

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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12 SUBSTANCES ADDED TO REACH AUTHORISATION LIST

The European Commission has added 12 SVHCs to REACH Annex XIV – the authorisation list.

They are the first substances to be included in Annex XIV, which now contains 43 substances, since the Commission adopted a moratorium on such additions in August 2014.

Of the 12, eight are category 1B substances toxic for reproduction with a sunset date of 4 July 2020:

- 1-bromopropane (n-propyl bromide) (used in washing and cleaning products, and in the manufacture of electrical and electronic equipment)
- Diisopentylphthalate (found in cosmetics)
- 1,2-benzenedicarboxylic acid di-C6-8-branched alkyl esters C7-rich (used in the manufacture of dyes, medicine and perfume)
- 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
- 1,2-benzenedicarboxylic acid, dipentylester, branched and linear
- Bis(2-methoxyethyl) phthalate (found in cosmetics)
- Dipentylphthalate
- N-pentyl-isopentylphthalate.

Two substances are carcinogenic (category 1B) and have PBT and vPvB properties with a sunset date of 4 October 2020:

- Anthracene oil (used in dyes); and
- Pitch, coal tar, high temperature.

Two substances have endocrine disrupting properties for the environment and have a sunset date of 4 January 2021:

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (used in paints and coatings)
- 4-nonylphenol, branched and linear, ethoxylated (used as an intermediate in the manufacture of substances used in detergents, paints and personal care products).

The sunset date is the date after which the substance cannot be used within the EU without authorisation from ECHA.

Article source: *ChemicalWatch.com*

https://chemicalwatch.com/56889/eu-commission-adds-12-substances-to-reach-authorisation-list?pa=true#utm_campaign=56734&utm_medium=email&utm_source=alert



2018 REACH REGISTRANTS MAKING 'GOOD PROGRESS'

ECHA has received 9,034 dossiers covering 4,454 substances for the 2018 REACH registration deadline, which is just one year away.

The agency says this number is in line with expectations and anticipates registrations will peak in the last quarter of 2017.

It estimates a total of 60,000 dossiers will be submitted for up to 25,000 substances by 31 May 2018.

The agency is encouraging companies to register as soon as possible to avoid "the last-minute rush". ECHA and industry associations should focus on reaching companies that are still unaware of their obligation to register, it says.

If companies are submitting several registrations and it is their first time, they should select one or two to familiarise themselves with the process and tools, rather than trying to register all at once.

It is also important, ECHA says, to initiate discussions on the formation of the substance information exchange forum (Sief) and joint submission as soon as possible, including the nomination of the lead registrant. The agency says this is a "crucial" step that must be addressed now as it can delay progress later.

Downstream users should also discuss registration intentions for critical substances with their suppliers, it adds.

To date, the agency has received 50,171 registrations for 10,831 substances from all three REACH deadlines – 2010, 2013 and for 2018. It says it will publish further updates of registration statistics this summer.

Meanwhile, an ECHA registration survey targeting SMEs will close on 2 June. The outcome will help the agency to estimate the total number of registrations and improve readiness for receiving them.

The survey will be followed by other market intelligence activities conducted by ECHA, its Directors' Contact Group and industry associations. The agency will release the results of these after the summer.

Article source: ChemicalWatch.com

https://chemicalwatch.com/56190/2018-reach-registrants-making-good-progress?pa=true#utm_campaign=56125&utm_medium=email&utm_source=alert

ECHA AUTHORISATION ENFORCEMENT PROJECT FINDS CASES OF NON-COMPLIANCE

About 90% of European companies are in compliance with their REACH authorisation obligations, ECHA's enforcement forum has found.

In the forum's second pilot project, national enforcement authorities (NEAs) checked the marketing and/or use of substances subject to authorisation. It marks the first-time NEAs also reviewed, where relevant, compliance with conditions laid down in the decisions.

Seventeen NEAs looked at compliance in the use and placing on the market of 13 substances of very high concern (SVHCs) with sunset dates in 2015. Where an authorisation had already been granted, inspectors also checked if the conditions set out in the application were being met.

The authorities conducted 802 inspections between January and October 2016. Most took place in Italy (162), followed by Denmark (120) and Sweden (106).

The majority of companies did not use (93%) or place on the market (92%) any of the substances that had a 2015 sunset date, according to the Forum's report.

LEGAL ACTION

Sixty-seven of inspected companies had placed substances on the market after the date. Six of these were in breach of REACH, the Forum says, which puts the non-compliance rate at 8.9% of cases.

In 16 cases, companies placed substances on the market according to the authorisation granted. In a further 16, it was based on a pending decision at the time of inspection. The NEAs considered these to be compliant.

Fifty-six companies used substances with a sunset date that had passed in 2015. The NEAs found six of these to be in breach of REACH, giving a non-compliance rate of 10.7% of cases.

The authorities took legal action against 13 of the companies, but only two faced a criminal complaint, with most receiving verbal or written advice by the relevant NEA.

The Forum recommends another pilot project for substances whose sunset dates have passed, to "gain more experience with enforcing authorisation decisions and the underlying conditions".

Article source: *ChemicalWatch.com*

https://chemicalwatch.com/57145/echa-authorisation-enforcement-project-finds-cases-of-non-compliance?pa=true#utm_campaign=57159&utm_medium=email&utm_source=alert



ECHA ISSUES UPDATED GUIDANCE ON SUBSTANCES IN ARTICLES

ECHA has published the long-awaited revision of its guidance on substances in articles.

The agency says the “comprehensive update”, which was expected in 2016, gives more clarity on communication and notification obligations when articles contain SVHCs.

It has included new examples, which it says are in line with the judgement of the European Court of Justice (ECJ) ruling in 2015. This said the 0.1% threshold for notifying SVHCs in articles applies to “each of the articles incorporated as a component of a complex product” rather than to the entire item.

Amendments to existing examples have been made as a result of consultation with member states, the European Commission and Echa’s accredited

stakeholders. Members at the Partner Expert Group (PEG) meeting in October last year submitted almost 700 comments.

ECHA published a “quick update” of the guidance in December 2015 after the ECJ ruling. The agency said this was done to “correct the parts” that were not consistent with the conclusions of the judgement.

ARTICLE 33

The guidance now features an illustrative example to check if requirements under REACH Articles 7 and 33 apply.

Article 7(2) says producers and importers of articles must notify ECHA if an SVHC is present at over one tonne per producer, or importer, per year, in a concentration



higher than 0.1% by weight.

While Article 33 requires companies to reply within 45 days if asked by consumers about the presence – above 0.1% concentration – of SVHCs in their products.

Article source: ECHA.Europa.EU <https://echa.europa.eu/-/guidance-on-substances-of-very-high-concern-in-articles-updated>

ECHA REVOKES FOUR REACH REGISTRATION DOSSIERS

ECHA has revoked three REACH registration dossiers for being incomplete and one for breaching the ‘one substance, one registration’ (Osor) principle.

The revocation of the three followed two campaigns to check completeness during 2016. The first ran from July and focused on cases where the registrants said they did not provide data because the study was not ready at the time of dossier submission.

The agency requested missing information for more than 140 endpoints from 39 registrations, covering 24 substances.

Registrants were given two opportunities to complete their dossiers with a final deadline in April.

Consequently, dossiers for 35 registrations were adequately updated, but two registration decisions for one company were revoked. The final decision on two registrations for one substance is pending.

ECHA ran a second campaign later in 2016 to review lead registrant dossiers containing invalid data waivers, instead of the required studies or adaptations, as stipulated under REACH.

The agency addressed 43 registrations from four companies and revoked one incomplete dossier. The final deadline for another is pending.

OSOR

In its other campaign, ECHA asked registrants to comply with their obligation to become part of a joint registration as required by REACH.

The registrations it reviewed were submitted before the implementing Regulation on joint submission of data and data sharing entered into force in January 2016.

The agency approached 118 individual registrants of charcoal, 81 of which subsequently joined the existing joint submission. Thirty-one filed disputes, which are still being processed.

For five companies, the deadline to join the joint submission has not yet passed, and ECHA says it will revoke one company’s registration decision.

Many small and micro-sized of these registrants expressed difficulties in negotiating access to the joint submission, the agency says. As a result, it will analyse the information, as well as previous or current disputes, to consider specific measures that could help potential and existing charcoal registrants to fulfil their obligations.

ECHA says that, during the course of 2017, it aims to address all situations where multiple registrations exist for the same substance.

It is also developing a strategy to “systematically verify” the completeness of dossiers that were submitted before the enhanced check came into force.

Article source: ChemicalWatch.com <https://chemicalwatch.com/57292/echa-revokes-four-reach-registration-dossiers>



ECHA'S SEAC ADOPTS RESTRICTION PROPOSALS ON FOUR PHTHALATES AND TFDA

ECHA' Committee for Socio-Economic Analysis (Seac) has adopted its final opinion on a restriction proposal on four phthalates (DEHP, DBP, DIBP and BBP) in articles.

It recommends they are restricted in items, such as:

- Flooring, coated fabrics and paper
- Recreational gear and equipment
- Mattresses, footwear, office supplies and equipment
- Other articles moulded or coated with plastic that cause exposure through the skin or by inhalation.

The committee proposed additional derogations for certain aircraft parts, products or appliances and articles for automotive vehicles. It also made minor adjustments in the justification for its opinion in response to public consultation comments.

The proposal is based on the combined effects of all four phthalates, ECHA says, although there was evidence that for some countries and populations there was a risk from individual substances.

It will apply three years after the amendment of REACH Annex XVII comes into force.

TDFA

The committee also supported the proposal by Denmark to restrict the placing on the market of sprays used by the general public containing tridecafluorooctyl silanetriol and derivatives (TDFA).

TDFA is used alongside organic solvents for:

- Automotive glass, float glass coating, glass doors of shower cabins
- Ceramics, such as kitchen tiles, sanitary ware, wash basins, bath tubs
- Enamel.

The measure requires that sprays should not be placed on the market if they contain TDFAs in a concentration equal to or greater than two parts per billion by weight in a mixture with organic solvents.

The proposed restriction will apply 18 months after the amendment of Annex XVII comes into force.

Article sources: *ChemicalWatch.com* <https://chemicalwatch.com/46597>

<https://echa.europa.eu/-/seac-adopts-two-restriction-proposals-on-four-phthalates-and-on-tdfas-in-sprays-used-by-the-general-public>



NORWAY PROPOSES ADDING SECOND PFC TO UN POPs CONVENTION

Norway has submitted a proposal to list perfluorohexane sulfonic acid (PFHxS), its salts and related compounds, for action under the UN Stockholm Convention on persistent organic pollutants (POPs).

If approved by the parties to the convention, it will become the second listing of a perfluorocarbon under the treaty, joining perfluorooctane sulfonic acid, its salts and its precursor, perfluorooctane sulfonyl fluoride.

The PFHxS compounds are used in firefighting foam, carpets and textiles, electronics and non-stick cookware.

The Norwegian environment ministry says these qualify as POPs because they are persistent, bioaccumulative, travel long-range distances and are toxic.

Earlier this year, Norway added the chemicals to its national list of priority substances, which means emissions must be eliminated or substantially reduced by 2020 and companies must find safer alternatives.

As well as describing them as a very persistent and very bioaccumulative (vPvB) substance, Norway says they are suspected of being an endocrine disruptor.

According to Trine Celius, the ministry's senior adviser on biocides and chemicals, PFHxS, its salts and related compounds make up a group of about 50 substances which are mainly produced in China.

They have been pre-registered under REACH and are under evaluation for inclusion on the candidate list, based on a SVHC dossier produced by Sweden.

Ronald Bock, EMEA risk management manager at Chemours, a global manufacturer of fluorinated substances, told Chemical Watch that PHFxS is mostly produced as a degradation product of fellow fluorinated chemical PFOS. To the best of his knowledge, it is not used or sold in the EU but he said it may be used in China as a substitute for PFOS in certain applications, mainly in the galvanic metal plating industry.

The proposal will be considered by the convention's POPs Review Committee at its October meeting in Rome. If it decides the substance meets the screening criteria, it will forward the proposal, and its own evaluation, to the convention's parties and observers.

*Article source: ChemicalWatch.com
https://chemicalwatch.com/56634/norway-proposes-adding-second-pfc-to-un-pops-convention?pa=true#utm_campaign=56587&utm_medium=email&utm_source=alert*



RAC OPINION MAKES CANDIDATE LIST UNLIKELY FOR TITANIUM DIOXIDE

An ECHA science committee's opinion on the carcinogenicity of titanium dioxide has made it unlikely the substance will ever be added to the REACH candidate list.

Nevertheless, the opinion of the Risk Assessment Committee (RAC) has disappointed industry.

France proposed a mandatory category 1B carcinogenicity classification. This would have made titanium dioxide eligible for REACH substance of very high concern (SVHC) status and inclusion on the candidate list for authorisation.

But, in an opinion recently released online, the RAC opted for a category 2 carcinogen via inhalation classification instead. ECHA will now send this to the European Commission, which will decide what, if any, regulatory measures should be taken.

Industry has been consistently critical of the proposal, saying that key data from studies of rats is not relevant to human toxicology. Classification of the hazard should focus instead on the available data from human epidemiological studies, it says. In the proposal, such data is considered "inadequate" based on "methodological limitations".

Robert Bird, chair of the Titanium Dioxide Manufacturers Association (TDMA), said there were no grounds for classifying the substance as carcinogenic for humans by inhalation.

Furthermore, classification would do nothing to increase the level of protection of human health and the environment.

Article source: ChemicalWatch.com

<https://chemicalwatch.com/56755/rac-opinion-makes-candidate-list-unlikely-for-titanium-dioxide>

REGULATION TO RESTRICT PFOA PUBLISHED

The European Commission has published its amending Regulation to restrict the manufacture, marketing and use of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances.

The restriction will apply to the use of PFOA and its salts at concentrations above 25 parts per billion (ppb); or 1,000ppb of one, or a combination of, PFOA-related substances.

Some uses are exempt, these include:

- Photographic coatings, applied to films, papers or printing plates
- Implantable medical devices
- Substances or mixtures used in semiconductor and photo lithography processes
- Fire-fighting foams, already placed on the market before the date of application of the restriction
- Semiconductor manufacturing equipment.

As advised by ECHA' Socio-economic Analysis Committees (Seac), the application is deferred for a period of three years, and for longer periods in relation to specified sectors, in order to enable stakeholders to comply.

This Regulation will enter into force on the twentieth day following its publication in the EU's Official Journal.

Article source: *ChemicalWatch.com*

https://chemicalwatch.com/56909/eu-commission-publishes-regulation-to-restrict-pfoa?pa=true#utm_campaign=56734&utm_medium=email&utm_source=alert

UK INTENDS TO PROPOSE DECHLORANE PLUS FOR CANDIDATE LIST

The UK authorities have submitted an intention to propose adding 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo [12.2.1.16,9.02,13.05,10] octadeca-7,15-diene (dechlorane plus) to the REACH candidate list of SVHCs.

The UK says the substance, used as a chlorinated flame retardant, is suspected of having very persistent and very bioaccumulative (vPvB) properties.

Submission of the proposal is expected by 7 August. It covers any of the substance's individual isomers or any combination.

Dechlorane plus was added to ChemSec's Substitute It Now (SIN) list in 2014 and NGOs say they support its inclusion on the candidate list.

CHEM Trust's Ninja Reineke says dechlorane plus is still widely used, despite concern about its persistent and bioaccumulative properties and its detection in the environment around the globe.

In the US, NGO Toxic Free Future has called on Washington state's Department of Ecology to add dechlorane plus to its chemicals of high concern list (CHCC).

Article source: *ChemicalWatch.com*

https://chemicalwatch.com/56227/uk-intends-to-propose-dechlorane-plus-for-candidate-list?pa=true#utm_campaign=56125&utm_medium=email&utm_source=alert

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WHEN YOU NEED TO BE SURE

