# **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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## UK GOVERNMENT 'FAILS TO RECOGNISE' CHEMICALS REGULATORY ISSUES

The UK government's response to a parliamentary committee report on chemicals regulation after Brexit "fails to recognise the unique nature of the regulatory issues facing industry", the Chemical Business Association (CBA) has said.

In early 2017, the House of Commons' Environmental Audit Committee (EAC) launched its second inquiry into the future of environmental law and policy. Speaking at a recent Brexit conference, committee chair MP Mary Creagh said the government "*did not answer*" the main points the committee had raised in its inquiry report.

The EAC subsequently sought stakeholder views on the government's reply. The CBA said the post-Brexit regulatory and business environment *"represents one of the more significant challenges facing the UK chemical supply chain"* and that the government response to the EAC's report *"fails to respond to this challenge"*.

In a press release, Ms Creagh said stakeholder comments show that many working in the chemicals industry *"are concerned by the government's failure to set out a vision for the sector post-Brexit"*.

Industry is clear, she added, that it will still need to meet EU regulations after leaving the Union in order to export to it. "However, the government position remains vague. This uncertainty could cost the taxpayer millions of pounds and leave our second largest export sector in disarray".

In his comment, Jean-Pierre Feyaerts, former head of the Belgium REACH help desk and former member of ECHA's socio-economic analysis committee, said the government gave a *"vague statement"* in response to the recommendation that REACH would be difficult to transpose directly into UK law.

And its reply to the recommendation that the government must urgently clarify its position on the future regulatory framework regarding the validity of REACH registrations *"is* 



really astonishing", Mr Feyaerts said. "It suggests that the government does not understand at all the concern". The government "just recognises the importance" of the concern, he added. "It does not seem to understand the risks of relocation".

#### LONG WAY TO GO

In its comments, the UK manufacturers' organisation EEF said the government's response is "a further reminder of how much still has to be decided and done if the UK is to have a functioning regulatory regime for chemicals in April 2019".

The degree of uncertainty is causing concern not just in the chemicals industry, but also among downstream manufacturing industries, which are reliant on a wide range of substances and chemical formulations, EEF said.

Downstream users are *"particularly concerned"*, it added, about the invalidation of authorisations held by UK firms which are needed for downstream formulation, component manufacture or aftermarket services in the single market.

The evidence submitted to the committee and published documents so far, focus on maintaining regulatory coherence and cooperation with the EU, EEF said. However, recent comments from the Secretary of State "indicate a preference for an alternative approach without specifying the timescale over which that might be achieved".

#### SUBSTANCE ASSESSMENT

The British Plastics Federation (BPF) said it wants the government to clarify *"at the earliest opportunity"* the issue of whether companies will be able to retain their REACH registrations.

Another uncertainty, it said, is the approach the UK government will take to substances proposed for inclusion in REACH Annex XIV – the authorisation list – that are still under discussion in ECHA committees on the day of the UK's exit.

Any future UK government agency may wish to make its own assessment of these substances, or it could adopt these decisions as a matter of policy, BPF added. Although exporting UK companies would need to comply with the Annex XIV requirements for its sales in the EU, *"it may be useful to have some form of UK consultation to check that the proposed substance showed a risk to human health or the environment in the UK"*.

## DENMARK TO CLAMP DOWN ON PHTHALATES WITH NEW INITIATIVE

The Danish Chemical Forum, comprising industry, NGOs and the government, has launched a new set of initiatives to ensure consumers "*do not bring home*" four phthalates that are being phased out in the EU.

The phthalates butylbenzyl phthalate (BBP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) are already banned in toys, and from 2019 in electrical goods. The European Commission is also considering a proposal to prohibit the endocrine disruptors in other consumer products.

Denmark has long spearheaded the drive against phthalates in Europe. The latest campaign, co-signed by the minister for environment and food, Esben Lunde Larsen, is targeted at products imported from non-EU countries.

These, the forum members say, "are not manufactured according to the same requirement for product safety for chemicals" as in the EU. Consumers and companies supplying them should reject these, it says.

Consumers must have the information they are entitled to, and ensure the four phthalates *"are not actively added"* to items, such as office and sports products, paints and varnishes, and chemical building products, it says. Instead they should choose products with one of the two official Ecolabels – the Swan or the Flower – which do not contain phthalates.

The forum's initiatives include:

 the Danish Environmental Protection Agency's chemicals inspectorate will monitor compliance with the rules, including the phthalate content in consumer products;



- make companies, especially those purchasing from non-EU countries and online, aware of industry guidelines and help them to identify the phthalates' presence in products;
- get members to focus on the information obligations of REACH Article 33, both to disclose information on candidate list substances and to seek such information from suppliers;
- provide consumer information on the phthalates in toys and electronics via different information channels, including social media; and
- raise awareness internationally about them and how they can be substituted.

Earlier this year, ECHA's Risk Assessment and Socio-economic Analysis (Rac and Seac) Committees agreed on a restriction proposal on the four phthalates used in articles. This was originally submitted by ECHA and Denmark.

And in June, Seac adopted its final opinion on the proposal. It recommends restriction of the substances in items, especially those that can cause exposure through the skin or by inhalation.

## **ECHA CLARIFIES BREXIT IMPACTS ON** UK, EU REGULATORY OBLIGATIONS

ECHA has launched a webpage that explains what will happen to the regulatory obligations of UK entities and EU member states, as well as agency operations, following Brexit.

The UK's withdrawal from the EU on 30 March 2019 will *"significantly reduce"* ECHA's cooperation with UK authorities and will not leave stakeholders *"untouched"*, the agency says.

After Brexit, the UK will no longer be bound to European chemicals legislation and there will be no legal provision for ECHA to cooperate with UK authorities. The *"major impact"*, ECHA says, will be the UK authorities' loss of access to the world's largest database on the properties of chemical substances. After Brexit, these agencies will only have access to public information on ECHA's websites.

The UK's function as an evaluating member state will also cease. For those pending evaluations at the time of withdrawal, ECHA and the European Commission – with cooperation from member state authorities – will decide how to ensure other authorities within the EU and European Economic Area (EEA) will resume responsibility. ECHA says it will provide updated information and publish a list of affected evaluations in due course.

In addition, the UK will no longer take part in ECHA's Committees for Risk Assessment and Socioeconomic Analysis (Rac and Seac), its Enforcement Forum and other networks, such as HelpNet. ECHA says that it will appoint in advance an alternative member to take over from Rac or Seac UK rapporteurs in its committees, and it will publish a list of such rapporteur mandates at a later date.



In June 2016, ECHA made the point that third countries can be invited to participate in the work of the agency, subject to the agreement of ECHA's Management Board. And earlier this year, a report from the House of Lords European Union Committee said the UK must continue to push its *"informal influence"* on EU discussions on chemicals legislation following Brexit.

#### RESOURCES

The UK's legal obligation to maintain a national helpdesk to provide UK-based companies with advice and assistance in fulfilling their obligations under EU chemicals legislation will also cease.

Companies that seek assistance from the ECHA help desk should address the agency via the dedicated contact form, it says. As third country entities, they will join others based outside the EU and the EEA to whom the help desk *"regularly replies"*, ECHA adds.

Brexit also brings changes to ECHA's recruitment process. While UK citizens can still apply for agency jobs until the exit date, in order to be eligible to work at ECHA, candidates must be EU or EEA nationals. Therefore, after Brexit UK citizens will no longer qualify.

ECHA says that despite the uncertainties of the Brexit process, it will continue to *"seamlessly"* implement chemicals legislation within the EU27 and EEA beyond the UK's withdrawal.

It adds that it will continue to update the webpage as developments unfold.

#### **ADVICE FOR COMPANIES**

ECHA advises UK-based companies to follow national legislative developments, as well as the withdrawal negotiations, "which may determine" their future obligations. Businesses that are part of a supply chain which links them to others located within the EU 27 will face "some fundamental changes". Similarly, EU-based companies with UK businesses in their supply chain could face new and different UK rules on the import and use of chemical substances, the agency says.

## ECHA TO SET UP SUPPLY CHAIN NETWORK TO PROMOTE SUBSTITUTION

ECHA plans to set up a European multistakeholder network that focuses on promoting the substitution of hazardous chemicals.

The agency will invite the European Commission, member state authorities, businesses, NGOs and academic institutions to join the network.

The aim is to share experiences and to take ECHA's substitution strategy forward. A final version of this is expected by the end of the year.

Speaking at the recent Nordic Chemicals Summit in Copenhagen, Matti Vainio head of the agency's risk and implementation unit, said that ECHA will set up some supply chain workshops in 2018. The first of these will be held in Bulgaria in February.

The workshops will bring together users of hazardous substances, along with their suppliers and downstream customers, providers of alternatives and those helping in their development and implementation, such as technological support or funding organisations. The workshops will identify obstacles in substituting a substance, as well as the solutions available.

#### **STRATEGY FEEDBACK**

The idea, says Mr Vainio, is one of the outcomes of the agency's first workshop on substitution, which was held over two days in October in Finland and attended by 50 participants. It was organised to get feedback on ECHA's substitution strategy, which lists many objectives including the need to increase capacity building.



Workshop participants, he said, were in favour of stronger European action on substitution, along the lines of the strategy.

In his presentation, Mr Vainio said that while ECHA is encouraging substitution – through the implementation of REACH classification, restriction and authorisation – it *"could do something more"*.

Mr Vainio said that having seen the success of similar networks in the US, such as the Green Chemistry and Commerce Council (GC3) facilitated by the University of Massachusetts Toxic Use Reduction Institute (Turi), it was important for Europe to organise its own network, "naturally based on its own needs".

A report commissioned by ECHA in 2015 – carried out by the Lowell Centre for Sustainable Production – recommends that the agency create or expand mechanisms for greater supply chain collaboration and engagement. The report sets out ten recommendations to ECHA, which were considered when the agency developed its strategy.

## EU MEMBER STATES APPROVE NEW BATCH OF AUTHORISATION APPLICATIONS

EU member states have approved applications for uses of certain chromates, listed as substances of very high concern (SVHCs) under REACH Annex XIV.

At the REACH Committee meeting on 27 September, they granted companies authorisation for the following substances and conditional uses:

- Veco for use of ammonium dichromate as a photosensitive component in a polyvinyl alcohol photolithographic lacquer system for the production of mandrels used in nickel electroforming processes. The recommended review period is seven years, expiring on 21 September 2024;
- Gruppo Colle for use of sodium dichromate as mordant in wool dyeing with dark colours. During committee discussions, some member states said suitable alternatives were available, and therefore the Commission reduced the recommended review period from seven years to four years from the date of adoption; and
- eight companies Hoogovens Court Roll Surface Technologies, Wavec, Trattamento Cilindri Laminazione, Walzen-Service-Center, Nord Chrome, Rhenaroll, Texturing Technology and NC Poland – for use of chromium trioxide in functional chrome plating of work rolls, used in the steel and aluminium industry. The recommended review period is 12 years, expiring on 21 September 2029.



Two companies were granted authorisation for separate uses of trichloroethylene with a seven-year recommended review period, expiring on 21 April 2023. They are:

- Entek International for use of the substance as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators, used in lead-acid batteries; and
- Microporous for use as a degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries.

Member states backed also an application by GE Healthcare Bio-Sciences for industrial use of 1,2-dichloroethane (EDC) 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.

According to a recent ECHA report, analysis of the first 100 applications for REACH authorisation shows the socioeconomic benefits of continued use of SVHCs *"outweigh"* the risks to human health and the environment.

### EU MEMBER STATES APPROVE RESTRICTIONS TO CMR SUBSTANCES

EU member state officials have backed the addition of 18 carcinogenic, mutagenic or reprotoxic (CMR) substances to REACH Annex XVII – the restricted substances list.

Members of the REACH committee approved the draft Regulation setting out the changes at their meeting on 27 September.

The additions include:

- Cadmium nitrate;
- Cadmium hydroxide; and
- Cadmium carbonate.

All three substances are subject to a current ECHA consultation to identify new SVHCs, which ends on 20 October.

They received new harmonised classifications as CMR category 1A or 1B, based on human and animal evidence respectively. The marketing or use for supply to the general public of the substances, as well as in mixtures containing them, will be prohibited above specified concentrations.

The Regulation will apply from 1 December 2018 with the exception of formaldehyde, which will apply from February 2018.

In April, the committee voted in favour of the addition of 25 CMR substances to REACH Annex XVII.

Article source: ChemicalWatch.com



## EU NOTIFIES WTO OF PLANS TO IDENTIFY TWO SUBSTANCES AS SVHC

The European Commission has notified the WTO of plans to identify the following two substances as substances of very high concern:

- Dicyclohexyl phthalate (DCHP); CAS No 84-61-7, and
- Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride, TMA), CAS No 552-30-7.

In June 2016, ECHA's Member State Committee backed a proposal by Sweden and Denmark to classify DCHP as an SVHC, and add it to the REACH candidate list on the grounds that it is a category 1B substance toxic for reproduction and an endocrine disruptor for human health.

And in December, ECHA agreed that TMA should also be added to the candidate list.

https://chemicalwatch.com/60008/ eu-notifies-wto-of-plans-to-identify-twosubstances-as-svhc?pa=true

#### NEW INTENTIONS TO IDENTIFY A SUBSTANCE OF VERY HIGH CONCERN

New intentions for identifying as a substances of very high concern have recently been received by ECHA for:

- Terphenyl, hydrogenated (EC 262-967-7), with an expected submission date on 7 February 2018;
- Phenanthrene (EC 201-581-5); and
- Pyrene (EC 204-927-3), with an expected submission date on 6 August 2018.

Article source: ECHA.europa.eu



## EUROPEAN AUTOMOTIVE GROUP DEVELOPS LIST OF ABSENT SVHC 'UNIQUE IDENTIFIERS'

The European Automotive Industries Association (Acea) has developed a list of unique substance identifiers missing from the REACH candidate list.

Acea says that there is a growing number of substances of very high concern (SVHCs) entering the REACH candidate list without these, such as a Chemical Abstract Service (Cas) or European Community (EC) number. This, it says, is making it difficult for the automotive industry to meet its communication and notification obligations, such as those under Article 33 (see box).

Candidate list entries without unique identifiers have come under group entries, where more than one substance is covered. Acea's list contains 385 substances with Cas numbers for the 171 candidate list entries.

Project lead Stefan Riewer, head of chemical analysis at Ford Europe, told Chemical Watch that *"depending on the chain length, a number of chemicals could fall under a category of candidate list substances."* 

"ECHA says that candidate list entries are not exhaustive for Article 33 communication, therefore there is no legal certainty that if we were to only focus on those Cas numbers on the list, it could be that others are also in scope," says Mr Riewer.

Speaking on behalf of Acea, Timo Unger, Hyundai's environmental affairs manager, says that "this is an uncomfortable situation for many sectors because most only search for Cas numbers that are officially on ECHA's candidate list".

Keeping track of substances on the list is a challenge by itself, says Mr Unger, but now "companies are being told that they have to be aware of substances that come under scope but are not on the list."



Acea's list is made available on its website and the trade body is encouraging others to add to it *"as it is non-exhaustive"*. It plans to offer the list to ECHA for official use.

#### NUMERICAL IDENTIFIERS 'NOT MANDATORY'

In a statement ECHA says it fully understands why the use of unique identifiers in the candidate list would be beneficial.

The agency, it continues, makes every effort to ensure that the information it provides on the substance group is sufficiently clear. It does this to *"enable users of chemicals to determine* whether their substance falls within the definition of that group".

"ECHA would like to highlight that numerical identifiers are not mandatory for the identification of substances under REACH and that they need only be provided if they are available or appropriate." It is important to note, the statement says, that substances without a Cas and EC number covered by these candidate list entries can *"exhibit the same property/properties, hence the same concern exists".* 

It added that if Acea offers this list for official ECHA use, any new numbers proposed to be associated with particular entries *"would have to be considered on a case-by-case basis".* 

#### **REACH ARTICLE 33**

Article 33 of REACH requires manufacturers to respond to a consumer's request for information on whether a product contains any SVHCs above a concentration of 0.1%. They must provide the information free of charge and within 45 days.

## HOW DO REACH AND CLP IMPACT INDUSTRY'S SUSTAINABILITY STRATEGIES?

According to the study commissioned by ECHA, companies still see chemicals management mainly in the context of staying compliant with all regulations relevant to them. Compliance with chemicals legislation is seen by companies as the baseline providing a *"licence to operate"* in their business fields, but they do not link this work directly to their sustainability strategies.

Good quality information in companies' REACH registration dossiers was not considered a commercial asset. Dossier quality does not have a role in industry's compliance programmes, and the 19 companies participating in this study do not have specific goals (e.g. key performance indicators) or strategies to deal with dossier quality.

However, REACH is seen as contributing indirectly to profitability or as benefitting companies' brand values in the long run. Companies striving for the sustainable use of chemicals particularly appreciate the predictability of regulatory action in order to stay "ahead of the game". The study shows that the candidate list of substances of very high concern is a major driver of innovation and substitution to less hazardous chemicals. In general, market demand for more sustainable products and production processes is increasing and is most apparent in consumer-facing businesses. Retailers play an important role in conveying trends in consumer demand.



The report's key finding is that the REACH and CLP regulations have a crucial though only indirect impact on companies' sustainability and business strategies. The Candidate List in particular impacts market demand and is being used as a measure for investors to benchmark companies' sustainability performance. Market and investor demands in turn have a direct impact on industry's integrated corporate business strategies, including sustainability strategies.

The study makes a number of recommendations for ECHA to grasp opportunities to further improve the situation. For example, ways to encourage companies to include good chemicals management in their integrated corporate sustainability strategies by developing reporting tools and benchmarks. Several of these recommendations may also help ECHA in achieving the World Summit Sustainable Development 2020 goals. ECHA will start discussing these ideas with industry, NGOs and other stakeholders.

Article source: ECHA.europa.eu

## PROPOSAL TO RESTRICT HAZARDOUS SUBSTANCES IN TATTOO INKS AND PERMANENT MAKE-UP

Due to the growing popularity of tattoos and no harmonised control in the EU on tattoo and permanent make-up inks, ECHA was asked by the European Commission to assess the chemicalrelated risks associated with the inks, the need for Union-wide action, and the relevant socio-economic impacts. ECHA asked member states if they wanted to be involved in developing the proposal and Denmark, Italy and Norway became co-responsible. In addition, Germany contributed significantly to the proposal. As a conclusion to this assessment, the dossier submitters have made the proposal for a restriction.

The aim of the proposal is not to ban tattoo inks or tattooing. Instead, the aim is to regulate specific hazardous substances present in tattoo inks so that they are safe for people.

The proposal suggests restricting the intentional use or concentration limit of approximately 4,000 substances when contained in tattoo inks. These include those substances already banned in cosmetic products or subject to certain harmonised classifications, such as carcinogens or skin sensitisers. Only some of these substances have been found in tattoo inks, but they are included in the proposal to prevent their potential use as substitutes in the future. Most of the substances are also covered by the recommendation by the Council of Europe on tattoo inks (ResAP(2008)1 and its predecessor) on which seven member states have based their national legislation.



Stakeholders are expected to be able to comply with the proposed restriction as it is largely similar to the national measures on tattoo inks of the seven member states. The proposal also takes into account other socio-economic impacts on the industry and the people who get tattoos.

It is expected that the restriction will significantly reduce the potential health risks for people getting new tattoos, such as allergic reactions to tattoo inks and possible long-term effects from exposure to hazardous substances injected under the skin. ECHA plans to launch a six-month public consultation on the proposed restriction in mid-December 2017. Stakeholders and the public at large are invited to provide comments on the proposal and its anticipated impacts. ECHA's Committees for Risk Assessment and Socio-economic Analysis are expected to give an expert opinion on the proposal by the end of 2018, taking into account the submitted information. A draft decision by the European Commission is expected after that.

Article source: ECHA.europa.eu

#### NORWAY FINDS ILLEGAL SUBSTANCES IN PROMOTIONAL GIFT ITEMS

An inspection of promotional gift items in Norway has found that almost half breached the law by containing prohibited substances or for being inadequately labelled.

Norway's Environment Directorate looked at 70 products, including small electronics, such as USB sticks, torches and emergency chargers, and several types of soft plastic products, such as reflexes and bathing balls.

The directorate found toys that contained the phthalate DEHP. It also discovered short-chain chlorinated paraffin's (SCCPs) in plastic products and lead and cadmium in several electrical and electronic (EE) products. Controls showed that manufacturers or importers of this type of product have poor knowledge of the regulations, it says.

"It is essential that industry ensures products are labelled properly so it is clear that small electronics such as USB sticks, charging stations and cables, must be handled as EE waste," Mathieu Veulemans, section leader at the directorate, says.

Article source: ChemicalWatch.com



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