

REACH E-NEWSLETTER

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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.

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MEMBER STATE COMMITTEE AGREES TO ADD **SEVEN NEW SUBSTANCES** TO THE CANDIDATE LIST AND UPDATE THE ENTRY FOR **BISPHENOL A**



The Member State Committee (MSC) has supported the increase of the SVHC Candidate list by seven substances. These substances are:

SUBSTANCE NAME	CAS NO	EC NO
Chrysene	218-01-9	205-923-4
Benz[a]anthracene	56-55-3	200-280-6
Cadmium dinitrate	10325-94-7	233-710-6
Cadmium dihydroxide	21041-95-2	244-168-5
Cadmium carbonate	513-78-0	208-168-9
Dechlorane Plus(TM)	13560-89-9	236-948-9
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].	-	-

In addition, the MSC supported the German proposal to additionally identify **bisphenol A (BPA)** (CAS 80-50-7, EC 210-245-8) as a substance of very high concern (SVHC) because of its endocrine disrupting properties which cause probable serious effects to the environment. Bisphenol A is already listed in the Candidate List due to its toxic for reproduction properties and due to its endocrine disrupting properties, which cause probable serious effects to human health. ECHA will update the current entry for BPA accordingly.

Legal obligations will start from the formal updating of the Candidate List which is expected in mid January 2018.

Article source: [European Chemicals Agency](#)

BREXIT LATEST: REACH TO BE CONVERTED INTO UK LAW, GOVERNMENT CONFIRMS



Current EU chemicals law, including REACH, will be incorporated into UK law, Steve Baker, a junior minister in the UK's Department for Exiting the European Union, has told MPs.

Speaking on 19 December at a House of Commons debate on the EU Withdrawal Bill, he said it was not necessary to introduce a new clause to the Bill that sets out to ensure Britain participates in REACH 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", and said he believes that renders the new clause – tabled by MP Mary Creagh, who is also chair of the House of Commons' Environmental Audit Committee (EAC) – "unnecessary".

Also addressing MPs yesterday, Ms Creagh said the Bill is an attempt to cut and paste EU law into UK law, but the government "cannot do that for the chemicals industry – a vital industry to this country".

According to the EAC, the UK government has previously said that "up to a third of EU environmental law cannot simply be 'copy-pasted' into UK law and will require additional work to ensure that the UK maintains the current level of environmental protection".

At the start of the year, the EAC launched its second inquiry into the future of environmental law and policy and concluded that the UK government "fails to recognise" chemicals regulatory issues.

Clause NC61 said:

- The secretary of state must take all reasonable steps to ensure that the UK participates in the standards and procedures established by REACH after exit day; and
- Subject to the provisions of the withdrawal agreement, steps under subsection (1) may include regulations under section 17, or another provision of this Act, providing for full or partial participation of the UK in REACH.

The regulatory uncertainty over Brexit is "sending shockwaves" throughout the industry, she said, adding that membership of REACH "is essentially a passport to the global chemicals marketplace".

Environment secretary Michael Gove had recently told her that when the UK leaves it will be "regulated better", she said. And in November, Ms Creagh added, he told the EAC he is examining how he can use ECHA and REACH to ensure Britain can trade freely.

"I'm telling him now we simply can't. To leave and diverge will harm jobs, growth, manufacturing and investment in this country."

In addition, she said that Steve Elliott, chief executive of the Chemical Industries Association (CIA), had written to Mr Gove this month to express his concerns. He said leaving REACH "would seriously bring into question ten years of investment as registrations and authorisations that permit access to the single market would become non-existent on exit day".

Last month, a speech by Mr Baker at a Brexit conference hosted by the CIA was due to say that the government wants existing REACH registrations and authorisations to remain valid in both the EU and UK markets after Brexit.

Mr Baker pulled out of speaking at the last minute, but supplied his speaker's notes, which also said REACH has been a key topic of the opening phase of Brexit negotiations.

Article source: ChemicalWatch.com

REACH PROPOSALS UNDER CONSIDERATION



SVHC INTENTIONS

ECHA has received three notifications of intentions for the identification of substances of very high concern (SVHCs).

Belgium notified two on the grounds of them being persistent, bioaccumulative and toxic (PBT), and having very persistent and very bioaccumulative (vPvB) properties: benzo(k)fluoranthene; and fluoranthene. The dossiers are expected by 6 August 2018.

And Sweden notified its intention for lead on the grounds of it being toxic for reproduction. The dossier is expected on 7 February 2018.

CALL FOR EVIDENCE ON FLAME RETARDANTS TCEP, TCPP AND TDCP

ECHA has issued a call for evidence on the flame retardant substances TCEP, TCPP and TDCP. It is aiming to collect further information in support of a possible restriction proposal, as well as comments on the draft screening report and its conclusions.

The report identified a risk for children from exposure in flexible polyurethane foams in childcare articles and residential furniture. The scope of the proposal may be broader than this, the agency says.

SUBSTANCE NAME	CAS NO	EC NO
tris(2-chloroethyl) phosphate (TCEP);	115-96-8	204-118-5
tris(2-chloro-1-methylethyl) phosphate (TCPP);	13674-84-5	237-158-7
Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester (TCPP);	-	-
tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	13674-87-8	237-159-2

The consultation period ends on 8 February 2018.

Article source: ChemicalWatch.com

GREEN ALLIANCE URGES UK GOVERNMENT TO STICK TO REACH

During Brexit talks, the UK should negotiate full access to REACH and maintain waste regulations, definitions and principles, a report by UK thinktank Green Alliance says.

The report was produced for the Circular Economy Task Force, a UK business group that includes a major home improvement company and high street pharmacy chain.

Attempting to create a UK equivalent to REACH would be “enormously expensive and time consuming”, the report says, and adds that some believe “it will be impossible” as a single country cannot replicate its scope and expertise.

Leaving REACH while copying its rules could make the UK vulnerable to legal challenges from businesses wanting to use potentially dangerous chemicals, it says. Maintaining REACH and accepting the jurisdiction of the Court of Justice of the European Union (CJEU) in this area “is necessary to keep the same levels of protection from chemicals in the UK,” the report says.

The report outlines two critical challenges it says the UK’s Department of the Environment, Food and Rural Affairs (Defra) will have to manage effectively over the next two years to achieve a good post-Brexit outcome for resources policy.



The first is managing divergence from existing EU waste and resource governance. Differing environmental standards create ‘non-tariff barriers’ that harm trading arrangements, it says. Retaining or recreating EU institutions to ensure adherence to chemicals, waste, recycling and products legislation will guarantee “sufficient equivalence” so the UK can continue trading freely with the EU.

The second challenge is creating new policy. “Failing to update and improve legislation once it is transposed risks opening an unpopular and environmentally harmful domestic policy gap after March 2019,” the report says. The UK should therefore focus its efforts on enhancing resource efficiency and productivity “to suit the UK’s particular circumstances”, the report says.

Article source: ChemicalWatch.com

ECHA LAUNCH LETTER TEMPLATES FOR DATA SHARING AND JOINT SUBMISSION NEGOTIATIONS

ECHA have published letter templates that companies, especially SMEs, can use when starting negotiations with co-registrants for sharing data and submitting jointly for REACH registration. The aim is to help companies that might not be familiar with the regulation to ask the right questions making sure that all aspects of the negotiations are considered by the parties involved.

The documents are part of ECHA's efforts to give companies, namely small and medium-sized enterprises (SMEs), practical help to fulfil their obligations under the REACH Regulation.

Companies have repeatedly identified data sharing and joint submission as a challenging and complex task. They are burdensome especially for those SMEs that do not primarily operate in the chemicals sector and that have limited regulatory experience.

The letter templates are to be seen in this context. They are not intended to be mandatory or prescriptive. They should rather serve as a guideline to make sure that all parties address a range of aspects when entering into data-sharing or joint submission negotiations. Companies affected can themselves assess the appropriateness of the templates on a case-by-case basis and decide which elements they wish to adopt (and at what level). Use of these templates does not prejudice the outcome of a dispute under Article 27 or Article 30 REACH.

ECHA state that "Companies/persons are to use the templates at their own risk. The European Chemicals Agency will not accept any liability or warranties resulting from the use of these templates and their application".

Article source: ECHA.europa.eu - Letter templates

MEMBER STATES CONSIDER EU TITANIUM DIOXIDE LABELLING ISSUE

The European Commission has asked member state competent authorities to come up with solutions to a titanium dioxide labelling problem, arising from the proposed carcinogenicity classification.

ECHA's Risk Assessment Committee (Rac) decided in July that the substance should be classified under EU CLP as a category 2 carcinogen by inhalation.

The toxic effect is specific to the inhalation of small titanium dioxide particles. In its Opinion, the Rac describes it as "particle carcinogenicity".

But the classification, and therefore also the labelling requirements, would apply to all forms of titanium dioxide, and mixtures containing it, including:

- Larger particles;
- So-called massive forms, in which the substance does not comprise particles at all, but rather distinct, solid blocks; and
- Suspensions, in which the substance as particles is dispersed evenly through a liquid.

The Commission has concerns because such forms and mixtures may not pose a hazard to human health. Consequently, last week, it asked member state Competent Authorities for REACH and

CLP (Caracal) for their views on the application of labelling 'derogations' for them.

A labelling derogation might apply to paints containing titanium dioxide under Annex 1, section 1.3.4 of CLP, if they qualified as mixtures containing polymers or elastomers, the Commission said. But it added that:

- The derogation would not apply to mixtures containing titanium dioxide if they did not also contain polymers or elastomers;
- The applicability to borderline cases, such as spray applications, would need to be clarified; and
- The derogation would require demonstration that there was no risk to human health by inhalation.

The Commission also said that Article 12 "could be taken into account" to avoid classification of mixtures containing titanium dioxide. This approach would be based on the idea that non-respirable particles do not lead to exposure and therefore there is no bioavailability.

A spokesperson for the Commission said that the problem was recognised by all the member states, but it would require some creativity. No solution has been arrived at yet.



As an expert group, Caracal has no decision-making responsibility – its role is advisory. Normally, the Commission provides general information about upcoming harmonised classifications. But in the case of titanium dioxide, it decided that wider involvement was needed.

Caracal is likely to discuss a draft amendment to technical progress (ATP) for harmonised classification, at its meeting next March. The final decision will be made by ECHA's REACH Committee, which in most cases signs off harmonised classifications according to Rac Opinions with few changes. Publication of the legislative changes is expected in early 2019, followed by an 18-month transition period.

Article source: ChemicalWatch.com

NANO DATA WILL BE ADDED TO SWEDISH PRODUCT REGISTER NEXT YEAR

A rule requiring companies in Sweden to notify data on nanomaterials in chemical products to the country's chemicals agency's (Kemi) product register will enter into force on 1 January 2018.

The obligation, which applies to the manufacture and import of products, will enable Kemi to obtain information about the type and quantity of nanomaterials used in the country. The data may form the basis for future regulatory developments in health, the environment and the workplace, the agency says.

There will be exemptions in place for:

- Nanomaterials that are naturally occurring or accidentally produced;
- Companies with annual sales of less than SEK5m (€502,000); and
- Pigment nanomaterials.

These will last three years while an evaluation is carried out. They will mean companies only need supply information on whether a component of a product is a nanomaterial.

Sweden joins Belgium, Denmark, France and Norway, which already require companies to report information on nanomaterials to their national inventories. They have acted because the European Commission has ruled out an EU register and instead opted for an EU observatory for nanomaterials (EUON) public website.

Companies have until February 2019 to comply.



Article source: ChemicalWatch.com

REACH AUTHORISATION 'ACHIEVING OBJECTIVES', SAYS COMMISSION

The REACH authorisation process "achieves its objectives in terms of substitution and improvements in the way SVHCs are used", the European Commission said at an ECHA authorisation conference in November.

The EU executive's comments accompanied the presentation of preliminary findings of its study, which aimed to assess the costs and benefits of the process and whether it reaches its goals. These are to substitute SVHCs with less hazardous substances and control risks where suitable alternatives are not available.

However, Valentina Bertato from DG Grow told delegates at the event that, according to the study results, "it is not possible" to conclusively say that the benefits of the process are higher than the costs. Meanwhile, ECHA's recent analysis of the first 100 applications for authorisation showed the socio-economic benefits of continued use of SVHCs "outweigh" the risks to human health and the environment.

Eighty-three manufacturers took part in a survey for the study. Thirty-seven said they had substituted a SVHC use, Ms Bertato said. They identified 53 examples of switching to an alternative substance and eight examples of changing to an alternative technology. This relates to 27 SVHCs; the most substituted being:

- Chromium trioxide;
- 1,2 dichloroethane; and
- HBCDD.

And there were 71 examples of substitution-related activities concerning use of an SVHC identified in the study, as provided by 44 respondents. This relates to at least 33 such substances. The most frequently mentioned are:

- Chromium trioxide;
- Boric acid; and
- 1-methyl-2- pyrrolidone (NMP).

Fifty-nine percent of respondents said REACH authorisation is a driver for substitution. And survey data



shows that a third of substances are being substituted when they are added to the candidate list, while a quarter are being replaced when included on Annex XIV – the authorisation list.

Authorisation is also improving risk management measures and operating conditions, Ms Bertato said. Out of 63 companies using SVHCs, 23 reported enhancing both. And about 83% of respondents indicated that these risk management measures reduced worker exposure.

LACK OF ALTERNATIVES

There is clearly "robust evidence" of substitution, ECHA's director of risk management Jack de Bruijn told delegates, and the authorisation system "as a whole has had a major impact".

Where companies have not started to replace hazardous substances, it is generally related to a lack of technical feasible alternatives, the conference heard. "Whether that is always true or perceived is a big question, perhaps – but for the majority of cases that was given as one of the reasons," Mr de Bruijn said.

Conference stakeholders discussed how alternatives providers can get more closely involved. "This is where the picture becomes less rosy", Mr de Bruijn said. Something to work on, he added, is how to get better information from these providers "preferably as early as possible but also during the decision-making process".

There are, he said, "clearly advantages" to better collaboration between authorities and industry in finding sustainable alternatives.

QUESTIONS REMAIN

Dolores Romano from NGO the European Environmental Bureau (EEB) agreed the authorisation list is good for substituting SVHCs and that risk management measures and operating conditions have improved. However, she said she is "not optimistic" about the risk reduction scenario because as long as SVHCs are granted authorised uses "thousands of workers, citizens and the environment will still be exposed".

She also questioned how authorisation conditions can be monitored and enforced because in many European countries "inspection capacity is not sufficient".

Article source: ChemicalWatch.com

REACH NEW SUBSTANCE REGISTRATIONS ESTIMATE 'MAY FALL SHORT'

ECHA has revealed that the number of new substances registered for the 2018 REACH registration deadline is less than expected and may not meet estimated figures.

The agency has so far received 12,918 dossiers covering 5,856 total substances for the May deadline, which is just six months away.

While the agency says this is in line with its original estimates, it also acknowledges that only 3,713 of the substances have not been registered in either of the previous 2010 or 2013 deadlines. And, it says, the number of these 'new' substances is less than it expected at this point.

"Currently, companies seem to mainly be registering those substances for which a registration already exists," the agency said in its latest newsletter.

"At this pace, it may be that we will not reach the estimated 25,000 registered substances by the deadline. We need to monitor this carefully, although industry associations have not yet raised this as a concern."

Approximately 15% of registrations are from SMEs, it says.

2018 REACH deadline figures

- Total registrations to date: 12,918
- Total expected registrations: 60,000
- Total substances to date: 5,856
- Total expected substances: 25,000

Directors' Contact Group

At a meeting on 27 November, the REACH Directors' Contact Group (DCG) issued a recommendation, urging companies to improve efforts to communicate their 2018 registration intentions to customers.

The DCG is an informal group of directors from the European Commission, ECHA and industry associations. It was set up to respond to concerns arising from companies' REACH registration obligations.

Disseminating this information, they said, will avoid crucial substances not being registered and help ensure supply chains are not disrupted. Companies should also identify the uses their registrations intend to cover and communicate them downstream, the group said.

Industry associations represented in the DCG "are committed" to pass on this recommendation to their members, ECHA says.

The directors also agreed to publish a factsheet on access to EU finance. According to ECHA, it provides helpful advice to companies that need to find resources to ensure safe handling of their substances, and to those that choose to act on substituting their chemicals with more sustainable alternatives.

In a recent interview earlier this month, ECHA head Geert Dancet said the high-cost of registrations is "the main stumbling block" in the process.

The DCG will next meet on 15 December to review the solutions it established for the 2010 and 2013 REACH registration deadlines.

It will also continue discussions to endorse an approach for easing the financial burden on SMEs, preparing to submit registrations in the one-ten tonnage band.

Article source: ChemicalWatch.com

WHY SGS?

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Our next REACH "Back to Basics" training course takes place on 7 February at our Ealing office. Contact GB.REACH@sgs.com for more information.

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