

REACH 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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ECHA ADDS FOUR SUBSTANCES TO CANDIDATE LIST

On 12 January 2017, ECHA added four new Substances of Very High Concern (SVHCs) to the Candidate List, based on proposals by France, Sweden, Germany and Austria, following the SVHC identification process with involvement of the Member State Committee.

Substances included in the Candidate List for authorisation on 12 January 2017 and their SVHC properties:



#	SUBSTANCE NAME	EC NUMBER	CAS NUMBER	SVHC PROPERTY	EXAMPLES OF USE(S)
1	4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Toxic for reproduction (Article 57c)	Manufacture of polycarbonate epoxy resins and chemicals; hardener in epoxy resins
2	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	206-400-3 - 221-470-5	335-76-2 3830-45-3 3108-42-7	Toxic for reproduction (Article 57c) PBT (Article 57d)	Lubricant, wetting agent, plasticiser and corrosion inhibitor
3	p-(1,1-dimethylpropyl)phenol	201-280-9	80-46-6	Toxic for reproduction (Article 57c)	Manufacture of chemicals and plastic products
4	4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances, which include any of the individual isomers or a combination thereof]			Toxic for reproduction (Article 57c)	Manufacture of polymers; formulation into lubricants

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". The aim of publishing such a list is to inform the general public and industry that these substances are candidates for possible 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 (12 January 2017) to notify ECHA.

Information on these obligations and related tools are available on the ECHA website.

Article source: *ChemicalWatch.com*.

https://chemicalwatch.com/51840/echa-adds-four-substances-to-candidate-list?pa=true#utm_campaign=51750&utm_medium=email&utm_source=alert

CALL FOR EVIDENCE ON PFAS

Germany and Sweden are considering a restriction proposal for the long-chain perfluorinated carboxylic alkyl acids (PFAS) of chain lengths between nine and 20 carbon atoms and related substances (those that may degrade to the C9-C20-PFCAs, such as long-chain flurotelomer alcohols).

They are requesting information about the manufactured and imported amounts of the respective substance groups and their potential alternatives, uses and the economic effects linked to these.

Any input should be submitted by 15 February 2017.

Article source: ChemicalWatch.com

<https://chemicalwatch.com/52213/echa-round-up>

ECHA CALLS FOR COMMENTS: DRAFT GUIDELINES ON NICKEL

ECHA has made a call for comments on the proposed guideline on the articles intended to come into direct and prolonged contact with the skin in relation to restriction entry 27 of Annex XVII to REACH: Nickel and its compounds

Following a request of the European Commission, a draft guideline has been prepared by ECHA providing non-exhaustive lists of articles and subtypes of articles falling within the scope of the restriction entry. The restriction entry restricts the use of nickel and nickel compounds in articles intended to come into direct and prolonged contact with the skin if the rate of nickel release from the parts of these articles is greater than 0,5 µg Ni/cm²/week. The Member States

have agreed on the scientific based interpretation of the "prolonged contact with the skin" and with the guideline the aim is to give practical examples of articles and parts of articles that are covered by or are out of the scope of the restriction entry. This guideline is based on information received during a survey conducted from February to April 2015, the case reports in open literature and other scientific literature. However, due to lack of information on precise contact times of articles, the guideline uses reasonable assumptions as a basis for division of articles falling and not falling under the scope of the restriction.

The guideline, after consideration by the Member State Competent Authorities,



is envisaged to be published on ECHA's website to serve as a tool that will provide the stakeholders and enforcement authorities with essential guidance on the scope of this restriction.

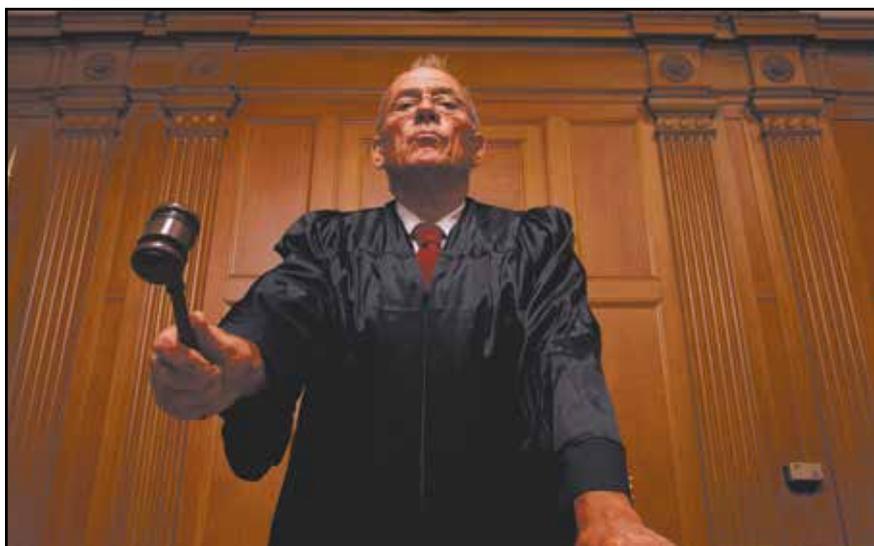
Article source: ECHA.Europa.eu <https://echa.europa.eu/addressing-chemicals-of-concern/restriction/calls-for-comments-and-evidence>

CLIENTEARTH SUES COMMISSION OVER DEHP AUTHORISATION

NGO ClientEarth is taking the European Commission to court over its controversial decision to grant authorisation for uses of the phthalate DEHP in recycled PVC until February 2019.

The case on the REACH authorisation process is the first to go before a court.

ClientEarth said the Commission's judgement was "deeply flawed" and it is now seeking to have the approvals overturned in the European Court of Justice (ECJ) in February 2017. The move follows the Commission's rejection, on 7 December, of a request



by the environmental law firm to conduct an internal review of its decision.

It said the Commission's decision in June to allow three recyclers - VinyLoop Ferrera, Stena Recycling and Plastic Planet - to use DEHP was a "huge mistake" and put the authorisation process "on the wrong track for cases to come".

"The Commission's approval of DEHP, despite the companies not submitting information required by law and proof that safe alternatives are available, clearly shows the authorisation process

[has] scant regard for the law or people's health," said ClientEarth chemicals lawyer Alice Bernard.

ClientEarth is using powers granted to NGOs, under the UN Aarhus Convention, on access to information, public participation in decision making and access to justice in environmental issues, to ask the Commission for an internal review.

But the Commission said in a letter to ClientEarth that the basis for this "has to be dismissed as unfounded" because it had "neither infringed any of the provisions of the REACH Regulation",

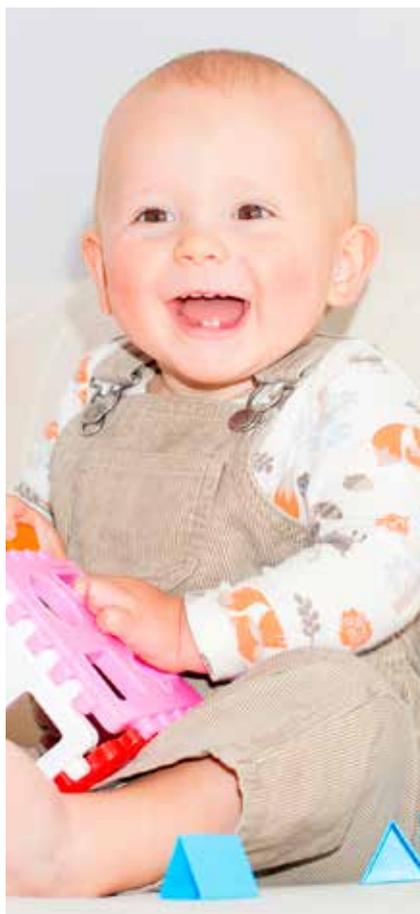
nor "any of the general principles of law mentioned therein".

The approvals were backed by most Member States on the grounds that there were no suitable alternative substances or technologies that were feasible for the three companies, and the socio-economic benefits outweighed the environmental and health risks.

Article source: ChemicalWatch.com

https://chemicalwatch.com/51782/clientearth-sues-commission-over-dehp-authorisation?pa=true#utm_campaign=51750&utm_medium=email&utm_source=alert

ECHA COMMITTEE HIGHLIGHTS RISK OF DiBP IN CHILDREN'S PRODUCTS



Echa's Risk Assessment Committee (RAC) has highlighted a potential risk from the phthalate DiBP in toys and childcare articles.

In the minutes of the 38th meeting of RAC, it says this risk "needs to be addressed."

DiBP is listed on Annex XIV of REACH, the authorisation lists. Because no application for authorisation of DiBP was submitted, its use in Europe was phased out by February 2015. However, this does not extend to imported articles.

ECHA and Denmark have proposed a REACH restriction on the use of DiBP and three other phthalates (BBP, DBP and DEHP) in consumer products where skin contact or contact with mucus membranes is likely.

The agency and Denmark believe that restricting the substance – as opposed to authorisation – may be necessary for the phthalates, because many articles containing them have been produced outside the EU. As such, they are unaffected by any authorisations, which only apply to chemicals and articles manufactured in the EU.

Unlike the three other phthalates (DEHP, BBP and DBP), DiBP is not restricted in childcare articles, although ECHA has said that the substance has "a similar anti-androgenic potency."

In the Annex XV restriction report for the four phthalates, it says: "DiBP is not restricted in childcare articles. Children could therefore be exposed dermally to DiBP from childcare articles as changing mats, bibs or car seats. If DiBP is used in a changing mat, the exposed dermal area could be as large as half of the body surface area".

The proposed restriction is supported by the European Council for Plasticisers and Intermediates (ECPI). ECPI manager Jean-Luc Wietor said the restriction of DiBP "would protect public health and ensure a level playing field for EU industry versus importers of articles manufactured outside the EU".

Many other consumer groups have also openly welcomed the proposed restriction.

Article source: ChemicalWatch.com

<https://chemicalwatch.com/51737/echa-committee-highlights-risk-of-dibp-in-childrens-products>

EU ENFORCEMENT PROJECT TO TARGET QUALITY OF SDS

Inspectors in EU Member States will focus on the quality of safety data sheets (SDSs), which contain guidelines on the safe use of hazardous substances, as they begin work on the fifth REACH enforcement project (Ref-5) this month.

The enforcement aims to ensure that workers handling hazardous chemicals, especially those dealing with SVHCs, receive sufficient and correct safety information, ECHA said in a release.

Throughout 2017, inspectors will check if the extended SDSs match the information established by the chemical safety reports (CSRs) that substance manufacturers prepare. They will also go through the exposure scenarios attached to the SDSs.

The project will also map how effectively extended safety data sheets are passed on and communicated all the way through the supply chain – from manufacturers of chemicals to users. This will be the first joint EU enforcement project to do so.

National inspectors will also check whether workers comply with the safety information at their workplaces. They will collaborate with labour inspectors to assess if the recommended operational conditions and risk management measures are fulfilled.

A report on the results of the inspections will be available in the fourth quarter of 2018. The Ref-5 project was adopted by ECHA's Forum for Exchange of Information on Enforcement at the end of 2015.



Article source: *ChemicalWatch.com*

https://chemicalwatch.com/52067/eu-enforcement-project-to-target-quality-of-sdss?pa=true#utm_campaign=51959&utm_medium=email&utm_source=alert

FRANCE TO SET LABELLING RULE FOR FURNITURE CHEMICAL EMISSIONS

France has notified the European Commission of a draft decree that will make it mandatory to label furniture, containing wood-based panels, with information about chemical emissions.

It will also be compulsory to give the consumer information on precautions to take when using the furniture. This does not apply to second-hand furniture and only applies to items intended for mainly indoor use.

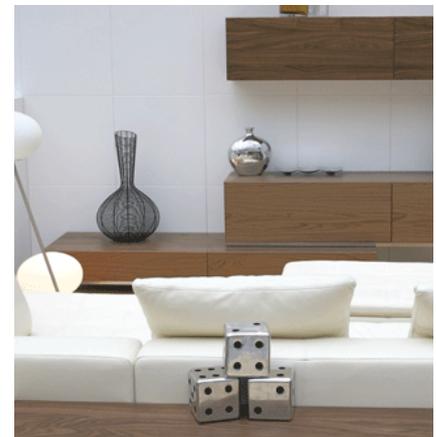
The provisions will come into force on 1 January 2020. For products placed on the

market before that date, and still on the market, they will apply 12 months later, on 1 January 2021.

In a brief statement, the French agency for food, environmental and occupational health and safety (Anses) says it has identified many substances, including carcinogens, mutagens or reproductive toxins that emanate from some furniture.

Article source: *ChemicalWatch.com*

https://chemicalwatch.com/52364/france-to-set-labelling-rule-for-furniture-chemical-emissions?pa=true#utm_campaign=52298&utm_medium=email&utm_source=alert



NEW COMMISSION REQUESTS TO ECHA RELATED TO RESTRICTIONS FOR PAH'S AND LEAD

The European Commission has requested ECHA to evaluate certain elements of the existing Annex XVII restrictions on polycyclic-aromatic hydrocarbons (PAHs) in rubber or plastic components of articles (entry 50) and lead in jewellery (entry 63) to support the Commission in their future reviews of these entries.



The task set by the Commission is to:

- Investigate the state of the art of scientific information in terms of available analytical methodologies to determine migration of lead from the different materials used in jewellery as well as the availability of alternatives to these materials and to those exempted by paragraph 4 of entry 63

- Investigate the state of the art of scientific information in terms of available analytical methodologies to determine the content and migration of the individual PAHs listed in entry 50 from plastic and rubber materials relevant to the scope of the restriction

Article source: [ECHA.Europa.eu](https://echa.europa.eu)

<https://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/current-activities-on-restrictions>

TEST METHOD FOR NICKEL IN SPECTACLE FRAMES AND SUNGLASSES HARMONISED

On January 13, 2017, EU Commission Communication 2017/C 011/02 was published in the Official Journal of the EU harmonising the list of methods for demonstrating presumption of conformity with nickel falling under entry 27 to Annex XVII of REACH. This Communication contains three methods:

EN 1811:2011+A1:2015 'Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin'

EN 12472:2005+A1:2009 'Method for the simulation of wear and corrosion for the detection of nickel release from coated items'

EN 16128:2015 'Ophthalmic optics – Reference method for the testing of spectacle frames and sunglasses for nickel release'. The scope of this standard applies to spectacle frames, ready-to-wear spectacles, sunglasses and other items for eye and face protection.

It is interesting to note that EN 16128:2015 has now been harmonised for presumption of conformity. The 2015 version contains a number of changes to the 2011 version. The Communication does not indicate an effective date but can be considered as immediate; 13 January 2017.



Both EN 1811:2011+A1:2015 and EN 12472:2005+A1:2009 are already in force for demonstrating presumption of conformity with nickel.

The effective date for the three methods is summarised in Table 1.

METHOD FOR NICKEL UNDER ENTRY 27 OF ANNEX XVII OF REACH			
Standard	EN 1811:2011+A1:2015	EN 12472:2005+A1:2009	EN 16128:2015
Effective date for demonstrating presumption of conformity	In force	In force	13 January 2017

Article source: [EUR-Lex.Europa.eu http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0113\(04\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0113(04)&from=EN)

FURTHER RESTRICTIONS ON LEAD PROPOSED



A Restriction dossier for lead and lead compounds has been submitted. The proposed Annex XVII entry aims at restricting the placing on the market of articles in whose production lead compounds have been used as PVC stabilisers. These articles are most

commonly produced from rigid PVC and are mainly used in building and construction relevant applications (making up 70-80% of PVC uses in the EU). Examples of such articles are window profiles, fittings, pipes and tubes, rolling shutters and gutters, wires and cables, roofing and flooring tiles.

Lead compounds cannot stabilise PVC in a satisfactory way at concentrations below approximately 0.5% (w/w) of the plastic material. Therefore, a restriction with the proposed concentration of 0.1% (w/w) would effectively end the intentional addition of lead-based stabilisers in the PVC compounding process. This would gradually eliminate the presence of lead in PVC articles manufactured or imported in the Union. A transitional period of 24

months after entry into force is proposed to allow use of existing stocks and to ensure that the information can be efficiently communicated within the relevant supply chains.

The restriction proposal dossier is available on ECHA's website to help increase transparency and help stakeholders prepare for the six-month public consultation on the dossier (expected in February 2017 if the dossier passes conformity).

Article source: ECHA.Europa.eu <https://echa.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions>

TiO₂ PRODUCERS DISPUTE SCIENCE BEHIND PROPOSED CARCINOGEN CLASSIFICATION

Titanium dioxide producers continued their fight against a proposal from the French authorities to introduce a mandatory classification for the substance as a category 1 carcinogen – something which could ultimately lead to it being added to the REACH candidate list and action to phase out its use except for those that gain authorisation to continue.

The substance is used in the manufacture of an extremely wide range of products and articles for consumer and professional use. It acts as a pigment in paints and related products and has been registered by more than 130 companies.

The producers, key argument against the proposal, written by the French authorities, is that the conclusions taken from a study using rats should not be applied to humans.

The Titanium Dioxide Manufacturers Association (TDMA) recently held a scientific meeting in Paris to discuss the proposals. Its overall conclusion, said the trade body, was that "the tests on rats used in the classification proposal are not a suitable model for humans for inhalation studies of poorly soluble particles of low toxicity in overload conditions".

The proposed classification report, published in June, focuses on exposure



by inhalation and a mode of action based on inflammation and oxidative stress. The authors say that the bio persistence and poor solubility of the substance are the root causes of the carcinogenicity.

The TDMA argues for the use of "extensive" human data from epidemiological studies "of over 24,000 workers in 18 manufacturing sites". These, the association says, "confirm no adverse health effects".

But in the report the human data are ruled "inadequate" on the basis of "methodological limitations" with the research and because of other issues.

They describe the animal data more favourably, finding that "lung tumours were

reported in one inhalation study and one intra-tracheal study of acceptable quality. Carcinogenic potential was also reported in two further (inhalation or intra-tracheal) studies of lower reliability but of adequate relevance".

ECHA's Committee for Risk Assessment (RAC) is expected to discuss the report, comments and responses in June 2017 and produce an Opinion for the Commission within 18 months.

Article source: ChemicalWatch.com https://chemicalwatch.com/51856/tio2-producers-dispute-science-behind-proposed-carcinogen-classification?pa=true#utm_campaign=51750&utm_medium=email&utm_source=alert

TURKEY REACH LAW POSTPONED TO 'FIRST QUARTER OF 2017'

Turkey has pushed back the publication of its already delayed REACH-like law to the first quarter of 2017, a senior ministry official has said.

The Ministry of Environment and Urbanisation (MoEU) had been expected to sign off the law, known as the KKDIK, by the end of 2016, but political upheaval and uncertainties over data-sharing arrangements have cast a shadow over the negotiations.

"The implementation of the KKDIK Regulation has been postponed to the first quarter of 2017 as it has become necessary to conduct certain evaluations," Yahya Kesimal, chemicals department head at the MoEU, said.

Mr Kesimal declined to elaborate on what these were, adding only that they were "entirely to do with public-sector duties" with "no concrete outcome achieved as yet".

Turkey has been aligning its chemical regulations with those of the EU, since membership negotiations began in 2005. But the final stage in the process, implementing the KKDIK, has been delayed several times from an initial end of 2015 deadline due to ministry overhauls and civil unrest.

The new Regulation, which mirrors REACH, has also been plagued by concerns over the significant compliance costs it creates for the industry. Turkish companies are particularly worried about data obligations under KKDIK, and the prospect of having to pay a lot to European consortiums to meet them. The latter have been urged by ECHA to share more data in order to ease the registration cost burden.

Companies in Turkey have been lobbying the MoEU to make a special provision on data and by some means gain access to REACH dossiers. But many in the

industry doubt this can be achieved and expect further delays to the Regulation's implementation.

Cost is a key challenge. "REACH is too expensive for Turkey," Mustafa Bagan, general secretary of the Turkish Chemical Manufacturers Association, said. "And there is no money or data in the [Turkish] industry."

One industry consultant said he remained sceptical about the 2017 forecast. "I don't think KKDIK is on the agenda even in the first quarter. It doesn't look like it will happen before June 2017."

Article source: ChemicalWatch.com

https://chemicalwatch.com/51746/turkey-reach-law-postponed-to-first-quarter-of-2017?pa=true#utm_campaign=51750&utm_medium=email&utm_source=alert

UK MOVES CLOSER TO BAN ON MICROBEADS IN COSMETICS

Following calls from MPs made in August the UK's environment ministry and the devolved administrations for Scotland, Wales and Northern Ireland have launched a consultation to ban microbeads in cosmetics and personal care products by October 2017.

The consultation outlines proposals to ban the manufacture and sale of cosmetics and personal care products containing microbeads. It also explores further steps to prevent other sources of plastic from

entering the marine environment. The consultation closes on 28 February.

Greenpeace welcomed the proposals but criticised the fact that they are "limited to just personal care and cosmetic products, despite the consultation document admitting that microbeads are found in 'washing powders, household cleaners' and other items not included in their draft ban."

Meanwhile, many leading UK retailers, including Tesco, Waitrose, Boots and

Superdrug have announced moves to phase out microbeads from the products they sell.

The Scottish government has also confirmed it will introduce legislation regulating the use of microbeads.

Article source: ChemicalWatch.com

https://chemicalwatch.com/51850/uk-moves-closer-to-ban-on-microbeads-in-cosmetics?pa=true#utm_campaign=51750&utm_medium=email&utm_source=alert

UK MPS LAUNCH INQUIRY INTO REACH AND BREXIT

The UK parliament's Environmental Audit Committee's second inquiry into the future of environmental law and policy, following the EU Referendum, will focus on the scope of REACH in the country.

"We are keen to inform the government's thinking on this issue as soon as possible," the committee said.

The future of the REACH Regulation in the UK was identified as a "challenging area" in the evidence to the committee's first inquiry on 21 July, it said.

Prime Minister Theresa May has said that leaving the EU will involve converting the body of EU law into UK law, under an act referred to as the Great Repeal Bill. But the committee notes that the UK government "has said that up to a third of EU environmental law cannot simply be 'copy-pasted' into UK law. [It]

will require additional work to ensure that the UK maintains the current level of environmental protection."

REACH is constantly evolving and has been amended 38 times since it was enacted in 2006, the committee said. However, "relatively little" of the Regulation has been transposed into UK law.

As reported in our special e-bulletin on 9 January, the new inquiry, which had a submissions deadline of 20 January, invited responses on questions including:

- What scope is there for the UK to pursue a divergent approach to chemicals regulation from the EU, once Brexit is complete?
- What principles should a UK chemicals regulation regime follow? and

- What are the likely practical implications of having a UK-only chemicals regulatory policy for the environment, public safety and UK industry?

UK-based Chemical Industries Association (CIA) said it is preparing a comment, while the Chemical Business Association (CBA) said they are considering submitting a response.

Article source: ChemicalWatch.com

https://chemicalwatch.com/51943/uk-mps-launch-inquiry-into-reach-and-brexite?pa=true#utm_campaign=51878&utm_medium=email&utm_source=alert

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WHEN YOU NEED TO BE SURE

