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Forecast for U.S. Federal and International Chemical Regulatory Policy 2019: Chemical Management EU and Brexit

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II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. EUROPEAN UNION (EU)

1. Chemical Substance Management in the EU

1.1 Introduction

Chemical substance management in the EU in 2019 will be a mix of new and ongoing activities. The EU faces unprecedented challenges in the form of the UK's decision to leave the EU (Brexit), possibly without an agreement between the UK and EU. The UK's transition to its own chemical substance management system is expected to be a major development in 2019. Ongoing compliance and enforcement challenges are expected to continue under REACH and the Biocidal Products Regulation (BPR). Updates to the EU's Classification, Labeling and Packaging (CLP) regulation, evaluation of EU food contact materials (FCM) legislation, and implementation of the criteria for identification of endocrine disruptors recently adopted by the European Commission (EC) will impact the management of chemical substances in 2019 and beyond.

B. BREXIT

On June 23, 2016, more than 30 million people voted in a referendum to decide whether the UK should remain in, or depart from, the EU. The "Leave Campaign" won the referendum by 52 percent to 48 percent, and since then "Brexit" has become an important matter globally with a wide range of stakeholders. Since the referendum in 2016, there have been numerous Brexit-related political and legal developments, including issuance of a Draft Withdrawal Agreement (DWA) and Political Declaration Outline. These documents, issued on November 14, 2018, can be regarded as the only substantive result of UK-EU negotiations to date -- and quite possibly represent the only basis for a Brexit outcome other than a "hard," "no deal," or "disorganized" exit. Critically, for the DWA to hold legal relevance, it requires approval from UK and EU Parliaments.

UK Prime Minister Theresa May delayed a House of Commons vote on the DWA scheduled for December 11, 2018, amidst concerns regarding being unable to obtain required support from Members of Parliament (MP). Mrs. May survived a Conservative party "no-confidence vote" in her leadership, and is in discussions with EU representatives to amend the DWA to achieve support from UK MPs. Among the key issues for discussion is the Irish "backstop." Mrs. May has indicated, to the Labor Party's frustration, that the UK's House of Commons will vote on the DWA during the week of **January 14, 2019**. The Labor party contends this is an unnecessary delay, and other UK political parties are urging Jeremy Corbyn to push for a no-confidence vote against Mrs. May's government as a whole, in contrast to the no-confidence vote mentioned above, which focused on Mrs. May. The

upcoming “meaningful vote” will play a critical role in determining the UK’s next Brexit steps. Meanwhile, the European Court of Justice has ruled that the UK can cancel Brexit without permission of the EU-27.

For many interested parties, the DWA represents a favorable practical Brexit process due to its transition period until **December 31, 2020**, and related EU-UK cooperation. If the DWA receives approval in the UK, it will be considered by the European Parliament (EP). It is far from certain that UK MPs will support Mrs. May’s proposed DWA. If the DWA does not obtain required support in the House of Commons, the default position would be for a “no-deal Brexit” to occur on **March 29, 2019**, which would raise a range of political and legal issues including an extension of the two-year timeframe under Article 50 of the Lisbon Treaty, changes in UK leadership, and further EU-UK negotiations. Much to “Brexiteers’” disbelief, an additional UK referendum on Brexit has also been suggested.

The Commons vote scheduled to occur in January 2019 is a critical Brexit moment. European approval and a full transition period are considered highly likely if the House of Commons votes in favor of the DWA, but the chances of this occurring are uncertain and a no-deal Brexit in **March 2019** is entirely possible. If the House of Commons does not support the DWA, the UK and entities globally face further Brexit-related uncertainty, as well as ongoing and significant political tensions in the UK. The good news is that we are quickly approaching **March 2019**, and it is expected that industry will understand better the Brexit process by this time, including its mechanics and timing.

Brexit has numerous potential consequences for chemical regulatory compliance and product stewardship in the EU and UK. Personnel addressing compliance or marketing products are well advised to review regularly information made available by ECHA and the UK’s Health and Safety Executive (HSE). It is anticipated that **early** to **mid-2019**will provide much meaningful information for the chemicals industry.

As expected, the UK has already signaled that it will oversee a robust regulatory framework for the management of chemicals post-Brexit. Chemical companies with interests in the UK market should follow developments in 2019 regarding the UK’s potential future chemical regulatory frameworks. Based on their corporate interests, companies may also wish to engage in advocacy or stakeholder discussions regarding potential future UK legislation (*e.g.*, UK REACH Regulation).

The DWA does not include measures that mitigate the regulatory impact of the UK becoming a “non-Community” or “third” country in the context of EU regulations, including REACH. Therefore, it appears, that the following Brexit-driven practical changes will occur, among many others, either on **March 29, 2019**, or at the end of the applicable transition period:

- UK chemical manufacturers become non-Community manufacturers, and are required to appoint EU-27 based Only Representatives (OR) if they wish to address REACH compliance for their EU-27 based customers;
- Exclusively UK-based ORs are considered outside the scope of REACH, and can no longer provide OR services from the UK; and
- UK-based Downstream Users under REACH are no longer required to inform UK- or EU-27-based suppliers of their uses.

In addition to REACH, Brexit has a range of potential consequences under many regulations including the BPR, the CLP Regulation, and the Prior Informed Consent (PIC) Regulation.

UK chemical manufacturers selling to the EU-27 market, EU-27 chemical manufacturers selling to the UK market, and chemical manufacturers established outside the UK and the EU-27 and engaged in either market must understand the impacts of the DWA for their businesses, and prepare to adapt accordingly and for a no-deal exit in **March 2019**. Preparing for both scenarios appears essential to support ongoing market access and business prosperity. A no-deal scenario, in particular, could raise significant challenges and have negative consequences for unprepared supply chains.

Chemical companies can benefit from monitoring diligently Brexit-related developments in 2019, and performing the following tasks to prepare their businesses for Brexit:

- Determine if legal entities addressing compliance are established in the UK or EU-27, and transfer operations to an EU-27 entity if required;
- Evaluate and re-negotiate contracts affected by Brexit; and
- Request confirmations from supply chain actors to document that Brexit-related measures are in place.

Brexit has attracted unparalleled levels of attention globally due to its significance and potential for worldwide impact on supply chains and financial markets. Good planning and sound regulatory and legal support are essential to managing the potential implications of Brexit and chemical companies addressing EU and UK

compliance that have a busy year ahead. The chemicals industry can benefit significantly from proactive and strategic planning to protect businesses from the potentially damaging consequences of Brexit on important issues such as market access and legality of sales.

With offices in the U.S., the UK, Europe, and China, The Acta Group (Acta®) offers expertise with regulatory programs and chemical product approvals in North America, Europe, South and Central America, Asia, the Middle East, and the Pacific Rim. Acta is the consulting affiliate of B&C, established to complement B&C's legal services by providing a full-range of global support for our clients' products from concept to approval, so they get to market quickly and efficiently, and stay there when challenged by a new issue or set of rules.

1. Biocides

The EU's BPR, which repealed and replaced the Biocidal Products Directive (BPD) on September 1, 2013, covers the "placing on the market" and use of biocidal products for the protection of humans, animals, materials, or articles against harmful organisms (*e.g.*, pests). BPR is intended to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. BPR promotes the reduction of animal testing by providing mandatory data sharing obligations and encouraging the use of alternative testing methods.

In the recent past, there have been several important developments in the European biocides space. These include approvals for biocidal products, determinations of ECHA's Biocidal Products Committee (BPC), activities of the Enforcement Forum's BPR Subgroup (BPRS), implementation under BPR of the scientific criteria for the determination of endocrine-disrupting properties, and of course, numerous Brexit-related matters. It is expected these recent matters will influence decision-making and drive many activities under BPR in 2019.

From a legal standpoint, perhaps the most interesting of these developments is the implementation of the criteria for endocrine-disrupting properties under BPR. As such criteria have not yet been applied in other important chemical regulatory sectors, many regard BPR as the proving ground for such criteria. Commission Delegated Regulation (EU) 2017/2100 provides the legal text for the endocrine disruptor criteria, and Member State Competent Authorities have issued agreed upon notes on how to apply the criteria.

Among the legal issues raised by the criteria, guidance, and notes is whether the criteria can be applied to biocidal product components other than the active substance. BPR indicates that the criteria on endocrine-disrupting properties are relevant in the context of exclusion of biocidal active substances. Supporting documents for the legal criteria paint a different picture, suggesting that non-active co-formulants within a biocidal product may lead to a conclusion that a biocidal product has endocrine-disrupting properties. It can be reasonably expected that, in due course, there will be challenges and clarification in this regard.

Further concerns raised by the endocrine disruptor criteria and supporting documents include application of the criteria to active substances that are still under review. To such substances, the complete criteria apply with immediate effect. Industry has already seen ECHA's BPC to support approval of an active substance, but sent the dossier back to the evaluating Member State to assess whether the substance meets the criteria. New data may need to be developed and submitted for purposes of the criteria, and companies need to prepare for these circumstances. The criteria represent an important measure in terms of biocidal product safety, but raise a number of questions at this late stage in the BPR timeline. Application of the criteria at this stage evidently threatens the goal of completing examinations by **2024**.

It is clear that the biocides sector has an interesting and challenging year ahead. As companies seek to bring biocidal products to market, it is expected the endocrine disruptor criteria will attract substantial attention and cause significant delays. As the criteria are progressively applied to cases, it can be expected there will be questions on, and additional supporting documentation regarding, the criteria. The BPR data sharing and compensation rules, which are similar to yet distinct from the REACH rules, are expected to continue to attract attention in 2019. Data sharing is typically contentious under chemical regulatory regimes, and BPR is no exception. The longstanding and much discussed requirements of fairness, transparency, and non-discrimination are expected to keep regulatory personnel busy this year as companies engage in mandatory data sharing. Many data sharing agreements will likely be exchanged, and it is expected that binding arbitrations and referrals of data sharing disputes to ECHA will also continue in 2019.

There are many deadlines in 2019 under BPR. These include deadlines for notification to ECHA to include substances in the Review Program, and deadlines for Union Authorization applications. Substances with deadlines in 2019 for Union Authorization applications include margosa extract, propan-1-ol, and imiprothrin. The BPC has a busy Work Program in 2019, and many companies globally with relevant product portfolios will likely follow closely regulatory consideration of their active substances.

Although enforcement of BPR is in the sole competence of Member States, BPRS plays an important role in

coordinating strategies and joint inspections. The main priority of BPRS is to coordinate enforcement projects on BPR issues in Member States. In 2019, BPRS will launch a coordinated enforcement project dedicated solely to BPR requirements regarding treated articles (BEF-1). BEF-1 aims at covering the full supply chain making treated articles available on the market. BEF-1 will be executed in 2019, and a report will be published in **2020**. BEF-1 will include broad participation from Member States, and is an important project because, to date, there is limited experience on specific enforcement of duties related to treated articles. Companies engaged in European commerce for treated articles are well advised to review and improve their compliance strategies to avoid unpleasant surprises this year under BEF-1.

Companies placing biocidal products on UK and EU-27 markets should follow closely Brexit-related developments and update compliance strategies as needed. As of the date of this writing, a DWA has been agreed between the UK and EU. To hold legal relevance, the document requires approval from the UK and EP. It is not certain that the DWA will receive required approvals, and this means a "no-deal" or "disorderly" Brexit is possible. Companies with interests in EU-27 and UK markets face the challenge of preparing appropriately for multiple potential Brexit outcomes and implementing plans timely. As reported extensively, among other changes, upon Brexit:

- UK-based biocidal product authorization holders will be considered outside the scope of EU BPR;
- EU-27 Member States will no longer be able to issue a national BPR authorization based on recognition of a UK authorization; and
- The UK will no longer act as an evaluating Competent Authority under BPR.

Based on the wide array of ongoing issues in the biocides arena, it is clear that companies' technical, scientific, regulatory, and legal personnel have vital roles to play this year. Coordinated and well-informed regulatory approaches, and assistance from external specialists as required, can assist entities in the biocides sector to achieve their compliance and business goals in 2019.

2. Classification and Labeling Initiatives

In January of 2009, Regulation (EC) No 1272/2008 of the Classification, Labelling and Packaging (CLP) of Substances and Mixtures came into force. CLP aims to harmonize several elements of hazard communication, and to ensure consistent communication of those hazards to the workers and consumers within the EU Member States. CLP repealed Directives 67/548/EEC and 1999/45/EC and amended Regulation (EC) 1907/2006. CLP is originally based on a combination of Revision 3 and Revision 4 of GHS. The eighth adaptation to technical progress (ATP) notes that CLP was reviewed against Revision 5 of the UN model and updated accordingly. In 2019, it is likely that the twelfth ATP will be published and adopted. It will align CLP to Revision 6 and Revision 7 of the GHS.

CLP contains, in Annex VI, substance-specific required classification and labeling. These substance level classifications can include specific concentration limits triggering the required classification when used in mixtures. CLP also includes supplemental hazards (*i.e.,* EU Specific Hazard (EUH) statements) and specific notes for consideration for classification of substances. CLP updates and amendments occur about once or twice annually. The thirteenth ATP was adopted on October 4, 2018, published in the EU *Official Journal*, entered into force on November 9, 2018, and shall apply beginning **May 1, 2020**. It amends CLP by adding the ECHA Risk Assessment Committee's (RAC) 2017 opinions on harmonized classification of several substances to Annex VI. The ATP includes 18 updates to existing entries and 16 new entries. In 2019, manufacturers and importers will need to review these changes to determine if any of the new or revised entries are present, and if the changes result in amended classifications. If a change in the classification is noted, safety data sheets (SDS) and labels will require updates as specified in the regulation.

3. Food Contact Materials

FCMs in the EU must comply with the Framework Regulation EC No. 1935/2004 and Good Manufacturing Practice EC No. 2023/2006. The general requirements are that the FCM must not release constituents into food at levels that are harmful to human health or change the organoleptic properties of food. There is no requirement for FCMs to be reviewed, monitored, or approved at the EC level at this time. The Framework Regulation includes, in Annex I, specific measures on materials. Currently, there is legislation that relates to specific materials (*i.e.,* plastics, recycled plastics, regenerated cellulose, ceramics, and active and intelligent materials). There is no material-specific legislation at the EU level for inks, coatings, paper and paperboard, rubber, and adhesives. There are substance-specific measures for vinyl chloride monomer, specific bisphenol-A based epoxy resins, nitrosamines, and n-nitrosables.

On September 24, 2018, DG SANTÉ of the EC organized an introductory workshop to commence the official start of the evaluation of EU FCM legislation. The EC, with the support of an external contractor, will collect data, analyze the findings, and issue a report by **September 2019**.

The consultation involves targeted interviews with stakeholders, focus group discussions, and an open public consultation. On the basis of the findings and analysis of the consultation, the EC will determine how it will revise the regulatory framework for the European FCM sector.

Those interested in commenting on the Framework's effectiveness and perhaps shaping the legislative process should look for opportunities during the open public consultation periods expected from December of 2018 until **February of 2019**. B&C will soon be releasing a podcast on EU FCM Legislation as part of its "All Things Chemical™" series available on iTunes, Spotify, Stitcher, and Google Play Music. Stay tuned!

4. SVHC/Restrictions/Authorizations

Substances of Very High Concern (SVHC) are those that fulfil one or more of the criteria defined in Article 57 of the REACH Regulation. Substances meeting the definition of a SVHC are those:

- Meeting the criteria for classification as carcinogenic, mutagenic, or reprotoxic (CMR), category 1 or 2;
- Considered PBT or very persistent and very bioaccumulative (vPvB); or
- For which there is an equivalent level of concern, for example endocrine disruptors and sensitizers.

The candidate list for authorization, or SVHC list, was first published in October 2008, but is updated regularly. The most recent update occurred in June 2018 when ten new substances were added, taking the total number of substances on the SVHC list to 191. In 2018, a total of 17 substances were added to the SVHC list. A list of the substances included on the SVHC list can be found at https://echa.europa.eu/candidate-list-table.

ECHA regularly assesses the SVHC list to decide which substances should be added to REACH Annex XIV, or the Authorization list, as a priority. This is primarily based upon information within the registration dossier, for example on uses and volumes. There are currently 43 substances listed on the Authorization list, no new substances were added in 2018. A list of the substances included on the Authorization list can be found at https://echa.europa.eu/authorisation-list. Four of the substances listed on the Authorization list, Dichromium tris(chromate (EC Number 246-356-2), Strontium chromate (EC Number 232-142-6), Potassium hydroxyoctaoxodizincatedichromate (EC Number 234-329-8), and Pentazinc chromate octahydroxide (EC Number 256-418-0), have their sunset date on **January 22, 2019**.

The ECHA SVHC Roadmap to **2020** gives an EU-wide commitment for having all relevant known SVHC included in the Authorization list by **2020** and outlines how ECHA intends to achieve this objective. The following groups of substances are to be covered by the implementation plan:

- CMRs (Categories 1A/1B);
- Sensitizers;
- PBTs or vPvBs;
- Endocrine disruptors; and
- Petroleum/coal stream substances that are CMRs or PBTs.

Each year, ECHA publishes a report on the progress of implementing the SVHC Roadmap. These reports summarize the achievements and activities carried out the previous year and set out the activities planned for the following year. The 2018 report is not yet available.

ECHA released on Decembers 14, 2018, its Strategic Plan for 2019**-2023**, in which it lays out its strategic outlook for managing chemicals in the years ahead.

Although there is no direct link between the Community Rolling Action Plan (CoRAP) and the authorization and restriction process, inclusion in the CoRAP means that a substance's potential risk is going to be evaluated by a Member State. Hence, a follow up may be that the Member State wishes to begin the authorization process. The draft CoRAP for 2019 **- 2021** currently contains 100 substances, four of which were added late in 2018. These will be evaluated by Member States in 2019, **2020**, and **2021**. It is planned that 31 of these will be evaluated in 2019, but the final plan will not be released until **March 2019**.

5. Post-2018 REACH

May 31, 2018, closed the last registration window for phase-in substances subject to registration in accordance with REACH. On June 1, 2018, ECHA issued a press release entitled "21,551 chemicals on EU market now registered." In its press release, ECHA states "[t]he 10-year registration period for existing chemicals is now complete following the last REACH registration deadline on 31 May 2018. 13 620 European companies have submitted information to ECHA in nearly 90 000 registrations for chemicals manufactured in or imported to the EU and [European Economic Area (EEA)] at above one tonne a year."

ECHA indicates that more is known today about chemicals used in Europe than ever before. This knowledge,

generated by industry, is stored and published by ECHA in the world's largest public regulatory database on chemicals and forms the basis for protecting citizens and the environment from the risks posed by chemicals. ECHA provides that over the first ten years of REACH, the EU has established a fair and transparent internal market for chemicals with strict safety rules, thereby promoting innovation towards safer substances and strengthening EU competitiveness.

ECHA's REACH Registration Results indicate that registrations for 21,551 substances were submitted to ECHA, and 20,608 of these registrations were completed. The total number of completed registrations, including co-registrations of the same substance and Notification of New Substance (NONS) notifications, is 82,874. The highest number of REACH registrations was submitted by Germany and the UK. The registrations are distributed among REACH tonnage bands as follows:

- 1-10 tonnes per year = 14,865 completed registrations;
- 10-100 tonnes per year = 11,080 completed registrations;
- 100-1,000 tonnes per year = 12,489 completed registrations; and
- 1,000 tonnes per year and more = 20,113 completed registrations.

The registration process is expected to slow down in 2019, but existing dossiers will require revisions and updates continually. In September, ECHA alerted member registrants that "[a]s of 1 January 2019, ECHA will start checking the compliance of all relevant dossiers for a given substance and will address its decisions to all registrants with non-compliant dossiers." This is a change from the previous approach that included primarily notifying the lead registrant. To this point, ECHA remindedcompanies in November that there is an expectation that completed registrations are to be kept up to date. ECHA noted that "[y]our registration has to reflect the **most up-to-date knowledge** on how a substance can be used safely at production sites and through the supply chain all the way down to the end user."

6. Endocrine Disruptors

The EC adopted on November 7, 2018, a Communication on the criteria for identification of endocrine disruptors as applied to biocides and pesticides. The Communication was developed in response to concerns expressed by the EP and Council in 2017 about keeping the EC strategy on endocrine disruptors "the most modern and fit-for-purpose in the world," and provides follow up on the 7th Environment Action Programme. The Communication follows the publication and subsequent application of endocrine disruptor criteria for biocidal products from June 7, 2018, and for plant protection products from November 10, 2018.

The European Food Safety Authority (EFSA) and ECHA were asked by the EC to develop guidance for applicants and Competent Authority assessors to apply in the context of the BPR (EU) No 528/2012 and the Plant Protection Products Regulation (EC) No 1107/2009 for identifying endocrine disruptors in accordance with the criteria in Commission Delegated Regulation (EU) No 2017/21003 (for biocidal products) and Commission Regulation (EU) No 2018/6054 (for plant protection products).

The document describes the process for compiling and evaluating all information relevant to an endocrine disruptor assessment and determination of whether the endocrine disruptor criteria, according to the WHO/International Program on Chemical Safety (IPCS) definition of an endocrine disruptor (WHO/IPCS, 2002) are fulfilled, including the use of mode of action analysis and a weight of evidence approach.

The EC is being pressed by non-governmental organizations (NGO) to step up efforts in 2019 to provide guidance for application in other regulatory contexts, including chemicals regulated under REACH, cosmetics, and FCMs. We can expect additional advocacy in this area in 2019.

7. Turkey REACH

As reported in Acta's 2018 Forecast and earlier memoranda, Turkey has implemented a REACH-like chemical regulatory program, KKDIK. KKDIK was published by Turkey's Ministry of Environment and Urbanization (MoEU) on June 23, 2017, and the regulation entered into force on December 23, 2017. Among other goals, KKDIK seeks to align rules for chemicals in Turkey with EU laws. KKDIK replaces the following Turkish chemical laws:

- Regulation on the Inventory and Control of Chemicals (CICR);
- Regulation on the Preparation and Distribution of SDS for Hazardous Materials and Products; and
- Regulation on Restrictions for the Manufacture, Marketing, and Use of Certain Dangerous Substances and Preparations.

Similar to the EU's REACH regulation, KKDIK is an ambitious law that covers a wide range of matters pertaining to chemical safety. The principles, rules, and requirements of KKDIK are very similar to EU REACH, and only few substantive differences exist between EU REACH and KKDIK. Similar to EU REACH, KKDIK is a hazard-based chemical regulatory program that requires registration for chemicals manufactured or imported in quantities of

one metric ton per annum or more. KKDIK contains the same annual tonnage bands as EU REACH (*i.e.*, 1-10 metric tons, 10-100 metric tons, 100-1,000 metric tons, 1,000+ metric tons). Similar to EU REACH, KKDIK contains pre-registration and registration deadlines for chemicals. In contrast to EU REACH, the registration deadline under KKDIK does not vary depending on the applicable tonnage band or differentiate "new" substances from "existing" substances. The pre-registration deadline under KKDIK is **December 31, 2020**, and the registration deadline is **December 31, 2023**,for all chemical substances or mixtures manufactured in or imported into Turkey in quantities of one metric ton or more annually.

KKDIK rules relating to OR, Restrictions, Authorizations, polymers, and "articles" are also very similar to those under EU REACH. Somewhat unsurprisingly, KKDIK submissions are required to be made in Turkish. While in most respects KKDIK resembles a Turkish translation of EU REACH, certain material differences exist between these two laws.

KKDIK Annex 18 provisions are unique to the Turkish legislation, and allow Turkish regulators to manage and oversee personnel who may engage in certain regulatory activities. Annex 18 contains qualification requirements for technical experts, as certain registration, notification, and SDS activities under KKDIK can only be performed by Chemical Assessment Experts certified by an institution that has been accredited by the Turkish Accreditation Institution. In addition to qualification requirements for the Experts, Annex 18 includes criteria for trainers and requirements for the institutions providing training.

Based on ongoing developments and the current state of play under KKDIK, 2019 promises to be a busy year under this important law, with the swiftly approaching pre-registration deadline driving increased demand for expert KKDIK services. Many companies with business interests in Turkey will likely seek, in 2019, to address pre-registration either via an OR or through their corporate entities established in Turkey. Global chemical companies addressing in-house regulatory compliance for industrial chemicals in Turkey will likely consider having appropriate personnel trained as Chemical Assessment Experts.

Although pre-registration activities focus on substance identity and a company's role in supply chains, entities globally are well aware of the potential challenges related to legitimate data citation for full registration under KKDIK. EU REACH data use is permissible under KKDIK, and many companies placing similar products on EU and Turkish markets will likely seek to secure legitimate use rights to EU REACH data for KKDIK reliance. For many entities, this may represent a significant challenge due to the nature of EU REACH contracts and joint data ownership.

Numerous EU REACH registration agreements specify that rights obtained by co-registrants are limited to EU REACH citation, and that additional data use requires a separate agreement with the data owner. Under these circumstances, entities interested in using EU REACH data for KKDIK would need to negotiate new data usage rights with data owners, and provide compensation as appropriate. If relevant study data are jointly owned, this presents a further hurdle for KKDIK usage because each of the owners would need to agree on terms for KKDIK data citation.

Based on experience gained under chemical regulatory programs similar to KKDIK, Acta believes that many global entities will likely be keen to sublicense data for KKDIK purposes, but some limited instances may exist where companies decline to provide data access for Turkish compliance. Due to these issues and potential challenges in obtaining rights for legitimate KKDIK data citation, numerous chemical companies will likely commence review, in 2019, of pertinent executed data sharing agreements.

Acta expects that additional information will be made available in 2019 regarding specific KKDIK processes, the operation of the regulation, and future plans. To date, limited KKDIK guidance documents are available in English. English translations of Turkish KKDIK guidance documents are important for industry globally to comply with the law, and stakeholders are well-advised to request from regulators official translations or develop such reliable translations themselves.

Acta also expects that 2019 may provide important information regarding the principles and operation of KKDIK Substance Information Exchange Forums (SIEF). Acta believes that SIEF operation in Turkey will be structured similarly to EU REACH SIEF operations. As implementation of KKDIK progresses, Acta expects that additional practical information on dossier development and submission will be made available. The Turkish Chemicals Registration System (KKS) is currently available for submission of KKDIK pre-registrations. It is anticipated that KKS, which can be regarded as a hybrid of International Uniform Chemical Information Database (IUCLID) and REACH-IT, will be updated progressively for harmonization with current versions of these EU REACH platforms. Based on experience gained under EU REACH, it would appear critical for a bulk submission utility to be incorporated into KKS sooner rather than later.

Acta foresees an interesting year ahead for chemical regulatory compliance in Turkey, anticipates that KKDIK will attract substantial attention globally from a range of interested parties, and that noteworthy efforts will be made

to comply in 2019. As activities increase under KKDIK, Acta believes that many aspects of the regulation, including its interpretation and enforcement, will be clarified to a much greater degree. Such information, which could be made available via official MoEU communications or industry discussions, would be useful as chemical companies refine their compliance approaches. Companies engaged in, or wishing to engage in, commerce for chemical products in Turkey should follow closely KKDIK developments and jurisprudence to achieve their business and regulatory compliance goals.

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