

REACH E-NEWSLETTER

REACH E-NEWSLETTER

N°14 • JULY 2017



- ▶ **ONE NEW SUBSTANCE ADDED TO THE CANDIDATE LIST, SEVERAL ENTRIES UPDATED**
- ▶ **CLP WEB PAGES REVAMPED**
- ▶ **ECHA'S RAC AND SEAC AGREE ON SODIUM DICHROMATE AUTHORISATION**
- ▶ **SUBSTANCE RESTRICTION UPDATES**
- ▶ **EU COMMISSION NOTIFIES WTO OF PROPOSED NMP BAN**
- ▶ **OECD LAUNCHES PFASs WEBSITE**
- ▶ **PAH RESTRICTION REMINDER**
- ▶ **SME BODY CRITICISES ECHA'S GUIDANCE ON SVHC'S IN ARTICLES**
- ▶ **INTENTION TO RESTRICT FIVE COBALT SALTS SUBMITTED**
- ▶ **THE NETHERLANDS INTENDS TO PROPOSE A RESTRICTION RELATED TO GRANULES USED IN SYNTHETIC TURFS**
- ▶ **TURKEY FACES LONG HAUL TO IMPLEMENT NEW KKDİK REGULATION**
- ▶ **UK MINISTER WANTS REACH 'MUTUAL RECOGNITION' ACCORD**
- ▶ **UPDATE TO THE GUIDANCE IN A NUTSHELL ON REGISTRATION PUBLISHED**

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.

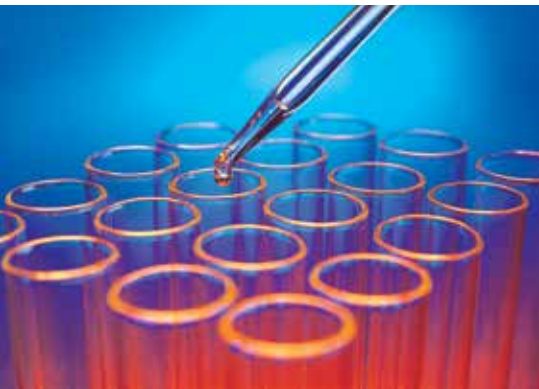
We bring information on proposed changes, confirmed changes and the possible effects of these changes from a manufacturing, retail and consumer perspective. Opinions from all concerned parties are reported so a full picture of the workings and effects of the regulation are shared.

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

One new substance added to the candidate list, several entries updated.....	3
CLP web pages revamped	4
ECHA's RAC and SEAC agree on sodium dichromate authorisation	4
Substance restriction updates.....	5
EU commission notifies WTO of proposed NMP ban.....	5
OECD launches PFASs website	6
PAH restriction reminder	6
SME body criticises ECHA's guidance on SVHC's in articles.....	7
Intention to restrict five cobalt salts submitted	8
The netherlands intends to propose a restriction related to granules used in synthetic turfs.....	8
Turkey faces long haul to implement new KKDİK regulation.....	9
UK minister wants reach 'mutual recognition' accord	10
Update to the guidance in a nutshell on registration published.....	10

ONE NEW SUBSTANCE ADDED TO THE CANDIDATE LIST, SEVERAL ENTRIES UPDATED



On 7 July, ECHA added one new very persistent and very bioaccumulative substance (PFHxS) to the Candidate List, based on a proposal from Sweden. Several other substances have had their entries updated.

NEW ENTRY

PFHxS belongs to the group of per- and polyfluoroalkyl substances (PFASs). This identification is part of a regulatory activity, targeting this large substance group with the aim to clarify the concerns and regulate the substances, as necessary. The aim is also to avoid undesired substitution with other PFASs. Several PFASs have already been identified as SVHCs, one group (PFOA and related substances) is now restricted, one restriction is under preparation and many assessments are underway.

UPDATED ENTRIES

The entry for bisphenol A (BPA) has also been updated to include endocrine-disrupting properties for human health.

This is based on a proposal from France, following the SVHC identification process with the involvement of the Member State Committee (MSC). The BPA entry was updated to reflect an additional reason for inclusion due to its endocrine-disrupting properties causing adverse effects to human health. BPA was included in the Candidate List due to its toxicity to reproduction in January.

Since the European Commission has decided on the endocrine-disrupting properties of four phthalates following MSC opinions on these substances, the existing entries for benzyl butyl phthalate (BBP), bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) were also updated.

Substances included/updated in the Candidate List for authorisation on 7 July 2017 and their SVHC properties:

#	SUBSTANCE NAME	EC NO.	CAS NO.	SVHC PROPERTY	EXAMPLES OF USE(S)
1	Perfluorohexane-1-sulfonic acid and its salts (PFHxS)	-	-	vPvB (Article 57e)	Not yet registered under REACH. May be used as a plasticiser, lubricant, surfactant, wetting agent, corrosion inhibitor and in fire-fighting foams.
2	4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Endocrine disrupting properties (Article 57(f) - human health)	Manufacture of polycarbonate, as a hardener for epoxy resins, as an anti-oxidant for processing PVC and in thermal paper production.
3	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Endocrine disrupting properties (Article 57(f) - human health)	Adhesives, sealants and coating products.
4	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Endocrine disrupting properties (Article 57(f) - human health)	Used as a plasticiser in polymers, such as PVC.
5	Dibutyl phthalate (DBP)	201-557-4	84-74-2	Endocrine disrupting properties (Article 57(f) - human health)	Used as a plasticiser in polymers, such as PVC.
6	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	Endocrine disrupting properties (Article 57(f) - human health)	Coating product, fillers, putties, plasters, modelling clay and polymers.

To increase clarity and transparency, the terminology used in the Candidate List, regarding the reason for inclusion for substances identified as SVHCs under Article 57(f) is replaced with a description of the properties causing the adverse effects. Therefore, the previous text concerning "equivalent level of concern" is replaced by a statement of the intrinsic properties relevant for identification under Article 57(f) in each of the applicable entries.

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. 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 (7 July 2017) to notify ECHA. Information on these obligations and related tools are available on ECHA's website.

Article source: fceg.espsrv.com

CLP WEB PAGES REVAMPED

ECHA's webpages related to the CLP regulation. Those on the harmonised classification and labelling (CLH) process, have been revamped to include a more detailed description of the process and updated information.

The updated sections are:

- Understanding CLP
- Classification of substances and mixtures
- Labelling and packaging
- Harmonised Classification and Labelling (CLH)
- Harmonised classification and labelling public consultations
- Submission of CLH dossiers



A new page: The role of testing in CLP has also been created. These pages are available in 23 EU languages.

Article source: ECHA.europa.eu

ECHA'S RAC AND SEAC AGREE ON SODIUM DICHROMATE AUTHORISATION



A company's application for authorisation to use sodium dichromate as a mordant in wool dyeing has been approved by ECHA's Risk Assessment and Socio-Economic Analysis Committees (RAC and SEAC).

Mordants fix dyes onto a fabric, and their consolidated opinion found the benefits of using the substance in the process "outweigh the risks by several orders of magnitude".

The authorisation is "clearly justified from a societal perspective", it says.

Italian textile fibre dyeing company Gruppo Colle requested a ten-year review period. The opinion says: "Authorisation would allow for the additional time needed to establish technical feasibility of the alternative through proper testing and implementation".

Article source: ChemicalWatch.com

SUBSTANCE RESTRICTION UPDATES

TATTOO INK AND PERMANENT MAKE-UP SUBSTANCES

Submission of a dossier on restricting the placing on the market of certain chemicals in tattoo inks and permanent make-up has been delayed until 6 October. The Commission asked ECHA to assess the risks late last year and the dossier was expected on 14 July. However, the agency says that "given the complexity of the dossier, which covers many thousands of substances," the submitters did not consider it possible to meet the deadline.

CALL FOR LEAD IN JEWELLERY EVIDENCE

The deadline for submitting evidence to ECHA's call for evidence to identify information necessary to review the current restriction on lead in jewellery has been put back from 7 July to 22 August.



EU COMMISSION NOTIFIES WTO OF PROPOSED NMP BAN

The European Commission has notified the WTO of a draft regulation banning the placing of the solvent 1-methyl-2-pyrrolidone (NMP) on the market. The intention is to address risks to workers caused by inhalation and dermal exposure to the substance.

The REACH restriction would be enforced unless:

- Registration dossiers are updated with the new derived no-effect levels (Dnels) for inhalation and dermal exposure indicated in the proposal. This effectively sets occupational exposure limits.
- Manufacturers and downstream users comply with these values in the workplace.

The draft proposes a two-year general deferral of the restriction's application to give stakeholders time to take the necessary compliance measures.



It makes special mention of the wire-coating industry, for which it is suggesting a longer deferral period of six years. This is because it recognises this sector must replace part of its older production lines prematurely to comply with the new Dnels.

The proposed date of adoption is the first half of 2018, with proposed entry into force 20 days after publication in the EU Official Journal. The WTO is accepting comments for 60 days.

Article source: ChemicalWatch.com

OECD LAUNCHES PFASs WEBSITE



The OECD has launched a website dedicated to per- and poly-fluoroalkyl substances (PFASs).

The mission for the Organisation for Economic Co-operation and Development (OECD) is to promote policies that will improve the economic and social well-being of people around the world.

The new PFAS website covers:

- Basic substance information
- Risk reduction approaches
- Alternatives
- Production and emissions
- Country specific information

The OECD and the UN Environment Programme (Unep) created a global perfluorinated chemicals (PFC) group in 2012 with the aim of bringing together experts in academia, government and industry, as well as representatives of NGOs and other international organisations.

The group is updating its [Lists of PFOS, PFAS, PFOA, PFCA, related compounds and chemicals that may degrade to PFCA](#) document, which was most recently reviewed in 2007. The updated document is expected in Q4 2017.

Article source: www.OEDC.org

PAH RESTRICTION REMINDER

Polycyclic Aromatic Hydrocarbons (PAH's) are a group of compounds eight of which are restricted under Entry 50 of Annex xvii of the REACH regulation.

These eight substances were originally restricted for use in extender oils, used to produce tyres or parts of tyres. In December 2013, the restriction was extended to include rubber and plastic products on sale to the general public, which could come into contact with the skin or oral cavities.

The limits allowed are 1.0mg/kg for each of the eight listed PAH's, but for toys and childcare articles this is reduced to 0.5mg/kg. If a product contains a PAH above these limits it cannot be sold in the EU.

PAHs are produced by the incomplete combustion of coal, wood oil and animal fats. They are also present in the particulate matter from vehicle gases, coal and petroleum processing.

They mainly occur as impurities and have been found as contaminations in plasticiser oils in rubber and plastics, in contaminated soot used as a black pigment and in contaminated lacquers.



Tests on animals have shown many PAHs to have carcinogenic properties; the most toxic is Benzo(a)pyrene (BaP).

Testing for these products is recommended especially where the product is a black rubber or black soft plastic which will come into contact with the skin.

SGS can offer testing for this group of substances to ensure compliance with the regulation. Please contact: GB.reach@sgs.com for more information.

SME BODY CRITICISES ECHA'S GUIDANCE ON SVHCS IN ARTICLES

ECHA's updated guidance on substances in articles does not provide the clarity companies need, says SME trade body, Ueapme.

The long-awaited revision was published last month to make clearer communication and notification obligations for articles containing SVHCs.

ECHA made the changes after the European Court of Justice (ECJ) ruled in 2015 that 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.

But Marko Susnik of Ueapme stated the document was too general and does not help SMEs to define what a 'complex article' is. He added that more industry sector specific examples were needed.

"An example which is relevant for the textile industry may not be for the automotive industry, for electronics or domestic furniture," he said.

An ECHA spokesperson said it defined a complex object as "any object made up of more than one article (for example, a bank card with chip, mobile phone, aircraft)", and further explained "that a supplier of such an object is also a supplier of its component articles and that the communication and notification obligations apply to Candidate List substances present in the component articles."

They added that the guidance also provides advice on how to identify and differentiate articles joined or assembled together. However, they acknowledged that it "does not address challenges which are specific to a certain sector or type of duty holder".



This posed a challenge, they said, because of "the diversity of actors and sectors involved in the production, import and supply of articles, as well as from the lower level of knowledge and experience of REACH of some of these, such as retailers".

The advice contains general principles applicable to all duty holders and "different industrial sectors need to apply these by comparing their own objects/articles with the scenarios and worked examples", they said.

The guidance 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.

Despite this perceived lack of clarity in the document by Ueapme, ECHA enforcement forum is preparing a pilot project on substances in articles with the intention of initiating inspections before the end of the year.

Article source: ChemicalWatch.com

INTENTION TO RESTRICT **FIVE COBALT SALTS SUBMITTED**



The Commission has requested ECHA to assess the risk of five cobalt salts in industrial and professional uses and restrict those uses where adequate control cannot be demonstrated. ECHA submitted the intention on 20 July 2017 for submission on 20 July 2018.

The restriction may also be implemented by imposing operational conditions and risk management measures.

The substances and their CAS numbers are given below:

COBALT COMPOUNDS	CAS NUMBER
Cobalt sulphate	10124-43-3
Cobalt dichloride	7646-79-9
Cobalt dinitrate	10141-05-6
Cobalt carbonate	513-79-1
Cobalt di(acetate)	71-48-7

Article source: ECHA.europa.eu

THE NETHERLANDS INTENDS TO PROPOSE A RESTRICTION RELATED TO **GRANULES USED IN SYNTHETIC TURFS**

The Netherlands notified its intention to prepare the restriction proposal on Polycyclic Aromatic Hydrocarbons (PAHs) in granules used as infill material in synthetic turf. ECHA will support The Netherlands in its work. Additional information on concerns regarding PAHs and other substances in the infill material will be collected during the process and actions will be formulated / recommended as appropriate.

A call for evidence to gather further information will start later on this summer and there will be a stakeholder workshop in autumn. The submission of the restriction proposal is planned for April 2018.

Article source: ECHA.europa.eu





TURKEY FACES LONG HAUL TO IMPLEMENT NEW KKDİK REGULATION

Now that Turkey has published its long-delayed legislation modelled on REACH, it faces a mammoth task to build its infrastructure and pave the way for industry, observers say.

The KKDİK regulation, published on 23 June after a delay of more than 18 months, will come into effect on 23 December. It sets a registration deadline of 31 December 2023 and a pre-registration deadline of end-2020.

But industry concerns linger over the lack of infrastructure in Turkey to accommodate what is likely to amount to 3,000 substance registrations.

“The government is throwing industry in the pool without teaching them how to swim,” said Mustafa Bagan, general secretary of the Turkish Chemical Manufacturers Association.

Unlike in REACH, there are no guidelines accompanying KKDİK to help industry with step-by-step instructions on dossier preparation, authorisation applications and data collection, Mr Bagan said.

Yahya Kesimal, head of the chemicals department at the Ministry of Environment and Urbanisation (MoEU), has said the registration deadline was pushed back by one more year to give businesses ample time to prepare for the new law.

“We decided to extend the deadline with industry in mind,” Mr Kesimal said. “Now they have almost seven years to get ready.”

Mr Kesimal also said, that although Turkey has been effectively implementing “60-70%” of REACH until now, enforcing KKDİK will mean chemicals are fully regulated “with no unregistered substances on the market”.

The KKDİK regulation, which is almost an exact copy of REACH, will align Turkey’s chemical laws with the EU – its main trading partner with which it has a customs union – and help prevent major industrial accidents, Mr Kesimal said.

Article source: [Chemicalwatch](#)

UK MINISTER WANTS A REACH 'MUTUAL RECOGNITION' ACCORD

The UK intends to secure an early 'mutual recognition' agreement on chemicals policy with the EU before it exits the Union, the country's lead minister on chemicals policy has said.

In her comments to the recent UK Chemicals Stakeholder Forum, Thérèse Coffey said the chemicals sector is an "important priority" for the government, which is looking at different options with "the intention to try to get to a point where we have regulatory equivalence" with the EU.

It would be in the interests of the EU and the UK, she added, to recognise recorded REACH registrations of UK-based entities after Brexit. Describing the registration process as "complex", she said there was "no need" for companies to go through it again.

"We are fully aware of the amount of investment companies have already put into registration," she told the forum. "We are aware of the issues [and] the complex relationships within the current regulatory regime, which extends beyond REACH being [just] a database."

Ms Coffey told the forum the government is "not trying to cherry pick" elements of the EU single market, but is "trying to ensure we have an



ongoing effective relationship and mutual recognition of regulations is a key part of that".

Since the UK's EU referendum last June, there has been speculation about whether the country could assume a role like Norway's in the European Economic Area (EEA) or like Switzerland's in the European Free Trade Area.

Ms Coffey said that "perhaps the Swiss approach is one to explore", as the country is not part of the EEA but has arrangements with the trade bloc.

Asked whether the UK would look to mimic the US's newly reformed TSCA

– something EU industry has rebuffed – she said it is not in the UK's interest "for any future agreement with the US or any other country [if it sees] a deterioration in environmental standards".

At the beginning of the discussions, it was "right to look at" the options, Ms Coffey said. But, she said "we recognise where much of our industry is, so going off in a completely different way would be a surprising move".

She added that the UK is "well progressed" in its thinking and the work it needs to do "to have that effective regulatory regime from day one".

Article source: ChemicalWatch.com

UPDATE TO THE GUIDANCE IN A NUTSHELL ON REGISTRATION PUBLISHED

Following the update of the Guidance on registration published in November 2016, the corresponding Guidance in a Nutshell on registration has now also been updated.

Version 3.0 aims to give a "simple and concise introduction to the information content of registration dossiers for chemical substances under REACH".

It also provides a brief outline of how to prepare and submit a registration dossier and any essential follow-up activities needed.

Article source: ECHA.Europa.eu



WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 90,000 employees, SGS operates a network of over 2,000 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your services and value chain by increasing performance, managing risks, better meeting stakeholder requirements and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language and understand the culture of the local market and operate in a consistent, reliable and effective manner.

TO LEARN HOW SGS CAN HELP YOU EXCEED CUSTOMER EXPECTATIONS, VISIT WWW.SGS.CO.UK OR CONTACT GB.REACH@SGS.COM FOR MORE INFORMATION.

WWW.SGS.COM
WWW.SGS.CO.UK

WHEN YOU NEED TO BE SURE

