

## International News in Chemical Policy and Regulation

Thursday, June 13, 2019

### ARGENTINA

#### **Industrial Chemicals Regulation Gains**

**Traction:** The *Ministerio de Medio Ambiente y Desarrollo Sostenible* (Ministry of Environment and Sustainable Development; MAyDS) partnered with other governmental agencies and the national chemical trade association, the *Cámara de la Industria Química y Petroquímica* (Chamber of the Chemical and Petrochemical Industry; CIQYP), to develop legislation managing industrial chemicals. Among the external programs the MAyDS and others have considered as models are Canada's Chemicals Management Plan (CMP) and the Swedish Chemicals Agency's programs such as the Products Register and the permit process for "very hazardous chemicals products."

The *Dirección de Sustancias y Productos Químicos* (Directorate of Chemical Substances and Products), a sub-unit under MAyDS, has included aspects such as the development of a national chemical inventory, risk management and risk assessment criteria (managed by a governmental committee), enforcement provisions, and specific protections for confidential business information and trade secrets in the [draft bill](#) submitted to the World Trade Organization (WTO) on June 3, 2019. The [WTO notification](#) does not provide a proposed date of adoption.

### AUSTRALIA

#### **SWA Will Seek Comment On Adopting Seventh GHS For Workplace Hazardous Chemicals:**

On June 6, 2019, Safe Work Australia (SWA) [announced](#) that, "[o]ver the coming months," it will be consulting on a proposal to adopt the seventh edition of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in the model Work Health and Safety (WHS) laws. Since January 1, 2017, the third edition of the GHS has been implemented under the model WHS laws. SWA states as Australia's transition to the GHS is now complete, it is time to move beyond the third edition of the GHS to ensure Australia's classification and labeling requirements for workplace chemicals are aligned with its key trading partners as they move to the 7th edition of the GHS. To be informed about the upcoming consultation, stakeholders should [register](#) on Engage, SWA's consultation platform.

### BRAZIL

**Environment Ministry Denies Industrial Chemicals Regulation Has Been Postponed:** The



Article By [Bergeson & Campbell, P.C.](#)  
[ACTA Group](#)  
[The ACTA Group Regulatory Developments](#)  
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Brazilian *Ministério do Meio Ambiente* (Ministry of Environment; MMA) is publicly refuting reports published elsewhere that their long-awaited *Regulamento Químico Industrial* (Industrial Chemicals Regulation; *Regulamento*) has been postponed. MMA Minister Ricardo Salles had been said to have cancelled all further development of the bill indefinitely. (As The Acta Group (Acta<sup>®</sup>) has reported previously, the *Regulamento* is currently undergoing review by the President's Chief of Staff Onyx Lorenzoni.) The *Associação Brasileira da Indústria Química* (Brazilian Chemical Industry Association; ABIQUIM) has reported it met with Minister Salles on April 16, 2019, and that the Minister remained committed to seeing the bill forward.

It is Acta's opinion that the reason for the misinformation elsewhere may have stemmed from an April decree eliminating all non-legally established (e.g., by Decree) committees, groups, and commissions. The group that had been reviewing and addressing the comments submitted, as well as being involved in the negotiations, the *Comissão Nacional de Segurança Química* (National Chemical Safety Commission; CONASQ), is included in this abolition. This is not relevant, though, as the *Regulamento* existed CONASQ some time ago.

## COLOMBIA

**Ministry Ends Public Consultation On Food Contact Regulation:** The *Ministerio de Salud Protección Social* (Ministry of Health and Social Protection; MINSALUD) has ended its public comment period on its draft regulation that would establish migration limits for various substances in glass and ceramic utensils that contact food. Should the draft regulation enter into force, it would mandate the use of the test methods set out in the 2014 Technical Standard 4634. Presently, compliance with this Standard is voluntary.

The draft, as currently written, would require the aforementioned product types to obtain a certificate from either the *Organismo Nacional de Acreditación de Colombia* (National Accreditation Body of Colombia; ONAC) or an organization that is endorsed by the International Accreditation Forum.

The draft regulation, if signed into law, is expected in **October 2019**.

## ECUADOR

**Ministry Repeals Product Labeling Technical Document:** The *Ministerio de Producción, Comercio Exterior, Inversión y Pesca* (Ministry of Production, Foreign Trade, Investment and Fisheries) has announced that the November 3, 2006, Technical Regulation [RTE INEN 015](#) has been [repealed](#). INEN 015 addressed labeling for products that did not have *El Servicio Ecuatoriano de Normalización* (Ecuadorian Standardization Service; INEN) standards otherwise establishing such requirements.

**INEN Sets Requirements For Paints:** INEN has published its "*Proyecto de Segunda Revisión del Reglamento Técnico Ecuatoriano PRTE INEN 061 (2R) 'Pinturas'*" (Draft second revision (2R) of Ecuadorian Standardization Institute Technical Regulation (PRTE INEN) No. 061 "Paints"). The notified Technical Regulation (TR) sets out the requirements to be met by paints, prior to the marketing of domestic and imported products, with the aim of protecting human safety and health, and preventing misleading practices. Among the requirements set forth are "total content of lead in dry base," a prohibition on the use of benzene in the preparation (creation) of paint for traffic signs, and a limitation on the amount of methanol (methyl alcohol) or chlorinated compounds in raw materials.

Per Section 2.1 of the TR, the following paint products and product types, which are also indexed by Harmonized Tariff System (HTS) Code, are subject to regulation: anti-corrosion paint; alkyd gloss enamel; architectural paints; water-based emulsion paints (latex); synthetic alkyd enamel for household use; synthetic alkyd enamel for vehicles; nitrocellulose base coats for repainting in the motor vehicle industry; anti-corrosion alkyd vehicle primers; anti-corrosion epoxy vehicle primers; acrylic lacquers for repainting vehicles; acid-catalyzed clear or matte lacquers for wood finishing; nitrocellulose lacquers for wood finishing; nitrocellulose lacquers for repainting vehicles; nitrocellulose and polyester fillers; anti-corrosion coatings for high temperatures; sandable nitrocellulose sealant for wood; paints for traffic signs; and paints for use by children and in schools.

## EU

**BoA Issues Landmark Decision In Data Sharing Dispute:** On April 15, 2019, the European Chemicals Agency's (ECHA) Board of Appeal (BoA) issued its [decision](#) in a data sharing dispute concerning access to data and cost sharing for the substance Acid Orange 7. The Appellants in the case before the BoA were REACH & Colours Kft and REACH & Colours Italia S.r.l. REACH & Colours Kft is the Lead Registrant for Acid Orange 7, and REACH & Colours Italia S.r.l. represents "several consortia which manage the substance information exchange forum ('SIEF') for Acid Orange 7 and also [manage] SIEFs for over 500 other dyes." The Interveners in the case in support of ECHA, represented by Centro Reach S.r.l., were Colorex S.r.l., Codyeco S.p.a., Colortex S.p.a., and Triade B.V.

Between November 9, 2012, and April 12, 2017, data-sharing negotiations took place concerning Acid Orange 7. These negotiations “took place mainly between the Appellants and Centro Reach S.r.l.” Centro Reach S.r.l. informed the Appellants that it was acting on behalf of the Dye-Staff Cooperation Group, and that the Interveners were members of the group. Two of the Interveners, Colorex S.r.l. and Codyeco S.p.a., also had individual e-mail exchanges with the Appellants. During the course of their negotiations, the Appellants and Interveners disagreed on the following “four aspects of the terms for sharing data and costs”:

- The identification of the studies to which access was being negotiated;
- The calculation of the costs of gathering and submitting to ECHA the information required for the registration of Acid Orange 7 (*i.e.*, administrative costs);
- An annual surcharge of eight percentage points applied to the price of a Letter of Access (LoA); and
- A surcharge of 15 percent applied to the value given to each study, regardless of how this value was calculated.

The Appellants and the Interveners did not find an agreement on the sharing of data and costs, and on April 13, 2017, the Interveners filed a data-sharing dispute with ECHA. On July 20, 2017, ECHA adopted the Contested Decision based on Article 30(3) of the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation. In the Contested Decision, ECHA found that the Interveners “had made every effort to ensure that data and costs were shared in a fair, transparent and nondiscriminatory way, whilst the Appellants had failed to do so.”

ECHA reached this conclusion primarily on the grounds that, despite repeated requests from the Interveners to that effect, the Appellants did not provide the Interveners with the titles and authors of the studies to which access was being negotiated, and failed to address the Interveners’ concerns regarding the calculation of administrative costs, the eight percent annual surcharge, and the 15 percent surcharge. The Contested Decision consequently granted the Interveners permission to refer to four studies on vertebrate animals contained in the registration dossier submitted by REACH & Colours Kft.

The Appellants filed the appeal before the BoA on August 4, 2017, and ECHA filed its Defense on October 9, 2017. On December 20, 2017, the BoA granted the Interveners “leave to intervene in support of [ECHA].” The Appellants requested the BoA to declare the appeal admissible, annul the Contested Decision, order the refund of the appeal fee, and take such other or further measures as justice may require. ECHA, supported by the Interveners, requested the BoA to dismiss the appeal.

The Appellants raised four pleas in law in support of their appeal, alleging that ECHA:

- Made several errors in its assessment of the parties’ efforts during the data-sharing negotiations;
- Exceeded its powers by going beyond the requirements of REACH and Commission Implementing Regulation (EU) 2016/9 on Joint Submission of Data and Data-sharing in accordance with the REACH regulation (Implementing Regulation 2016/9);
- Breached the principle of the protection of legitimate expectations by contravening its Guidance on data-sharing; and
- Breached the principle of equal treatment by preventing the Appellants from imposing the eight percent annual surcharge and the 15 percent surcharge.

The BoA rejected the first plea, and found that the Appellants failed to be transparent in terms of the identification of the studies to be shared, and insisted on unfair and/or discriminatory terms for the calculation of administrative costs, the eight percent annual surcharge, and the 15 percent surcharge. The BoA found that the Interveners “made every effort” by consistently challenging the Appellants on identification of studies, calculation of administrative costs, and the surcharges. The BoA indicates “[w]hilst the Appellants did respond to the Interveners’ questions, this did not lead to any changes to the proposed terms.” The BoA stated “[ECHA] was therefore correct in finding in the Contested Decision that the Interveners made every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.”

The BoA rejected the second plea on the basis that “under Article 5(1) of Implementing Regulation 2016/9, which implements Article 30(3) of the REACH Regulation, [ECHA] is competent to assess, following the submission of a data-sharing dispute, whether the proposed terms to share data and costs are fair, transparent and non-discriminatory.” The BoA indicated this position is consistent with its Decision in Case A-017-2013, Vanadium R.E.A.C.H. Forschungsund Entwicklungsverein, dated December 17, 2014.

Regarding the third plea, the Appellants argued that ECHA disregarded its own Guidance on data-sharing, according to which “administrative costs can be recorded by activity rather than by substance or endpoint.” ECHA, supported by the Interveners, argued that the Appellants had no legitimate expectations that their way of calculating administrative costs would be accepted. The BoA provides that, contrary to the Appellants’ argument, the Contested Decision does not state that administrative costs cannot be recorded by activity rather than by substance or endpoint. In contrast, the BoA states “the Contested Decision correctly finds that the Appellants have failed to address the Interveners’ concerns as regards the calculation of administrative costs.” Regarding the relevant text on pages 117 and 118 of ECHA’s Guidance on data-sharing, the BoA states “[t]his part of the Guidance is couched in very generic language ... It is not precise and unconditional within the meaning of the case-law referred to in [paragraphs] 180 and 181 [of the BoA’s decision].” The third plea was rejected by the BoA.

Regarding the fourth plea, the BoA stated that in deciding on a data-sharing dispute, ECHA can either grant or deny permission to refer to information submitted by a previous registrant. The BoA indicates that ECHA was correct in finding in the Contested Decision that the Interveners made every effort to ensure that costs are determined in a “fair, transparent and non-discriminatory way.” The BoA provides that, having reached this conclusion, ECHA “was obliged to grant the Interveners permission to refer to the four studies on vertebrate animals.” The BoA states that ECHA had no discretion in this regard and that it cannot, therefore, have breached the principle of equal treatment. The BoA provides further that the Contested Decision does not prevent the Appellants from recovering costs that they claim are covered by the surcharges. The fourth plea was rejected by the BoA.

As “all the Appellants’ pleas and arguments” were rejected, the BoA dismissed the appeal and decided that the appeal fee will not be refunded. This case is expected to have significant implications for fairness and non-discrimination in data sharing under REACH.

***EP Passes Resolution Urging Next EC To Tackle Endocrine Disruptors “Swiftly”:*** The European Parliament (EP) passed a [resolution](#) on April 18, 2019, urging the next European Commission (EC) to tackle endocrine disruptors “swiftly,” especially in toys, cosmetics, and food contact materials. The resolution asks the next EU executive to develop a horizontal definition for endocrine disrupting chemicals based on the World Health Organization (WHO) definition no later than **June 2020**. The resolution includes provisions calling on the EC to:

- Make legislative proposals no later than **June 2020** to insert specific provisions on endocrine disruptors into the Cosmetics Regulation, similar to those on carcinogenic, mutagenic, or toxic to reproduction (CMR) substances;
- Draw up legislative proposals no later than **June 2020** to insert specific provisions on endocrine disruptors into the Toy Safety Directive, similar to those on CMR substances but without any reference to thresholds of classification, as such thresholds are not applicable for endocrine disrupting chemicals;
- Calls on the EC to revise the Regulation on Food Contact Materials no later than **June 2020** to reduce the content of hazardous substances therein, with specific provisions to substitute the use of endocrine disruptors;
- Considers that there is an urgent need to accelerate test development and validation to identify endocrine disruptors, including new approach methodologies;
- Calls on the EC to ensure that data requirements are continuously updated in all the relevant legislation to take account of the latest technical and scientific progress so that endocrine disruptors can be properly identified;
- Calls on the EC to take mixture effects and combined exposures into account in all relevant EU legislation;
- Calls on the EC to ensure adequate bio-monitoring of endocrine disruptors in human and animal populations, as well as the monitoring of endocrine disruptors in the environment, including in drinking water;
- Calls on the EC to ensure that the EU framework on endocrine disruptors becomes an effective contribution to the EU strategy for a non-toxic environment, to be adopted as soon as possible; and
- Calls on the EC to promote research into endocrine disruptors, in particular with regard to their epigenetic and transgenerational effects, their effects on the microbiome, novel endocrine disruptor modalities, and characterization of dose-response functions, as well as safer alternatives.

The resolution passed by a vote of 447 to 14 with 41 abstentions. It is not legally binding and does not have any immediate practical effect. To date the EC has established criteria to identify endocrine disrupting chemicals only

for biocides and pesticides.

**ECHA Releases New Submission Portal For Poison Centers:** On April 24, 2019, ECHA issued a press release entitled "[ECHA releases new submission portal for poison centres.](#)" ECHA provides that its new portal allows companies to prepare and submit information on hazardous mixtures that can be used by poison centers. ECHA states that its submission portal for poison centers is a secure, online way to manage notifications centrally -- "creating, submitting and following their status." The [submission portal](#) is based on the harmonized format that defines the information requirements set in the Classification, Labeling, and Packaging (CLP) regulation.

ECHA indicates that, under the CLP regulation, entities placing hazardous mixtures on the market have to provide information about these mixtures to the relevant national appointed bodies. This information must be provided in a harmonized format:

- From **January 1, 2020**, for mixtures for consumer use;
- From **January 1, 2021**, for mixtures for professional use; and
- From **January 1, 2024**, for mixtures for industrial use.

The appointed bodies in Member States make this information available to [poison centers](#) "so that they can provide rapid medical advice in the event of an emergency." Poison centers provide medical advice to citizens and healthcare professionals on health emergencies arising from exposure to hazardous chemicals or to other toxic agents, such as medicines, plants, bites, and stings. Poison centers in the EU answer calls for support daily and around the clock.

ECHA's submission portal allows companies to notify several Member States in which they intend to place their products on the market with a single submission. ECHA indicates this will reduce companies' administrative burden and costs when submitting information on hazardous mixtures to appointed bodies in EU Member States and European Economic Area (EEA) countries. ECHA is not charging a fee for use of the portal, and indicates "some Member States may levy fees to cover their costs." Notifications submitted through the portal will be valid once the relevant Member State is ready to accept them.

ECHA indicates that "further improvements to the user interface and more functionalities" will be implemented in future releases of the portal in **July and November 2019**.

**EP Research Service Publishes Overview Of Latest Developments At EU Level In Context Of Plant Protection Products:** On April 25, 2019, the EP Research Service (EPRS) [announced](#) that it published an overview of the latest developments at the EU level in the context of plant protection products. The paper provides a "desk research-based" overview of the key moments of the (scientific and regulatory) debate on endocrine disruptors, with a focus on the latest developments at the EU level, namely Commission Regulation (EU) 2018/605, which establishes scientific criteria for endocrine disruptor properties, and the EC communication published in November 2018, "Towards a comprehensive European Union framework on endocrine disruptors," in the particular context of plant protection products. It outlines three main axes of the debate on endocrine disruptors that have also impacted the latest regulatory and strategic approaches in the EU:

- Gaps and divergences at the scientific level;
- Regulatory issues at stake; and
- Strongly opposing views between the two main categories of stakeholders: those representing safety, public health, and environmental protection interests (non-governmental organizations) and industry actors.

The paper states that to achieve the objectives of ensuring a high level of protection for humans and the environment and to reduce human exposure to harmful substances, "it seems appropriate that the attention of policy-makers and regulators should be focused on the need to address the issue more comprehensively and coherently under the existing regulations." Furthermore, according to the paper, given that chemicals are currently regulated as separate classes based on their use, and that only Regulation (EU) No 528/2012 on Biocidal Products (BPR) and Regulation (EC) No 1107/2009 on the Placing on the Market of Plant Protection Products (PPPR) have criteria to identify chemicals as endocrine disruptors, "going beyond this approach is an option that is worth considering."

**ECHA Database Will Allow Users To Search EU Legislation For Chemical-Specific Requirements:** According to an [article](#) in ECHA's May 2019 *Newsletter*, ECHA plans to launch an online service in **2020** that will allow companies to find out how their substances are being regulated in the EU and what legal

obligations they have. The European Union Chemical Legislation Finder (EUCLEF) will initially cover 40 pieces of EU legislation. Through EUCLEF, companies will have access to a wide range of legislative information on areas such as:

- Cosmetic products;
- Pesticides;
- Waste;
- Toy safety; and
- Food safety and food contact materials.

According to ECHA, EUCLEF will also support the work of the EC and national authorities by helping them identify substances for which there may be regulatory overlaps or gaps. The current plan is to create a EUCLEF landing page on ECHA's website. This page will list the pieces of legislation covered by the service and not managed by ECHA -- 35 at first -- and provide access to an overview of the scope of the legislation, exemptions, regulatory activities, obligations, and substance lists. ECHA states that it "plans to continue developing the service over the next few years, adding further pieces of EU legislation and enriching the kind of information that can be accessed through ECHA's web pages." These plans include integrating information on national occupational exposure limits and emission limit values from individual Member States to EUCLEF at a later stage.

**EC Publishes Glossary Of Common Ingredient Names For Use In Labeling Cosmetic Products:** On May 8, 2019, the EC published in the *Official Journal of the European Union* a [notice](#) establishing a glossary of common ingredient names for use in labeling cosmetic products. Under Article 33 of Regulation (EC) No 1223/2009, the EC must compile and update a glossary of common ingredient names. According to the notice, the inventory and nomenclature has become outdated as a result of the high number of new ingredients introduced onto the market every year. The notice notes that some ingredients used in perfume and aromatic compositions do not have an International Nomenclature of Cosmetic Ingredients (INCI) name. The notice states that "[s]o-called 'perfuming names'" have been used in the EU to label cosmetic products containing these ingredients. Therefore, for these ingredients, the glossary should list the perfuming names that have previously been used for them in the EU. The listed common ingredient names are to be applied, for the purpose of labeling cosmetic products placed on the market, at the latest 12 months after publication of the glossary in the *Official Journal of the European Union*.

**EC Requests Data Regarding Potential Endocrine Disruptors In Cosmetics:** On May 16, 2019, the EC commenced a "[Call for data on ingredients with potential endocrine-disrupting properties used in cosmetic products](#)." The period of consultation ends on **October 15, 2019**, and the EC requests data from "[a]ny interested parties, including academic and other research institutes, EU countries' authorities, manufacturers of cosmetic products, producers of the substances concerned and consumers associations."

The EC invited interested parties to submit scientific information relevant to safety assessment for 14 chemical substances. The EC states "[t]o prepare requests for scientific opinions to the [Scientific Committee on Consumer Safety (SCCS)], interested parties are invited to submit any relevant scientific information including data regarding all physicochemical properties, toxicokinetics and toxicological end-points, assessment of exposure through consumer products and/or an indication of the suggested safe concentration limits for the substances." The substances are:

- Benzophenone-3;
- Kojic acid;
- 4-Methylbenzylidene camphor;
- Propylparaben;
- Triclosan;
- Resorcinol;
- Octocrylene;
- Triclocarban;

- Butylated hydroxytoluene;
- Benzophenone;
- Homosalate;
- Benzyl salicylate;
- Genistein; and
- Daidzein.

The EC indicates that data submitted should be in line with the SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation (tenth revision).

**EC Launching Study On Managing Information Flows From Supply Chains To Waste Operators:** The EC has contracted with Oekopol Institute and RPA to undertake a “feasibility study on the use of comprehensive tools to manage information flows from product supply chains to waste operators.” This is a “Circular Economy” issue and related to substance declaration, supply chain engagement, and the environmental impact of products. This study is not, however, connected to ECHA’s parallel development of a substances of very high concern (SVHC) database under the recent amendment to the Waste Framework Directive.

The EC study will involve supply chain and life cycle mapping for different types of products through a number of case studies, with the aim of improving information flow in line with REACH Article 33 and also including waste management, and consideration of whether more information on the content of substances of concern in articles would impact how those articles are managed at the end of life stage.

It is anticipated that such case studies will provide an opportunity to explore what added benefit (as well as costs) there would be from increased requirements for the transfer of data on substances of concern through the supply chain.

The aims of the study are to identify:

- What types of information flow may be of value -- what, to whom, and from whom;
- Would there be added value from new requirements given the types of systems that already exist for products within the sector of concern;
- How can the challenges associated with greater information flow be addressed, such as those arising from confidentiality issues;
- What types of technologies could be used to facilitate the transfer of information; and
- What would the implications be for the waste sector, including the need for new technologies, changes to markets.

**Safer Chemicals Conference Materials Available Online:** On May 21-22, 2019, ECHA held a two-day [conference on safer chemicals](#). ECHA intended the conference to offer stakeholders insight into the current priorities in EU chemicals regulation after the final REACH registration deadline. The topic on May 21, 2019, was training on notifying hazardous mixtures to poison centers, and ECHA has posted the following materials:

- [Notifying hazardous mixtures to Member States](#);
- [Poison Centres Notification Preview Report](#); and
- [Hands on training: example data](#).

On May 22, 2019, the presentations included:

- Session 1 – Improving compliance of REACH registration data:
  - [Setting the scene](#) -- Bjorn Hansen, Executive Director, ECHA; [video](#);
  - [Grouping of substances](#) -- Mike Rasenberg, ECHA; [video](#);
  - [Taking action to ensure compliance](#) -- Ofelia Bercaru, ECHA; [video](#);

- [Compliance challenges and solutions](#) -- Sylvie Lemoine, European Chemical Industry Council; [video](#);
- [What citizens and workers need to know about REACH compliance](#) -- Tatiana Santos, European Environmental Bureau; [video](#); and
- [Discussion](#).
- Session 2 -- Tackling substances of concern:
  - [10 years of regulatory risk management](#) -- Matti Vainio, ECHA; [video](#);
  - [Case study: microplastics](#) -- Sandrine Lefèvre-Brévert, ECHA; [video](#);
  - [Tools for tackling substances of concern](#) -- Jerker Ligthart, International Chemical Secretariat; [video](#); and
  - [Discussion](#).
- Session 3 – Improving safe use of chemicals:
  - [Improving safe use in the supply chain](#) -- Kevin Pollard, ECHA; [video](#);
  - [Healthy workplaces campaign](#) -- Elke Schneider, European Agency for Safety and Health at Work; [video](#);
  - [What have we learnt through inspections](#) -- Sinead McMickan, Health and Safety Authority, Ireland; [video](#);
  - [Case study on improving safe use](#) -- Marianne Lyngsaae, Brenntag Nordic A/S; [video](#)
  - [Closing remarks](#) -- Jukka Malm, Deputy Executive Director, ECHA; [video](#); and
  - [Discussion](#).

**ECHA Indicates “Improving Compliance” Is Its Key Priority:** On May 21, 2019, ECHA issued a press release entitled “[Improving compliance is ECHA's key priority](#).” In its press release, ECHA indicates that non-compliant information on chemicals is a “serious issue that needs to be fixed.” ECHA notes that REACH places the burden of proof on industry to “make sure that their chemicals are safe to use.”

The press release provides that, by law, ECHA needs to check the compliance of at least five percent of REACH registrations. ECHA indicates that, in ten years of evaluation, it has checked more than 2,700 dossiers for compliance. For high-volume substances, “the checks cover 25 [percent] of the substances.” ECHA states “[t]his has led to improved knowledge and safer use of chemicals.”

According to ECHA, it does not have the legal mandate to revoke market access based on its compliance checks. If companies do not provide the necessary information, national authorities are responsible for enforcing the law. ECHA states “[i?]mproving compliance with the law is our key priority.” ECHA states that, through its [annual evaluation reports](#), it has consistently highlighted the issue of non-compliant information and given REACH registrants [recommendations](#) on how to improve.

ECHA states in its press release that, as a next step, it is preparing an action plan with the EC to increase its actions for compliance checks, “raising the percentage of dossiers to be checked and increasing efficiency.” ECHA states it is committed to “screening all registered substances by **2027**, and checking compliance of all substances that need it.” ECHA provides that there can be several reasons for checking compliance of substances, including their hazardous properties. In conclusion to its press release, ECHA states “[t]he plan will be published **before the summer**.”

**EC Grants REACH Authorizations For Diglyme:** The EC has granted authorization under REACH to two companies for use of diglyme, a SVHC included in REACH Annex XIV. Diglyme is included in the REACH Authorization List due to its reprotoxic properties, and the substance had a sunset date of August 2017.

On April 24, 2019, the EC granted authorization to [Life Technologies](#) for use of diglyme as a process chemical in the manufacture of Dynabeads<sup>®</sup>. The decision granting an authorization for diglyme to Life Technologies,

published in the *Official Journal of the European Union* on May 2, 2019, provides that the “[d]ate of expiry of review period” is **August 22, 2029**. The “[r]easons for the decision” section in the *Official Journal of the European Union* indicates: (1) risk is adequately controlled in accordance with Article 60(2) of REACH; and (2) there are no suitable alternatives.

On May 14, 2019, the EC granted to [Roche Diagnostics](#) authorization for use of diglyme as a process chemical in the manufacture of “one specific type of Dynabeads<sup>®</sup> used in immunodiagnostic assays (in vitro diagnostic).” The decision granting the authorization to Roche Diagnostics was published in the *Official Journal of the European Union* on May 21, 2019, and includes the same “[d]ate of expiry of review period” and reasons as the decision in favor of Life Technologies.

**EC Completes Consultation For Inclusion Of 12 Additional Substances In REACH Authorization List:** On May 22, 2019, the EC completed a public consultation on a [Draft Regulation](#) and [Annex](#) that provide for inclusion of 12 additional substances in REACH Annex XIV, the Authorization List. The Authorization List currently covers 43 chemical substances, and inclusion of the additional 12 substances would result in an expanded Authorization List covering 55 substances.

The EC performed public consultation for the following substances:

- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear -- Toxic for reproduction (Category 1B);
- Dihexyl phthalate -- Toxic for reproduction (Category 1B);
- 1,2-benzenedicarboxylic acid, di-C6- 10-alkyl esters; 1,2- benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with = 0.3% of dihexyl phthalate -- Toxic for reproduction (Category 1B);
- Trixylyl phosphate -- Toxic for reproduction (Category 1B);
- Sodium perborate; perboric acid, sodium salt -- Toxic for reproduction (Category 1B);
- Sodium peroxometaborate -- Toxic for reproduction (Category 1B);
- 5-sec-butyl-2-(2,4-dimethylcyclohex3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group) -- Very persistent and very bioaccumulative (vPvB);
- 2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol (UV-328) -- Persistent, bioaccumulative, and toxic (PBT), vPvB;
- 2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol (UV-327) -- vPvB;
- 2-(2H-benzotriazol-2-yl)-4-(tertbutyl)-6-(sec-butyl)phenol (UV-350) -- vPvB;
- 2-benzotriazol-2-yl-4,6-di-tertbutylphenol (UV-320) -- PBT, vPvB; and
- Diazene-1,2-dicarboxamide (C,C'- azodi(formamide)) (ADCA) -- Respiratory sensitizing properties (Article 57(f) – human health).

The Draft Regulation and Annex will be considered, and potential updates to REACH Annex XIV will be completed, consistent with EU lawmaking procedures.

## ISRAEL

**EU Concerned With Israel’s Draft Cosmetics Regulation:** The EU has expressed concern that comments it made as part of the review process for Israel’s draft cosmetics regulation, the Pharmacist Regulations (Cosmetics), appear to have been disregarded. The EU had particular concerns because, although the Israeli draft has areas in which it deviates, it is based on the EU’s Regulation (EC) No. 1223/2009. The draft, which is currently being debated in the Israeli Knesset, includes a requirement for the “responsible person” to issue a quarterly report for each product, an aspect not included in No. 1223/2009. The EU Regulation links each cosmetic product to an individual responsible for it. The Israeli requirement is believed to be unduly burdensome on companies, while simultaneously not providing any significant benefit to the public.

Further discrepancies between the draft and the EU Regulation are the Israeli requirement to obtain a Good Manufacturing Practice certificate from the authority, a process not required by most other countries’ regulations,

and a requirement in the draft to notify the authority six months in advance of any nanomaterial-containing products.

**Draft GHS Regulation Published:** As expected in our "[Forecast for U.S. Federal and International Chemical Regulatory Policy 2019](#)," Israel published its draft GHS standard in the Official Government Gazette, known as "Reshumot," on April 12, 2019. Readers may recall that, as part of its membership in the Organization for Economic Cooperation and Development (OECD), and the OECD's May 25, 2018, "[Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals](#)," Israel is required to implement GHS.

Presently available only in Hebrew, "SI 2302 Part 1 - Dangerous Substances and Mixtures: Classification, Labelling, Marking and Packaging" and "SI 2302 Part 2 - Dangerous Substances and Mixtures: Transportation -- Classification, Labelling, Marking and Packaging" are expected to come into national law on **August 9, 2019**. Both documents were originally drafted in December of 2013, and the 2019 publication contains many revisions to the initial documents. For example, many more substances and product types appear to be classified as hazardous under the revised standards.

Entities will then have a three-year transition period to implement the GHS program -- until **August 9, 2022** -- provided the law enters into force as anticipated.

## MEXICO

**Environment Ministry Plans To Implement Rotterdam Convention:** The *Secretaría de Medio Ambiente y Recursos Naturales* (Ministry of Environment and Natural Resources; SEMARNAT) has announced plans to update its national chemicals action plan (National Plan Development **2019-2024**) to implement the provisions of the 1998 (signed)/2004 (implemented) Rotterdam Convention. The Rotterdam Convention is a multilateral treaty passed with the manifest purpose of promoting shared responsibility and the open exchange of information among signatory countries with respect to certain hazardous chemicals.

In addition to implementing the Convention, Mexico plans to use the activity as a springboard toward developing a comprehensive strategy for chemical substance and pesticide management in the country. In a [press release](#), SEMARNAT stated it would strengthen chemical registration efforts (although interestingly, no mention was made of Mexico's still-to-be-implemented *Inventario Nacional de Sustancias Químicas* (National Inventory of Chemical Substances of Mexico; INSQ)), risk assessments, and lifecycle management.

## SWEDEN

**SweNanoSafe Launches Free Web Tool To Help Register Nanomaterials Under REACH:** On May 16, 2019, the Swedish National Platform for Nanosafety (SweNanoSafe) [announced](#) the availability of [eREACHNano](#), "a new web tool focused on helping small and medium-sized companies that may lack sufficient in-house expertise on the regulation covering nanomaterials." The web tool explains the data requirements for nanoforms according to the REACH guideline documents, including:

- Definition of nanomaterials;
- Types of nanomaterials;
- Overview of nanomaterial-specific annexes to existing REACH guidance;
- Chemical and physical characterization of nanomaterials;
- Testing of nanomaterials; and
- Exposure and risk assessment of nanomaterials.

SweNanoSafe notes that the December 2018 amendments clarifying the information requirements for nanomaterials have not yet been included. The information requirements will apply beginning **January 1, 2020**. The information requirements will be included in a subsequent version of the web tool to be launched later in **2019**.

## UNITED KINGDOM (UK)

**MPs Issue Letter To DEFRA Regarding Duplicate Animal Testing Due To Brexit:** On April 25, 2019, 12 Members of Parliament (MP) issued a [letter](#) regarding duplicate animal testing due to Brexit, on behalf of Cruelty

Free International, to Dr. Thérèse Coffey MP of the Department for Environment, Food, and Rural Affairs (DEFRA). The opening paragraph to the letter states:

On behalf of Cruelty Free International we are writing to seek a commitment that there will be no duplication of animal testing for chemical registrations as [a] result of the UK's withdrawal from the [EU].

The MPs indicate in the letter that, “despite repeated requests,” the UK government has been unable to provide a “clear assurance” that there will be no duplication of animal testing “either as a result of a no-deal exit or when a new UK REACH comes into effect.” In the letter, the MPs welcome Dr. Coffey’s commitment to the “EU Energy and Environment Sub-Committee earlier this year that the [Health and Safety Executive (HSE)] will be encouraged to [recognize] the validity of animal testing already undertaken to ‘avoid the need for further testing.’”

The letter provides that the 12 MPs share the “widely held concerns” that this position will be undermined by confidentiality conditions relating to data in existing contracts, resulting in the need for testing to be replicated. In conclusion, the letter states “[g]iven the urgency of this situation, we look forward to your swift response.”

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