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Updated Biocides IT Tools Available: On October 23, 2018, the European Chemicals Agency (ECHA) issued a press release entitled "Updated biocides IT tools available." In its press release, ECHA provides that the latest version of the biocides submission tool, Register for Biocidal Products (R4BP 3), which includes enhanced workflows and controls for applications. ECHA states further that the new version of the Summary of Product Characteristics (SPC) Editor improves the text search in SPCs.

The new features in R4BP 3 include:

- A new "Cc" field that allows users to copy recipients in a message, and the corresponding possibility to "Reply to all."
- A workflow that allows authorities to request updated IUCLID files during the peer review phase of active substance applications.
- Features to support Brexit-related database adaptations.

The new features in SPC Editor include:

- A functionality for finding and replacing text in SPC files.
- Enhanced text formatting options supporting the use of superscripts.
- The possibility to export the content of the SPC in Word format.

If companies' deadlines in R4BP 3 were during the tool's maintenance break from October 20-23, 2018, the deadlines were extended automatically. Additional information regarding the updated biocides IT tools is available in the release note.

BPC Adopts Eight Opinions: On October 23, 2018, ECHA issued a press release entitled "[Biocidal Products Committee (BPC)] proposes not to approve three silver-containing active substances." In its press release, ECHA indicates that the BPC "adopted eight opinions in total, including one on Union [Authorization] and one on a [European Commission (EC)] request related to a dispute between Member States in a mutual recognition procedure."

The BPC concluded that the following active substances should not be approved because their efficacy is not sufficiently demonstrated:

- Silver zeolite for product-types 2 and 7;
- Silver copper zeolite for product-types 2 and 7; and

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- Silver sodium hydrogen zirconium phosphate for product-types 2 and 7.

The BPC adopted a positive opinion on an application for Union Authorization for a teat disinfectant biocidal product family in veterinary hygiene (product-type 3). The BPC also adopted an opinion addressing a request from the EC on unresolved objections during the mutual recognition of a biocidal product family in insecticides (product-type 18) containing 1R-trans phenothrin for use against ants. The BPC was able to address the EC's questions, which means that the EC can take a decision leading to the authorization of the biocidal product family.

During the BPC's meeting in October 2018, it also discussed draft opinions on the following active substances without reaching a conclusion:

- Silver zinc zeolite for product-types 2, 4, 7, and 9;
- Silver zeolite for product-types 4 and 9;
- Silver copper zeolite for product-types 4 and 9; and
- Silver sodium hydrogen zirconium phosphate for product-types 4 and 9.

The discussion on these opinions will continue in BPC meetings. The EC, together with EU Member States, will take the final decision on the approval of active substances and on Union Authorization of biocidal products. Additional information is available in the Annex to ECHA's News Alert.

ECHA Urges Companies To Keep Registrations Up To Date: On November 6, 2018, ECHA issued a press release urging registrants to review their registration dossiers regularly and update them when information becomes available. ECHA stresses that a 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. The information in the registration dossier must be updated, for example, when a registrant learns something new about the composition of the substance, its properties, how it is used by clients, or the specific risk management measures needed. ECHA states that "[s]ignificant changes" in the production or import volumes and the company information must also be reported to ECHA. In addition, new information may become available when new companies want to join the joint submission, and this must also be reflected in the joint dossier. More information is available in ECHA's November 6, 2018, press release, "Keep your registration up to date."

EC Updates Strategy On EDCs: On November 7, 2018, the EC issued a press release entitled "Endocrine disruptors: A strategy for the future that protects EU citizens and the environment." In its press release, the EC provides that it has adopted a Communication confirming its commitment to protecting citizens and the environment from hazardous chemicals. The EC provides that "[t]he Communication also outlines how the [EC] intends to ensure that the EU approach remains the most modern and fit-for-purpose in the world."

The EC states that the Communication delivers on the commitment made by the EC last year, when working with Member States on the criteria to identify endocrine disrupting chemicals (EDC) in the areas of biocides and pesticides. The EC notes further that the Communication addresses "the concerns of the [European Parliament (EP)] and the Council and follows up from the 7th Environment Action Program."

In the press release, the EC states that it "is updating its approach for the years to come." The EC states that the EU's strategic approach towards EDCs will continue to be based firmly on science and application of the Precautionary Principle. The approach aims at:

- Minimizing our overall exposure to EDCs, paying particular attention to important life periods, such as pregnancy and puberty;
- Accelerating the development of a thorough research basis for effective and forward-looking decision-making in the context of Horizon Europe, building on the existing research and paying particular attention to areas where knowledge gaps exist; and
- Promoting active dialogue allowing all stakeholders to be heard and to work together.

For the first time, the EC will launch a comprehensive screening of the legislation applicable to EDCs through a Fitness Check that will build on the data already collected and analyzed. The EC states "[w]ithout putting into question the general science-based EU approach to the management of chemicals, the Fitness Check will involve an assessment of the current legislation on whether it delivers on the objectives of protecting human health and the environment." As noted in the Communication, the Fitness Check will also include a public consultation.

The Communication "outlines initiatives currently considered by the [EC] to ensure that the implementation of existing policies on [EDCs] reaches its full potential." This includes the identification of EDCs, improving

communication throughout supply chains by using Safety Data Sheets (SDS), and taking forward the scientific assessment of EDCs with further regulatory action. Additional detail is available in the Communication and related Questions and Answers.

ECHA Launches New Web Pages To Prepare Companies For Brexit: On November 14, 2018, ECHA issued a press release entitled "New web pages to prepare companies for [the United Kingdom's (UK)] withdrawal from EU." In its press release, ECHA states "[t]he UK's withdrawal from the EU will affect companies including those that manufacture or use chemicals in the UK as well as in the EU-27 … ECHA's updated web section aims to help affected companies who have registered substances or use [authorized] chemicals in supply chains."

In its press release, ECHA indicates that the UK is withdrawing from the EU at the **end of March 2019**. ECHA states "[h]ow the withdrawal will affect companies depends on their role in the supply chain … For some companies the withdrawal can have significant consequences." As an example, ECHA states that if a UK-based company registered a substance under the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, the registration will no longer exist with ECHA after the UK's withdrawal from the EU. ECHA provides that if a UK chemicals manufacturer wants to continue doing business in the EU after the UK's withdrawal, it can:

- Appoint an only representative within the EU Member States remaining after the UK's withdrawal (EU-27) to manage registrations; or
- Move operations related to the registered substance to a legal entity within the EU.

ECHA indicates that REACH, the Classification, Labelling, and Packaging (CLP) regulation, the Biocidal Products Regulation (BPR), and the Prior Informed Consent (PIC) regulation will no longer apply to UK companies that place chemical substances, mixtures, articles, biocidal products, or active substances on the market only in the UK. ECHA states "[t]his is also the case when companies export certain chemicals directly from the UK to non-EU/[European Economic Area (EEA)] countries."

The EU and the UK are working towards a withdrawal agreement. The agreement needs to be concluded and ratified by both sides to take effect. ECHA states this could take until **early 2019**. ECHA indicates that "[i]f and only when this occurs, companies may benefit from a transition period, which gives them more time to prepare for the effects of the UK's withdrawal." ECHA will update its Brexit support pages in accordance with progress on the withdrawal agreement.

Further information is available in ECHA's website section on the UK withdrawal from the EU.

EC Publishes Draft Brexit Agreement: The EC published the draft agreement on the withdrawal of the UK from the EU, as agreed at the negotiators' level on November 14, 2018. The draft agreement does not include specific provisions addressing chemical substances. Instead, an article on non-regression in the level of environmental protection states that the EU and the UK shall ensure that the level of environmental protection is not reduced below the level provided by the common standards applicable at the end of the transition period in relation to several areas, including the prevention, reduction, and elimination of risks to human health or the environment arising from the production, use, release, and disposal of chemical substances. Under the draft agreement, the UK would be excluded from nominating, appointing, or electing members of EU agencies, including ECHA, and would not be allowed to participate in the decision-making and governance of EU agencies, including ECHA. During the transition period, the UK would not act as the leading authority for risk assessments, examinations, approvals, or authorizations.

The Chemical Industries Association (CIA) and European Chemical Industry Council (Cefic) issued a joint press release on November 15, 2018, welcoming the draft agreement but noting that ensuring continued participation in REACH through ECHA "is the best outcome for the chemical industry in both the UK and the Europe as well as the health and environment agenda across the continent." The associations intend to continue to work with the EP and members of the House of Lords to ensure there is an agreement for the UK to leave the EU and trade with EU Member States "with minimum disruption to the chemical sector."

EU-27 leaders met for a special meeting of the European Council on November 25, 2018. They endorsed the draft Brexit agreement, as presented by the negotiators of the EU and the UK. Leaders also approved the political declaration on future EU-UK relations, which accompanies and is referred to in the withdrawal agreement. Following the meeting, EU-27 leaders met with Prime Minister Theresa May to discuss the next steps.

EC Welcomes Industry Pledges To Boost Market For Recycled Plastics, Encourages Further Action: The EC announced on November 20, 2018, that a preliminary assessment of voluntary industry pledges shows that EU industry "is significantly committed to recycling plastics -- at least 10 million tons of recycled plastics could be supplied by **2025** if the pledges are fully delivered." The EC notes that on the demand side, only five million tons

are expected so far, however, "demonstrating that more will be needed to achieve the objective of a well-functioning EU market of recycled plastics." The main pledges came from plastics recyclers, industry associations for Expanded Polystyrene, and brand owners mainly for polyethylene terephthalate (PET) packaging. Although the official pledging exercise announced in the Plastics Strategy is now closed, the EC states that it is "well aware that more companies are preparing their commitments -- which we strongly encourage." According to the EC, "the demand for recycled plastics may increase quickly if good quality material becomes available in stable quantities and at competitive prices." Based on the pledges received to date, the EC states that the demand for recycled plastics needs developing. The EC will publish a more detailed assessment in the **first quarter of 2019**. This analysis will help identify gaps between supply (recyclers) and demand (producers, converters, and manufacturers) for the different plastic types, and guide future actions, including the ongoing assessment of regulatory or economic incentives in targeted sectors such as the automotive, construction, and packaging sectors that were announced in the Plastics Strategy. The EC will continue to encourage strongly initiatives that contribute to boosting the market of recycled plastics in the EU. The EC will cooperate with stakeholders and facilitate close stakeholder collaboration across the supply chain to achieve this objective. A first stakeholder meeting will be organized in **early 2019**. More information is available in the EC's November 20, 2018, press release, "EU Plastics Strategy: Commission welcomes voluntary pledges from industry to boost the market for recycled plastics and encourages further action."

ECHA's Enforcement Forum Starts Preparation For REF-8: On November 21, 2018, ECHA issued a press release entitled "Inspectors prepare for EU-wide control of chemicals sold online." In its press release, ECHA provides that its Forum for Exchange of Information on Enforcement (Enforcement Forum) and the Forum's BPR Subgroup (BPRS) held meetings in November. The Enforcement Forum and its BPRS "kicked off preparations for a coordinated project where inspectors will control the chemicals sold online in all EU and EEA countries" (*i.e.*, REACH-EN-FORCE-8 (REF-8)), and discussed the quality of SDSs with stakeholder organizations in an open session.

REF-8 will "cover duties under REACH restriction, [CLP,] as well as BPR duties relevant to biocidal products sold online." Preparations will run through **2019**, where inspectors will identify common methods of targeting goods online and dealing with internet duty holders. Inspections will be carried out during **2020**, and the REF-8 report is expected in **2021**.

The Enforcement Forum also adopted its Work Program for **2019-2023**. ECHA states that the Work Program lists clearly the enforcement priorities for the coming years for all pieces of legislation covered by the Enforcement Forum and BPRS. The Work Program will be published by the **end of 2018**. Additional information is available in ECHA's Annex to the News Alert.

ECHA Finds That Intentionally Added Microplastics Are Likely To Accumulate In Terrestrial And Freshwater Environments: ECHA issued a November 22, 2018, press release announcing that, according to its assessment, "microplastics that are added to products are more likely to be released to, and accumulate in, terrestrial and freshwater environments rather than the oceans." Peter Simpson, ECHA's Senior Scientific Officer, spoke at the MICRO 2018 Fate and Impact of Microplastics conference, stating that the sources of microplastics in the environment include intentional uses in cosmetics, detergents, other household products, paints, and agricultural uses. According to Simpson, many microplastics are washed down the drain. Although they are not typically released directly to aquatic environments, they are more likely to concentrate in sewage sludge that is frequently applied to agricultural soils as a fertilizer. The EC asked ECHA to investigate whether an EU-wide restriction for intentionally added microplastics would be warranted. ECHA is assessing the risks that microplastics could pose to the environment once they are released, and states that it will "specifically address their extreme persistence in the environment and the difficulty in removing them once they are there." According to ECHA, it expects to issue a final restriction proposal on microplastics at the **beginning of 2019**. ECHA's scientific committees, the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC), typically take about 14 months to issue opinions. The RAC and SEAC opinions should be sent to the EC "around **April 2020**." ECHA notes that it is separately examining the risks posed by oxo-degradable plastics. More information is available in ECHA's November 22, 2018, press release, "Intentionally added microplastics likely to accumulate in terrestrial and freshwater environments."

EC Begins Consultation Towards An EU Product Policy Framework Contributing To The Circular Economy: On November 29, 2018, the EC began a public consultation "Towards an EU Product Policy Framework contributing to the Circular Economy." The EC seeks comments from the general public, businesses, non-governmental organizations, and national and regional authorities in EU Member States. The EC notes that EU policies affect the products on the EU market in many different ways. As such, all citizens, businesses, and other stakeholders are affected by these policies. Citizens in their role as consumers buy, use, and discard products. Businesses and industries are involved in all life-cycle phases including design, manufacturing, importing/exporting, purchasing, consumption, and recycling/waste handling at the end of the product lifetime. The EC states that all these parties make decisions related to products based on certain perceptions, under the

influence of incentives and limitations set in (among others) EU policies. According to the EC, "[i]t is therefore vital to obtain views from a wide range of stakeholders on these perceptions and incentives, in particular those relating to EU product policies." This will help identify how much the current EU product policy framework supports a circular economy and what potential there is to increase this contribution. The public consultation will end **January 24, 2019**.

EC Amends REACH To Require Information On Nanomaterials: The EC announced on December 3, 2018, that it adopted amendments to several REACH Annexes to clarify the information requirements for nanomaterials. The EC notes that REACH "has always applied to nanomaterials, but did not contain specific provisions for them, which is why companies often did not know how to register these 'substances in nanoform.'" According to the EC, the modifications and new requirements will help close the knowledge gap concerning which nanomaterials are placed on the market and in what quantities. The EC states that "[t]he new provisions will have to be implemented for all substances in nanoform that fall within the scope of REACH, from the already widely used and registered 'legacy' nanomaterials in all their product grades and variations to the specifically engineered nanomaterials placed on the market by the newly founded SMEs." ECHA's December 3, 2018, press release states that nanoforms of substances are those covered by the EC's recommendation for a definition of a nanomaterial. ECHA "strongly encourages registrants of nanoform substances to familiarise themselves with the amendments and assess what action they need to take to comply." ECHA is currently assessing the need to update existing guidance or issue new guidance to help registrants comply with the new requirements. The information requirements will apply beginning **January 1, 2020**. More information is available in the December 3, 2018, press releases released by the EC, "REACH: Closing the gap for nanomaterials," and ECHA, "Companies to provide more information on nanomaterials."

Council Of The EU Agrees To Reduce Occupational Exposure To Five Carcinogens: The Council of the EU announced on December 6, 2018, that it adopted its position on a proposal that will update the existing rules on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Directive 2004/37/EC). The proposal, including the Council's proposed amendments, would set the following new limits that "are in line with new scientific and technical data and evidenced-based practices for measuring exposure levels at the workplace":

- Cadmium -- 0.001 milligrams per cubic meter (mg/m^3). This value will apply after a seven-year transitional period during which the limit value 0.004 mg/m^3 should apply;
- Beryllium -- 0.0002 mg/m^3. This value will apply after a five-year transitional period during which the limit value 0.0006 mg/m^3 should apply;
- Arsenic acid -- 0.01 mg/m^3. This value will apply for the copper smelting sector after a two-year transitional period;
- Formaldehyde -- 0.37 mg/m^3 for eight-hour exposure and 0.74 mg/m^3 for a short-term exposure. These limit values will apply after a three-year transitional period; and
- 4,4'-Methylene-bis(2-chloroaniline) (MOCA) -- 0.01 mg/m^3 with a skin notation to indicate possible dermal uptake.

The press release states that with regard to cadmium, the EC "shall assess no later than five years from the entry into force of the Directive the option of a further amendment to Directive 2004/37/EC which would add the combination of an airborne occupational exposure limit with a biological limit value." The proposal allows EU Member States to introduce at the national level more stringent binding limit values and does not prevent them from applying additional measures, such as a biological limit value. The agreement reached by the Council will serve as the basis for negotiations with the EP. More information is available in the Council of the EU's December 6, 2018, press release, "More protection for workers: Council agrees to reduce the exposure to 5 carcinogens."

EP Proposes Blueprint To Improve Approval Procedure For Pesticides: The EP issued a press release on December 6, 2018, announcing that the special committee on pesticides put forward plans intended to increase trust in the EU approval procedure by making it more transparent and accountable. According to the press release, the committee agreed that "the public should be granted access to the studies used in the procedure to authorise a pesticide, including all the supporting data and information relating to the applications." Concerns were raised about the right of applicants to choose a particular EU Member State to report on the approval of an active substance to the European Food Safety Authority (EFSA), "as this practice is seen as lacking in transparency and could entail a conflict of interests." The committee recommends that the EC allocate the authorization renewal to a different Member State. The press release states that during the procedure, applicants should be required to register all regulatory studies that will be carried out in a public register, and allow for a "comment period," during which stakeholders are able to provide additional existing data to ensure

that all relevant information is taken into account before a decision is made. Post-market evaluation should be strengthened, and the EC should launch an epidemiological study on the real-life impact of pesticides on human health. The committee also proposes to review existing studies on the carcinogenicity of glyphosate and to set maximum residue levels for soils and surface water. The committee "stress[es] the need to ensure political accountability when authorisation is adopted in the form of implementing acts -- in the so-called 'comitology procedure.'" The committee states that the EC and Member States should publish detailed minutes and make their votes public. The committee adopted its recommendations by a vote of 23 to five with one abstention. The full House will vote on the report during its **January 14-17, 2019**, plenary session in Strasbourg. More information is available in the EP's December 6, 2018, press release, "Pesticides: MEPs propose blueprint to improve EU approval procedure."

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