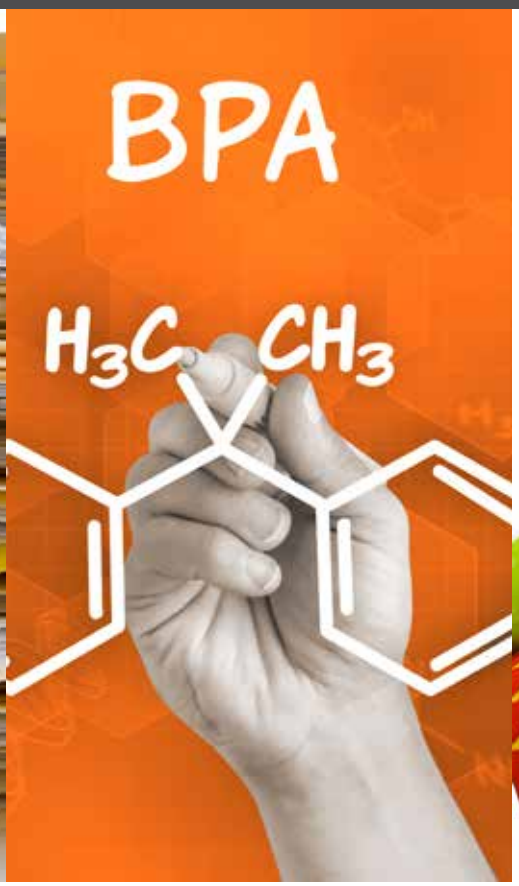
REACH NEWSLETTER



- DANISH COOP TO PHASE OUT 'DIRTY DOZEN'
- CHANGE LAW ON SVHCs IN ARTICLES, URGES UEAPME
- ECHA PUBLISHES INFORMATION ON UPCOMING PUBLIC CONSULTATION ON APPLICATIONS FOR AUTHORISATION
- EU PROPOSES TO REGULATE PFOA UNDER ANNEX XVII OF REACH
- EUROPEAN COMMISSION VOTES TO STRENGTHEN MERCURY REGULATION
- MEPs CALL FOR BAN ON BPA IN FOOD CONTACT MATERIALS
- EU PROPOSES TO RESTRICT METHANOL IN CERTAIN PRODUCTS
- NGOs SEEK TO OVERTURN LEAD PIGMENTS AUTHORISATION
- NO RISK FROM PHTHALATE SUBSTITUTES IN TOYS, SAYS FRENCH AGENCY
- RESTRICTION DOSSIER FOR DIISOCYANATES SUBMITTED
- LEAD REGISTRANT LIST PUBLISHED BY ECHA
- SUBSTANCES ON THE AUTHORISATION LIST TO BE INCREASED

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.

CONTENTS

Danish coop to phase out 'dirty dozen' 3

Change law on SVHCs in articles, urges UEAPME 3

ECHA publishes information on upcoming public consultation on applications for authorisation 4

EU proposes to regulate PFOA under Annex XVII of REACH 4

European Commission votes to strengthen mercury regulation 5

MEPs call for ban on BPA in food contact materials 5

EU proposes to restrict methanol in certain products 6

NGOs seek to overturn lead pigments authorisation 6

No risk from phthalate substitutes in toys, says French agency 7

Restriction dossier for diisocyanates submitted 7

Lead registrant list published by ECHA 8

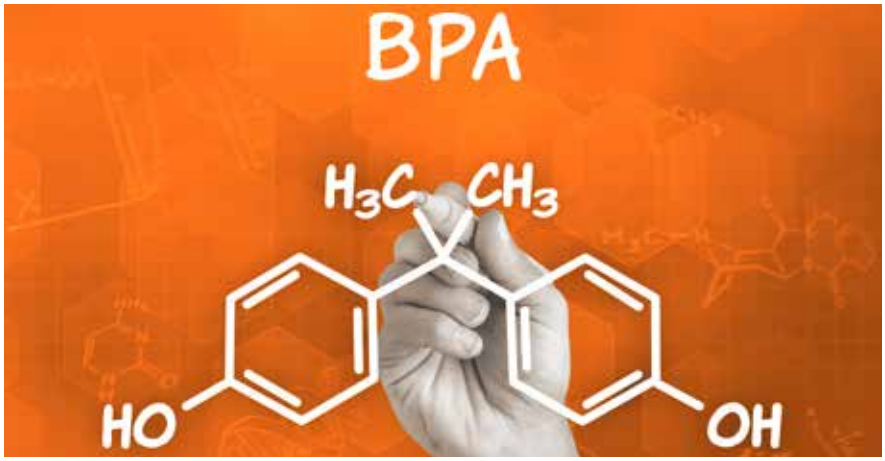
Substances on the authorisation list to be increased 8

DANISH COOP TO PHASE OUT 'DIRTY DOZEN'

Coop in Denmark plans to phase out a list of twelve substances or broad groups of chemicals, ranging from all SVHCs to fluorinated compounds, from its private label products by the end of 2017.

The substances on the Coop`s "dirty dozen" list are:

- Bisphenol A (BPA)
- Fluorinated compounds
- Polluting washing detergents
- Pesticides
- Suspected endocrine disruptors
- PVC and phthalates
- Chemicals in textiles
- Substances identified as SVHCs
- Allergenic scented substances and preservatives
- Tricoslan
- Cleaning products with chlorine and cationic surfactants
- The preservative methylisothiazolinone (MI)



The retailer also plans to place pressure on suppliers of branded products to phase out the twelve groups of substances.

Fluorinated compounds were banned from its products in 2014 and replaced with silicone in items such as baking paper. The store banned BPA and bisphenols in June this year, and replaced them with epoxy lacquer in cans, after co-operation with the Danish packaging industry association.

Article source: ChemicalWatch.com https://chemicalwatch.com/49963/danish-coop-to-phase-out-dirty-dozen

CHANGE LAW ON SVHCs IN ARTICLES, URGES UEAPME

Europe's SME trade body has urged ECHA and the European Commission to look for ways to simplify notification of SVHCs in articles under REACH.

UEAPME's secretary general Peter Faross wrote to the agency and the Commission's environment and industry directorates in advance of a meeting of the Partner Expert Group (PEG).

This will discuss ECHA's latest draft of its revised guidance on requirements for substances in articles. The latest draft was published in July and has been circulated for comment. It is much revised since the December 2015 guidance was published in response to the ECJ decision.

The changes aim to align the guidance with last year's European Court of Justice ruling. 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 article.

In his letter, Mr Faross expressed concern at the interpretation of the term 'article' and the functioning of REACH Articles 33 and 7(2).

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

Mr Faross said the court ruling was based on a "fundamental misunderstanding related to proportionality" as it said requiring the article producer or importer to provide, as a minimum, the name of any SVHCs in an article, could not be regarded as an "excessive burden".

Describing Article 33 as "dead law, which is fundamentally eroding the credibility of our legal system," the letter urges the Commission to use the opportunity provided by the second REACH review to see how it could be changed.

"In practice", said Mr Faross, the submission of a chemical name is "actually only the last step of a very burdensome process" and that the court had not taken into account the necessary practical efforts to be able to state whether a substance is present in an article or not. "Since this could require testing and/or other investigation methods," he said, "these efforts need to be considered as they are the main part of the burden."

Mr Faross said UEAPME is glad to contribute to the PEG consultation but "does not think that the new version of the guidance will improve the situation because the legal obligation is too complex for an average SME."

After the PEG meeting, ECHA will revise the draft and submit it for consultation by its Enforcement Forum and the Competent Authorities for REACH and CLP (Caracal). This should happen by early next year, with the final guidance published soon afterwards. It is understood that EU member states are planning a six-month enforcement pilot in early 2017.

Article source: ChemicalWatch.com https://chemicalwatch.com/50419/change-dead-law-on-svhcs-in-articles-urges-ueapme#utm_campaign=50318&utm_medium=email&utm_source=alert

ECHA PUBLISHES INFORMATION ON UPCOMING PUBLIC CONSULTATION ON APPLICATIONS FOR AUTHORISATION

ECHA has decided to start publishing information about the uses and substances that will be covered in upcoming consultations, to give third parties as much time as possible to prepare comments for public consultations on applications for authorisation.

The next public consultation for applications for authorisation will start on 9 November 2016 and information about the uses and substances is available from ECHA's website.

The current list shows applications for 30 uses and comprises mainly chromium compounds and 1,2-dichloroethane.

Article source: ECHA.Europa.eu https://echa.europa.eu/documents/10162/13637/afa_pc_pre-notification_en.pdf/38531d55-5a36-4136-a1a3-bd7fbe9f6772

EU PROPOSES TO REGULATE PFOA UNDER ANNEX XVII OF REACH

On 6 October 2016, the World Trade Organization (WTO) circulated notification G/TBT/N/EU/411 from the European Union (EU) to announce its draft regulation to regulate perfluorooctanoic acid (PFOA), its salts and other PFOA-related substances in a wide variety of products and applications. According to the definitions, PFOA-related substances are defined as any related substances, including their salts and polymers, with a linear or branched perfluoroheptyl group (C7H15) attached directly to another carbon atom.

According to the draft regulation, attached to WTO document 16-5339, PFOA is identified as a persistent, bioaccumulative and toxic substance (PBT). It has been on the candidate list of Substances of Very High Concern (SVHCs) since June 2013, and is a candidate for listing under Annex XIV (Authorisation List) of REACH.

The substances in this draft regulation are used in a wide variety of applications, such as anti-repellent agents for grease, oil and/or dirt in textile and paper materials, manufacture of fluoropolymers and fluoroelastomers for non-stick coatings in pans and cookware, and as surfactants in fire-fighting foam.

There are a number of exemptions on the use of these substances in this proposal. Some of these are:

- The manufacture of implantable medical devices (Directive 93/42/EEC)
- In photographic coatings applied to films, paper or printing plates
- In semi-conductor photo-lithography processes or etching processes for compound semiconductors

The regulation would restrict the manufacturing, the use and placing on the market of PFOA, its salts and PFOA-related substances as a substance on its own and as a constituent of other substances, in mixtures, or in articles or any part thereof, in a concentration equal to or greater than 25ppb of PFOA or 1000 ppb of one or a combination of related substances.

Application of the restriction is deferred for 36 months to allow industry sufficient time to adapt and achieve compliance. Specific deferred dates are provided for the exemptions listed in the annex. The proposed date of adoption is the first half of 2017.

Article source: WTO.org https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=&Serial=%2216-5339%22&IssuingDateFrom=&IssuingDateTo=&CATTITLE=&ConcernedCountryList=&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList

EUROPEAN COMMISSION VOTES TO STRENGTHEN MERCURY REGULATION

The European Parliament's Environment Committee (ENVI) has voted in favour of amendments to a Commission proposal for a mercury regulation.

The amendments include:

- Aligning the export ban on mercury-added products with restrictions already applied within the EU
- Expanding the regulation to include three more mercury compounds
- Phasing out mercury in dentistry by the end of 2022, and for children and pregnant women within one year from entry into force of the regulation
- Prohibiting the import of mercury and listed compounds
- Import for disposal is permitted initially until December 2027
- Parliament will now begin discussions with the European Council to see if they can reach an agreement before the end of the year.

Article source: ChemicalWatch.com https://chemicalwatch.com/50365/european-commission-votes-to-strengthen-mercury-regulation#utm_campaign=50318&utm_medium=email&utm_source=alert

MEPS CALL FOR BAN ON BPA IN FOOD CONTACT MATERIALS

A large majority of Members of the European Parliament (MEPs) have backed an environment committee (ENVI) report calling for a ban on the use of bisphenol A (BPA) in all food contact materials (FCM).

The report criticises the major gaps in EU legislation and calls for harmonised regulation for all FCMs and wants priority given to paper and board due to its high market penetration.

The call to ban BPA in FCMs was introduced as an amendment to the report at a meeting of MEPs earlier this month. The report, with the new BPA amendment, was then voted on by 616 MEPs; 91% supported the report, 5% were against and 4% abstained.

The report and vote do not force the Commission to act, but do apply pressure.

Earlier this year the European Commission issued a draft regulation to set a tighter migration limit of 0.05mg of BPA per kg of food to plastic materials as well as articles, varnishes and coatings found in canned foods. The current limit is set at 0.6mg of BPA per kg of food.

MEPs say this is not good enough. In their amendment to the ENVI report, they referred to new evidence from the Dutch National Institute for Public Health and the Environment (RIVM). This says the current tolerable daily intake (TDI) does not protect foetuses or infants from the effects of BPA on the immune system.

In September the French authorities submitted a proposal for adding BPA to the REACH candidate list of SVHCs on the grounds that it is an endocrine disruptor and a CMR.

Article source: ChemicalWatch.com https://chemicalwatch.com/50185/meps-call-for-ban-on-bpa-in-food-contact-materials#utm_campaign=50173&utm_medium=email&utm_source=alert

EU PROPOSES TO RESTRICT METHANOL IN CERTAIN PRODUCTS

On 6 October 2016, the World Trade Organisation (WTO) circulated notification number G/TBT/N/EU/410 announcing a draft regulation from the European Union (EU) to restrict methanol in certain mixtures, namely windscreen washing or defrosting fluids and denatured alcohol. The draft regulation would create a completely new entry 69 in Annex XVII of REACH. The restriction aims at the following:

- To minimise incidences of severe methanol poisoning resulting from consumption by alcoholics
- To prevent methanol poisoning resulting from accidental ingestion, including poisoning in children

The draft regulation is proposed to be adopted in the first half of 2017. The restriction could become effective by the second half of 2018; approximately 13 months after the date of entry into force.

Highlights of the draft regulation are summarised below:

Article source: WTO.org https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=&Serial=%2216-5331%22&IssuingDateFrom=&IssuingDateTo=&CATTITLE=&ConcernedCountryList=&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList

PROPOSED ENTRY 69 TO ANNEX XVII OF REACH			
SUBSTANCE	**SCOPE**	**REQUIREMENT**	**EFFECTIVE DATE**
Methanol	• Denatured alcohol • Windscreen washing or defrosting fluids	≤ 0.6%	By the second half of 2018

NGOs SEEK TO OVERTURN LEAD PIGMENTS AUTHORISATION

A group of NGOs are contesting the European Commission's decision to authorise the use of two lead chromate pigments.

Environmental law group, ClientEarth, the European Environmental Bureau (EEB), ChemSec and International POPs Elimination Network (IPEN), are using powers granted to NGOs under the UN Aarhus Convention to conduct a formal review of the Commission's decision.

The Commission has 12 weeks to respond. If this is 'unsatisfactory', the case will be taken to the European Court of Justice, say the NGOs.

Authorisation has been granted to Canadian company Dominion Colour Corporation (DCC), for the pigments Red 104 and Yellow 34. These cover a wide range of uses in industrial coatings, plastics and road markings.

According to their mandatory classifications, both substances are carcinogenic, reprotoxic and toxic to aquatic life.

Tatiana Santos, senior policy officer at the EEB says other paint companies, including major firms in Europe, have already stopped using lead in paint and support the ban.

Last year, government officials from across the globe, meeting in a major UN chemicals summit, agreed a resolution which urges countries to consider adopting rules banning the use of lead in paint.

A Commission spokesperson has stated that it will examine the arguments made in the request and will respond within the deadline.

According to the Commission's Decision, for the industrial application of paints on metal surfaces or as road marking, and the professional use in hot-melt road marking, the review period expires on 21 May 2019. For the other uses applied for, the review period ends on 21 May 2022.

Article source: ChemicalWatch.com https://chemicalwatch.com/50606/ngos-seek-to-overturn-lead-pigments-authorisation#utm_campaign=50473&utm_medium=email&utm_source=alert

NO RISK FROM PHTHALATE SUBSTITUTES IN TOYS, SAYS FRENCH AGENCY

An expert opinion from the French agency for food, environmental and occupational health and safety (ANSES) has found no health risk to children from mouthing plastic toys, containing four phthalate plasticiser substitutes.

The substances found to be safe, through oral exposure, were:

- Acetyl-tributyl-citrate (ATBC)
- 1,2-cyclohexane dicarboxylic acid diisonyl ester (DINCH)
- Diethylhexyl-terephthalate (DEHTP)
- 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB)

Other routes of exposure, for example, through skin and dust inhalation, were not investigated.

Daily exposure doses were estimated, and toxicity reference values calculated, from the literature on ATBC, DINCH and DEHTP. The ratio of these values showed there was no health risk. But for TXIB the judgement was based on margin of exposure as the critical effect for toxicity has not been identified.

The expert committee advises that the use of one substitute, bis(2-ethylhexyl) isophthalate (DOIP), should be avoided until data exists to show that it is safe. It concluded it was "concerned" that the substance had been found in toys. Some safety data sheets also indicate that the substance causes reprotoxic effects, the assessment says, and a proposed classification by one manufacturer is as a category 1B reprotoxicant.

It also concluded that:

- Many restricted or prohibited phthalates are still found in toys marketed in Europe
- It should be mandatory to perform migration tests, before toys for children under three years can be placed on the market
- In vivo tests in children under three should be conducted to validate the testing protocol
- Risk assessments for other substances likely to migrate into saliva should be conducted, such as tributyl citrate (TBA) and diethyl phthalate (DEP)

Article source: ChemicalWatch.com https://chemicalwatch.com/50511/no-risk-from-phthalate-substitutes-in-toys-says-french-agency#utm_campaign=50473&utm_medium=email&utm_source=alert

RESTRICTION DOSSIER FOR DIISOCYANATES SUBMITTED

On 7 October Germany submitted a proposal to restrict diisocyanates (EC: n.a.) as substances on their own, as constituents in other substances or in mixtures for industrial and professional uses, unless certain criteria are met. The level of restriction proposed is 0.1% by weight.

ECHA's committees are currently performing a conformity check on the dossier. ECHA has published the dossier on its website to increase transparency and to help stakeholders prepare for the six-month public consultation on the dossier. The public consultation is expected to start mid November 2016 if the dossier passes conformity.

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

LEAD REGISTRANT LIST PUBLISHED BY ECHA

On 28 September 2016, ECHA published a list of substances for which a lead registrant has been declared in REACH-IT. The list will be updated regularly as more information about substances and joint submissions becomes available. The list is currently 92 pages long and contains over 7,700 entries and shows all substances entered into REACH-IT up to 19 September 2016.

If you are planning to register any of these substances, you can contact the lead registrant company and start negotiating to get access to the joint submission. If the lead registrant of your substance is not visible on the list, you can find their full contact details in REACH-IT. If your pre-registered substance does not yet have a declared lead registrant, you can consider becoming the lead and announcing it to your co-registrants on the pre-SIEF page in REACH-IT.

If you manufacture or import a substance into Europe in a quantity greater than 1 tonne/year, then you are likely to need to register that substance under REACH and you must start working on your registration dossier as soon as possible.

Article source: ECHA.Europa.eu https://echa.europa.eu/documents/10162/5039569/registration_statistics_lr_js_en.pdf/cf1c8cd9-890d-4277-bc1e-740bd6eab2bb

SUBSTANCES ON THE AUTHORISATION LIST TO BE INCREASED

The World Trade Organisation (WTO) has circulated a notification from the European Union (EU) announcing its draft regulation to amend the list of substances of very high concern (SVHCs) in Annex XIV of the REACH Regulation Authorisation List.

In February 2011, the first list of SVHCs subject to authorisation was published. This list was further expanded in February 2012, April 2013 and August 2014. As of today, there are 31 SVHCs in Annex XIV of REACH.

On September 21, 2016, the WTO circulated notification number G/TBT/N/EU/407 announcing the EU's intention to expand the list of SVHCs under the Annex XIV 'Authorisation List' of REACH The draft regulation would expand the number of SVHCs on this list from 31 entries to 43 entries. The list includes seven entries for phthalates.

According to the draft regulation, there are no exemptions for specific uses for each of the 12 new SVHCs. The draft regulation is proposed to be adopted in May 2017, and enter into force 20 days after publication in the Official Journal of the EU (OJEU). The latest proposal contains three sets of dates for 'latest application' and 'sunset' dates. These are:

Entries 32 to 39 (Table 1)

- Date of entry into force + 18 months (latest application date)
- Date of entry into force + 36 months (sunset date)

Entries 40 and 41 (Table 1)

- Date of entry into force + 21 months (latest application date)
- Date of entry into force + 39 months (sunset date)

Entries 42 and 43 (Table 1)

- Date of entry into force + 24 months (latest application date)
- Date of entry into force + 42 months (sunset date)

The earliest date of latest application could be in late 2018 or early 2019

When SVHCs are added to Annex XIV, a 'latest application date' and a 'sunset date' is set for each SVHC. After the sunset date, the use of an SVHC on this list is prohibited unless an authorisation has been granted for that use. If an application has been made by the latest application date, an applicant can continue to use the SVHC after the sunset date, until the European Commission (EC) has made a decision. It is important to note that imported articles containing an SVHC in Annex XIV are not subject to authorisation (but may be subject to a restriction).

Highlights of the draft regulation to include 12 SVHCs in Annex XIV of REACH 'Authorisation List' are summarized in Table 1.

Table 1: Proposed New entries to Annex XIV (Authorization List) to Regulation (EC) 1907/2006 (REACH)

ENTRY NO	SUBSTANCE	EC NO. (CAS NO)
32	1-Bromopropane (n-propyl bormide)	203-445-0 (106-94-5)
33	Diisopentyl phthalate	210-088-4 (605-50-5)
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich	270-084-1 (71888-89-6)
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6 (68515-42-4)
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2 (84777-06-0)
37	Bis(2-methoxyethyl) phthalate	204-212-6 (117-82-8)
38	Dipentyl phthalate	205-017-9 (131-18-0)
39	N-pentyl-isopentyl phthalate	(776297-69-9)
40	Anthracene oil	292-602-7 (90640-80-5)
41	Pitch, coal tar, high temp.	266-028-2 (65996-93-2)
42	4-(1,1,3,3 Tetramethylbutyl) phenol, ethoxylated*	
43	4-Nonylphenol branched and linear, ethoxylated**	

**Covering well-defined substances and UVCB substances, polymers and homologues (substances of unknown or variable composition, complex reaction products or biological materials)*

***Substances with a linear and/or branched alkyl chain containing nine carbon atoms that are covalently bound in position 4 of phenol, ethoxylated covering UVBC- and well defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof.*

From Safeguards http://www.sgs.com/en/news/2016/10/safeguards-16316-eu-proposes-to-expand-svhcs-under-annex-xiv-of-the-reach-authorization-list?utm_source=ExactTarget&utm_medium=Email_SafeGuardS&utm_campaign=co141016&j=3550939&e=tony.smith%40sgs.com&l=501117_HTML&u=107179763&mid=6128519&jb=0

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