

## Top International News in Chemical Policy and Regulation: March 2018: Europe and United Kingdom

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Friday, March 23, 2018

**Registrants Initiating Laboratory Testing By March 31, 2018, May Be Granted Extension Of REACH Deadline For Complete Dossier Submission:** As reported in our March 22, 2018, memorandum, the European Chemicals Agency's (ECHA) Directors' Contact Group (DCG) recently posted [guidance for companies that are required to register under the European Union's \(EU\) Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) regulation by May 31, 2018](#). This guidance focuses on specific important issues for companies managing compliance under the 2018 REACH deadline, and should be read in conjunction with DCG's "[Summary Paper on \[Four\] Issues](#)." Among the most helpful aspects of the guidance is "DCG Issue 10.3 -- Completeness of Registration Dossiers -- Data required in Annexes VII and VIII of REACH not yet available by the registration deadline" addressed to companies "which have ordered tests in a timely manner but have not received the results in due time to complete their registration dossier." This DCG Solution is particularly important due to the number of substances being registered by **May 31, 2018**, extensive REACH data requirements, and limited laboratory capacity to meet industry's compliance needs.

### EU

#### **EC Notifies WTO Of Draft Implementing Decision**

**Identifying 3-Benzylidene Camphor As An SVHC:** On January 29, 2018, the European Commission (EC) notified WTO of a draft implementing decision on the identification of 3-benzylidene camphor as a substance of very high concern (SVHC) in accordance with REACH Article 57(f) due to its

endocrine disrupting properties whose effects on the environment give rise to an equivalent concern to other SVHCs. According to the notification, the objective of the draft implementing decision is to identify 3-benzylidene camphor as an SVHC due to these properties and to include it in the Candidate List. The proposed date of adoption and entry into force is **April 25, 2018**.

**ECHA Recommends Adding Seven SVHCs To Authorization List:** ECHA announced on February 5, 2018, that it proposed seven SVHCs for authorization. According to ECHA, it prioritized the seven SVHCs from the Candidate List "because of their intrinsic properties in combination with high volume and widespread uses, which may pose a threat to human health or the environment." While some of the substances are currently not used in the EU, ECHA notes they could replace other substances recommended for or already on the Authorization List. The SVHCs are:



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Substance name	SVHC property	Examples of uses in the scope of authorization
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-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)	Fragrance in soaps and detergents
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	Persistent, bioaccumulative, and toxic (PBT), vPvB	Ultraviolet (UV) stabilizer, e.g., in plastic products, rubber, coatings
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	vPvB	(1)
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	vPvB	(1)
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	PBT, vPvB	(1)
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 (EC 201-559-5)	Toxic for reproduction	Plasticizer in polyvinyl chloride (PVC) compounds, adhesive
1-methyl-2-pyrrolidone (NMP)	Toxic for reproduction	Widely used solvent, e.g., in coatings, cleaning agents, functional fluids, etc.

(1) The substance has no registered uses but is recommended based on grouping consideration (structural similarities with UV-328). This is to avoid “regrettable substitution.”

The final decision on the inclusion of the substances in the Authorization List and on the dates by which companies will need to apply for authorization to ECHA will be taken by the EC in collaboration with the EU Member States and the EP. More information is available in ECHA’s February 5, 2018, press release, “[ECHA proposes seven substances for authorisation.](#)”

**EUON Links Nanomaterials Used In Cosmetic Products To Registration Data:** In summer 2017, the EC published a [catalog of nanomaterials used in cosmetic products](#) on the EU market. On February 5, 2018, the EU Observatory for Nanomaterials (EUON) [published a table](#) linking nanomaterials listed in the catalog to their REACH registration data in ECHA’s database. According to EUON, the linking was done by matching chemical substances in ECHA’s database through their Chemical Abstracts Service (CAS) numbers and/or with the name of the nanomaterial in the catalog. EUON notes that as the registration of nanomaterials under the Cosmetics Regulation and the registration of substances under REACH have different scopes, it is not always possible to have a perfect match. Some catalog entries are more specific in scope than the substances registered under REACH. EUON cautions that a REACH registration may not specifically cover the nanofoms of the substances used in cosmetics.

**Harmonized Enforcement Project On Restrictions Finds Phthalates In Toys And Asbestos In Second-Hand Products:** On February 13, 2018, ECHA announced the availability of the Forum for Exchange of Information on Enforcement's [final REACH-EN-FORCE-4 \(REF-4\) project report](#). ECHA states that the project report "shows a relatively high number of products on the European market containing chemicals that are restricted under REACH." According to ECHA, inspectors in 27 European countries checked 1,009 mixtures, 4,599 articles, and 17 substances. Overall, out of 5,625 targeted product checks, 18 percent did not comply with the restrictions. The most frequent breaches were phthalates in toys, cadmium in brazing filler, and asbestos fibers in products. ECHA notes that the products containing asbestos -- for example, catalytic heaters, thermos flasks, and brake pads -- were mostly second-hand and probably produced before the restrictions prohibiting the sale of products containing asbestos came into force. In addition, inspectors also found high concentrations of chromium VI in leather articles and cadmium in jewelry. Overall, according to ECHA, most of the breaches were found with products that had origins that could not be identified (39 percent of such products did not comply), followed by products imported from China (17 percent). More information is available in ECHA's press release, "[Inspectors find phthalates in toys and asbestos in second-hand products](#)."

**EU And EEA Inspectors Begin Checking Classification And Labeling Of Mixtures:** ECHA announced on February 20, 2018, that inspectors in EU and European Economic Area (EEA) Member States have begun checking whether the classification and labeling of a mixture corresponds to the information presented in the safety data sheet (SDS) for the mixture. The checks began in January 2018 under the enforcement project REACH-EN-FORCE-6 (REF-6). ECHA states that 31 European countries will participate in the project. Member States may also include the following additional modules in their inspections: exemptions concerning labeling and packaging requirements; the obligation to apply harmonized classification and labeling (CLH); the specific requirements of the Classification, Labeling, and Packaging (CLP) Regulation for liquid laundry detergent capsules; and the authorization and labeling of biocidal products. Inspection activities will continue throughout **2018**. According to ECHA, a report on the results of the inspections will be available in the **fourth quarter of 2019**. More information is available in ECHA's February 20, 2018, press release, "[Inspectors begin controls of classification and labelling of mixtures](#)."

**REACH Committee Approves 1,2-Dichloroethane, Diglyme, And Trichloroethylene Authorization**

**Applications:** At the REACH Committee meeting on February 21-22, 2018, Member States granted four companies authorization for conditional uses of 1,2-dichloroethane, which is included in REACH Annex XIV as an SVHC. The authorizations relate to the following companies and uses:

- H&R Ölwerke Schindler and H&R Chemisch-Pharmazeutische Spezialitäten:
  - Industrial use as a solvent and anti-solvent of the feedstock and intermediate product streams in combined de-waxing and de-oiling of refining of petroleum vacuum distillates for the production of base oils and hard paraffin waxes;
- Grupa Lotos:
  - Extraction solvent in de-waxing of petroleum vacuum distillates and de-asphalted oil and de-oiling of slack wax to produce base oils and paraffinic waxes;
- Lanxess Deutschland:
  - Industrial use as a swelling agent and reaction medium during the phthalimidomethylation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of anion exchange and chelating resins; and
- Dow Italia and Dow France:
  - Industrial use as a sulphonation swelling agent of polystyrene-divinylbenzene copolymer beads in the production of strong acid cation exchange resins.

REACH Committee members approved Bracco Imaging's application to use diglyme as a processing aid in the purification of 5-amino-2,4,6-triiodoisophthalic acid dichloride by precipitation. Member States also approved Blue Cube Germany's application for the following five uses of trichloroethylene:

- Use in industrial parts cleaning by vapor degreasing in closed systems where specific requirements exist;
- Industrial use as process chemical in Alcantara Material production;
- Use as extraction solvent for bitumen in asphalt analysis;
- Use in packaging; and

- Use in formulation.

**EP Committee Approves Waste Legislation:** On February 27, 2018, the European Parliament (EP) Committee on the Environment, Public Health and Food Safety approved a package of bills that will amend existing EU laws on overall waste targets, landfilling of waste, packaging waste, and specific waste streams such as batteries, electronics, and vehicles. The EP's February 27, 2018, [press release](#) states that the package includes the following targets:

- Waste and packaging waste: By **2025**, at least 55 percent of municipal waste (from households and businesses) should be recycled. The target will rise to 60 percent by **2030** and 65 percent by **2035**. Sixty-five percent of packaging materials will have to be recycled by **2025**, and 70 percent by **2030**. Separate targets are set for specific packaging materials, such as paper and cardboard, plastics, glass, metal, and wood; and
- Landfilling: EU Member States should endeavor to ensure that as of **2030**, all waste suitable for recycling is not accepted in a landfill. The draft law also limits the share of municipal waste to be landfilled to a maximum of ten percent by **2035**.

The EP will vote on the package during its **April 16-18, 2018**, session, and the package must also be formally approved by the Council of the EU. EU Member States will then have two years to adopt national legislation.

**ECHA Finds Information On Chemicals Still Has To Improve:** ECHA announced on February 28, 2018, the availability of its annual progress report on evaluations under REACH. Since 2008, ECHA has checked the compliance of 1,952 registrations, most of them with suspected data gaps. According to ECHA, in the "vast majority" of cases, important safety information on chemicals was missing, mostly related to pre-natal developmental toxicity, mutagenicity or genotoxicity, reproduction toxicity, and long-term aquatic toxicity. Overall, ECHA has issued 2,586 information requests to registrants. In 2017, ECHA checked the compliance of 222 registrations, most of them on substances of potential concern. In 151 cases, ECHA requested further information that is essential for demonstrating the safe use of the substance.

ECHA states that it currently carries out 300-350 follow-up evaluations each year to check whether registrants have provided the data required in ECHA's decisions. According to ECHA, by focusing on substances of potential concern, ECHA also considers the need for further risk management measures. Since 2013, based on dossier evaluation, ECHA has flagged 73 substances for potential harmonized classification.

Between 2012 and 2017, EU Member State authorities evaluated 221 substances to clarify suspected concerns. For 159 substances, further information was requested from registrants. Overall, 74 substance evaluations were concluded. In 43 percent of the concluded cases, the national authorities considered further measures to manage the substances' risks.

ECHA offers the following key recommendations:

- Update dossiers with relevant new information;
- Justify and document weight-of-evidence approaches; and
- Provide robust grouping and read-across arguments.

More information is available in ECHA's February 28, 2018, press release, "[Information on chemicals still has to improve.](#)"

**ECHA Restructures ROI:** On February 28, 2018, ECHA announced that it restructured the Registry of Intentions (ROI), which contains information on substances intended for CLH, identification as SVHCs, or restriction. According to ECHA, the change will make it easier for users to find information on the possible future regulation for these substances. Previously, the ROI listed substances according to their dossier status (*i.e.*, intention received, dossier submitted, or intention or submission withdrawn) under each regulatory process. Substance information is now presented in three lists based on regulatory process (CLH, identification as SVHCs, restriction). By referring to the newly added "Status" field, users will be able to track what stage the substance is at for a given process. ECHA also expanded the status information on CLH dossiers to cover all the steps of the regulatory process, from submission of the intention to publication of the substance in the table of harmonized entries. The CLH information also includes opinions adopted by the Committee for Risk Assessment (RAC). ECHA intends a similar expansion for the SVHCs and restrictions list entries "in the near future." More information is available in ECHA's February 28, 2018, press release, "[Information on future regulation of substances easier to find.](#)"

**EC Publishes Ten-Year Review Of REACH:** The EC published on March 5, 2018, its ten-year review of REACH.

According to the EC's March 5, 2018, press release, REACH has provided the following concrete results to Europeans:

- Safer products for consumers, workers, and the environment: Under REACH, the EU has made progress in restricting or banning the use of certain chemicals that may be harmful to human health or the environment and driving their replacement by safer alternatives. Some examples are:
  - Banning harmful chemicals: Eighteen restrictions have been issued for different groups of substances such as chromium, nickel, and lead in consumer products; bisphenol A, an endocrine disruptor, in cash register receipts, and also nonylphenol compounds, toxic to the aquatic environment, in textile articles; and
  - Replacing the most dangerous substances (SVHCs) with safer alternatives: So far, 181 chemicals that can have serious effects on human health and the environment have been identified as such and 43 are included on the REACH authorization list, which means that companies need to obtain an authorization to use them and that they are being gradually phased out as suitable alternatives become available;
- Non-animal testing: REACH promotes alternative, non-animal methods for the hazard assessment of chemicals, reducing the need for tests on animals; and
- A comprehensive dataset for chemical safety on the EU Single Market: So far, the REACH registration procedure has gathered information on more than 17,000 substances in 65,000 registration dossiers of the main chemicals manufactured and used in the EU. This has improved communication and transparency in the supply chain, allowing Europe to address better risks linked to chemicals and further harmonize the internal market for chemicals.

The EC proposed a number of concrete actions intended to improve the implementation of REACH. These measures are put forward to improve the quality of registration dossiers submitted by the companies, to simplify the overall authorization process, and to ensure a level playing field between the EU and non-EU companies. The EC states that it wants to support SMEs further in their compliance and enhance enforcement by national authorities. The EC also wishes to improve the coherence of REACH with worker protection and waste legislation. The EC will discuss the outcomes and follow-up actions of the second REACH review with the EP, EU Member States, and stakeholders at a public conference, planned for **June 2018**. More information is available in the EC's March 5, 2018, press release, "[Ten years of REACH: making chemicals safer for consumers, workers and the environment.](#)"

***ECHA Begins Public Consultations On Eight Proposals To Identify SVHCs:*** On March 8, 2018, ECHA began [public consultations](#) on eight proposals to identify the following substances as SVHCs:

- Octamethylcyclotetrasiloxane (D4): Used in washing and cleaning products, cosmetics and personal care products and polishes and waxes;
- Decamethylcyclopentasiloxane (D5): Used in cosmetics and personal care products, polishes and waxes, washing and cleaning products and textile treatment products and dyes;
- Dodecamethylcyclohexasiloxane (D6): Used in polishes and waxes, washing and cleaning products, and cosmetics and personal care products;
- Ethylenediamine: Used in adhesives and sealants, coating products, fillers, putties, plasters, modeling clay, and pH regulators and water treatment products;
- Terphenyl hydrogenated: Used as plastic additive, as solvent, in coatings/inks, in adhesives and sealants;
- Lead: Used in metals, welding and soldering products, metal surface treatment products, polymers and heat transfer fluids;
- Disodium octaborate: Used in antifreeze products, heat transfer fluids, lubricants and greases and washing and cleaning products; and
- Benzo[ghi]perylene: Not registered under REACH; typically not produced intentionally, but rather occurs as a constituent or impurity in other substances.

Comments are due **April 23, 2018**.

***ECHA Promises Faster REACH Dossier Processing Before April:*** On March 14, 2018, ECHA issued a press release entitled "[Benefit from a faster processing of your REACH dossier.](#)" In its press release, ECHA states:

“Submit your REACH 2018 registration dossier before the **end of March** and receive ECHA’s decision on your registration within three weeks. If you make your submission in **April** or **May**, it may take up to three months for you to get ECHA’s decision.” For Lead Registrants, ECHA states: “[K]eep in mind that you should submit your dossier early enough to allow time for the member registrants to submit their company-specific dossiers by the [deadline].”

ECHA provides that longer periods of time will be required to assess completeness of dossiers as the **May 31, 2018**, registration deadline approaches due to the high number of registrations expected to arrive close to the deadline. In its press release, ECHA reminds registrants to run the validation assistant in IUCLID for the dataset and dossier to ensure required information is complete. ECHA further advises registrants to submit their dossier “only once the [v]alidation assistant shows that you do not have any failures.” ECHA also stated in its press release that from March 16, 2018, onwards, REACH-IT (*i.e.*, dossier submission and communication tool) will be available 24 hours a day, seven days a week, to assist registrants in managing compliance with the upcoming REACH deadline.

**ECHA Launches Website On “Chemicals In Our Life”:** ECHA announced on March 15, 2018, the launch of “[Chemicals in our life](#),” a website available in 23 EU languages that “provides useful information on the benefits and risks of using chemicals and explains how the EU legislation on chemicals protects us.” The website includes a “[Trending](#)” section for topical news, and it is connected to ECHA’s chemicals database, “the world’s largest database of its kind.” ECHA notes that users can also explore parts of EUON and that several articles on nanomaterials related to health, the workplace, and consumer products are available. More information is available in ECHA’s press release, “[New ‘Chemicals in our life’ website informs consumers about chemicals.](#)”

**ECHA Announces New Enforcement Project On Chromium VI:** ECHA announced on March 16, 2018, that the Forum for Exchange of Information on Enforcement will launch a third pilot project on authorization. The pilot project, planned for **2019**, will check whether chromium VI compounds and several other substances subject to authorization are placed on the market and/or used according to a valid authorization. Downstream user notifications will also be checked. According to ECHA, the precise timeline of the project will be set by the **end of 2018**.

The Forum also examined the results of its pilot project on CLP, which focused on the control of Internet sales of chemicals. Fifteen countries participated in the project, which checked whether advertisements for mixtures classified as hazardous, or as containing hazardous substances, mentioned the hazards on the label of the product. ECHA states that a total of 1,314 desktop inspections were conducted in 2017 and that the results show high levels of non-compliance. ECHA expects to publish the final report on its website in **April 2018**.

The Forum also decided to prolong the operational phase of the pilot project on substances in articles. Inspections will run until the **end of 2018**. The report will be made available in **mid-2019**. In addition, the Forum began the preparation of its next Multi-Annual Work Program covering the years **2019-2023**. More information is available in ECHA’s press release, “[New enforcement project on chromium VI launched.](#)”

## UNITED KINGDOM (UK)

**CIA Issues Brexit Memo:** The UK’s Chemical Industries Association (CIA) has issued a memorandum entitled “[Making Brexit Work for the Chemical Industry](#).” The memorandum includes several sections, including “Trade,” “Chemical Regulations,” “Industrial Emissions Directive,” “Energy and Climate Change,” and “Skills.”

In the section on trade, CIA states that it is important to secure “zero tariffs” on trade between the EU and UK following Brexit because the majority of the UK’s chemical trade is with the EU, representing 60 percent of exports and 75 percent of imports. CIA states that Europe remains the biggest market for UK chemical companies, despite the trade importance of jurisdictions such as the U.S., India, and China. CIA provides that if the UK were to revert to WTO rules, upon departure from the EU, it would impact negatively “trade in both directions.”

Regarding chemicals regulation, CIA addresses in the memorandum important issues related to recognition of existing compliance commitments, the EU Withdrawal Bill, and transition arrangements, and provides the following key messages:

- In light of the UK decision to leave the EU, the chemical industry does not argue for lower regulatory standards in the area of chemicals regulations but regulatory consistency and continuity;
- EU exit implications for the regulatory framework in which the UK chemical sector operates should not be underestimated;
- Many companies want to continue to secure access to the EU market place by remaining fully within

REACH, or as a minimum, as close as possible to REACH; and

- Any post-Brexit future needs to protect the UK chemical industry's existing compliance commitments, avoid duplication of costs, and assist the UK's ability to negotiate free trade deals with the EU and beyond.

In the memorandum, Steve Elliott, Chief Executive at CIA, expresses the importance of post-Brexit regulatory consistency and maintaining access to skilled personnel, and states “[a]s we progress with the Brexit negotiations we will continue to work with Government to ensure the best possible solution for the sector.”

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