

ACTA Update January 23, 2020: Top International News in Chemical Policy and Regulation

Article By:

ACTA Group

Forecast For U.S. Federal And International Chemical Regulatory Policy 2020: Bergeson & Campbell, P.C. (B&C[®]) and its consulting affiliate The Acta Group (Acta[®]) are pleased to offer you our [Forecast 2020](#). In this detailed and comprehensive document, the legal, scientific, and regulatory professionals of B&C and Acta distill key trends in U.S. and global chemical law and policy, and provide our best informed judgment as to the shape of key developments we are likely to see in the New Year. The full memorandum can be downloaded as a PDF [here](#). B&C's podcast *All Things Chemical*[™] has released a special episode in conjunction with the Forecast featuring Lynn L. Bergeson, Sheryl Lindros Dolan, Chris Bryant, and Dr. Richard Engler engaging in spirited discussion about what is in the pipeline for 2020. Search for *All Things Chemical* on your favorite podcasting service, or stream the episode [here](#) to listen!

AUSTRALIA

IMAP Tranche 28 Now Available For Public Comment: On December 12, 2019, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) published [Tranche 28](#) of the Inventory Multi-Tiered Assessment and Prioritization (IMAP) framework for public comment. The objectives of IMAP are to:

- Identify and rapidly assess existing chemicals of concern; and
- Support the risk management of industrial chemicals in Australia by enhancing the flow of chemical safety information.

As of July 1, 2019, NICNAS had published a cumulative total of 20,554 chemical risk assessments. Publication of Tranche 28, which comprises 2,806 chemical risk assessments, brings the total number of chemical risk assessments to 23,360. Comments on Tranche 28 are due **February 21, 2020**.

NICNAS Publishes Summary Of Feedback On General Rules And Categorization Guidelines: NICNAS has [published on its website](#) stakeholder feedback that it received on the General Rules and Categorization Guidelines and its responses. NICNAS states that it broke down its responses into the

following main themes “for clarity and ease of understanding”:

- Transitional arrangements;
- Use of animal test data;
- Categorization of industrial chemicals;
- Information requirements;
- Use of international information;
- Compliance and record-keeping; and
- Other feedback.

SWA Plans To Include Two-Year Transition Period For Adoption Of GHS Revision 7: Safe Work Australia (SWA) [announced](#) on January 10, 2020, that it is working toward adopting Revision 7 of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) under the model Work Health and Safety (WHS) laws from **July 1, 2020**, with a two-year transition period for manufacturers and importers. According to SWA, the two-year time frame will allow manufacturers and importers time to prepare new classifications, labels, and safety data sheets (SDS) for hazardous chemicals to meet GHS Revision 7 requirements. SWA notes that suppliers and users of hazardous chemicals will not be affected by the move to GHS Revision 7 and will be able to continue to supply and use chemicals classified and labeled under GHS Revision 3 until their stocks run out. SWA intends to release more information on the adoption of GHS Revision 7 “in the coming months.”

BRAZIL

Bill Presented In Chamber Of Deputies Would Create National Inventory Of Chemical Substances: A [bill \(PL 6120/2019\)](#) was presented in the Chamber of Deputies on November 21, 2019, that would create a National Inventory of Chemical Substances to consolidate information on chemicals produced in or imported into Brazil. The bill would require manufacturers, exporters, and importers of chemicals to report the amount of chemical substances annually produced and imported and the contents of material safety data sheets (MSDS) in accordance with GHS, including recommended uses, hazard classifications, and chemical risk assessment analysis studies for recommended uses. Under the bill, the government would create a Chemicals Evaluation Committee to assess chemical risks and recommend management measures to protect human health and the environment. The bill was received by the Commission for Environment and Sustainable Development (CMADS) on December 4, 2019.

As reported in our July 5, 2016, memorandum, “[A Critical Review of Brazil’s Just-Published Industrial Chemicals Regulation \(Regulação de Substâncias Químicas Industriais\)](#),” Brazil released a draft *Regulamento Químico Industrial* (Industrial Chemicals Regulation) in 2016 that would create a national chemical substance inventory and notification process. The final text of the Regulation was agreed upon in September 2018. In 2019, the Brazilian *Ministério do Meio Ambiente* (Ministry of Environment; MMA) publicly refuted reports that the long-awaited Regulation had been postponed. The *Associação Brasileira da Indústria Química* (Brazilian Chemical Industry Association) reported that it met with MMA Minister Ricardo Salles on April 16, 2019, and that the Minister remained

committed to seeing the bill forward. This is not the bill presented in the Chamber of Deputies on November 21, 2019, however.

CANADA

Canada Publishes Updated Science Approach Document For Ecological Risk Classification Of Inorganic Substances: On January 6, 2020, Canada published the updated [Science Approach Document: Ecological Risk Classification of Inorganic Substances](#). Environment and Climate Change Canada (ECCC) characterized inorganic substances from the third phase of the Chemicals Management Plan (CMP) for their potential to cause ecological harm. ECCC applied the ecological risk classification of inorganic substances (ERC-I) to a broad group of inorganic substances that met the categorization criteria under Section 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA) or were considered a priority on the basis of other human health concerns. The updated Science Approach Document presents the ERC-I approach and the results of its application only to inorganic substances identified as having a low level of ecological concern. The Science Approach Document states that inorganic substances not identified as being of low ecological concern by the ERC-I approach will be subject to a more refined analysis in other publications. Considering inherent hazard properties, current use patterns, and quantities in commerce, as well as the analysis of water quality monitoring data sets, ECCC classified 80 substances as being of low ecological concern. According to the Science Approach Document, substances that were classified as being of low ecological concern primarily on the basis of current low exposures may be subject to follow-up or tracking of use pattern information to inform future priority-setting.

EUROPEAN UNION (EU)

Industry Associations Provide Statement On RoHS Directive: In response to the European Commission's (EC) [public consultation](#) regarding the Restriction of Hazardous Substances (RoHS) Directive, industry associations have issued a [Joint Industry Statement](#). The Joint Industry Statement, issued by several groups, including the European Chemical Industry Council (Cefic), PlasticsEurope, and Eurometaux, "constitutes the collective contribution of various organisations and associations representing the electrical and electronics value chain to the assessment of the Effectiveness, Efficiency, Coherence, Relevance and EU-Added Value of the RoHS Directive."

The Joint Industry Statement provides several recommendations, including:

- Based on RoHS's European and international value, RoHS restrictions and exemptions should remain in place and "supporting processes should be more closely integrated with other restriction legislations."
- Emphasis on the importance of "improving the coherence and consistency of the implementation of RoHS restrictions and exemptions worldwide, perhaps as part of EU's bilateral programs and trade agreements with the more than 40 jurisdictions having adopted EU-RoHS as a framework for regulating hazardous substances in [Electrical and Electronic Equipment (EEE)]."
- More "transparency and predictability" during RoHS restriction and exemption decision-making processes.
- Implementation of "synergies" between RoHS and the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation.

- “Applying the existing [European Chemicals Agency (ECHA)] Guidance documents and methodologies which would be relevant for restrictions and exemptions, including that of socio-economic analysis, under RoHS.”
- Ensuring synergies between Substance Evaluation and Risk Management Option Analysis conducted under REACH and RoHS Annex II dossier preparations.
- Establishing a comparable position for chemicals in the RoHS Inventory and ECHA’s Integrated Regulatory Strategy, based on agreed criteria.

ECHA Committees Conclude On Two Restrictions And Ten Harmonized Classification And Labeling Opinions: In a [press release](#) dated December 10, 2019, ECHA indicated that its Committee for Socio-economic Analysis (SEAC) adopted its final opinion on the proposal by Italy to “restrict the uses of the N,N-dimethylformamide (DMF) on its own or in mixtures in a concentration equal to or greater than 0.3 % w/w.”

ECHA provides further that its Committee for Risk Assessment (RAC) and SEAC “supported the proposal by ECHA” to restrict the placing on the market of siloxanes (D4, D5, and D6) “as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1 % w/w of each substance.” RAC adopted its opinion in support of ECHA’s proposal, and SEAC agreed on its draft opinion in support of ECHA’s proposal. SEAC concluded that the proposed restriction is the most appropriate EU-wide measure to address identified risks “in terms of the proportionality of its socio-economic benefits to its costs.” ECHA indicated that a 60-day consultation on the draft SEAC opinion “launches on 18 December 2019,” and that “the Committee is expected to adopt an opinion at its **March 2020** meeting.”

ECHA indicates further that RAC adopted ten opinions on harmonized classification and labeling, “including opinions on eight active substances used in biocidal products and/or plant protection products and two industrial chemicals.” RAC also agreed on 14 draft opinions on authorization applications for uses of chromium (VI) substances and octyl- and nonylphenol ethoxylates. SEAC agreed on 25 draft opinions on uses of chromium trioxide; coal tar pitch, high-temperature; anthracene oil; and octyl- and nonylphenol ethoxylates. Furthermore, RAC and SEAC discussed key issues in 17 applications for authorization received by ECHA in August 2019. Further information is available in the [Annex to ECHA’s press release](#).

Council Of The EU Invites EC To Present New OSH Framework: On December 10, 2019, the Council of the EU [adopted conclusions](#) inviting the EC to present a new EU strategic framework on occupational safety and health (OSH) at work for **2021-2027** and offering the Council’s input into that strategic framework. The Council notes that the conclusions recognize that some positive results have been achieved, as many EU Member States have adopted national action plans based on the existing framework. The Council states that the EC, Member States, and social partners “are invited to intensify their efforts in the area of the changing world of work, including on psychological risks, work-related accidents and diseases and the inclusion of disabled and older workers.” To eliminate hazards and prevent diseases, including cancer, resulting from the use of dangerous substances in workplaces, the Council asks the EC to:

- Propose further binding limit values for priority carcinogens and other dangerous substances, based on the precautionary principle and on up-to-date scientific evidence, and update existing limit values, if required, for the protection of workers;

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- Develop guidance on measuring the binding limit values introduced at the EU level, including, where relevant, biological limit values; and
 - Clarify the interface between OSH and REACH legislation and improve coordination by developing transparent procedures and criteria to be used when selecting the most appropriate substance-specific regulatory options.

ECHA Indicates Revised Completeness Checks Will Be Launched In April: On December 11, 2019, ECHA issued a press release entitled "[Revised completeness check to be launched in April 2020](#)." In its press release, ECHA provides that completeness checks will be extended to Chemical Safety Reports (CSR), "to ensure they contain all the elements required under REACH." So far, CSRs have been outside the scope of completeness checks, which have focused on other elements of REACH registration dossiers.

ECHA provides that "[w]ith experience gained in performing manual completeness checks on certain dossier elements," it is now ready to "tackle the content" of CSRs. With this improvement, ECHA indicates it can fulfill better its obligation to ensure that all the required elements are included in REACH registrations. ECHA states that the decision to cover CSRs in completeness checks supports its regulatory strategy, "which foresees requests under evaluation to mainly be used for obtaining hazard information." ECHA provides that extending completeness checks to CSRs is expected to enable better prioritization of substances for regulatory action by authorities, enhance the dissemination of use information, and improve the starting point for appropriate supply chain communication.

ECHA indicates that it will also strengthen computerized completeness checks on use information. In particular, ECHA states that cases where the service life description of an article is expected but has been left out of the registration dossier will be detected. ECHA also foresees completeness check improvements for "the endpoints related to mutagenicity, reproductive toxicity and degradation." ECHA indicates the revised completeness checks will be launched with the release of a new version of the International Uniform Chemical Information Database (IUCLID) in **April 2020** and will apply to "both new registrations and updates of existing ones." ECHA states "[r]egistrants should, therefore, prepare for the changes as registrations submitted before may no longer pass the revised completeness check rules."

ECHA "aims to minimise unwanted impact for registrants and will provide support in addressing the areas of the completeness check revision and preparing to successfully submit their registrations." ECHA will host a [webinar](#) "explaining the changes in the completeness check" on **January 29, 2020**. Further information is available in the [Annex to ECHA's press release](#).

EC Provides Detailed Information Regarding Green Deal: On December 11, 2019, the EC made available a [Communication](#) and related [Annex](#) regarding the "European Green Deal." In its Communication, the EC states that the European Green Deal "resets the Commission's commitment to tackling climate and environmental-related challenges," and that the Green Deal "is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in **2050** and where economic growth is decoupled from resource use."

The EC indicates that all EU actions and policies will have to contribute to the European Green Deal objectives. The EC provides that "[t]he challenges are complex and interlinked" and that the policy

response must be bold and comprehensive and “seek to maximise benefits for health, quality of life, resilience and competitiveness.” The Green Deal incorporates various elements, including:

- Increasing the EU’s climate ambition for **2030** and **2050**;
- Supplying clean, affordable, and secure energy;
- Mobilizing industry for a clean and circular economy;
- Building and renovating in an energy- and resource-efficient way;
- Accelerating the shift to sustainable and smart mobility;
- From “Farm to Fork”: Designing a fair, healthy, and environmentally friendly food system;
- Preserving and restoring ecosystems and biodiversity; and
- A zero pollution ambition for a toxic-free environment.

To ensure a toxic-free environment, the EC states that it will present a chemicals strategy for sustainability that will help to protect citizens and the environment better against hazardous chemicals while also encouraging innovation for the development of safe and sustainable alternatives. According to the Communication, the EC will review how to use better the EU’s agencies and scientific bodies to move toward a process of “one substance -- one assessment” and to provide greater transparency when prioritizing action to deal with chemicals.

The EC indicates, in the Communication, that it “has estimated that achieving the current **2030** climate and energy targets will require €260 billion of additional annual investment, about 1.5% of 2018 GDP.” The EC will present a Sustainable Europe Investment Plan to “help meet the additional funding needs.” Further information regarding the European Green Deal, specific measures, and related timelines is available in the Communication and Annex.

BPC Concludes On Four Active Substances And Two Union Authorization Applications: On December 12, 2019, ECHA issued a press release entitled “[Conclusions on four active substances and two applications for Union authorisation.](#)” In its press release, ECHA provides that the Biocidal Products Committee (BPC) adopted seven opinions supporting the approval of four active substances and two opinions supporting Union Authorization. The BPC concluded on applications for the following active substance and product-type combinations:

- Icaridin for product-type 19 (repellents and attractants);
- Cyanamide for product-types 3 (veterinary hygiene) and 18 (insecticides, acaricides, and products to control other arthropods);
- Formaldehyde for product-types 2 (disinfectants and algacides not intended for direct application to humans or animals) and 3; and
- Carbendazim for product-types 7 (film preservatives) and 10 (construction material preservatives).

The BPC adopted positive opinions on two applications for Union authorization of biocidal product families based on propan-2-ol (product-type 2) and iodine/PVP-iodine (product-types 2 and 4 (food and feed area)). The EC, together with EU Member States, will make the final decision on approval of the active substances and Union authorization of the biocidal products. Further information is available in the [Annex to ECHA's press release](#).

REF-6 Finds Significant Classification And Labeling Non-Compliance: On December 17, 2019, ECHA issued a press release entitled "[44 % of hazardous mixtures not compliant with classification and labelling obligations](#)." In its press release, ECHA provides that its Enforcement Forum's REACH-EN-FORCE 6 (REF-6) project focused on the classification and labeling of mixtures. The most common mixtures checked under REF-6 included washing and cleaning products, biocidal products, paints, coatings, adhesives, and air freshener products. Under REF-6, inspectors in 29 countries checked 3,391 mixtures and inspected 1,620 companies (e.g., manufacturers, importers, downstream users, and distributors).

The "main findings" of REF-6 were:

- 43 percent of all reported companies were found to have at least one non-compliance, and 44 percent of reported mixtures were non-compliant in some way.
- 17 percent of reported mixtures were using an incorrect classification, "which may result in incorrect labelling on the mixtures, and thereby incorrect safe use advice."
- Nine percent of substances checked that were subject to EU-wide harmonized classification and labeling had not applied the required harmonized classification and labeling.
- 33 percent of reported mixtures had incorrect labeling.
- 33 percent of the checked safety data sheets (SDS) were non-compliant with the requirements checked in the project.
- For 22 percent of the checked liquid laundry detergent capsules, "the closure of the outer packaging did not maintain its functionality when repeatedly opened and closed during the life span of the packaging."
- Approximately seven percent of checked biocidal products lacked "either valid authorisation according to the Biocidal Products Regulation (BPR) or to national legislation during the transitional period," and labels for 17 percent of the biocides were non-compliant.

ECHA indicates that manufacturers, importers, and downstream users "have to put more effort into deriving the right classification for mixtures and communicating it down the supply chain." ECHA states this will prevent dissemination of incorrect information in SDSs and on labels. Furthermore, ECHA emphasizes the importance of improving SDSs and knowledge of BPR to support compliance and improved information in supply chains. Further information is available in the REF-6 [Mandate](#) and [Project Report](#).

EC Begins Public Consultations On Fitness Check Of EU Legislation Regarding Endocrine Disruptors: As part of its Fitness Check of EU legislation regarding endocrine disruptors, the EC has

begun two public consultations: a public consultation (designed from a citizen's perspective) and a stakeholder consultation (designed for stakeholders and experts). The [public consultation](#) will close **March 9, 2020**, and targets the general public. The [stakeholder survey](#) will close on **January 31, 2020**, and targets stakeholder organizations such as businesses, public authorities, academic research and non-governmental organizations (NGO), and experts working in such areas responding in their professional capacity.

Public Consultation

The EC states that it is holding the public consultation to:

- Assess public concerns and needs with respect to endocrine disruptors in the EU;
- Evaluate the extent to which current EU legislation meets the concerns and needs of citizens; and
- Identify opportunities for improvement in the way endocrine disruptors are assessed and managed and how potential risks are communicated.

Stakeholder Consultation

The aims of the stakeholder consultation are to:

- Collect views on possible legislative inconsistencies and assess their impact on stakeholders;
- Collect information from stakeholders on the effectiveness of the current EU legislation for the identification and risk management of endocrine disruptors; and
- Collect information on the efficiency of procedures for the identification and risk management of endocrine disruptors (e.g., duplication of efforts) and to identify opportunities for improvement.

More information is available in our December 18, 2019, memorandum, "[EC Begins Public Consultations on Fitness Check of EU Legislation Regarding Endocrine Disruptors.](#)"

ECHA Publishes Q&A From Webinar On Revised REACH Annexes For Nanomaterials: As of January 1, 2020, companies must provide more information on nanomaterials on the EU market under the updated REACH Annexes. ECHA [organized a webinar](#) on November 12, 2019, on the revised Annexes and how companies can prepare to meet the new requirements. During the webinar, participants had the chance to ask questions from ECHA experts. In December 2019, ECHA published a [question and answer \(Q&A\) document](#) that compiles and groups Q&As received during the webinar. In the document, ECHA further elaborated on the replies and complemented them with additional advice intended to support registrants.

EC Issues Overview Report On Biocides: The EC has made available an "[Overview Report of a Series of Fact-Finding Missions on Biocides in EU Member States 2017-2018.](#)" The Overview Report contains several sections, including "Background to the Fact-Finding Mission Series," "Overview of Main Findings and Conclusions," and "Action Taken by the Commission Services." The Overview

Report provides a summary on the outcome of fact-finding missions carried out in five Member States in 2017 and 2018 by the Health and Food Safety Directorate-General of the EC.

The Executive Summary in the Overview Report describes BPR objectives and transitional arrangements, and provides that the “complexity of the review processes, poor quality of dossiers, lack of synchronised procedures and insufficient staff resources including resources wasted on applications which are withdrawn during the evaluation process were among the challenges for [Member States] identified.” The Report highlights that these challenges increase burdens on resources “and, where these are insufficient, result in delays in completing the review process.”

The Overview Report provides that the use of planning and forecasting tools and improving the quality of dossiers through awareness raising activities and additional pre-submission meetings with applicants were some of the potential good practices identified by which Member States have been able to minimize delays, “although these may not be sufficient to avoid the need for additional staff resources.” The Report emphasizes the importance of enhanced cooperation and coordination within and between the national authorities involved with biocides and provides that establishing further harmonized EU guidance would facilitate the evaluation process and save time and resources in the long run.

Importantly, the Overview Report states that the significant amount of biocidal products “which are not authorised for the market where they are made available” shows that further attention should be paid to BPR enforcement, “particularly aimed at products containing active substances still under evaluation in the Review Programme.” Further information is available in the Report.

Restriction For BPA In Thermal Paper Enters Into Force: [Commission Regulation \(EU\) 2016/2235](#) adds the following entry to REACH Annex XVII:

- Bisphenol A (BPA) “[s]hall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02 % by weight after 2 January 2020.”

The Commission Regulation, published in December 2016, indicates that in 2014 France submitted to ECHA a dossier pursuant to REACH Article 69(4) “in order to initiate the restriction procedure set out in Articles 69 to 73 of that Regulation.” The dossier “indicated a risk for workers (primarily cashiers) and consumers exposed to [BPA] by handling thermal paper receipts and proposed a restriction on the placing on the market of BPA in thermal paper in a concentration equal to or greater than 0,02 % by weight.”

The Commission Regulation provides details regarding RAC’s activities related to the BPA restriction, and states “RAC concluded that the risk for consumers is adequately controlled but confirmed the risk for workers.” On June 5, 2015, RAC adopted its opinion, concluding that the proposed restriction “is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness in reducing those risks.” The Commission Regulation indicates further that, on December 4, 2015, “SEAC adopted its opinion and considered the proposed restriction unlikely to be proportionate in terms of comparing its socioeconomic benefits to its socioeconomic costs, but highlighted possible favourable distributional and affordability considerations.” SEAC confirmed that an EU-wide measure is justified, and concluded that the “proposed restriction is an appropriate measure to address the human health risks to workers.”

Based on opinions of RAC and SEAC, the EC concluded that “there is an unacceptable risk to the

health of workers who handle thermal paper containing BPA in a concentration equal to or greater than 0,02 % by weight.” The EC considered the restriction “would address the identified risks without imposing significant burden on industry, supply chain or consumers.” Thus, the EC decided that the restriction for BPA proposed by France is an “appropriate Union wide measure.” Application of the restriction was deferred until January 2, 2020, “to enable industry to comply with it.”

ECHA Starts Work On Making Drinking Water Safer: On January 14, 2020, ECHA issued a press release entitled “[ECHA starts work on making drinking water safer.](#)” In its press release, ECHA states that with the recast of the Drinking Water Directive, it has been given a task to compile and manage “an EU positive list of chemicals that can be safely used in materials that come into contact with drinking water.” ECHA provides that the first positive list is expected to cover approximately 1,500 chemicals and will be adopted by the EC by **2024**.

ECHA indicates that as the first EU positive list will be based on the existing lists in Member States, a review program will be introduced through which it will “reassess all substances on the list within 15 years from its publication.” ECHA will “prioritise substances for the systematic review and recommend expiry dates for them.” ECHA provides that each approved substance will be authorized for use for a limited period of time, and that “[t]he timing of the reviews will be based on the hazardous properties of the substances as well as the quality of and how up to date underlying risk assessments are.”

ECHA states that companies will need to submit a review application to ECHA “if they want to keep their substances on the positive list.” Companies will also need to submit an application if “they want to add new substances to the list.” ECHA provides that Member States can also submit dossiers to ECHA to remove substances from the list or to update entries (e.g., change in concentration limit for a substance in drinking water). ECHA will assess applications and dossiers, and RAC “will form its opinion for further decision making by the Commission.”

ECHA indicates it will support the EC in developing information requirements for applicants and assessment methods. ECHA will complete these tasks “in close collaboration with the European Food Safety Authority (EFSA) due to the close links with food contact materials.”

Four New Substances Added To Candidate List: ECHA has added three new substances to the [Candidate List of Substances of Very High Concern \(SVHC\)](#) “due to their toxicity to reproduction and a fourth due to a combination of other properties of concern.” The following substances were added to the Candidate List on January 16, 2020:

- Diisohexyl phthalate -- Toxic for reproduction (Article 57 (c));
- 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone -- Toxic for reproduction (Article 57 (c));
- 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one -- Toxic for reproduction (Article 57 (c)); and
- Perfluorobutane sulfonic acid (PFBS) and its salts -- Equivalent level of concern having probable serious effects to human health and the environment (Article 57(f)).

ECHA states that PFBS and its salts “causes probable serious effects to human health and the

environment, giving rise to an equivalent level of concern to carcinogenic, mutagenic and reprotoxic (CMR), persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances.” The decision to include PFBS and its salts in the Candidate List “was taken with the involvement of the Member State Committee (MSC).” The Candidate List of SVHCs now contains 205 substances. Further information is available in ECHA’s January 16, 2020, press release entitled “[Four new substances added to Candidate List.](#)”

Inspections Begin Of Products Sold Online That Contain Harmful Substances: ECHA announced on January 20, 2020, that inspections for REACH-EN-FORCE 8 (REF-8) have begun. REF-8 will check whether companies selling hazardous substances, mixtures, biocidal products, and articles online in EU Member States and European Economic Area (EEA) countries comply with REACH, CLP, and BPR. The project will target products for the general public and professionals, available in private companies’ web shops and in marketplace platforms, such as Amazon and eBay. According to ECHA, inspectors will check whether buyers are informed about the existence of hazardous substances before completing their purchases and if particular aspects of the regulations are fulfilled. ECHA states that inspectors will examine restricted substances found in products commonly sold online, such as toys and textiles and check them against REACH requirements. Inspectors will also check whether the advertisements for hazardous chemical substances sold online adequately inform consumers about the hazard class and the applicable hazard categories of the substance or mixture as required by CLP. For BPR, the project covers both authorized biocidal products and those available under the transitional regime (the period of time during which biocidal products are still governed by national provisions in each Member State). ECHA notes that while the project will focus on the online product information and online advertisements, inspectors may visit the companies for on-site inspections whenever they consider it relevant. ECHA states that it expects to publish the results of the project at the **end of 2021**. More information is available in ECHA’s January 20, 2020, press release, “[Inspectors to check products sold online that contain harmful substances.](#)”

EU Chemicals Legislation Finder To Go Live In March 2020: According to ECHA, the EU Chemicals Legislation Finder (EUCLEF) will go live in **March 2020**, enabling companies, especially small- and medium-sized enterprises (SME), to find out how their substances are being regulated in the EU and what legal obligations they have. Through EUCLEF, stakeholders will have access to a much wider range of legislative information, “seamlessly integrated into [ECHA’s] chemicals database.” ECHA expects EUCLEF to cover 40 pieces of EU legislation and will later expand it to include more.

TAIWAN

Taiwan Revises Regulations To Implement Toxic And Chemical Substances Of Concern Control Act: On January 16, 2019, the Toxic Chemical Substance Control Act was amended and renamed the Toxic and Chemical Substances of Concern Control Act (TCSCCA). As reported in Taiwan Environmental Protection Administration’s (Taiwan EPA) October 22, 2019, press release, “[Amendments Preannounced for the Management and Handling of Toxic and Chemical Substances of Concern](#),” the amended TCSCCA requires amendments to the Permit Registration and Approval Regulations for Toxic Chemical Substances, the Regulations Governing Recordkeeping for the Handling and Release of Toxic Chemical Substances, and the Toxic Chemical Substances Labeling and Materials Safety Data Sheets (MSDS) Regulations. In January 2019, Taiwan EPA issued the following revised regulations implementing TCSCCA:

- [The Administrative Measures for the Labeling and MSDSs of Toxic and Chemical Substances](#)

[of Concern](#), which includes the following provisions:

- When there are any difficulties with labeling caused by the appearance or material of the container or packaging, alternative methods may be used, such as using fold-out labels, attaching hang tags, or directly printing required information on the containers; and
 - To enhance risk communication for handling processes, labeling and MSDSs are to be in Chinese, with an English translation when necessary. A grace period will be provided to those who need to revise their label content and MSDSs based on this regulation.
- [Administrative Measures for the Permit Registration and Approval of Toxic and Chemical Substances of Concern](#)., which includes the following provisions:
 - Class 4 Toxic Chemical Substances are now regulated by these Administrative Measures instead of the Management Regulations Governing Permission to Use Class 4 Toxic Chemical Substances;
 - To simplify the application and review process, permit, registration, and approval documents are to be applied for and granted based on the handlers or operating sites instead of having separate permits for each individual chemical substance; and
 - Provisions governing the replacement, revision, or extension of permits are added.

UNITED KINGDOM (UK)

Acta Publishes FAQs Regarding Brexit: The results of the UK's December 12, 2019, elections give the Conservative Party under the leadership of Boris Johnson a clear mandate to withdraw from the EU, a process colloquially known as "Brexit," by the **January 31, 2020**, deadline agreed with the EU. The mandate is clear, the details of withdrawal are not, and the forthcoming negotiation with the EU promises to be challenging. Brexit has attracted unparalleled levels of attention from the global chemicals industry due to its significant implications for business operations. Brexit is expected to have widespread consequences for managing compliance with EU chemical laws (e.g., REACH, BPR), and it is also anticipated that the UK will implement its own jurisdiction-specific robust regulatory framework for industrial chemicals, biocides, and pesticides. As the diverging regulation of chemicals in the EU and UK approaches, companies with interests in the UK and EU-27 need to understand Brexit implications, comprehend related regulatory issues and nuances, and act quickly to minimize adverse business impacts.

From offices in Manchester, UK, and Brussels, Belgium, Acta provides local expertise and boots-on-the-ground representation to assist clients in gaining and maintaining compliance in both jurisdictions. Based on the experience we have gained supporting global clients in Brexit preparations, we have prepared a number of frequently asked questions (FAQ) regarding Brexit, which we are pleased to share with our clients and affiliates. Acta's December 13, 2019, FAQs are available at "[FAQs Regarding Brexit -- What Chemical Companies Need To Know.](#)"

CIA Responds To General Election Result: In a [press release](#) issued on December 13, 2019, the Chemical Industries Association (CIA) stated "[t]he chemical industry -- the UK's biggest

manufacturing export sector -- has responded to the general election result.” In the press release, Steve Elliott, Chief Executive of CIA, stated:

The Country now has the political clarity and certainty which business has been seeking. Now we have that we must get Brexit right and secure an exit and future trading relationship between the UK and the EU that enables broader manufacturing and the chemical industry to maintain and grow its contribution to the whole of the UK economy and to people’s everyday lives ... We now look forward to working with the Prime Minister, his Government, all political parties across Parliament and the Devolved Administrations to ensure a strong UK manufacturing presence across the Country.

In its press release, CIA emphasizes the importance of a UK-EU “friction-less, free trade agreement” and states that it believes it is in the UK’s “environmental and commercial best interests” to secure close regulatory alignment with the EU and to ensure that the UK “can continue to attract and retain the very best skilled, specialist people from anywhere around the world.”

CIA stated that “after three and half years of political stalemate,” it hopes that rapid progress can be made on the “EU exit and future relationship.” Regarding “great challenges,” CIA references “delivering net zero emissions by **2050**” and indicates that this can only be achieved through products and technologies of chemical businesses. CIA states “[o]ur industry supports this ambition and we look forward to working with the new Government to secure the investment in technology and infrastructure that will help us reach this.”

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