# **REACH E-NEWSLETTER**

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### **WELCOME**

Dear Reader,

The UK REACH e-bulletin brings you key issues relating to the EU REACH (Registration Evaluation and Restriction of Chemicals) regulation.

We bring information on proposed changes, confirmed changes and the possible effects of these changes from a manufacturing, retail and consumer perspective. Opinions from all concerned parties are reported so a full picture of the workings and effects of the regulation are shared.

The information in the following pages is sourced from European Chemicals Agency (ECHA) and Chemical Watch. Each of our articles are linked back to source for further reading.

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### **TWO NEW SVHCs PROPOSED**

On 9 March 2017, the European Chemicals Agency (ECHA) launched its first public consultation of 2017 on two potential Substances of Very High Concern (SVHC). The SVHCs candidate list will expand to 174 if the two proposals are accepted.

Interested parties have until 24 April 2017, to submit to ECHA any comments and further information on use, exposure, alternatives and risks associated with the substances.

Two SVHC proposals were published in the 2017 first consultation list. Noticeably, one of the proposed substances is Bisphenol A. Bisphenol A was included in the SVHC candidate list on 12 January 2017, based on its classification of Repr. 1B according to CLP Regulation (EC) No 1272/2008 and it is now additionally recommended for SVHC listing due to its endocrine disrupting properties in accordance with Article 57(f) of REACH for effects in relation to human health.

The second proposed SVHC is the ninth long-chain perfluorinated compound and the first perfluorinated sulphonic acid – Perfluorohexane-1-sulphonic acid and its salts (PFHxS). The listing stems from its vPvB properties. PFHxS is a known impurity during production of Heptadecafluorooctane-1-sulphonic acid (PFOS) and it could be used as an alternative for PFOS.

The potential uses of the two potential SVHCs are summarised in Table 1.

Table 1. Possible uses of the potential SVHCs in the Consultation List published by ECHA on 9 March 2017

No.	Substance	CAS No./ EC No.	Classification	Potential uses
1	4,4'- Isopropylidenediphenol	80-05-7 / 201-245-8	EQC	Anti-oxidant for processing PVC
	(Bisphenol A)			<ul> <li>Use in epoxy resin hardeners, epoxy adhesives and encapsulants</li> </ul>
				<ul> <li>Manufacture of thermal paper, polycarbonate, epoxy resins, coating materials</li> </ul>
2	Perfluorohexane-1- sulphonic acid and its	355-46-4 / 206-587-1	vPvB	Component of fire- fighting foam
	salts			Surfactants
				Manufacture of     fluoropolymers
				<ul> <li>Water and stain protective coatings for carpets</li> </ul>

#### ABBREVIATIONS

EQC: Equivalent level of concern

Repr 1B: Toxic for reproduction category 1B

vPvB: Very persistent and very bioaccumulative



### **CHEMSEC UPDATES SIN LIST**

NGO ChemSec has added 30 Substances of Very High Concern (SVHCs) to its Substitute It Now (SIN) list. The list now has 912 entries.

The new substances originate from the NGO's addition of CAS numbers for the newly agreed group of heptylphenols added to the candidate list in January. This is one entry on the candidate list, but consists of several CAS numbers.

The NGO has also added CAS numbers to existing entries:

- two salts of nonadecafluorodecanoic acid (PFDA); and
- three varieties of octylphenol ethoxylates.

This information comes from supporting documents for each substance placed on the REACH candidate list.

In addition to these substances, ChemSec has also included newly classified category 1A and 1B carcinogenic, mutagenic and reprotoxic (CMR) substances from the 9th and 10th adaptation to technical and scientific progress (ATP) to the Classification Labelling and Packaging regulation (CLP).

Article source: ChemicalWatch.com https://chemicalwatch.com/54047/chemsec-updates-sin-list



### COMMISSION AUTHORISES 1,2-DICHLOROETHANE AS EXTRACTION SOLVENT

The European Commission has published an authorisation decision on 1,2-dichloroethane.

Laboratoires Expanscience is granted authorisation for the use of the substance as a process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients.

The Commission says the socio-economic benefits outweigh the risk to human health arising from the use of the substance. And, it adds, there are no suitable alternative substances or technologies.

The review period for the authorisation expires on 22 November 2029.

Last month, ECHA's Risk Assessment and Socio-economic Analysis Committees (Rac and Seac) adopted Opinions supporting the substance's authorisation as an extraction solvent.

Article source: ChemicalWatch.com https://chemicalwatch.com/54112/commission-authorises-12-dichloroethane-as-extraction-solvent

#### **REACH E-NEWSLETTER**



### DENMARK IMPOSES FORMALDEHYDE LIMITS ON NEW WOODEN MATERIALS

Denmark has notified the European Commission of changes to its legislation restricting the use and sale of new wood-based materials, including furniture, that emit formaldehyde – a suspected carcinogen.

The government's decree says wood-based materials that emit formaldehyde in a concentration above 0.124mg/m3 of air should not be used in the manufacture of furniture and related parts. For sales of fixed and movable objects, which also includes furniture and kitchen elements, the concentration limit is 0.134mg/m3 of air.

The restriction will not apply to existing furniture and parts that comply with current Danish standards, and those manufactured for export to non-EU countries. Construction products and furniture padding and upholstery are also excluded.

The Danish EPA may waive the limits "in special cases" according to the decree. It may also set conditions for permits.

The new limits will become effective six months after the decree's entry into force for wood-based materials, and one year after for fixed and movable funiture.

Article source: ChemicalWatch.com https://chemicalwatch.com/54024/denmark-imposes-formaldehyde-limits-on-new-wooden-materials



## ECHA PUBLISHES REACH DATA ON 15,000 CHEMICALS

ECHA has published information on approximately 15,000 substances registered under REACH.

The information, which comes from manufacturers and importers, includes details of each substance's properties and its impacts on human health and the environment.

Regulatory authorities, businesses and researchers can use the data to improve safe use of chemicals, help reduce animal testing and boost innovation, the agency says.

Members of the public can also access and download data, it says, but because it is structured in a luclid 6 database, they might not find it easy to follow. Instead, it recommends they use the 'information on chemicals' portal on ECHA's website.

ECHA says to respect the ownership rights of registrants, only select data can be downloaded. This is limited to:

- results from studies conducted by companies, but not the full summary; and
- information that is not claimed as confidential in the registration dossier.

ECHA says that 2% of all dossiers have a confidentiality claim, but this does not mean that the entire dossiers are not published – only those limited elements that are claimed are not published.

ECHA executive director Geert Dancet says making the data downloadable, in a format that can be reused by others, is "another step towards safer chemicals in Europe".

Industry can use the data to improve the way in which it uses chemicals – by enhancing safety data sheets and the classification and labelling of substances and products, ECHA says.

Article source: ECHA.Europa.eu https://echa.europa.eu/-/data-on-15-000-chemicals-now-available-to-use



### ECHA RECOMMENDS SEVEN SVHCs FOR REACH ANNEX XIV

ECHA has opened a consultation on its draft eighth recommendation to add seven priority substances to the authorisation list.

The agency's public consultation on a draft recommendation typically runs once a year. Its selection of the candidate list substances is primarily based on information in registration dossiers on uses and volumes of the substance in the scope of authorisation. As such, it encourages registrants to keep their dossiers up to date.

The recommended substances, their grounds for consideration and uses are:

- 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): this has very persistent and very bioaccumulative (vPvB) properties and is used as a fragrance ingredient in applications such as fine fragrances, soaps and detergents;
- 1-methyl-2-pyrrolidone (NMP): this is suspected of being toxic for reproduction (category 1B). Its uses include: formulation and (re)packing of substances and mixtures, in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, functional fluids, polymer processing, and in water treatment;
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328): this has persistent, bioaccumulative and toxic (PBT) and vPvB properties. Some examples of its uses are: formulation and use of preparations containing additives, compounds in the manufacture of plastics products, formulation and use of adhesives and sealants, as well as applications in printing inks. This and the other three phenolic benzotriazoles can be used as UV stabilisers;
- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327): is suspected of having vPvB characteristics. It is found in industrial sites and in plastic articles;
- both 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) have vPvB properties, with the latter also having PBT properties. They can be used in plastic articles and coatings; and
- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; and 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5): this is suspected of being toxic for reproduction (category 1B). Uses of the first substance include industrial use in polymer processing and by professionals and consumers in adhesives, coatings, paints and thinners. The latter substance is not registered and no information is available.

The deadline for commenting on the consultation for all substances is 2 June.

Note: NMP is the subject of an ongoing restriction procedure in the EU.

Article source: ChemicalWatch.com https://chemicalwatch.com/53974/echa-recommends-seven-svhcs-for-reach-annex-xiv

#### **REACH E-NEWSLETTER**



#### INVESTIGATION REPORT ON FORMALDEHYDE AND FORMALDEHYDE RELEASERS PUBLISHED

At the request of the European Commission, ECHA has prepared an investigation report on formaldehyde and formaldehyde releasers.

ECHA identified several formaldehyde releasers and potential ones that would be subject to REACH and clarified their uses.

The report aims to assist the Commission in their consideration of whether or not to request ECHA to prepare an Annex XV restriction dossier. This dossier will then be reviewed to determine if the substance should be restricted under Annex XVII of the regulation.

The report can be found at: https://echa.europa.eu/addressing-chemicals-of-concern/restriction/echasactivities-on-restrictions/completed-activites-on-restriction



### **PFA RESTRICTION PROPOSAL** BY GERMANY

Germany has notified their intention to restrict the manufacturing, placing on the market, industrial and professional use of the following substances, which include their salts and precursors. The expected submission date is 14 July 2017.

Perfluorononan-1-oic acid (PFNA)

- Nonadecafluorodecanoic acid (PFDA)
- Henicosafluoroundecanoic acid (PFUnDA)
- Tricosafluorododecanoic acid (PFDoDA)
- Pentacosafluorotridecanoic acid (PFTrDA
- Heptacosafluorotetradecanoic acid (PFTDA)

The restriction details available are:

- 1. Shall not be manufactured, used or placed on the market
  - as substances
  - as constituents of other substances
  - in a mixture
- 2. Articles or any parts thereof containing one of the substances shall not be placed on the market

Article source: ECHA.Europa.eu. https://echa.europa.eu/web/quest/registry-of-current-restriction-proposal-intentions



#### **REACH-IT UPDATE AT THE END OF APRIL**

ECHA have served notice of downtime on one of their main REACH-IT tools. They say:

"Our dossier submission tool, REACH-IT, will be updated on 25 April. The update will focus mainly on increasing the capacity of the system to handle the large number of dossiers expected for the 2018 deadline. It also includes a new submission type for the alternative chemical name requests under the CLP Regulation.

"To manage the update, we will close REACH-IT from Thursday 20 April at 14.00 (EET) to Tuesday 25 April at 10.00 (EET). Regulatory deadlines that may affect companies during the closing period (e.g. completeness check deadlines) will be moved to 25 April.

"Similarly, any completeness check deadlines falling during the Easter closure, 14 April to 17 April, will be moved to the 18 April."

ECHA advices registrants to pay attention to their messages in REACH-IT in the days before the closure, in particular those that are undergoing a dossier evaluation or substance evaluation assessment.

The last major update of REACH-IT before the 2018 substance registration deadline is expected to be in October 2017.

Article source: ChemicalWatch.com https://chemicalwatch.com/54739/echa-round-up?q=REACH-IT+update



### SWEDISH AGENCY FINDS BANNED SUBSTANCES IN THIRD OF JEWELLERY

Random checks on jewellery sold in Sweden have shown that nearly a third of the marketed items tested contain levels of lead and cadmium above permitted levels.

The Swedish Chemicals Agency (Kemi) analysed 143 pieces of jewellery, including necklaces, bracelets and earrings. Thirty per cent of the items contained harmful substances at prohibited levels.

Most of the offending articles were imported from Asia, often after having been bought online from websites specialising in low-priced products.

The most common problem concerned the presence of cadmium and lead. However, three of the products examined leaked too much nickel. One piece also contained low levels of mercury, and a leather bracelet had prohibited azo dyes.

Kemi says most of the jewellery with banned substances came from small businesses that sell unbranded articles. It has reported 19 companies to prosecutors for suspected environmental crime.

"Companies that do not live up to the law need to strengthen their knowledge of the regulations so that they can set distinct chemical requirements when purchasing goods," says agency inspector Camilla Westlund.

"It is the responsibility of companies to ensure that their jewellery does not contain prohibited substances. Taking steps to comply with the legislation helps companies [strive towards] a non-toxic living, and a non-toxic environment."

Kemi carried out the checks in 2016 and stresses their findings do not reflect the entire jewellery market. The work is a follow-up to a 2014 project. The agency says some companies with many deficiencies then were revisited again this time. Overall, the results indicate that they are increasingly following the rules compared with similar companies that were not previously checked.

#### Article source: ChemicalWatch.com

https://chemicalwatch.com/54359/swedish-agency-finds-banned-substances-in-third-of-jewellery?pa=true#utm\_campaign=54133&utm\_medium=email&utm\_source=alert



#### TRADE BLOC PASSES REACH-LIKE EURASIAN CHEMICALS SAFETY REGULATION

After a delay of almost three years, the Eurasian Economic Union (EEU) has adopted a technical regulation on the safety of chemical products.

The regulation, which was signed on 4 March, will set uniform requirements for all chemical products manufactured in the Union, which comprises Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia.

It will also set "single rules and assessment criteria" for identification, terminology, labelling and use of substances, Valerij Koreshkov, minister of technical regulation at the Eurasian Economic Commission (EEC), a governing body of the Union, said.

A single registry of chemical materials and substances, manufactured and used in the EEU countries, will also be established. Substances on this will receive a state registration certificate approving their use.

The registry will list hazards under 13 categories including: explosive, selfdecomposing (materials and substances), self-heating (materials and substances), chemical products and hazardous in contact with water.

The regulation is expected to come into force by 2 June 2021.

Following the passing of the chemicals safety regulation, Union parties are expected to "hasten" the passing of two other related regulations – safety of paints and lacquers and of synthetic detergents, the EEC spokesperson said.

In October 2016, Russia passed its own regulation, which will come into effect on 1 July 2021. It had planned to pass it at the same time as the EEU's but following the stalemate acted on its own, arguing that urgent national legislation was needed to tackle poorly controlled imports of foreign chemical products. Russia's government says it will seek to improve chemical safety by substituting imports of foreign chemical products and materials with domestically manufactured products.



## UK MPS QUIZ MINISTER ON POST-BREXIT REACH PLANS

MPs used the last session of their inquiry into the future shape of UK chemicals regulation after Brexit to press the government on the extent to which it plans to replicate REACH – but got few clear answers.

Junior environment minister Thérèse Coffey, the lead minister on chemicals policy, told the House of Commons Environmental Audit Committee that the government *"will certainly have ready a regime that can be put into effect from day one"* after leaving the EU.

But there appeared to be confusion between the minister and one of her senior officials, Gabrielle Edwards, who appeared alongside her, about how this will happen. While Ms Edwards said the 'Great Repeal Bill', which will aim to transfer EU law into UK law, Ms Coffey said there may need to be a separate bill addressing REACH.

#### **OPERATIONAL ISSUES**

The minister and her official agreed, however, that there are operational issues under REACH, such as the role of ECHA and European Commission committees, that need addressing. *"It is not just a cut and paste [into UK law],"* said Ms Coffey. *"We will not be part of the single market and we will not have European Court jurisdiction. If we end up doing BREACH – British REACH – there are certain things we will need to replicate."* 

Ms Edwards said how this happens will depend on the arrangements that are created for the UK's future relationship with the EU, and what future relationship the UK has with ECHA.

Asked by committee chair Mary Creagh if there will be provisions, either this year or next, to set up a UK chemicals agency, and whether these provisions would be in the repeal bill or a separate bill, Ms Coffey declined to say. She also said she was not clear whether the environment ministry or another, such as the Brexit ministry, will take the lead on negotiating the UK's future role in REACH.

#### DIVERGENCE

The minister said there "may be some things on which we might want to diverge slightly". For example, while UK companies will have to continue to comply with the provisions of the authorisation list and of restrictions, it may decide to set different rules for its domestic market. Although she expects the UK to have "a very similar regime ... there will be the opportunity, potentially, in a future chemicals policy, to decide to be able to make certain choices ourselves".

Ms Edwards stressed that *"fundamental elements"* of REACH, such as the requirement to register substances, and the processes of authorisation and restriction, will be rolled over into UK law, but a solution will need to be found to the problem that registration data is held within ECHA.

Although the inquiry is supposedly concerned with the future of all chemical regulation, its focus has been almost exclusively on REACH, with little attempt to discover Brexit's impact on classification and labelling, for example, or on biocides.

#### Article source: ChemicalWatch.com

https://chemicalwatch.com/54364/uk-mps-quiz-minister-on-post-brexit-reach-plans?pa=true#utm\_campaign=54133&utm\_medium=email&utm\_source=alert

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