REACH E-NEWSLETTER



SGS

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.

CONTENTS

SEVEN NEW SUBSTANCES ADDED TO THE CANDIDATE LIST, ENTRY FOR BISPHENOL-A UPDATED

The Candidate List of substances of very high concern (SVHCs) for authorisation now contains 181 substances.

On 15 January ECHA added seven new substances of very high concern (SVHC) to the Candidate List and updated the entry for bisphenol-A (BPA) following the SVHC identification process with the involvement of the Member State Committee (MSC).

The BPA entry was updated to reflect an additional reason for inclusion due to its endocrine disrupting properties causing adverse effects on the environment.

Substances included/updated in the Candidate List for authorisation on 15 January 2018 and their SVHC properties:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION	EXAMPLES OF USE
(bisphenol-A; BPA)	201-245-8	80-05-7	Endocrine disrupting properties (Article 57(f) - environment)	Manufacture of polycarbonate, as a hardener for epoxy resins, as an anti-oxidant for processing PVC and in thermal paper production.
Chrysene	205-923-4	218-01-9	Carcinogenic (Article 57a) PBT (Article 57d)vPvB (Article 57e)	Normally not produced intentionally but rather occurs as a constituent or impurity in other substances.
Benz[a]anthracene	200-280-6	56-55-3	Carcinogenic (Article 57a) PBT (Article 57d)vPvB (Article 57e)	Normally not produced intentionally but rather occurs as a constituent or impurity in other substances.
Cadmium nitrate	233-710-6	10325-94-7	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used for the manufacture of glass, porcelain and ceramic products and in laboratory chemicals
Cadmium hydroxide	244-168-5	21041-95-2	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used for the manufacture of electrical, electronic and optical equipment and in laboratory chemicals.
Cadmium carbonate	208-168-9	513-78-0	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used as a pH regulator and in water treatment products, laboratory chemicals, cosmetics and personal care products.

1, 6, 7, 8, 9, 14, 15, 16, 17, 17, 18, 18 - Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10] octadeca - 7, 15-diene ("Dechlorane Plus"TM) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	-	vPvB (Article 57e)	Used as a non-plasticising flame retardant, used in adhesives and sealants and in binding agents.
Reaction products of 1, 3, 4-thiadiazolidine - 2, 5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	-	Endocrine disrupting properties (Article 57(f) – environment)	Used as a lubricant additive in lubricants and greases.

The Candidate List is a list of substances that may have serious effects on human health or the environment. Substances on the Candidate List are also known as "substances of very high concern" and are candidates for eventual inclusion in the Authorisation List. Once they are on the Authorisation List, industry will need to apply for permission to continue using the substance after the sunset date.

Companies may have legal obligations resulting from the inclusion of the substance in the Candidate List. These obligations may apply to the listed substance on its own, in mixtures or in articles. In particular, any supplier of articles containing a Candidate List substance above a concentration of 0.1% (weight by weight) has communication obligations towards customers down the supply chain and consumers. In addition, importers and producers of articles containing the substance have six months from the date of its inclusion in the Candidate List (15 January 2018) to notify ECHA. Information on these obligations and related tools are available on ECHA's website.

If you need further assistance, SGS can help you in meeting your regulatory requirements. Please contact GB.REACH@SGS.COM

Article source: Courtesy of ECHA Press Department

ECHA SUBSTITUTION STRATEGY SETS OUT FOUR 'AREAS OF ACTION'

ECHA's recently published substitution strategy says the organisation will focus on four areas of activity that aim to promote the replacement of hazardous substances with safer chemicals.

The four areas are:

- Capacity building; mainly through the facilitation of supply chain workshops at the member state level;
- Identifying and promoting better access to funding and technical support;
- Facilitating the use of registration, classification and risk management data for substitution purposes; and
- The development of networks related to the substitution of chemicals of concern.

The strategy – presented to the ECHA management board in December – says its overall purpose is to support "informed and meaningful substitution" of chemicals of concern in the EU and to boost the availability and adoption of safer alternative substances and technologies.

CAPACITY BUILDING

ECHA, with member state and EU-level authorities, industry associations and possibly NGOs working on substitution, will organise workshops on specific substitution challenges.

And, the strategy says, several member states and stakeholder organisations have shown interest in organising the workshops, with some being scheduled this year in Italy, Denmark, Sweden and the Netherlands. Trade bodies Euratex and Eurometaux, as well as the NGO ChemSec, have also shown interest.

The workshops will help identify the technological, functional and capacity building/training needs of companies at the operational level.

FUNDING

Funding for the substitution of hazardous chemicals is scarce, the strategy report says. Technical support is available from research and technical institutions, but companies confronted with a substitution issue are not always aware of this.

To tackle this, ECHA will first work with members states, the European Commission and stakeholders to map all available funding mechanisms and institutions that could finance substitution. It will then disseminate this information and "facilitate the involvement of these institutions in projects".

DATA

The agency intends to further share and improve access to the vast amounts of information it holds on substances because, the report says, effective substitution requires a proper understanding of the hazards and risks associated with both the substance to be replaced and the alternative. And it sets out several ways of how it could do this, including:

- The potential to develop a function that searches registration data by uses, as well as sectors of use;
- Publishing information on alternatives analysis submitted through authorisation applications and restrictions, as well as key information obtained during public consultations; and
- Possibly setting up an open-ended public webform for the submission of information on alternatives, outside of any REACH regulatory process, to create a database on potential alternatives.

NETWORK

The fourth action involves the formation of a multi-stakeholder network that focuses on promoting substitution.

Currently, there is no specific network to support substitution among EU member states, the Commission and stakeholders. Therefore, there is no systematic way to "routinely and effectively connect and collaborate on substitution challenges and opportunities", the report says.

Resources and indicators

To carry out the work, ECHA has allocated three full-time staff positions. It is also considering developing indicators for the four actions that could help in analysing the strategy's success. Examples of indicators include, the number of workshops organised, participants' satisfaction scores, amount of R&D funding supporting substitution and the number of network teleconferences.

The agency says information obtained from the supply chain collaboration workshops will help in further developing the substitution strategy from 2019 onwards and, by the end of this year, it will elaborate on the activities on substitution for 2019 in its annual work plan.

Article source: ChemicalWatch.com

ECHA TO CONSIDER RESTRICTIONS ON THE USE OF OXO-PLASTICS AND MICROPLASTICS

The European Commission has asked ECHA to prepare proposals for possible restrictions concerning oxo-plastics and intentionally added microplastic particles. These activities support the Commission's plastics strategy, which was made public on 16 January 2018.

Current evidence suggests a potential risk to the environment and human health from microplastic particles that are intentionally added to certain consumer or professional products such as cosmetics, detergents and paint. Oxo-plastics, also called oxo-degradable plastics, facilitate the rapid degradation of polymer materials into very small particles, and may potentially contribute to microplastic pollution.

Stakeholders will be invited to provide relevant information to ECHA during the preparation for these two restriction proposals. To this effect, calls for evidence will be launched in spring 2018 to assist with the risk and socio-economic assessment of intentionally added microplastics and oxo-degradable plastics.

Other types of material that may lead to generation of microplastics, such as the degradation of textiles and carpets, are not covered by the requests of the Commission.

WHAT ARE OXO- AND MICROPLASTICS?

Oxo-plastics or oxo-degradable plastics are conventional plastics that contain additives which promote the oxidation of the material under certain conditions. They are used in applications such as agricultural films, rubbish and carrier bags, food packaging, and landfill covers. They can break down into very small particles, potentially contributing to environmental contamination by microplastics.

Microplastics are synthetic, water-insoluble polymer items smaller than 5 mm, which are of concern for the aquatic environment. The potential impact of microplastics on the (aquatic) environment and human health have generated concerns in Member States of the European Union and worldwide.

Article source: ECHA.europa.eu

EU ISSUES REGULATION RESTRICTING D4, D5 IN WASH-OFF COSMETICS

On the 10 January 2018, the European Commission published its Regulation to restrict the use of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in wash-off cosmetic products in a concentration equal to or greater than 0.1% by weight.

This adds a new entry No 70 to annex xvii of the REACH Regulation 1907/2006.

The UK first proposed the limit in April 2015.

This Regulation will enter into force 20 days after its publication in the EU's Official Journal. It will apply 24 months later – from 1 February 2020.

Article source: ChemicalWatch.com

HELPING REGISTRANTS IN EXCEPTIONAL CASES

The Directors' Contact Group (DCG) - a platform of the European Commission, ECHA and industry associations – has identified exceptional scenarios where registrants may, through no fault of their own, find it difficult to submit a complete registration dossier by the registration deadline.

ECHA is again offering help for companies affected by the four scenarios identified by the DCG. ECHA does so either by relying on its discretionary rights under REACH or by providing companies with a transparent means to demonstrate good faith.

The four scenarios where exceptional circumstances could apply are:

1. Completeness of dossiers

Companies that may have difficulties in providing data required in annexes VII and VIII of REACH in due time or importers of mixtures that have difficulties in getting compositional and analytical data of the substances in the mixture from their suppliers.

2. Legal entity changes

Companies that do not hold a pre-registration due to legal entity changes.

3. Dependency on the lead registrant

If the lead registrant fails to submit a complete registration dossier on time, the member registrants may need exceptional support.

4. Substance with no registration intentions

If no registration is planned for their critical substances, downstream users may consider taking up the role of an importer and submitting a registration, or engaging another importer to do so on their behalf.

The conditions under which the solutions apply are described on the DCG section of ECHA's website. It also describes how an affected registrant should contact ECHA.

Every affected company will need to contact ECHA as far ahead of the deadline as possible, and by 24 May 2018 at the latest. The registrant needs to provide detailed justification of its situation and an explanation of the measures that it has taken to comply with its obligations under REACH. When ECHA receives this information, it will give instructions on how to submit a registration by the deadline.

Article source: ECHA.europa.eu

INDUSTRY: ECHA CONSIDER FUTURE OF SIEFS AFTER REACH DEADLINE

ECHA is looking to clarify how members of substance information exchange forums (Siefs) can continue to collaborate beyond the last REACH registration deadline at the end of May.

The REACH Regulation says that Siefs will cease to exist on 1 June, the day after the last registration of substances. Yet it is not clear how registrants will team up for post-deadline activities such as dossier updates, new information requests by ECHA and cost sharing.

The agency says it has already expressed its wish to the European Commission for a "continuation of a collaboration platform to take care of the post-registration duties", and hopes to clarify the situation before the deadline. It is in talks with the Commission's legal services over the issue.

"Whether [the new platforms] will be called Sief in the future or something else, that's still to be decided," said an ECHA spokesperson.

The Siefs have been in use since the start of REACH registration ten years ago. Their purpose is to help information exchange to avoid duplication of tests, prepare joint registration dossiers and decide the classification and labelling of substances.

As registration is based on the principle of 'one substance, one registration'. Each substance has one Sief, with members producing or importing at different tonnages. The fora have expanded with the three different REACH registration phases – the previous deadlines were in 2010 and 2013 – and some Siefs now comprise hundreds or even thousands of members.

ECHA has estimated that 25,000 new substances could be registered under the 2018 deadline. Data-sharing disputes on these chemicals are expected to rise sharply after the cut-off, especially with the 2016 implementing Regulation imposing higher transparency demands on lead registrants.

ECHA is also likely to push registrants harder for dossier improvements and regular information updates – a top priority for the agency's new head Bjorn Hansen.

Article source: ChemicalWatch.com

NGOs FIND HIGH PBDE LEVELS IN EU TOYS, CHILD ACCESSORIES

A test conducted by Czech NGO Arnika and the International POPs Elimination Network (Ipen) has found high levels of polybrominated diphenyl ethers (PBDEs) in recycled plastic children's toys and hair accessories in the Czech Republic.

They tested 47 products and found that seven out of 16 toys and eight out of 31 grooming and hair accessories contained the substance.

PBDEs, as well as hexabromocyclododecane (HBCDD), are common brominated flame retardants (BFRs).

Six of the toys and seven grooming products contained levels of PBDEs above 50ppm. The toys were also analysed for HBCDD; out of 15 analysed products only one contained 91ppm - the others had fewer than 10ppm.

The Stockholm Convention currently sets the hazardous waste limit for polychlorinated biphenyls (PCBs) at 50ppm, due to concerns for human health and the environment.

"As PBDEs strongly resemble PCBs in structure and activity, environmental health experts advocate a 50ppm health advisory level for PBDEs as well," Arnika's Karolina Brabcová says.

The convention objective to eliminate BFRs is "undermined" by the existence of a recycling exemption for materials that contain them, the NGOs say. Under this, materials containing commercial penta- and octaBDE may be recycled into new products.

The six toys and seven grooming products were also found to be contaminated with octa- and decaBDE in concentrations ranging from 1-514ppm, and 6-2,234 ppm, respectively, the NGOs add.

The levels of BFRs found in some of these products exceed regulatory limits. For example, they say, 11 of them would not meet the POPs Regulation limit of 10ppm for octaBDE concentrations.

Article source: ChemicalWatch.com

THREE AUTHORISATION APPLICATIONS GIVEN EU GO AHEAD

The European Commission has granted authorisations for three substances, two chromates and a solvent. The decisions, taken on 15 December, were all for listed substances of very high concern (SVHCs) under REACH Annex XIV.

They are:

- Sodium Dichromate, granted to Gruppo Colle for use as a mordant in wool dyeing with dark colours. The review period will expire on 15 December 2021.
- Ammonium Dichromate, granted to Veco for use as a photosensitive component in a polyvinyl alcohol photolithographic lacquer system for the production of mandrels, used in nickel electroforming processes. The review period ends on 21 September 2024.
- 1,2 -Dichloroethane, granted to GE Healthcare Bio-Sciences for use as an emulsifying solvent in the manufacture of porous particles for beaded chromatography and cell culture media. The recommended review period is 12 years and will expire on 22 November 2029.

EU member states approved the applications, at the REACH Committee meeting on 27 September.

A total of 110 authorisations have been granted to date.

Article source: EUR-lex.europa.eu

UK MICROBEADS BAN ENTERS INTO FORCE

A ban on the manufacture of cosmetics and personal care products containing plastic microbeads comes into effect from the 1 January in the UK. and according to a notification of the draft Regulation to the World Trade Organization (WTO) in July. A ban on sales of such products will follow on 30 June, it said.

"Microbeads are entirely unnecessary when there are so many natural alternatives available," environment minister Thérèse Coffey said in an announcement. "I am delighted that from today cosmetics manufacturers will no longer be able to add this harmful plastic to their rinse-off products."

She added that the government will explore how it can build on its ban and address other forms of plastic waste.

In its WTO notification, the UK said that up to 680 tonnes of microbeads are used in cosmetic products sold in the UK every year. More than 72% of major UK cosmetics companies expected to have stopped selling products with microbeads in them by the end of last year, the notification said.

The UK government published the draft legislation in September, following a public consultation on the proposed ban.

Some respondents called for its scope to be broadened to cover all products that result in microbeads being washed down the drain. This would include leave-on make-up and sunscreen. Others called for inclusion of some polymers and cleaning products.

The draft law kept to the scope originally proposed. But UK environment ministry Defra has committed to work with the Hazardous Substances Advisory Committee (HSAC) to assess the case for addressing further categories of products.

Article source: ChemicalWatch.com

BREXIT LATEST: UK AUTHORISES £5.8M FOR POST-BREXIT CHEMICAL REGISTRATION IT

The UK's Secretary of State for the Environment has authorised spending on IT capability to enable registration and regulation of chemicals placed on the UK market. The project is scheduled to begin next month.

In an 18 January letter to Environment Secretary Michael Gove, Defra's permanent secretary Clare Moriarty asked for £5.8m (€6.64m) in funding and said the department is "implementing a major programme of work at pace in order to be ready for a range of scenarios". This includes the possibility of a 'no deal' exit without a transition period.

Mr Gove approved the expenditure on the same day and directed Ms Moriarty to "proceed with the planned work".

The chemicals IT platform is one of six "planned EU Exit readiness activities" being carried out by Defra, for which it has asked £16m in advance of the EU Withdrawal Bill receiving royal assent – when the Queen formally agrees to make the Bill into an Act of Parliament (law).

Ms Moriarty asked for the funding because Defra was "not able to incur expenditure on new services" prior to royal assent. Should the funds not have been made available sooner, the delay would have "serious implications across all sectors and issues for which Defra is responsible", she added, and could have resulted in "severe disruption to vital public services".

Defra has said that it is working "to ensure a smooth transition for the chemical industry as we leave the EU".

Its priority, a spokesperson said, "is to maintain an effective regulatory system for the management and control of chemicals to safeguard human health and the environment, respond to emerging risks and allow trade with the EU that is as frictionless as possible".

'REACH IT'

In its correspondence, the Defra spokesperson referred to the system as "the REACH IT project", but did not elaborate on any engagement with ECHA, which operates the EU system.

ECHA said it has "had no technical discussions" about the UK's withdrawal from the EU. However, it added, "it appears that Defra has calculated its budgetary needs for developing an equivalent to REACH-IT for its own post-Brexit domestic needs".

The agency went on to say, "it could be that Defra has based its IT system calculations on the costs of REACH-IT, which are available to them as they are participants in the ECHA Management Board."

'CONTINGENCY' PLAN

The UK's IT system will be developed "with user engagement from the chemicals industry to ensure requirements are met and streamlined wherever possible", Defra said.

The CEO of the UK's Chemical Business Association, Peter Newport, said he was aware of the system but it was "presented to us as contingency planning, just in case". He added that the CBA understands the need for such planning "but that should be all that the exercise is for, and nothing else".

He reiterated that the CBA wants to retain REACH in full, continue to use ECHA and accept jurisdiction of the European Court of Justice.

Chemical Industries Association head Steve Elliott said he was not aware of the IT system, but that he does "understand the need for contingency planning" in the event of unsuccessful negotiations.

"We also understand that this is not a signal of preferred policy options – more the need to make a potential budgetary commitment at this stage that may or may not materialise.

"In the meantime, we look forward to a reply to our letter to the Environment Secretary of State, in which we encourage the UK government to align itself as closely as possible (ideally within) with REACH and the central agency in Helsinki."

Michael Warhurst, from NGO CHEM Trust, said the budget of £5.8m "is the tip of the iceberg of what the UK will have to spend to create a poor-quality copy of the EU's rules on chemical safety".

At the end of December, Steve Baker, a junior minister in the UK's Department for Exiting the European Union, told MPs that current EU chemicals law, including REACH, will be incorporated into UK law after Brexit. The government "will use the powers in this Bill to convert current EU chemicals law, including REACH, into domestic law". This will mean, he added, that the standards established by REACH "will continue to apply in the UK",

NEW AND UPDATED Q&AS ON BREXIT

ECHA have updated their set of Q&As on REACH and biocides concerning the UK's withdrawal from the European Union. To stay up to date on the topic, check their web pages regularly - they are continually improving them as the withdrawal process moves forward.

Article source: ChemicalWatch.com

WHY SGS?

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