Global Chemical Product Innovation and Development for March 12, 2019: Australia, Europe, South America & South Korea

Tuesday, March 12, 2019

ARGENTINA

Banned Pesticide Active Ingredient List Updated By Authority: The Administración Nacional de Drogas, Alimentos y Dispositivos Médicos (Argentinian National Administration of Drugs, Foods and Medical Devices; ANMAT) has compiled a list of banned active ingredients (AI) that are found in rodenticides, insecticides, fungicides, and related products. The list, which is not available on the ANMAT website, contains 86 discrete AIs, while a second list includes 14 AIs whose use is restricted in the country.

AUSTRALIA

OECD Publishes Third Environmental Performance Review Of Australia: On January 30, 2019, the Organization for Economic Cooperation and Development (OECD) published its third Environmental Performance Review of Australia. It evaluates progress towards sustainable development and green growth, and includes special features on threatened species protection and sustainable use of biodiversity and chemical management. The chapter on chemical management reviews Australia’s frameworks relating to chemical management, with a particular focus on industrial chemicals. It includes legislation and policies across all tiers of government, provides an overview of the main challenges associated with chemical management, and discusses strengths and weaknesses of the system. OECD notes that “[w]hile it is too soon to know the effects of state/territorial and Commonwealth legislative and policy reforms currently being developed, the chapter looks into how they may address gaps in the risk management system and what else could be done.”

Parliament Passes Industrial Chemicals Bill 2017: On February 14, 2019, the Senate passed an amended Industrial Chemicals Bill 2017. The House of Representatives approved the amendments on February 18, 2019. The Industrial Chemicals Bill, along with the Transitional Provisions and Amendment Bills, which have also been passed by both the Senate and the House, are currently awaiting Royal Assent by the Governor-General to become Australian law. According to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the most significant amendment to the Industrial Chemicals Bill was a change to obligations for introducers using the exempted category under the new scheme, the Australian Industrial Chemical Introduction Scheme (AICIS). The Bill was also amended so that AICIS will commence on July 1, 2020. The ban on the use of new animal test data for ingredients used solely in cosmetics will also begin on July 1, 2020. NICNAS expects the other bills relating to fees and charges for the new scheme to be considered by the Senate during the budget sittings in April 2019.
CHILE

**Congress Proposes Changes To Product Stewardship Regulation:** The lower house of Chilean legislature, the **Cámara de Diputados** (Chamber of Deputies) has introduced **Bill No. 12329**, which would modify the existing Recycling and Extended Producer Responsibility Law, No. 20.920. The Bill mandates certain “priority products” to have labels that contain product composition as well as information as to their recycling feasibility. The Bill is still early in its First Constitutional procedure, so it is unclear as to how it may develop during debate.

EUROPEAN UNION (EU)

**ECHA To Provide Accession Support To Serbia And Montenegro:** On January 24, 2019, the European Chemicals Agency (ECHA) issued a press release entitled “**More targeted capacity building for EU candidate countries.**” In its press release, ECHA indicates that it continues to support the accession process of EU candidate countries with capacity building through bilateral visits, specific trainings, and events. To increase the impact of these efforts, “an in-depth assessment of the status and needs of two candidate countries, Montenegro and Serbia, will be carried out between **2019** and **2021.**”

ECHA will run, between **March 2019** and **February 2021**, its fifth **Instrument for Pre-Accession Assistance (IPA)** project. IPAs are the “means by which the EU supports reforms in the ‘enlargement countries’ with financial and technical help.” The European Commission (EC) states “[t]he IPA funds build up the capacities of the countries throughout the accession process, resulting in progressive, positive developments in the region.”

ECHA provides that the fifth IPA project will enable information sharing and capacity building through participation in EU-level events, specific trainings, study visits to Member States and ECHA on regulatory issues, and translation of key documents. ECHA indicates that the overall aim is to equip candidate countries with the knowledge necessary to participate fully in the implementation of EU chemicals policy and, in particular, in the work of ECHA.

ECHA will carry out a detailed assessment of the legal and institutional capacities in Montenegro and Serbia -- the countries most advanced in the accession process -- as part of the project. ECHA indicates that the outcome will assist in identifying the more specific needs, and actions that will help improve the preparedness of these candidate countries.

**EC Announces Agreement To Add Five Chemicals To CMD:** On January 29, 2019, the EC **announced** that the European Parliament (EP), the EU Council, and the EC reached a provisional agreement on the EC’s third proposal to broaden the list of recognized cancer-causing chemicals in the workplace. Under the agreement, the following five chemicals will be added to the Carcinogens and Mutagens Directive (CMD):

- Cadmium and its inorganic compounds;
- Beryllium and inorganic beryllium compounds;
- Arsenic acid and its salts, as well as inorganic arsenic compounds;
- Formaldehyde; and
- 4,4’-Methylene-bis(2-chloroaniline) (MOCA).

According to the EC’s press release, the agreement will be submitted to the Council’s Permanent Representatives Committee for approval. Once the Member States’ Permanent Representatives confirm the agreement, it will be subject to a final vote by the plenary of the EP.

**BoA Rules ECHA Breached Right To Be Heard And Procedural Rules:** On January 29, 2019, ECHA’s Board of Appeal (BoA) issued its **decision in case number A-005-2017** related to the One Substance, One Registration (OSOR) principle, substance sameness, and the right to be heard. The Appellant in the case was Thor GmbH and the Intervener was Solvay Solutions UK Limited. As background to the dispute, the BoA’s decision provides that multiple registrations for tetrakis (hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea were submitted for the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation registration deadlines in 2010 and 2013, including a registration by Thor GmbH.

Following entry into force of **Implementing Regulation (EU) 2016/9 on Joint Submission of Data and Data-sharing in accordance with REACH (Implementing Regulation)**, which emphasizes the importance of the OSOR principle, Solvay Solutions UK Limited created a joint submission for the substance and submitted the lead registration dossier. Solvay Solutions UK Limited sent a letter to the members of the Substance Information Exchange Forum (SIEF), including Thor GmbH, in February 2016 inviting SIEF participants to become members of the joint...
Between May and December 2016, Thor GmbH and Solvay Solutions UK Limited exchanged communications regarding the boundary composition of the substance, classification and labeling, the price and conditions for purchase of a Letter of Access (LoA), and “the scope of the joint registration.” In February 2017, ECHA addressed a communication (i.e., Contested Decision) to all registrants for the substance in relation to the joint submission obligation. ECHA informed Thor GmbH in the Contested Decision “that the joint submission obligation has been breached, because separate registrations have been submitted for the same substance.” The Contested Decision requested all registrants of the substance to submit jointly information required by August 2017, and emphasized the importance of making every effort to find an agreement to register jointly.

Thor GmbH requested that the BoA:

- Revoke or annul the Contested Decision or alternatively order ECHA to act to that effect; and
- Order the refund of the appeal fee.

Thor GmbH argued that the BoA confirmed in its decision in case A-022-2013 (i.e., REAcCheck Solutions) that to comply with the information requirements of Annex VI, a registration dossier must identify a lead registrant, and that pursuant to REACH Article 20(2) ECHA is entitled to assess whether registrants have complied with this requirement. According to Thor GmbH, the Contested Decision was therefore a decision taken pursuant to REACH Article 20.

Thor GmbH adopted the position that decisions taken under REACH Article 20 are appealable to the BoA under REACH Article 91(1), irrespective of the fact that the Contested Decision was entitled a “communication.” Furthermore, Thor GmbH argued that Article 20(2) does not entitle ECHA to reassess the completeness of an existing registration dossier for which a registration number has already been assigned. Thor GmbH argued further that the “Contested Decision is not a preparatory measure and creates legal effects.” Thor GmbH referenced that the Contested Decision stated that if it did not join the joint submission or initiate a data sharing dispute, its registration would be revoked. The BoA found that the Contested Decision was equivalent to a decision adopted under REACH Article 20(2) as it provided that the joint submission obligation had been breached and set out the consequences for the breach. As decisions under Article 20(2) are appealable under Article 91(1), the appeal by Thor GmbH was deemed admissible.

Thor GmbH raised the following pleas in support of its appeal: (1) breach of the right to be heard; (2) breach of the principle of proportionality; (3) breach of the principle of good governance; and (4) breach of the procedural requirements set out in Articles 41, 50, and 51. Thor GmbH argued that its right to be heard was not respected by ECHA as it did not assess the “details of the underlying registration process and previous discussions within the SIEF,” and therefore Thor GmbH was unable to explain to ECHA that it had registered the substance as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB) in 2013 following discussions on substance identity. Thor GmbH argued further that as the joint submission was created in February 2016, it could not have joined the submission when it submitted its registration. Thor GmbH raised further arguments pertaining to ECHA’s lack of consideration of discussions between it and Solvay Solutions UK Limited, and “the fact that the substances registered by them are not the same.”

The BoA decided that by failing to follow the procedures in REACH Article 20 or 41, ECHA breached Thor GmbH’s procedural rights, in particular the right to be heard and the right to appeal. The BoA considered the outcome of the procedure could have been different without this irregularity, and ordered that the Contested Decision be annulled, the case be remitted back to ECHA for further action under Article 20 or 41, and that the appeal fee be refunded.

**ECHA Proposes To Restrict Intentionally Added Microplastics:** On January 30, 2019, ECHA issued a press release entitled “ECHA proposes to restrict intentionally added microplastics.” In its press release, ECHA provides that it has submitted a restriction proposal for microplastic particles that are intentionally added to mixtures used by consumers or professionals. ECHA indicates that, if adopted, the restriction could reduce the amount of microplastics released to the environment in the EU by approximately 400,000 metric tons over 20 years.

ECHA assessed the health and environmental risks posed by intentionally added microplastics, and concluded that “an EU-wide restriction would be justified.” ECHA’s assessment found that intentionally added microplastics are most likely to accumulate in terrestrial environments, as the particles concentrate in sewage sludge that is frequently applied as fertilizer. ECHA observed that a “much smaller proportion of these microplastics is released directly to the aquatic environment.”

In its press release, ECHA provides that the “persistence and the potential for adverse effects or
bioaccumulation of microplastics is a cause for concern ... Once released, they can be extremely persistent in the environment, lasting thousands of years, and practically impossible to remove ... Currently it is not possible to determine the impact of such long-term exposure on the environment.” ECHA indicates further that data available on effects of microplastics are limited, particularly for the terrestrial environment, “which makes risk assessment difficult.”

ECHA states “[o]verall, the use of microplastics in products that result in release to the environment [is] not adequately controlled.” ECHA’s proposed restriction targets “intentionally added microplastics in products from which they will inevitably be released to the environment.” The restriction scope covers a wide range of uses in consumer and professional products in multiple sectors, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medicinal products, and various products used in the agriculture, horticulture, and oil and gas sectors.

ECHA assessed the socio-economic impact of the proposed restriction, and “is aware that the restriction is likely to result in different costs depending on the type of product affected.” Importantly, ECHA indicates that implementing the restriction is expected to be cost-effective in all sectors, including the agricultural sector, which is identified in the proposal as the biggest source of intentionally added microplastics.

Additional information is available in the Annex XV Restriction Report, and related Annex.

**ECHA Provides Information To Assist Companies In Managing Brexit:** On February 8, 2019, ECHA issued a press release entitled “Act now to stay on the EU market after the UK’s withdrawal.” In its press release, ECHA states that all companies placing chemical substances “onto the markets of the [EU] and [European Economic Area (EEA)]” need to prepare for the United Kingdom’s (UK) withdrawal from the EU. ECHA recommends in the press release that companies prepare for a “no deal” scenario ahead of the UK’s withdrawal at the end of March 2019.

Due to “continued political uncertainty regarding the withdrawal agreement,” ECHA urges companies to “act now” to continue complying with their obligations under the REACH regulation, the Classification, Labelling, and Packaging (CLP) regulation, the Prior Informed Consent (PIC) regulation, and the Biocidal Products Regulation (BPR).

ECHA indicates in the press release that, to keep substances that are registered under REACH legally on the EU-27/EEA market, “UK-based manufacturers and formulators can either transfer their business to, or appoint an [Only Representative (OR)] in, one of the EU-27/EEA countries.” ECHA advises that subject to further developments it will open a “Brexit window” in REACH-IT from March 12-29, 2019, to enable UK-based companies to make changes and transfer registrations. ECHA indicates that if an OR is not appointed by UK-based companies, the EU-27/EEA importers “will have to submit their own registrations.”

ECHA advises that step-by-step instructions for using the Brexit window are available on ECHA’s webpages for the UK’s withdrawal from the EU. ECHA states that companies in the EU-27/EEA will need to prepare for placing substances on the UK market following Brexit, and indicates that the UK’s Health and Safety Executive (HSE) has published guidance in this regard. Further information is available in the List of Substances Registered Only by UK Companies, ECHA’s guidance document entitled “How to transfer your UK REACH registrations prior to the UK withdrawal from the EU,” and ECHA’s Questions and Answers for Companies.

**EC Begins Public Consultation On Evaluation Of FCMs:** The EC began a public consultation on February 11, 2019, on the evaluation of food contact materials (FCM). The purpose of the evaluation is to assess whether the current EU legislative framework for FCMs is fit for purpose and delivers as expected. The evaluation covers the functioning of Regulation (EC) No 1935/2004 (Regulation) in its entirety and the rules and tools provided for by the legislation, such as specific implementing measures. It also examines the situation concerning materials for which there are no EU measures and which are subject to permitted national measures. The consultation targets all stakeholders groups with an interest in the FCM legislation, including:

- The general public;
- All businesses at any stage of the FCM supply chain and their European or national representatives;
- Non-governmental associations and consumer organizations; and
- Public authorities, including public enforcement laboratory and regional/local enforcement offices.

**ECHA Issues Updated Formats For Authorization Applications And Review Reports:** On February 13, 2019, ECHA issued a press release entitled “Clearer requirements for applications for authorisation.” In its press release, ECHA indicates that updated formats for applications for authorization and review reports are available on its [website](http://echa.europa.eu). ECHA states the updated formats are compatible with the updated opinion format of ECHA's scientific committees, and instruct applicants on how to present their analysis of alternatives and socio-economic analysis when applying for continuing the use of a substance of very high concern (SVHC). The updated formats, which cover exposure scenarios of the chemical safety report, will become mandatory for authorization applications and review reports starting **June 1, 2019**.

ECHA advises that, during a transitional period until **May 31, 2019**, applicants should still use the earlier formats for applications and review reports to be submitted within the February and **May** submission windows. ECHA recommends that applicants familiarize themselves with the new formats as soon as possible and include, if feasible, specific sections (e.g., summary tables) in their applications.

ECHA states that the latest application date for ethoxylated octyl and nonylphenols is **July 4, 2019**. To facilitate the use of the new format for applications concerning these two substances, ECHA will “exceptionally add an additional submission window” running from **June 20 - July 4, 2019**. In conclusion to its press release, ECHA states “[t]he updated formats aim to improve the transparency and efficiency of the application process and to speed up the decision making on applications for [authorization] and review reports.”

**REACH Committee Rejects Proposed Authorization For Sodium Dichromate:** On February 15, 2019, the EC announced that the REACH Committee agreed to the EC’s proposals to reduce further workers' exposure to two SVHCs, following recommendations by ECHA. The EC states that the decision will oblige companies that have applied to use chromium trioxide, an SVHC due to its carcinogenic properties, to implement strict risk management procedures for various uses of the substance in the automotive, aerospace, and other sectors. It also provides a maximum of seven years for companies to reassess the availability of safer alternatives or substitute the substance earlier when possible. The REACH Committee also followed the EC’s proposal to, “for the first time ever,” reject the authorization for the continued use of sodium dichromate, an also potentially carcinogenic substance by a company using it for treatment of micro-surgical instruments. According to the press release, the EC “is due to adopt the above mentioned decisions in the coming weeks.”

**EC Notifies WTO Of Draft Regulation Adding 12 SVHCs To The Authorization List:** On February 15, 2019, the EC notified the World Trade Organization (WTO) of a draft regulation that would amend REACH Annex XIV to add the following 12 SVHCs:

- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear;
- Dihexyl phthalate;
- 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate;
- Trixylyl phosphate;
- Sodium perborate, perboric acid, sodium salt;
- Sodium peroxy metametaborate;
- 5-Sec-butyl-2-(2H-benzotriazol-2-yl)-4,6-diterpentylphenol (UV-328);
- 2,4-Di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327);
- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350);
- 2-Benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320); and
- Diazene-1,2-dicarboxamide (C,C"-azodi(formamide)) (ADCA).

The proposed date of adoption is **October 2019**.

**OECD QSAR Toolbox Includes REACH 2018 Registration Data:** ECHA announced on February 18, 2019, that...
EC Publishes Report On Implementation Of Circular Economy Action Plan And Strategy For Plastics In A Circular Economy: On March 4, 2019, the EC published a comprehensive report on the implementation of the Circular Economy Action Plan adopted in December 2015. According to the EC’s press release, the report “presents the main results of implementing the action plan and sketches out open challenges to paving the way towards a climate-neutral, competitive circular economy where pressure on natural and freshwater resources as well as ecosystems is minimised.” The EC discussed the findings of the report during the annual Circular Economy Stakeholder Conference held March 6-7, 2019. The EC states that the Circular Economy Action Plan can be considered fully completed. Its 54 actions have now been delivered or are being implemented. According to the findings of the report, implementing the Circular Economy Action Plan has accelerated the transition towards a circular economy in Europe, which in turn helped put the EU back on a path of job creation. In 2016, sectors relevant to the circular economy employed more than four million workers, a six percent increase compared to
2012. Circularity has also opened up new business opportunities, given rise to new business models and developed new markets, domestically and outside the EU. In 2016, circular activities such as repair, reuse or recycling generated almost €147 billion in value added while accounting for around €17.5 billion worth of investments.

The EC also published on March 4, 2019, the EU strategy for plastics in a circular economy, “the first EU-wide policy framework adopting a material-specific lifecycle approach to integrate circular design, use, reuse and recycling activities into plastics value chains.” The strategy sets out a clear vision with quantified objectives at EU level, so that inter alia by 2030 all plastic packaging placed on the EU market is reusable or recyclable. To boost the market for recycled plastics, the EC launched a voluntary pledging campaign on recycled plastics. According to the EC, 70 companies have already made pledges, which will increase the market for recycled plastics by at least 60 percent by 2025. The EC notes that there is still a gap between supply and demand for recycled plastics, however. To close this gap, the EC launched the Circular Plastics Alliance of key industry stakeholders supplying and using recycled plastics.

The EC states that much is still needed to scale up action at the EU level and globally to close the loop and secure the competitive advantage a circular economy brings to EU businesses. Increased efforts will be needed to implement the revised waste legislation and develop markets for secondary raw materials. Also, the work started at EU level on some issues (like chemicals, the non-toxic environment, eco-labeling and eco-innovation, critical raw materials, and fertilizers) needs to be accelerated if Europe wants to reap the full benefit of a transition to a circular economy. According to the EC, interaction with stakeholders suggests that some areas not yet covered by the action plan could be investigated to complete the circular agenda. Building on the example of the European Strategy for Plastics in a Circular Economy, many other sectors with high environmental impact and potential for circularity such as IT, electronics, mobility, the built environment, mining, furniture, food and drinks, or textiles could benefit from a “similar holistic approach to become more circular.”

**OECD**

**OECD Publishes Report On Substitution Of Hazardous Chemicals:** On January 30, 2019, OECD published a Synthesis Report: OECD Workshop on Approaches to Support Substitution and Alternatives Assessment. The OECD Ad Hoc Group on Substitution of Harmful Chemicals held an expert workshop on “Approaches to Support Substitution and Alternatives Assessment” in May 2018. The goal of the workshop was to exchange experiences on policy, regulatory, and other approaches used to support alternatives assessment and the substitution of chemicals of concern. The workshop covered the following topics:

- Approaches that have been used to support alternative assessments and substitution;
- The strengths of the approaches and challenges to design and implementation, and how these challenges have been overcome;
- Linking innovation, in particular in science and technology, and progress in substitution and alternatives assessment;
- How innovation policy is helping to further develop the field; and
- How can countries and other entities work together to facilitate data sharing and other collaborative efforts, such as sharing the results of alternatives assessments.

The workshop also included updates on the OECD Substitution and Alternatives Assessment Toolbox and discussions on ideas for further development. The workshop was the second in a series of workshops organized by the OECD on substitution and alternatives assessment. The first workshop was organized in May 2015. One of the conclusions from the 2015 workshop was the need for countries to learn from each other and share information on policy, regulatory, and other approaches used to support substitution. The OECD Ad Hoc Group conducted a Cross Country Analysis collecting information directly from countries and stakeholders through a survey. OECD used information collected from the survey as background material to prepare for the May 2018 workshop. OECD states that it will publish the results from the survey, with added information from the 2018 workshop, in a separate report. The report summarizes the main conclusions from the workshop.

**SOUTH KOREA**

**MoE Publishes K-BPR Implementation Plan:** South Korea’s Ministry of Environment (MoE) has published its implementation plan for the Consumer Chemical Products and Biocides Safety Act (K-BPR). K-BPR entered into force on January 1, 2019, and regulates consumer chemical products, biocidal products, and biocide-treated articles. There are currently almost 3,000 existing biocidal substances in South Korea that are used in consumer...
products, and these existing biocidal substances are subject to a registration grace period until 2030. MoE intends to offer incentives to companies for early registration of these substances.

MoE issued an announcement in Korean on January 31, 2019, outlining:

- Plans to collect toxicity information on biocidal substances to support registration;
- Efforts to support industry;
- Labeling rules for biocidal products; and
- Plans to introduce a chemical monitoring system.

MoE will introduce a pilot scheme for selected manufacturers in December 2019. This pilot scheme will support the complete K-BPR approval process for the most widely manufactured biocidal substances. MoE will also commence risk assessments in 2019 for sterilizers, insecticides, and repellents. If the products are considered to represent a high level of risk, they will be banned from sale. Furthermore, any substance considered to represent a high risk will be banned from use in children’s products.

Beginning in 2020, MoE plans to introduce safety standard markings and safe-use information pictograms that would apply to all biocidal products. In 2019, MoE intends to introduce a chemical substance checking and reporting system, which will assign identification numbers to substances to facilitate tracking through the supply chain in the context of manufacturing, importation, transportation, and use.

**UNITED KINGDOM (UK)**

**UK Parliamentary Committee Launches Inquiry Into Impact Of Toxic Chemicals In Everyday Life:** On February 12, 2019, Parliament’s Environmental Audit Committee launched an inquiry into the impact of toxic chemicals in everyday life on human health and the environment. The inquiry will focus on how toxic chemicals are used in products such as furniture, food, and toys; current government regulation of these substances; and the environmental and human health problems associated with them. The Committee requests written evidence on the following points:

**Why Toxic Chemicals Are Used**

1. Why are toxic chemicals used in consumer products? What benefit do they offer? How are levels of toxicity measured?

2. What new technologies and materials are being developed to reduce the use of toxic chemicals? Are they widely available and affordable for producers?

**Health Risks**

3. Which toxic chemicals pose a significant risk to human health? How pervasive is the risk? Who is most at risk? How do producers make consumers aware of health risks identified in their products?

4. How does the government measure the health risks of toxic chemicals? What actions does the government take to limit consumers’ exposure to toxic chemicals? Should maximum residue limits (MRL) be applied to toxic chemicals in consumer products? Are current trading standards sufficient to monitor toxic chemicals in consumer products (e.g., children’s toys) and food?

**Environmental Concerns**

5. What is the environmental risk from toxic chemicals? As part of its commitment in the 25 Year Environment Plan, what measures is the government taking to reduce harmful chemicals in the environment? Will these measures be effective?

6. How are flame retardant treated products currently disposed of and what problems have been identified with these methods of disposal? What is international best practice for disposal?

7. Is current legislation on producer responsibility and management of waste sufficient for recyclers to identify toxic chemicals in products? Should materials treated with flame retardants be available for use as recycled material in consumer products?

**UK Policy**
8. Are the Furniture and Furnishings (Fire Safety) Regulations 1988 (as amended in 1989, 1993 and 2010) fit for purpose? If not, which aspects should be updated?

9. Does the government’s plan to target £9bn in savings through regulation by 2022 pose risks for chemical regulation?

10. What risks or opportunities does Britain exiting the EU pose to regulation and import of these chemical substances or products containing these substances? What is the likely status of the UK’s continued participation in the RAPEX system in the event of Britain leaving the EU?

11. How should SVHCs be regulated after the UK leaves the EU? How should the government manage risk from newly identified toxic chemicals after the UK has left the EU?

12. What steps can the Foreign and Commonwealth Office take to influence other countries to reduce the manufacturing and improve control of toxic chemicals in consumer products?

Comments were due March 8, 2019.

**CBA Survey Highlights Industry Concerns Regarding UK REACH:** On February 18, 2019, the Chemical Business Association (CBA) issued a press release entitled “CBA Survey Confirms Industry’s Concerns About UK REACH Post-Brexit.” In its press release, CBA indicates that a survey of the UK’s chemical supply chain revealed that “three-quarters of companies do not own the testing data for registrations they currently hold under [EU REACH].” CBA states “[t]his fact confirms the industry’s worst fears and creates a major impediment to the Government’s plans to transpose EU REACH into UK law following Brexit.”

The online survey, conducted from February 6-15, 2019, “covered 38 key companies in the UK chemical supply chain that currently hold 351 registrations under EU REACH.” In its press release, CBA states that it has “repeatedly told Ministers, Select Committees, and officials that UK companies do not own or have access to the testing data necessary [to] support the registration of substances under UK REACH ... They pay a fee to its owner for [LoAs] enabling the company to rely on the data set held by [ECHA].”

CBA Chief Executive, Peter Newport, stated:

It is not a simple proposition, as the Government assumes, for UK companies to access this testing data. It is a commercial decision for its owners -- generally consortia of European companies -- not by ECHA or by UK business.

This fact renders the Government’s current proposals unworkable, it represents a potentially massive hike in the industry’s compliance costs, it weakens its competitiveness, as well as raising the issue of additional animal testing.

CBA indicates that over half of the member companies replying to the survey held registrations in the “1 – 10 annual tonnage band indicating they [specialize] in distributing low volume, high value, chemical substances critical to UK manufacturing businesses.” Approximately 29 percent of respondents were currently in discussions with data owners regarding use of data under UK REACH, but only eight percent of respondents had agreed a fee for this purpose. The survey also indicated that “for over 30 [percent] of substances the fee demanded by the data holder will exceed the administrative costs of supplying it.”

The 38 companies that responded to the survey plan to perform 326 registrations under UK REACH, and indicated “they are considering notifying a further 1266 registrations as an importer from the EU27 countries.” In conclusion, CBA’s press release states that the survey highlights the need for the UK Government to revisit its plans for UK REACH which involve a number of intractable issues “concerning access to testing data, a double-whammy on compliance costs, increased animal testing, and misgivings about its long-term sustainability.” CBA emphasizes the importance of “frictionless access to the EU market” for UK companies, and suggests the only way for this to be achieved is through “Associate Membership” of ECHA or some arrangement guaranteeing “regulatory compliance with the EU regime and allowing continued access to European markets -- even in the case of a No Deal Brexit.”

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