

REACH E-NEWSLETTER

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N°15 • AUGUST 2017



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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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CALL FOR EVIDENCE ON RESTRICTION PROPOSAL ON PAHs IN PLASTIC AND RUBBER GRANULATES



The Netherlands has notified its intention to prepare a restriction proposal on polycyclic aromatic hydrocarbons (PAHs) in granulates used as infill material in synthetic turf pitches. It will, in cooperation with ECHA, assess the risks to human health associated with the use of these PAHs.

Interested parties can now submit any information they have related to the PAHs in infill material to help prepare the dossier. Other information on the possible risks of using synthetic turf are also welcome.

This call for evidence is open until **18 October 2017**.

Article source: ECHA.europa.eu

DANISH TESTING FINDS SUSPECTED EDCs IN PUSHCHAIRS

Tests carried out on pushchairs in Denmark have found carcinogenic and suspected endocrine disrupting chemicals in more than half of the products, according to the Danish Consumer Council's Think Chemicals initiative.

Substances such as chlorinated paraffins, the flame retardant TCPP, and the polycyclic aromatic hydrocarbon (PAH) naphthalene were found in the handles or seats of six out of 11 pushchairs tested, it said.

Although not banned in baby products, naphthalene is classified as possibly carcinogenic, while chlorinated paraffins are on the Danish EPA's list of unwanted substances and a suspected Endocrine Disruptive Chemical (EDC). TCPP is banned in the EU in toys for children up to three years old due to its carcinogenic properties.

Think Chemicals said exposure from a single product is "not necessarily problematic in itself", but it contributes to children's combined exposure to hazardous chemicals from different sources.

The following pushchairs were found to have harmful substances:

- Britax Smile 2 (chlorinated paraffins in the handle);
- Cybex Balios M (chlorinated paraffins in the handle and seat);
- Gb QBIT Plus (chlorinated paraffins in the handle);
- Maxi Cosi Stella (chlorinated paraffins and naphthalene in the handle);
- Mutsy Nexo (TCPP in the seat); and
- Phil and Teds Smart (chlorinated paraffins in the handle and naphthalene in the seat).

Smaller amounts of chlorinated paraffins were found in the handle of the Hauck Rapid 4 pushchair.

In three other products, only very small amounts of PAHs were present in the handle. These are:

- Baby Jogger City Premier;
- Basson Baby Uno; and
- Joie Litetrax 4.

The Britax B motion 4 Plus pushchair performed best in the test with the least amount of harmful chemicals present.

The test also examined the content of phthalates in the pushchairs, but none were found.

Article source: ChemicalWatch.com



ECHA CONFIRMS IT WILL REJECT **INADEQUATE TESTING PROPOSALS**



Where it believes possible alternatives exist, ECHA has confirmed it will reject REACH registration testing proposals if they do not adequately consider methods other than animal testing.

In a July letter to the European Coalition to End Animal Experiments (ECEAE), ECHA said when checking a proposal that includes animal testing, it does check the registrant's assessment of alternatives along with any third-party comments. If, on the basis of all the available information, ECHA considers the test is unnecessary it can reject it.

However, the agency says it does not *"actively and specifically evaluate"* whether a registrant has explored and evaluated all possible alternatives to animal testing.

The ECEAE had complained to the European Ombudsman that ECHA was claiming to abide by a September 2015 ruling while in practice *"systematically and openly ignoring it"*.

At the time, ECHA said it was not able to reject a testing proposal for a standard REACH information requirement on the grounds that the registrant had not considered all viable alternative methods.

The ECEAE later urged the Ombudsman to resolve the issue by reiterating that ECHA can and should reject the testing proposals as described.

In letters from June and July this year, the Ombudsman said she is satisfied that the agency has an effective system in place.

Dr Katy Taylor, Director of Science at ECEAE, said that ECHA's confirmation is *"significant progress"*. However, she would like the agency to take *"an even more proactive role"* in evaluating potential alternative methods. *"We hope this constitutes a renewed approach and that we start to see some more proposals for animal tests rejected."*

Article source: ChemicalWatch.com

ENGLISH TRANSLATIONS OF TURKEY 'REACH' LAW AVAILABLE

The Turkish Government has produced English text translations of its REACH-like law, KKDIK.

Three documents are available on the website of its general directorate of environmental management. They are:

- a draft by-law on the EU's REACH (KKDIK Yönetmeliği – İngilizce);
- Annex 17: restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (KKDIK Ek 17 – İngilizce); and
- Annex 18: conditions for receiving a competency certificate for chemical assessment experts (KKDIK Ek 18 – İngilizce).

After long delays, the Regulation was published in the country's Official Gazette on 23 June and will come into effect on 23 December this year.

It will bring various Turkish chemicals legislation under one law, by replacing three existing regulations: The Inventory and Control of Chemicals; the Preparation and Distribution of Safety Datasheets for Hazardous Materials and Products; and the Restrictions Relating to the Production, Supply to the Market and Use of Certain Hazardous Materials, Products and Goods.

The law sets a registration deadline of 31 December 2023 and a pre-registration deadline of 31 December 2020 in order to give businesses ample time to prepare.



Building up infrastructure and the training of experts required will take many years, industry has said.

Article source: ChemicalWatch.com

EU MEMBER STATES BEGIN **RMOAs** OF NEW SUBSTANCES

EU member states are starting risk management option analyses (RMOAs) of two new substances under ECHA's public activities coordination tool (PACT), which also assesses hazards.

Germany is assessing bisphenol A (BPA), which is suspected of having endocrine disrupting properties, and France is assessing the substance for this and its potential carcinogenic, mutagenic and reprotoxic (CMR) properties.

The Netherlands is carrying out analysis on penta-1,3-diene, with concerns relating to the environment and human health.

Meanwhile, Germany has listed its intention to conduct an RMOA on decamethylcyclotetrasiloxane and

octamethylcyclotetrasiloxane, both of which it says could be persistent, bioaccumulative and toxic (PBT) substances; and Denmark is also to assess perfluorobutanoic acid and its salts and precursors for their suspected PBT and CMR properties.

Further updates to PACT include Sweden's notification that it will not initiate further regulatory risk management action, following an RMOA on the suspected sensitisers (1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] diacrylate and 2-ethylhexyl acrylate; and the Netherlands the same for cobalt titanite green spinel, which it assessed because of concerns with properties affecting human health and the environment.

Article source: ChemicalWatch.com



EU NOTIFIES **WTO** OF **CMR** SUBSTANCES ADDED TO ANNEX VII OF REACH



The European Union has notified the WTO of a draft Commission Regulation to include substances recently classified as carcinogenic, mutagenic and reproductive (CMR) category 1A and 1B under CLP within the scope of entries 28 to 30 of Annex XVII of REACH.

The substances make up more than 20 entries, including cadmium compounds and formaldehyde reaction products.

The action has the effect of restricting their placement on the market, or use for supply to the general public as substances on their own, as constituents of other substances, or in mixtures. It also imposes the requirement of marking packaging with the label "restricted to professional users".

The proposed date of adoption is the first quarter of 2018. The proposed date of entry into force is 20 days from publication in the *Official Journal of the EU*.

In accordance with Article 2(2) of the Act, the restriction will apply to formaldehyde from the date of entry into force of the Regulation and to the other substances from 1 December 2018.

The final date for comments is 60 days from the 28 July notification.

Link to draft commission regulation: https://members.wto.org/crnattachments/2017/TBT/EEC/17_3403_01_e.pdf

Article source: ChemicalWatch.com

EUROPEAN COURT DISMISSES PFOA CASE AGAINST NORWAY

Norway did not infringe on European Economic Area law by maintaining a national restriction on perfluorooctanoic acid (PFOA) for four years before a Europe-wide restriction was agreed under REACH, a free trade court has concluded.

The country introduced a restriction on the substance in 2013, using Article 128(2) of REACH that allows EEA states to adopt national rules to protect human health and the environment in cases “*where REACH does not harmonise the requirements on manufacture, placing on the market or use*”.

This preceded European action; the Commission published an amending Regulation to restrict PFOA only in June this year, following a 2014 proposal by Norway and Germany.

The application of the European restriction has been deferred for at least three years.

As a member of the European Free Trade Association (EFTA), Norway is part of the EEA internal market and therefore governed by the same basic rules as EU member states. The EFTA Surveillance Authority (ESA) opened proceedings against Norway, saying that restrictions on substances raising EEA-wide concerns can only be adopted through a REACH process. The ESA argued that REACH entails a harmonisation of all substances falling within its scope, and national restrictions are prohibited except in urgent cases.

Norway, however, stated that it was entitled to introduce a national prohibition,

since the requirements on PFOA were not harmonised.

1. COURT JUDGEMENT

The EFTA court said in its judgement on 14 July that Norway “*did not breach its obligations under the REACH Regulation by invoking Article 128(2)*”, since PFOA had not been subject to a final decision under REACH at the end of the period set in ESA’s opinion.

The requirements mentioned in Article 128(2) “*are harmonised only when a substance has been subject to a final decision under the REACH restrictions procedure*”, the court said.

Moreover, a substance “*may give rise to sufficiently serious concern for an EEA State*” if the requirements have not yet been harmonised, and Article 128(2) will accommodate such concerns, it noted.

It also said that a national measure pending a final decision is not disruptive of the overall REACH system, while such a step “*will be provisional and cannot be maintained in contravention of the final outcome of the REACH restrictions procedure*”.

2. PFOA RESTRICTION

NGOs have criticised the Commission’s decision on PFOA, saying that the agreed concentration limits render the restriction meaningless because they will not reduce global consumption or emissions.

The restriction published on 13 June ((EU) 2017/1000) will apply to the use of



PFOA, its salts and related substances at concentrations above 25 parts per billion (ppb) of PFOA; or 1,000ppb of one, or a combination of, PFOA-related substances. The original proposal from Germany and Norway had suggested a 2ppb limit for PFOA.

It is classified as a substance of very high concern (SVHC) under REACH. Due to their special properties, such as high friction and heat resistance, as well as water, grease, oil and dirt repellence, PFOA and related substances have widespread uses. These include fire-fighting foams, grease-resistant food packaging, leather protectants and stain-resistant carpeting and textiles.

The restriction comes into force on 4 July 2020 with some deferrals.

Article source: ChemicalWatch.com

IUCLID CLOUD LAUNCHED – SIMPLER FOR SMALLER COMPANIES



The IUCLID Cloud for SMEs service is now available for preparing REACH registration dossiers. In April, ECHA launched a trial version that remains available for training and testing.

If you subscribe to IUCLID Cloud for SMEs, you no longer have to install IUCLID locally on your computer, but you will have direct access to the latest version in your web browser – anytime, anywhere say ECHA. The service comes with up to 1GB of data storage, fully managed backups and dedicated helpdesk support, at no charge.

Consultants helping SMEs with their registrations are encouraged to use the Cloud service so that their clients can easily access their data in the Cloud as well.

ECHA will continue improving IUCLID Cloud and release a further simplified interface by the end of the year.

A webinar on the use of the IUCLID Cloud services for SMEs will be hosted in September.

Article source: ECHA.europa.eu

NEW INTENTIONS TO IDENTIFY A SUBSTANCE OF VERY HIGH CONCERN



New intentions for identification as a substance of very high concern have been received for:

- benz[a]anthracene (EC 200-280-6; CAS 56-55-3), and
- chrysene (EC 205-923-4; CAS 218-01-9).

Both have been proposed by Germany and meet the following SVHC categories:

Carcinogenic (Article 57 a); PBT (Article 57 d); vPvB (Article 57 e)

The expected submission date is 7 August 2017 (information has not been submitted at the time of writing).

These two substances are currently restricted under entry 50 of Annex XVII for use in rubber and plastic components that come into contact with the skin. They are also included in a proposal by the Netherlands to restrict their use in synthetic turf pitches.

Article source: ECHA.europa.eu

PAINT INDUSTRY URGES EU: REJECT PROPOSED TITANIUM DIOXIDE CARCINOGEN CLASSIFICATION

The paint and coatings industry has called on the European Commission and ECHA to reject a proposal to classify titanium dioxide as a carcinogen (category 2) by inhalation.

If adopted, companies would have to label some consumer and professional products – such as paints – in a manner that will cause “*major and unnecessary alarm to users and consumers*”, the British Coatings Federation (BCF) says.

The proposed classification is based on evidence of carcinogenicity for titanium dioxide in the form of dust. Under CLP companies would have to label some products containing it as “*suspected of causing cancer*”. But the BCF says this is unnecessary when the dust is suspended in a liquid.

ECHA’s Risk Assessment Committee (RAC) expects to publish its opinion in early September.

If the Commission and ECHA do not “*see sense and reject*” it, the BCF says it will “*push to break the link between this opinion and the requirement to label paint products with ‘suspected of causing cancer’ labels*”.

It is raising the issue in a letter to Greg Clark, UK Secretary of State for Business, Energy and Industrial Strategy, which will be signed by industry CEOs and other supply chain organisations.

UK ACTIVITY

The UK Health and Safety Executive (HSE) says it understands industry’s concerns. However, it adds, classification under CLP and GHS reflects the type and severity of the intrinsic hazards of a substance or mixture.

“It should not be confused with risk, which relates to the actual exposure of humans or the environment to the

substance or mixture displaying this hazard in specific circumstances, such as when a paint containing titanium dioxide is applied by brush, roller or by spraying.”

The UK Government says it will continue to seek to influence the Commission’s fitness check of chemicals legislation, excluding REACH, but this work will be affected by activities relating to the country leaving the EU.

Later this year, and after publication of the RAC opinion, the Commission is expected to make a decision on whether dust is within the scope of CLP. The REACH Committee is slated to discuss the topic at a meeting in 2018.

Article source: ChemicalWatch.com



UK BREXIT PAPER 'REASSURING' FOR CHEMICAL INDUSTRY'S COMMITMENTS

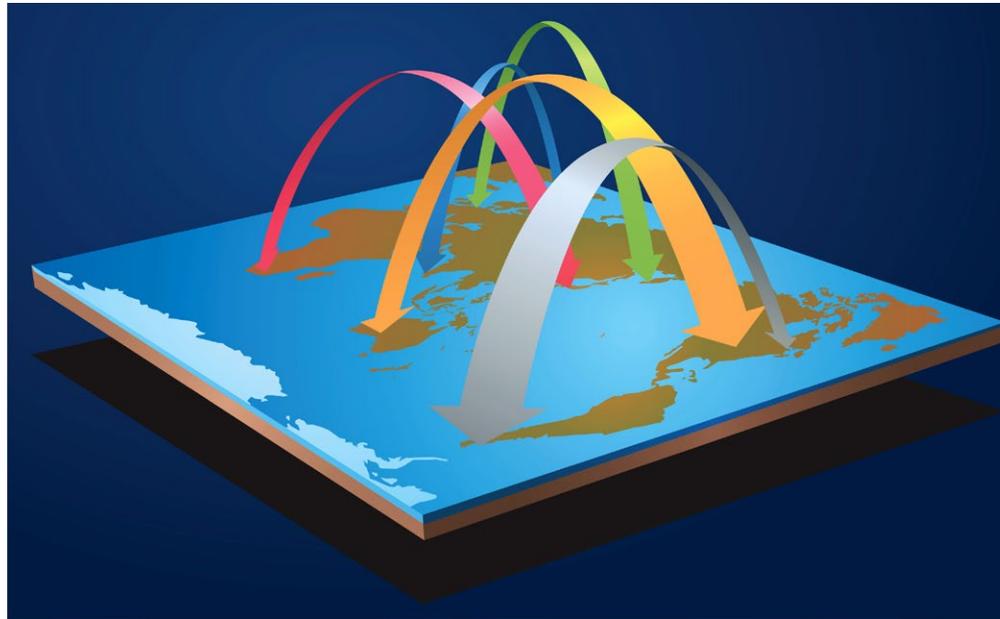
UK businesses "should not be required to duplicate" compliance activities, such as those obligations under EU chemicals regulations, when the country leaves the EU, the British Government has said in its latest Brexit position paper.

The paper, *Continuity in the availability of goods for the EU and the UK*, says that in preparation for placing goods on the single market, businesses will have undertaken a number of "complex, lengthy and often costly" procedures to ensure that goods and practices are compliant with European legislation.

It mentioned chemicals as an example in its suggestions for ensuring trade in goods and services can continue after Brexit. "This could include, for example, undergoing an inspection by an EU-recognised body to ensure production is in accordance with good manufacturing practice or collecting and submitting data on the hazards and risks of a chemical substance."

The Government acknowledges "the need for chemical businesses to be reassured that significant regulatory commitments and related costs, such as those already undertaken under REACH, will remain valid after exit from the EU".

The Chemical Industries Association (CIA) says Whitehall's suggestion is "exactly the right approach". It acknowledges "the need for chemical businesses to be reassured that significant regulatory commitments and related costs, such as those already undertaken under REACH,



will remain valid after exit from the EU," chief executive Steve Elliott says.

And, he says, with 60% of UK exports going to the EU and 75% of imports coming from it, "it is absolutely essential" that UK chemical businesses can continue to trade both finished goods and raw materials "without any disruption" during an appropriate transition period.

Furthermore, he says, the UK needs to take account of the relationship after the Brexit transition and current discussions should prepare for that. Accepting the "ongoing validity" of all pre-Brexit registration activities "marks a significant step in securing that outcome".

CERTAINTY LACKING

Meanwhile, technology trade association techUK says the paper "gives certainty" for products already on the market, but does not offer any for products or substances in development. "Manufacturers are planning their 2019 – 20 product ranges now and need answers on how the UK will recognise 2018 REACH registrations, access ECHA data and more widely how EU laws such as RoHS, WEEE and CE marking will apply."

In another paper issued this month, the government proposed an interim customs union agreement after Brexit. This, CIA said, could bring about regulatory uncertainty.

Article source: ChemicalWatch.com

WHY SGS?

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