substances With Lead Registrants: On September 28, 2016, ECHA announced that it published a list of substances for which a lead registrant has been declared in REACH-IT. The list includes around 7,000 substances that have an active lead registrant declared in REACH-IT (through the joint submissions functionality). Substances are listed by name, and information is included about their identifiers, registration type, and whether the lead dossier has been submitted. The list includes the names of those lead registrant companies who have given their permission to publish. ECHA suggests that if a company is planning to register any of the listed substances, it can contact the lead registrant company and begin negotiating to obtain access to the joint submission. If the lead registrant is not visible on the list, the full contact details are available in REACH-IT. If the pre-registered substance does not yet have a declared lead registrant, the company can consider becoming the lead and announcing it to their co-registrants on the pre-Substance Information Exchange Forum (SIEF) page in REACH-IT. ECHA encourages all lead registrants to allow the publication of their names on ECHA's website, so that their customers and other registrants of the same substance can make best use of the list. ECHA states that it will update the list regularly as more information about substances and joint submissions becomes available. More information is available in ECHA's press release, "[List of substances with lead registrants available.](#)"

MEXICO

Mexico Proposes Packaging And Labeling Requirements For Domestic Cleaning Products:

The Mexican *Comisión Federal de Mejora Regulatoria* (COFMER; Federal Commission on Regulatory Improvement) has issued a draft NOM, [NOM-189-SSA1/SCFI-2015](#), modifying NOM-189-SSA1/SFCI-2002, addressing cleaning products designed and marketed for consumer home use. Overarchingly, the NOM aligns the Standard with current market needs; that is, to incorporate and address new applications and market environments.

In addition to outlining packaging and labeling requirements for such products, the draft NOM updates the list of items incorporated by reference (e.g., other legislation), adjusts the definitions for clarity, now includes "flavorings" (fragrances) in the product classification, and adds additional labeling requirements for poisonous and corrosive products options.

NEW ZEALAND

New Zealand EPA Consults On Proposals For Notice For Classification And Labeling, SDSs, And Packaging: The New Zealand Environmental Protection Authority (New Zealand EPA) began a public consultation on September 19, 2016, on three consultation papers concerning proposed changes to the rules on hazardous substances. The consultation papers address:

- Classification, labelling, safety data sheets (SDS), and packaging of hazardous substances: This consultation document sets out proposed changes to the way hazardous substances are managed. The document proposes retaining the current Hazardous Substances and New Organisms Act (HSNO) classification framework and proposes updates to proposals for labelling, SDSs, and packaging rules;
- Forms and information required in hazardous substance applications: The consultation paper focuses on information requirements for hazardous substance applications made under the HSNO. The Forms and Information Notice will replace the majority of the regulations in the

Hazardous Substances (Forms and Information) Regulations 2001. The proposal maintains most of the current requirements, with no major policy change; and

- Import certificates for explosives: The requirements for explosives import certificates would be shifted from the Hazardous Substance (Tracking) Regulations 2001 into the Importers and Manufacturers Information Notice 2015. The current requirements would be maintained.

According to New Zealand EPA, the proposed changes are part of the government's broader initiative to improve workplace health and safety. Comments are due **October 14, 2016**.

SINGAPORE

RoHS Regulation Will Take Effect June 1, 2017: The Ministry of the Environment and Water Resources (MEWR) promulgated a RoHS-like regulation that will take effect **June 1, 2017**. The regulation restricts the same substances as EU RoHS -- lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers. Unlike EU RoHS, the regulation applies to a narrower list of products: mobile phones; laptops; refrigerators; air conditioners; panel television sets; and washing machines. Products excluded from the regulation include batteries and accumulators, and products designed for industrial use only.

SWEDEN

KEMI Issues Report On UN's 2030 Goals: The Swedish Chemicals Agency, Kemikalieinspektionen (KEMI) issued a report, in Swedish, entitled "[Underlag för Sveriges genomförande av Agenda 2030](#)." The English summary of the report states "[i]n 2015 the [United Nations (UN)] General Assembly adopted Agenda **2030** with 17 goals and 169 targets which by the year **2030** will bring about sustainable economic, social and environmental development. Sweden is to achieve the agenda's objectives at the national level and to contribute to the achievement of the objectives at the global level."

The report contains four main parts: (1) a description of how the safe management of chemicals is a prerequisite for sustainable development; (2) a review of how the goals and targets in Agenda **2030** relate to the Swedish environmental quality objective of a Non-Toxic Environment, the milestone targets for hazardous substances, and the generational goal; (3) an assessment of how KEMI's activities are affecting the implementation of Agenda **2030**; and (4) the need for further measures.

The report provides that three main areas need to be strengthened in the long-term to develop a Non-Toxic Environment and support Agenda **2030**:

- The government's special investment in the action plan for a Non-Toxic Everyday Environment needs to be made permanent and, in the long run, to be expanded;
- KEMI's groundwork as an expert in the area of EU legislative processes needs to be strengthened if Sweden is to maintain its highly ambitious approach in the development of regulations within the EU; and
- KEMI's possibility for promoting research, development, and innovation needs to be strengthened through special research funding and a mandate.

TAIWAN

Companies Can Now Apply To Protect CBI On SDSs And Labels: As of September 1, 2016, companies can apply to protect confidential business information (CBI) on SDSs and labels in

Taiwan. The Ministry of Labor (MOL) published a procedure that allows companies to protect the following information:

- The name and concentration of hazardous chemical ingredients; and
- The name of the manufacturer, importer, or supplier.

If MOL accepts the company's application, the above information will not be displayed on SDSs or labels. Companies can submit applications through an [online platform](#), which launched on September 1, 2016.

Taiwan OSHA Consults On Amendments To Inventory Of Existing Chemicals: On September 9, 2016, the Taiwan Occupational Safety and Health Administration (Taiwan OSHA) announced that companies have until **October 31, 2016**, to amend entries on the Taiwan Chemical Substance Inventory (TCSI). Companies may propose changes to:

- Chemical Abstracts Service (CAS) Numbers
- Serial Numbers; and
- Chemical Names.

To propose a change, companies must submit a document indicating the current TCSI entry and the requested correction, with justification and supporting documents. Amendments will be accepted subject to approval by the Taiwan Environmental Protection Administration (Taiwan EPA).

BSMI Will Phase In RoHS Deadlines For Product Compliance: The Bureau of Standards, Metrology, and Inspection (BSMI) will implement CNS 15663, Taiwan's RoHS-like regulation, using the following compliance deadlines:

- December 1, 2016: Drinking fountains;
- July 1, 2017: Information technology (IT) equipment; and
- January 1, 2018: Word processors.

All products will need to be registered and obtain a registration of product certification, include the BSMI mark and RoHS label on packaging, and comply with the testing standard CNS 15050. CNS 15663 restricts the same substances as EU RoHS -- lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers.

UNITED KINGDOM (UK)

Environmental Audit Committee Issues Report On Microplastics: The House of Commons Environmental Audit Committee issued a report on the "[Environmental Impact of Microplastics](#)." The report contains sections on "Microplastic Pollution," "Microbeads," "Microplastic Prevention and Solutions," and "Conclusions and Recommendations."

The report states "[i]t is important to address microplastic pollution as a transnational problem and to understand that plastic in the ocean is in constant motion. The Government should continue international cooperation despite uncertainties arising from the EU referendum. It is clear that international action is needed. We recommend the Government maintain existing cooperation with international partners in tackling microplastic pollution. Up to now, NGOs have taken the lead role in addressing this issue. However, this is unsustainable given the increasing costs and demands relating to microplastic pollution. As more evidence emerges about the impact of microplastic

pollution, the Government must take on that role.”

The report provides that approximately 680 tonnes of plastic microbeads are used in the UK annually, and that a single shower can result in 100,000 plastic particles entering the sewage system. Additionally, the report states that microplastics from cosmetic products represent 0.01 percent to 4.1 percent of the total microplastics entering the marine environment. The report refers to cosmetic products as “a low-hanging fruit in the context of tackling wider plastic pollution.”

In the “Microplastics Prevention and Solutions” section, the report provides that the most effective way to tackle microplastic pollution in the marine environment is to tackle it at its source, which means stemming the flow of primary microplastics and general plastics entering the marine environment. Furthermore, the report recommends that the Government and Environment Agency work with Water Companies to understand the feasible options for monitoring and ultimately reducing microplastic pollution.

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