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ACTA Update October 27, 2017: Top International News in Chemical Policy and Regulation

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ARGENTINA

Argentine Ministry Begins Work On New Hazardous Waste Law: The Argentinian *Ministerio de Medio Ambiente y Desarrollo Sostenible* (Ministry of Environment and Sustainable Development) has begun discussions with the *Consejo Federal de Medio Ambiente* (Federal Environmental Council, COFEMA) regarding a draft hazardous waste regulation to replace the existing statute, *Reglamentación de la Ley* N° 24.051 . COFEMA was established in 1992 to serve as a space for dialogue and exchange of ideas among provincial and federal environmental agencies in Argentina.

BRAZIL

Discussion On Brazil's Industrial Chemicals Regulation Continues: As discussed in The Acta Group's (Acta®) **June 28, 2017**, article "Brazil Inches Forward On Industrial Chemicals Regulation Implementation," over 801 comments from 236 individuals were received by the Brazilian Ministry of Environment (*Ministério do Meio Ambiente*, or MMA) on the proposed regulation. As part of the legislative process, the review of these comments began at the extraordinary meeting of the National Commission of Chemical Safety (CONASQ) at the end of June 2017.

As of October 20, 2017, the MMA is still analyzing the comments. Since June, it has held two extraordinary meetings of CONASQ, and has validated only the issues considered out of scope and issues related to the regulation of the law. Presently, the text of the bill remains the same. The next CONASQ meeting on **November 22, 2017**, will be extremely important, as discussion of the specific comments related to the legislation itself will be considered. The discussions may lead to some changes in the draft text.

CANADA

Government Intends To Modernize And Improve CEPA: On October 6, 2017, Minister of Environment and Climate Change Catherine McKenna sent a letter to the House Standing Committee on Environment and Sustainable Development, responding to the

Committee's report, *Healthy Environment, Healthy Canadians, Healthy Economy: Strengthening the Canadian Environmental Protection Act, 1999*. According to the letter, the government agrees that changes are necessary to modernize and improve the Canadian Environmental Protection Act, 1999 (CEPA). The letter states that the government will consider each of the report's recommendations and respond by **June 2018** with a report on actions taken, and to be taken, in response to the Committee's proposals. The government commits to examining potential amendments to CEPA and publishing a detailed report explaining its overall approach to improving implementation of CEPA to provide environmental and health protection as effectively as possible. The letter notes that the government is on track to meet the Chemicals Management Plan's (CMP) goal of completing assessments for the 4,300 chemical substances in commerce that were identified as needing assessment by the categorization process that finished in 2006. According to the letter, in parallel with the review of CEPA, the government is consulting a broad range of stakeholders to determine what the focus of chemicals management should be in the **post-2020** period.

Health Canada Proposes To Amend HPR To Allow Use Of Prescribed Concentration Ranges On SDSs: On October 21, 2017, Health Canada published a notice in the *Canada Gazette* proposing to amend the Hazardous Products Regulations (HPR) to provide industry with the option to use prescribed concentration ranges rather than actual chemical ingredient concentrations or concentration ranges on safety data sheets (SDS) for hazardous workplace products in Canada rather than requiring confidential business information (CBI) applications under the Hazardous Materials Information Review Act (HMIRA). The prescribed concentration ranges would be spelled out directly in HPR. The concentrations and concentration ranges of ingredients in the product that present a health hazard could be disclosed on the SDS as either:

- The actual concentration or actual concentration range of the material or substance in the hazardous product; or

- One of the following prescribed concentration ranges within which the actual concentration or actual concentration range of the material or substance in the hazardous product falls:

    a. From 0.1 to 1 percent;

    b. From 0.5 to 1.5 percent;

    c. From 1 to 5 percent;

    d. From 3 to 7 percent;

    e. From 5 to 10 percent;

    f. From 7 to 13 percent;

    g. From 10 to 30 percent;

    h. From 15 to 40 percent;

    i. From 30 to 60 percent;

    j. From 45 to 70 percent;

k. From 60 to 80 percent;

l. From 65 to 85 percent; and

m. From 80 to 100 percent.

In addition, if the actual concentration range falls between 0.1 and 30 percent and does not fit entirely into one of the prescribed concentration ranges of (a) to (g), a single range created by the combination of up to three applicable consecutive ranges between (a) and (g) could be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the actual concentration range in which the ingredient is present in the hazardous product. The amendment would require any supplier who uses a prescribed concentration range to protect from disclosure the actual concentration or concentration range to provide immediately following that prescribed range a statement to the effect that the actual concentration or concentration range is being withheld as a trade secret. Publication of the notice began a 30-day comment period.

Health Canada Publishes Notice Of Intent For Possible HMIRA And HPA Amendments: Health Canada published a notice in the October 21, 2017, *Canada Gazette* seeking written comments on questions relating to possible HMIRA amendments and the exclusion for consumer products under the Hazardous Products Act (HPA). The notices states that the following two issues related to HPA and HMIRA have been raised during conversations with stakeholders:

1. Whether the chemical names, Chemical Abstracts Service (CAS) numbers, and any unique identifiers of carcinogens, mutagens, reproductive toxicants, and respiratory sensitizers should be able to be claimed as CBI under the HMIRA; and

2. Whether the HPA exclusion for consumer products should be amended so that, for consumer products intended for use, handling, or storage in workplaces, hazard information through labels and SDSs would be required under the HPA.

Health Canada states that the notice of intent is an opportunity for the public to provide early comments and input into the proposal to amend HMIRA and HPA to address the issue of CBI for carcinogens, mutagens, reproductive toxicants, and respiratory sensitizers and the provision of hazard information for consumer products. According to Health Canada, some items to consider would be if changes regarding these two issues would have any effect, both positively or negatively, on trade, business requirements, training obligations, health and safety in the workplace, and the ability to meet obligations as an employer or supplier. Interested parties (including chemical manufacturers and distributors, employers, workers, provincial, territorial, and municipal governments, interested groups, and the general public) may, until **November 20, 2017**, provide comments.

CHINA

Revised Data Requirements For China Pesticide Registration Issued: On September 29, 2017, the Ministry of Agriculture of China (MOA) issued the final revisions to Data Requirements on Pesticide Registration (MOA Proclamation No. 2569). The revisions will become effective on **November 1, 2017**, under the new Regulation on Pesticide Administration (RPA) and Pesticide Registration Management Measures (MOA Order No. 3, 2017). The draft revisions to Data Requirements on Pesticide Registration were initially released for public comment on June 30, 2017.

The new Data Requirements include 10 chapters and 14 annexes and a category of pesticides for specialty minor crops has been added.

MOA Order No. 3, 2017 requires chemistry and toxicology tests to be completed in laboratories located in China approved by the MOA or overseas laboratories that have a mutual recognition agreement with the relevant Chinese Authority. The new Data Requirements on Pesticide Registration do not provide any additional information about the acceptance of data generated in overseas laboratories.

It remains unclear whether, for example, for literature or data prepared in a foreign language, entire study reports/articles, or only summaries, must be translated into Chinese. In addition, the final revision of Data Requirements on Pesticide Registration deletes the category of "Pesticides for Overseas Uses Only" that was set forth in the draft revision of Data Requirements on Pesticide Registration.

The new RPA, MOA Order No. 3, 2017, and the Data Requirements on Pesticide Registration significantly change the registration requirements and the registration process for pesticides in China. These new requirements, and the many ambiguities they contain, will likely extend the time for obtaining registrations and impose additional challenges on manufacturers to overcome, particularly foreign manufacturers who wish to bring pesticide products to the Chinese market.

COSTA RICA

Costa Rica Formally Schedules GHS Implementation: On June 29, 2017, the Costa Rican Executive Decree No. 40457-S was published in the official journal, *La Gaceta Diario Oficial*, upon its approval by both the *Presidencia de la República de Costa Rica* and the *Ministerio de Salud* (President of the Republic and the Ministry of Health, respectively). Formally adopted just over two months previously, the "*Reglamento Técnico RTCR 481: 2015 Productos Químicos. Químicos peligrosos. Etiquetado*" (Technical Regulation RTCR 481: 2015 Chemicals. Hazardous chemicals. Labeled*)* will enter into force on **December 30, 2017**, and will formally implement the Globally Harmonized System of Classification and Labeling (GHS), specifically Revision 6, in the country. Note that while Executive Decree No. 40457-S does allow for a five-year transition period (to **December 30, 2022**) for ensuring product labels and attendant SDS comply with GHS, there are no separate transitions for substances and for mixtures. The labeling requirements set out under Executive Decree No. 28113 of 1999 will be replaced by those in Executive Decree No. 40457-S at the time of its full implementation in **2022**.

EL SALVADOR

El Salvador Proposes Adjustments To Its Chemical Regulatory Requirements: In June 2017, the customs systems of Honduras and Guatemala were integrated, to ease movement of goods among the two nations. El Salvador has now expressed interest in joining this system. As part of the first round of negotiations among the three countries, El Salvador has identified several key issues to be addressed: internal taxes, customs procedures, migration, tariffs, and sanitary and phytosanitary permits. The last two items are critical, as they speak to food and agriculture, respectively, regulatory requirements. Generally speaking, permits relating to these types of products have specific requirements (*e.g.,* permitted substances, permitted amounts of such substances) in or on the products for which the permit is granted. Economically, El Salvador has historically used these permits as a non-tariff barrier for foreign goods. The hope is that, through the customs system entry negotiations, El Salvador will adopt the permit requirements and processes of the other two

countries, thus making the movement of such goods more harmonized.

EUROPEAN UNION (EU)

PETA Issues Letter To EC And ECHA Regarding Animal Testing: On September 7, 2017, the non-governmental organization (NGO) People for the Ethical Treatment of Animals (PETA) issued a press release entitled "100,000 Demand That Europe Lead the Way in Animal-Free Science." PETA's press release states: "With the [European Commission's (EC)] upcoming formal evaluation of [the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation] due by October 2017, compassionate citizens are demanding that Europe become a world leader in progressive and innovative science by ending cruel experiments on animals and accepting cutting-edge, non-animal research methods."

PETA stated that the REACH Regulation is the largest animal testing program in the world, and that PETA estimates, based on recent reports, that by 2016 more than one million animals had been used in tests to meet REACH requirements. PETA issued an "open letter to the [EC] and the [European Chemicals Agency (ECHA)] signed by thousands." The letter states:

- "Please stop requiring the use of animals to test chemicals. So long as REACH relies on animal tests, the goal of ensuring the safe use of chemicals will never be met."
- "REACH means that Europe -- once regarded as the world leader in animal protection -- is, for now, committed to unreliable and cruel testing methods that are causing the suffering and painful deaths of countless animals."
- "We urge you to seize the REACH [REFIT] evaluation as an opportunity for Europe to lead the world in progressive and innovative science by ending these cruel experiments and accepting cutting-edge research methods that don't harm animals."

EC Issues Report On Strategy For A Non-Toxic Environment: The EC issued a report entitled "Study for the Strategy for a Non-Toxic Environment of the 7th Environment Action Program." The EC's report includes a number of sections, including "the role of chemicals in modern society and industry"; "the state of play, including new and emerging health and environmental concerns"; and "workshop participants' views on status quo and improvement opportunities."

The 7th Environment Action Program, adopted in 2013, mandates the EC to develop by **2018** a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes, including non-chemical solutions. The EC's study supports development of the strategy by providing a comprehensive overview "of the state of play" and by identifying "gaps and deficits" in the current EU chemicals policy and legislative framework in relation to the following aspects:

- Substitution, including grouping of chemicals and measures to support substitution;
- Chemicals in products (articles and non-toxic material cycles);
- The improved protection of children and vulnerable groups from harmful exposure to chemicals;

- Very persistent chemicals;
- Policy means, innovation, and competitiveness;
- Program on the development of new, non/less toxic substances; and
- Early warning systems for examining chemical threats to human health and the environment.

The EC's report provides that "[t]he chemicals regulatory framework put in place by the [EU] is widely regarded as the most advanced comprehensive legal framework for the control of chemicals in the world. It applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals they place on the market."

The report states that the use of chemicals is ever-increasing and this "poses new challenges for the goal of protecting humans and the environment from chemicals-related harm." In particular, the EC's report highlights concerns in relation to articles, vulnerable populations, and achievement of the goal of the Circular Economy.

EP Resolution Proposes To Reform Global Value Chains: On September 12, 2017, the European Parliament (EP) passed a resolution that proposes measures intended to protect workers and the environment by reforming global value chains. According to the EP's September 12, 2017, press release, the suggestions include:

- Boosting corporate social responsibility by including corporate social responsibility rules in the trade and investment agreements negotiated by the EU;
- Requiring the EC to consider stipulating extensive "due diligence" measures in supply chains, similar to those used for conflict minerals and the timber supply;
- Including enforceable rules on labor and human rights in trade deals;
- Developing an EU strategy to protect whistle-blowers in forced labor and trafficking cases; and
- Making the "social impact of production" visible on goods to raise consumer awareness and help bring about lasting change.

The resolution was approved by 497 votes to 124, with 56 abstentions.

EC Holds Consultation On Revising Recommendation On Definition Of Nanomaterial: On September 15, 2017, the EC began a public consultation on the revision of the 2011 EC Recommendation on the definition of nanomaterial. According to the Roadmap, the intention is to prepare a revised Recommendation to be adopted by the EC, accompanied by a Staff Working Document that will report on the review undertaken and the rationale for the modifications. The Roadmap states that it is envisaged that the EC will then:

- Promote the revised Recommendation within the EU and, as appropriate, in the international community;
- Develop guidance (including technical requirements), sector-specific guidance, and

implementation tools;

- Support the uptake of the Recommendation in the relevant policy areas, such as chemicals, cosmetics, and food; and

- Set up a system of continuous monitoring of implementation across sectors, facilitate quick dissemination and uptake of any relevant scientific/technical developments, and if considered appropriate, trigger actions to support quality assurance and control of the measurements and their application in the nanomaterial definition.

Comments on the Roadmap were due October 13, 2017.

Report Analyzes REACH Authorization Applications: On September 18, 2017, ECHA announced the availability of a report based on its analysis of the first 100 applications for authorization submitted and evaluated by the end of 2016. According to ECHA, the requirements for authorization have introduced stricter controls of use and have therefore reduced risks from harmful chemicals to workers and the population at large. ECHA states that the authorization requirements, as well as the reputational issues of continued use of substances of very high concern (SVHC), have driven companies to substitute hazardous substances with safer alternatives as witnessed by the non-receipt of applications for seven substances on the Authorization list. ECHA notes that three findings stand out:

- While the remaining risks associated with the continued use of SVHCs are important, the risk reductions brought about by the authorization system have reduced the exposure to harmful chemicals of workers and the population at large;

- The aggregate benefit of authorizations (*i.e.*, the costs that applicants, their clients, and society as a whole would have to bear if the authorizations had not been granted) were estimated to outweigh the remaining monetized risks to human health and the environment by on average a factor of 15 to one; and

- While ECHA's scientific committees recommended to the EC that all the authorizations be granted, they suggested additional conditions and/or monitoring requirements in two-thirds of the uses. Furthermore, they recommended that the review periods be, on average, 2.5 years shorter than proposed by the applicants. Thus, the scientific scrutiny of the applications manifests itself in the opinion-making process.

More information is available in ECHA's press release, "Report: ECHA's scrutiny has a profound impact on authorisation decisions."

EC Industrial Policy Strategy Calls For Investing In Smart, Innovative, And Sustainable Industry: On September 18, 2017, the EC issued a press release entitled "State of the Union 2017 -- Industrial Policy Strategy: Investing in a smart, innovative and sustainable industry." President Jean-Claude Juncker stated in his annual State of the Union address: "I want to make our industry stronger and more competitive. The new Industrial Policy Strategy we are presenting today will help our industries stay or become the world leader in innovation, digitisation and decarbonisation." The EC states that the renewed EU Industrial Policy Strategy "brings together all existing and new horizontal and sector-specific initiatives into a comprehensive industrial strategy." The main new elements include:

- A comprehensive package to reinforce industry's cybersecurity;
- A proposal for a regulation on the free flow of non-personal data that will enable data to circulate freely across borders, helping to modernize industry and "create a truly common European data space";
- A new series of actions on the circular economy, including a strategy on plastics and measures to improve the production of renewable biological resources and their conversion into bio-based products and bio-energy;
- A set of initiatives to modernize the intellectual property framework, including a report on the functioning of the directive on the enforcement of intellectual property rights and a communication on a balanced, clear and predictable European licensing framework for standard essential patents;
- An initiative to improve the functioning of public procurement in the EU, including a voluntary mechanism to provide clarity and guidance to authorities planning large infrastructure projects;
- Extension of the skills agenda to new key industry sectors, such as construction, steel, paper, green technologies and renewable energies, manufacturing, and maritime shipping;
- A strategy on sustainable finance to orient better private capital flows to more sustainable investments;
- Initiatives for a balanced and progressive trade policy and a European framework for the screening of foreign direct investments that may pose a threat to security or public order;
- A revised list of critical raw materials where the EC will continue to help ensure the secure, sustainable, and affordable supply for the EU manufacturing industry; and
- New proposals for clean, competitive, and connected mobility, including tightened carbon dioxide emission standards for cars and vans, an alternative fuels infrastructure action plan to support the deployment of charging infrastructure, and actions to foster autonomous driving.

ECHA Posts Information On Impact Of UK's Withdrawal From The EU: ECHA announced on September 25, 2017, that a new section on its website provides information on the impact of the United Kingdom's (UK) withdrawal from the EU. According to ECHA, the withdrawal will have "profound implications as the EU regulatory regimes that have been established for numerous sectors of the internal market economy will thereafter no longer directly apply" to the UK. Upon the UK's withdrawal, cooperation with the UK will no longer be based on the Biocidal Products Regulation (BPR), Classification, Labeling, and Packaging (CLP) Regulation, Prior Informed Consent (PIC) Regulation, and REACH. A new section on the ECHA website provides information on the impact of the withdrawal on the work of ECHA, as well as advice to business operators in the format of questions and answers. ECHA states that as the negotiation process will take time, it will incrementally expand and update information as the withdrawal process becomes clearer. ECHA advises readers to consult such updates in light of developments. More information is available in ECHA's press release, "A new section on the ECHA webpages provides information on the impact of the United Kingdom's withdrawal from the European Union."

Biocides Stakeholders' Day Held In September: On September 26-27, 2017, ECHA held Biocides Stakeholders' Day 2017. The conference provided stakeholders the latest information on the BPR and the tools and support available. The focus was on experiences from companies, EU Member States, ECHA, and the EC. ECHA has postedvideo recordings of the sessions, as well as the following presentations:

Session 1 -- Biocides Regulatory Developments

- Opening remarks -- Geert Dancet, Executive Director, ECHA;
- Future outlook on biocides -- Martinus Nagtzaam, EC;
- Upcoming developments -- Hugues Kenigswald, ECHA; and
- Endocrine disruptors -- Where are we -- Simon Gutierrez Alonso, ECHA.

Session 2 -- Building a Biocides Application

- IT tools and support -- Valerio Spinosi, ECHA;
- Working in a consortium -- An Ghekiere, ARCHE Consulting;
- Applications for free radicals and other *in situ* generated substances: Experiences & challenges -- Brigitte van Noorloos, Dutch Board for the Authorization of Plant Protection Products and Biocides; and
- Biocidal product family application -- Caroline Hall, Evonik Nutrition and Care.

Session 3 -- Tips from Authorities

- How to do a successful Union authorisation application -- Chiara Pecorini, ECHA;
- Treated articles -- Member State advice -- Ulrike Frank, Swedish Chemicals Agency (KEMI);
- What to expect from enforcement -- Francesca Ravaioli, Ministry of Health, Italy; and
- Closing remarks -- Jack de Bruijn, Director of Risk Management, ECHA.

EC Issues Documents On Biocides And Brexit: The EC has issued a "Notice to Business Operators in the Field of [Biocides]" and "Questions and Answers Related to the [UK's] Withdrawal from the [EU] with Regard to the Biocides Sector" (Q&A). The EC's Notice states: "In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, all interested parties are reminded of certain legal repercussions stemming from currently applicable rules of [EU] law if the [UK] becomes a third country … In particular, business operators should consider that, according to [EU] law, third countries cannot act as [evaluating] Member States or reference Member States."

Regarding submissions of any new applications, the EC states that business operators should take into account the expected timelines of the different regulatory procedures in which the UK would be acting as an evaluating or reference Member State. The Notice states: "For example, where there is

a risk that those procedures are not concluded by the date when the [UK] will leave the [EU], applicants may choose by preference another evaluating Member State or reference Member State to carry out the evaluation."

Concerning ongoing procedures for which the UK is carrying out an evaluation, the Notice provides that business operators should carefully monitor progress, and take actions as appropriate (*e.g.*, change to another evaluating Member State). The Notice highlights that under EU law, holders of biocidal product authorizations "must be established within the [EU] (or [European Economic Area (EEA)] countries or Switzerland)," and that active substance or product suppliers included in the Article 95 List must be established in or have a representative established in the EU, EEA, or Switzerland.

The EC's Q&A addresses a number of important questions for biocides companies, including:

- "My non-EU company is listed in accordance with Article 95 together with my EU representative; what if my EU representative is established in the UK?";
- "What if the manufacturing site of my active substance is located in the UK?"; and
- "What if the manufacturing site of my treated articles is located in the UK?"

ECHA Announces New Executive Director: ECHA announced on September 29, 2017, that its Management Board has selected Bjorn Hansen as ECHA's next Executive Director. In June 2003, Bjorn joined the Chemicals Unit of DG Environment in Brussels, where he worked as a head of unit. ECHA states that from 2007 to 2008, "he was seconded to ECHA as the Director of Operations and has been involved in the development of REACH from its very early days." Before joining DG Environment, Hansen worked as an area coordinator for the existing substances team at the European Chemicals Bureau at the EC's Joint Research Center in Ispra, Italy. As part of the appointment procedure, Hansen will make a statement before the EP and answer questions. Hansen is scheduled to sign the contract at the Management Board's **December 14-15, 2017**, meeting. Geert Dancet, ECHA's current Executive Director, will retire as of the **beginning of 2018**. The term of office of the Executive Director is five years. It may be prolonged by the Management Board once for a further five years. Dancet was appointed as ECHA's first Executive Director in January 2008. More information is available in ECHA's press release, "Bjorn Hansen selected as ECHA's new Executive Director."

EP Publishes Briefing Paper On Chemicals And The Circular Economy: On October 2, 2017, the EP published a briefing paper entitled "Chemicals and the circular economy: Dealing with substances of concern." According to the briefing paper, the main challenge in relation to chemicals and the circular economy is increasing recycling and reuse, while simultaneously making sure consumers are not at risk from exposure to substances of concern that may be present in products and passed on to waste. More specific challenges relate, among other things, to long-term exposure, lack of information, trade aspects, and implementation of EU law. The briefing paper states that increased policy coherence in the current regulatory framework could help the situation. More specifically, elements of possible remedies include disseminating information about the presence of substances of concern in products, reducing and substituting them, and improving the management of substances of concern that cannot be substituted. There may be some difficulties in implementing these solutions, however, in particular regarding the administrative burden and costs. The briefing paper notes that the EP "supports the development of non-toxic material cycles so that recycled

waste can be used as a major, reliable source of raw materials. Stakeholders' views on the topic are mixed."

EP Resolution States Tangible Progress Still Needed On Brexit Withdrawal Terms: On October 3, 2017, the EP passed a resolution by a vote of 557 to 92, with 29 abstentions, stating that sufficient progress on the EU's priority aims, "a prerequisite for negotiating any transition period or future relationship between the EU and UK," has not been achieved. According to the EP's October 3, 2017, press release, the EP expects the UK government to table, without delay, specific proposals to:

- Safeguard the full set of rights that 4.5 million EU and UK citizens currently enjoy;
- Honor the UK's financial obligations to the EU in full; and
- Resolve the Republic of Ireland/Northern Ireland border issue, in full compliance with the Good Friday Agreement.

According to the press release, an additional condition for concluding the first phase of negotiations is a guarantee that EU law will be respected until the UK's official withdrawal from the EU. If sufficient progress is not made on the key aims of the EU, the resolution states that the government leaders of the EU27 Member States should postpone their assessment of Brexit, which is scheduled to be held **October 20, 2017**.

ECHA Addresses REACH 2018 Challenges For SMEs: On October 3, 2017, ECHA issued a press release entitled "[Small- and Medium-sized Enterprises (SME)] face financial challenges registering under REACH." In its press release, ECHA states: "A recent study on the segmentation of the [SME] market confirms uncertainties regarding the SMEs' intentions to register their substances by the [**May 31, 2018**, deadline]. The main hurdle seems to be the cost of data needed for registration. It also makes recommendations for [ECHA] on how to convince SMEs to use and benefit from the ECHA Cloud Services."

ECHA provides that the following three types of SME market segments were introduced in the study, based on SMEs' role within REACH and their attitudes towards registration:

- Product builders and suppliers that manufacture and import substances and have direct registration duties;
- Advice givers that assist and guide the first segment; and
- Experts, who are either service providers or in-house experts.

Within the first "type," ECHA stated that the segment is further divided into companies that have a good understanding of REACH and have set aside resources for registration; companies that are not sure whether or not they need to register; and SMEs that fear losing business as they cannot afford to register. Among these segments, the key finding was that while most SMEs (95 percent of respondents) are aware of their duties, a sizeable number struggle with the high costs of registration, including Letter of Access and Substance Information Exchange Forum (SIEF) participation costs. As a result, a "proportion of companies" are rationalizing their substance portfolios and finding alternative solutions (*e.g.*, remaining below the one metric ton threshold).

The study proposes actions for ECHA, Member States, and the EC to "help SMEs register by the **2018** deadline and to prevent the negative impact of their failure to do so on European competitiveness and employment." These actions include: (1) mobilizing resources to support the registration of substances by SMEs by the **2018**deadline; (2) providing information on available funding for compliance on the ECHA website; (3) requiring notification of SIEF costs and publishing information; (4) providing best practices for SIEF pricing; and (5) providing examples of well justified opt-out cases.

There is also a possibility, based on a separate paper from ECHA, that SMEs will be granted "free access" to data for their registrations. In the paper, ECHA stated "[?i]t is proposed that the [Directors' Contact Group (DCG)] endorses this proposal which is published as a DCG solution."

Study Examines How REACH And CLP Impact Industry's Sustainability Strategies: ECHA announced on October 4, 2017, the availability of a study on the impact of REACH and CLP implementation on industry's strategies in the context of sustainability. According to the study, which ECHA commissioned, companies still see chemicals management mainly in the context of staying compliant with all regulations relevant to them. Compliance is seen by companies as the baseline providing a "licence to operate" in their business fields, but they do not link this work directly to their sustainability strategies. ECHA states that the report's key finding is that REACH and CLP "have a crucial though only indirect impact on companies' sustainability and business strategies." The Candidate List in particular impacts market demand and is being used as a measure for investors to benchmark companies' sustainability performance. Market and investor demands in turn have a direct impact on industry's integrated corporate business strategies, including sustainability strategies. The study includes recommendations for ECHA to improve the situation, such as ways to encourage companies to include good chemicals management in their integrated corporate sustainability strategies by developing reporting tools and benchmarks. ECHA notes that several of the recommendations may also help ECHA in achieving the World Summit Sustainable Development **2020** goals. ECHA will start discussing these ideas with industry, NGOs, and other stakeholders. More information is available in ECHA's October 4, 2017, press release, "How do REACH and CLP impact industry's sustainability strategies?"

EC Notifies WTO Of Intent To Identify TMA, DCHP As SVHCs: On October 4, 2017, the EC notified the World Trade Organization (WTO) of two draft implementing decisions that would identify the following chemicals as SVHCs:

- Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride, TMA) (CAS Number 552-30-7): The draft decision identifies TMA as an SVHC due to its respiratory sensitization properties according to REACH Article 57(f); and

- Dicyclohexyl phthalate (DCHP) (CAS Number 84-61-7): The draft decision identifies DCHP as an SVHC due to its classification as toxic for reproduction properties according to REACH Article 57(c) and due to its endocrine disrupting properties whose effects to human health give rise to an equivalent level of concern according to REACH Article 57(f).

The proposed date of adoption and entry into force is **March 1, 2018**.

EP Rejects EC's Proposed EDC Criteria: On October 4, 2017, the EP issued a press release entitled "Identifying endocrine disruptors: Parliament blocks plans exempting some pesticides." The EP's press release states: "[The EP] blocked an [EC] proposal which would have exempted some

chemicals in pesticides from being identified as endocrine disruptors … [Members of European Parliament (MEP)] say that the [EC] exceeded its mandate by proposing to exempt substances which are actually designed to attack an organism's endocrine system."

The objection to the EC's proposal, introduced by MEPs Jytte Guteland and Bas Eickhout, was approved by 389 votes to 235 votes, with 70 abstentions, producing the absolute majority needed to block the EC's proposal. MEPs agreed with Ms. Guteland and Mr. Eickhout's objection to the EC's proposal, including that the EC exceeded its mandate by proposing to exempt some substances designed to attack organisms' endocrine systems from the criteria, even when the substances cause harm to non-target organisms of the same group of species.

MEPs provided that this proposal by the EC was unlawful because it would change an essential element of the Plant Protection Products (PPP) Regulation, which provides that active substances having endocrine disrupting properties on species other than the ones targeted shall not be approved, unless "the exposure of non-target organisms to that active substance in a [PPP] under realistic proposed conditions of use is negligible." On the contrary, the last paragraph of the EC's draft regulation states: "[?I]f the intended plant protection mode of action of the active substance being assessed, consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as having endocrine disrupting properties with respect to non-target organisms." Mr. Eickhout indicated that such a change to the PPP Regulation would need to be adopted through a different legislative process with approval of the EP and the EC

The EP's objection to the EC's proposal states: "[?I]t is not scientific to exclude a substance with an intended endocrine mode of action from the identification of being an [endocrine disrupting chemical (EDC)] for non-target organisms." The EC will therefore need to draft a new proposal for identification of EDCs, taking into account the EP's input. The objection to the EC's proposal "[c]alls on the [EC] to": (1) "withdraw the draft regulation and submit a new one"; and (2) "modify the draft regulation by deleting its last paragraph."

The EC's press release issued following the EP's vote states: "Commissioner Andriukaitis regrets today's vote in the [EP]. He strongly believes that in this case no deal is a bad deal for EU citizens. The [EP] decided to stop the adoption of scientific criteria which would have ensured better protection of human health and the environment as well as served as a stepping stone to a wider strategy on endocrine disruptors. Today's vote means that the scientific criteria put forward by the [EC that] had been supported by Member States in early July after months of thorough discussions cannot be adopted. The [EC] will now need to reflect on next steps to take."

In response to the EP's vote, the Center for International Environmental Law (CIEL) issued a press release entitled "Historic vote: the EU Parliament rejects Commission's criteria to identify endocrine disrupting chemicals, stands up for EU health." In the press release, CIEL states: "The proposed EDC criteria contained a dangerous exemption that would allow endocrine disrupting pesticides, despite an existing full ban on all EDCs. Last week, legal analyses by CIEL and ClientEarth found this exemption to be unlawful and advised the [EP] to vote against the criteria … In its vote today, [the EP] defended the rule of law and protected human health and the environment in the EU."

Giulia Carlini, Staff Attorney at CIEL, stated: "[T]oday, MEPs refused to be complicit in the [EC's] attempt to break the law and stood up for our health in defiance of a powerful pesticide industry lobby … Hopefully, the [EC] will finally get the message and present legally sound scientific criteria to identify EDCs."

BPC Adopts Ten Opinions: On October 5, 2017, ECHA issued a press release entitled "[Biocidal Products Committee (BPC)] adopts 10 opinions." BPC's adopted opinions relate to applications for approval of three active substances for use in biocidal products used as disinfectants and preservatives. The active substances and product-types are:

- Chlorophene for product-types 2 and 3;
- Azoxystrobin for product-types 7, 9, and 10; and
- PHMB (1415; 4.7) for product-types 1, 2, 4, 5, and 6.

BPC's conclusion is that for product-types 2 and 4, PHMB (1415; 4.7) may be approved. For product-types 1, 5, and 6, it cannot be approved. Regarding azoxystrobin, BPC concluded the substance may be approved for the above-mentioned product-types.

For chlorophene, the conclusion of BPC is that it cannot be approved for product-type 3. For product-type 2, the conclusion is that it may normally not be approved, unless one of the conditions for derogation in BPR Article 5(2) is met, because chlorophene meets the exclusion criteria.

The adopted opinions will serve as the basis for final decision-making by the EC and Member States. Additional information is available in the draft agenda for the BPC's meeting.

EC Proposes To Amend REACH Annexes To Address Nanomaterials: On October 9, 2017, the EC began a public consultation on a draft regulation that would amend REACH Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances. The draft regulation states that:

- Clarifications to requirements for the registration of substances with nanoforms and related downstream user obligations should be included in Annexes I, III, and VI to XII;
- Manufacturers and importers should assess and, where relevant, generate the necessary information and document in the chemical safety report that the risks arising from the identified uses of the substance with nanoforms are adequately controlled;
- As the majority of nanomaterials are expected to be nanoforms of phase-in substances, the conditions for the requirements for generation of new toxicological and ecotoxicological information on phase-in low volume substances should be elaborated to ensure that the assessment criteria are based also on the predicted properties of nanoforms;
- All different nanoforms and sets of nanoforms should be considered by the registrant in the demonstration of safety;
- To allow efficient assessment of the potential exposure for inhalable nanoforms, in particular in workplaces, information on dustiness should be provided for the different nanoforms or sets of nanoforms;
- Although acute toxicity testing for the lowest tonnage is required via the oral route, for nanoforms, inhalation or in very specific cases the dermal route may be considered as a more appropriate route of exposure;
- A number of specific physico-chemical properties, in addition to those used to identify the

different nanoform or sets of nanoforms, may be considered relevant for scientific understanding of the properties of a nanomaterial, with the necessary parameters depending on the individual case. For reasons of workability and proportionality, only registrants for higher volume substances than 100 tonnes per year should be required to consider explicitly such further information in case other particle properties significantly influence hazard or exposure to those nanoforms; and

- Compliance with the provisions of the proposed amendment should not be required immediately to allow all registrants and downstream users adequate time to adapt to the more specific requirements for substances with nanoforms. The amendment would apply from **January 1, 2020**.

Comments are due **November 6, 2017**.

ECHA Begins Public Consultations On Proposals To Support RAC In Adopting OEL Opinions: On October 10, 2017, ECHA began public consultations on its scientific evaluations of occupational exposure limit (OEL) values for benzeneand nickel and its compounds. ECHA began a third public consultation, on October 13, 2017, on acrylonitrile. In May 2017, the EC requested that ECHA's Executive Director support the Committee for Risk Assessment (RAC) in adopting opinions on OELs in accordance with Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. ECHA prepared the proposals for consideration by RAC. Comments on the proposals for benzene and nickel and its compounds are due **November 7, 2017**. Comments on the proposal for acrylonitrile are due **November 10, 2017**. According to the proposals, RAC's final opinions will be published on ECHA's website by **March 26, 2018**.

EC Report Finds EU Member Countries Should Use Pesticides More Sustainably: On October 10, 2017, the EC adopted a report on the sustainable use of pesticides Directive (2009/128/EC). The report takes stock of progress made by the EU Member States in applying measures to reduce the risks and impacts of pesticides. According to the EC's October 10, 2017, press release, the report indicates insufficient implementation of the Directive. The report concludes that while the Directive offers the potential to reduce greatly the risks from pesticide use, these improvements are limited and insufficient to achieve the environmental and health improvements the Directive was designed to achieve. This is largely due to the uneven implementation of the Directive. The EC states that key findings include:

- Aerial spraying is banned in all EU countries, with exceptions granted only under strict conditions;

- Pesticide use is banned or minimized in public parks, sports grounds, hospitals, and schools;

- Protection of aquatic environments or specific areas such as public parks is difficult to assess given the lack of measurable targets in most National Action Plans (NAP);

- Integrated Pest Management (IPM) remains underused by Member States. This is despite the fact that the number of EU-approved low risk/non-chemical pesticide substances has doubled since 2009. Compliance at the individual grower level is not being systematically checked by Member States; and

- Training and certification systems for professionals have been set up in all EU countries, and

to date almost four million farmers have been trained to use pesticides safely. Furthermore, 900,000 sprayers have been tested for accurate and safe application.

According to the EC, when revising their NAPs, Member States need to improve their quality, primarily by establishing specific and measurable targets and indicators for a long-term strategy for the reduction of risks and impacts from pesticide use. The EC will continue to monitor and support implementation by Member States to provide assurance that the objectives of the Directive are being achieved. This monitoring includes a range of actions such as audits, the evaluation of revised NAPs, and other follow-up activities. The EC will also work with Member States to develop EU harmonized risk indicators, based on Member States' experience with their national indicators.

Under Proposed CoRAP, Member States Will Evaluate 107 Substances In 2018-2020: ECHA announced the proposed Community Rolling Action Plan (CoRAP) on October 24, 2017. Under the proposed CoRAP, 26 substances are expected to be evaluated in **2018**, 37 in **2019**, and 44 in **2020**. ECHA states that it "encourages registrants of the listed substances to start coordinating their actions and to contact the evaluating authorities in the Member States. Downstream users of the listed substances are invited to review the information they hold and share that with registrants." ECHA notes that it is important that use and exposure scenarios as well as the exposure estimations are up-to-date and clearly documented within the chemical safety reports of the registrants. For the 26 substances to be evaluated in **2018**, dossier updates, where relevant, should be made before **March 2018**. More information is available in ECHA's press release, "Member States to evaluate 107 substances in 2018-2020."

EP Approves Legislation Intended To Protect Workers By Reducing Exposure To Carcinogens: On October 25, 2017, the EP approved legislation that amends Directive 2004/37/EC and establishes OELs for:

- Ten chemical agents: 1,2-epoxypropane, 1,3-butadiene, 2-nitroproprane, acrylamide, bromoethylene, vinyl bromide, chromium (VI) compounds, ethylene oxide, hydrazine, and o-toluidine, and refractory ceramic fibers; and

- Process-generated crystalline silica dust, created by mining, cutting, or crushing of materials such as concrete, bricks, or rocks.

The legislation also revises OELs for two substances already on the list, hardwood dusts (produced by cutting or pulverizing wood), and vinyl chloride monomer (mainly used to produce polyvinyl chloride). Employers will have to identify and assess risks to workers who are exposed to these substances and take preventive measures. The EP's press release, "Protecting workers by reducing exposure to carcinogens," notes that the EP ensured that the EC "will have to assess the possibility of including reprotoxic substances, *i.e*. those having effects on sexual function and fertility, in the dangerous substances list by the **first quarter of 2019**." According to the press release, the legislation "will particularly benefit workers in the construction sector, chemical, automotive, woodworking and furniture industries, manufacturers of food products and textiles, the healthcare sector and hospitals."

TAIWAN

Taiwan EPA Begins Consultation On Proposed Amendments To Registration Regulation: In September 2017, the Taiwan Environmental Protection Administration (Taiwan EPA)

announced proposed amendments to the regulation regarding the registration of new and existing chemical substances. According to the notification that Taiwan EPA submitted to WTO, the amendments include:

- Harmonizing the information requirement between Taiwan EPA and the Ministry of Labor regarding hazard assessment and exposure assessment;
- Clarifying the quantity that triggers the obligation of the existing chemical substance phase 1 registration;
- Clarifying the period of confidentiality of information on chemical substances included in the inventory of existing chemical substances, and ensuring consistency in the period of the information confidentiality and the validity of registration approval;
- Requiring an annual report on new and existing chemical substances registered and approved;
- Indicating the calculation of the review period, and that the review period is calculated anew upon the registrant's supplementation or correction to the registration application;
- Extending the limit on the time period and the number of times that supplementations and corrections may be made for a registration application, taking into account the scientific and technical feasibility;
- Accepting written appeals with stated reasons for which the registrant may have concerns over the review results; and
- Deleting outdated provisions.

Publication of the proposed amendments began a 60-day comment period. More information is available on Taiwan EPA's website.

TURKEY

Turkey Continues Progress Towards Comprehensive KKDIK Implementation And Support: KKDIK, Turkey REACH, was published on June 23, 2017, after long delays, and will enter into force on **December 23, 2017**. Turkey's Ministry of Environment and Urbanization (MoEU) will make available 13 guidance documents by the **end of the year** to assist industry with compliance.

Guidance documents to be issued by the **end of the year** will address the following issues, among others: (1) dossier and substance evaluation; (2) dossier preparation and harmonized classification and labelling; (3) information requirements and chemical safety assessment; (4) scientific research and development and product- and process-oriented research and development; (5) information on chemical risks and safe use; and (6) preparation of Annex XV dossiers for identification of high priority substances. The KKDIK guidance documents are similar to ECHA's guidance documents, and will be available only in Turkish.

Turkey's MoEU will host a seminar on KKDIK in Istanbul on **October 27, 2017**, to provide industry with detail on important issues under the new law. Approximately 200 industry representatives and other stakeholders are expected to attend the seminar, including local representatives of foreign

chemicals manufacturers. The seminar will feature presentations from officials to explain KKDIK requirements, implementation of the requirements, and who is responsible for compliance. The seminar will include Q&As, and will last approximately three hours.

UNITED ARAB EMIRATES (UAE)

UAE Implements Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Regulation: On April 28, 2017, the UAE's Emirates Authority for Standardization and Metrology (ESMA) enacted Regulation No. 10, "Prescribing Restrictions on the Use of Hazardous Materials in Electronic and Electrical Devices" (Arabic only). While not identical in scope to EU "Directive 2011/65/EU", many similarities exist between the two pieces of legislation. There are three significant deadlines for mandatory substance restrictions, as follows:

- **January 1, 2018**: Restrictions on lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment (EEE), other than equipment listed in Category 11;

- **January 1, 2020**: Restrictions on lead, mercury, cadmium, hexavalent chromium, PBB, and PBDE in medical devices, *in vitro* diagnostic medical devices, monitoring and control instruments, and industrial monitoring and control instruments and Category 11 products. In addition, there will be restrictions on di(2-ethylhexyl) phthalate (DEHP), n-butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP) in EEE; and

- **January 1, 2022**: Restrictions on lead, mercury, cadmium, hexavalent chromium, PBB and PBDE in cables and spare parts of medical devices, *in vitro*diagnostic medical devices, monitoring and control instruments, and industrial monitoring and control instruments. In addition, there will be restrictions of DEHP, BBP, DBP, and DIBP in medical devices, *in vitro* diagnostic medical devices, monitoring and control instruments, and industrial monitoring and control instruments -- including cables and spare parts.

The implementation of Regulation No. 10 has not been without concerns from industry. Perhaps chief among these is that the implementing guidelines released October 1, 2017, by ESMA appear to require full test reports as part of the registration process. Those entities which are end users and/or further removed from the source in the supply chain may potentially have difficulties with this aspect. Several industry trade groups are presently seeking clarification on the relevant section of the guidance -- Section D, Conformity Assessment -- as well as requesting that the **January 1, 2018**, implementation date be postponed for at least one year.

VIETNAM

Vietnam Publishes Decree Regarding New Chemical Law: On October 9, 2017, the Vietnam Chemicals Agency announced the availability of Decree No. 113/2017/ND-CP Specifying and Providing Guidelines for Implementation of Certain Articles of the Law on Chemicals. The new Law on Chemicals will replace the 2007 Chemical Law as implemented via Decree 108/2008/ND-CP. The Vietnam Chemicals Agency notified WTO on July 7, 2017, of a draft version of the Decree, and stated that it addressed:

- General requirements to ensure safety in producing and trading chemicals;

- Chemicals produced and traded with conditions for industry;
- Conditions of producing and trading industrial precursors;
- Restricted chemicals produced or traded in the industrial sector;
- Banned chemicals;
- Plans and measures for preventing and responding to chemical incidents;
- Safe distance for dangerous chemical facilities;
- Classification of chemicals and SDSs;
- Chemicals declaration; and
- Chemical safety training.

Decree No. 113/2017/ND-CP will take effect **November 25, 2017**.

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