

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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IMPROVING COMPLIANCE WITH RESTRICTIONS

ECHA's Enforcement Forum's latest project (REF-4) has shown serious breaches in compliance with restrictions, for example, for asbestos, plasticisers and mercury in consumer products.

The aim of the project was to understand the degree to which restrictions are being complied with and, where necessary, to follow up with enforcement actions. It covered 14 entries from the list of substances restricted under REACH (Annex XVII). The overall goal is to improve the level of compliance with restrictions and, in doing so, protect our health and the environment. The project covered 14 restriction entries and mercury which was assessed by the UK authorities but outside the scope of the project.

The following paragraphs are taken from the final report published by ECHA and describe the substances found and the products they were found in.

WHAT WAS FOUND?

A total of 5,625 inspections were carried out in total for more than 1,000 mixtures, nearly 4,600 articles and 17 substances. The average non-compliance rate was 18%.

Given that restrictions are put in place for uses of chemicals that pose the highest risk to health or the environment, this number is too high. Enforcement authorities tend to work on cases where they are likely to see the most non-compliance and, for this reason, the results are not deemed to cover all related products on the European market.

The highest non-compliance rates were for phthalates in toys, asbestos fibres in products, as well as mercury in measuring devices – an entry inspected outside the scope of the main project.



There were also high levels of non-compliance for cadmium in brazing fillers and jewellery, chromium (VI) in leather articles, nickel in metal parts of clothing, and polycyclic aromatic hydrocarbons (PAHs).

PLASTICISERS IN TOYS AND CHROMIUM IN LEATHER

The restriction of phthalates was done to protect children from the harmful effects of chemicals. Some phthalates are suspected of being toxic for reproduction and endocrine-disrupting. Under REACH, restrictions apply to toys and childcare products containing phthalates in concentrations above 0.1% by weight of the plasticised material that can be placed in the mouth by children.

As such, it is alarming that the presence of phthalates in toys is so high – almost 20% of more than 460 inspected products contained higher levels of the phthalates DEHP, DBP and BBP than they should, and 10% of more than 300 products checked contained considerable amounts of the phthalates DINP, DIDP and DNOP.

Inspectors also found overly high-levels of chromium VI in leather articles. Chromium VI is restricted in leather articles that touch the skin. The articles cannot be placed on the market if chromium VI is present in concentrations equal or greater to 3 mg/kg. Almost 500 leather articles were tested and more than 13% breached the restriction.

ASBESTOS IN SECOND-HAND PRODUCTS

Asbestos fibres have been restricted in the EU for many years. They can cause cancer of the lungs, larynx and ovaries, and lung fibrosis. Therefore, it is surprising that asbestos was found in nearly 14% of products checked. The fibres were found in 20 catalytic heaters, three thermos flasks, two brake pads, two cement materials, a sky lantern and a jug flask. In the EU, producing, placing on the market and using these fibres and any articles containing them is banned.

One reason that the fibres may have been found is that many of the articles containing them were second-hand and therefore probably produced before the restriction came into force. However, even if this is the case, selling these products is still illegal if they do not meet the requirements in force today. There are some exemptions to the restriction. If articles containing the fibres were already installed or in service before 1 January 2005, then their use is exempted from the restriction.

MERCURY IN MEASURING DEVICES

UK inspectors checked almost 400 measuring devices and nearly 90% were found to contain mercury above the allowed limit. Mercury is toxic and inhalation of mercury vapours can cause harm to the nervous, digestive and immune systems. The high non-compliance could be because the UK inspectors were using alerts on online auction sites that allowed them to specifically target articles where mercury is indicated as being present and avoid those that are categorised as 'mercury-free'.

While the devices were only inspected by United Kingdom enforcement authorities, the high proportion of devices that were found to have mercury above the limit suggests that other countries should do similar checks.

RESTRICTED HEAVY METALS IN JEWELLERY

Illegal levels of heavy metals are still being found in jewellery used in the EU. Nearly 7% of inspected items contained lead, 8% contained nickel, and more than 12% contained cadmium above the respective restriction limits. The risks from heavy metals vary. Nickel can cause skin allergies, cadmium can cause osteoporosis, cancer, and is also toxic to the environment, and lead can cause damage to the nervous system and impair intellectual development.

These rates suggest that the presence of heavy metals in the products is not accidental, but either a result of producers consciously using the raw material during manufacture or lacking sufficient knowledge about what their materials contain.

WHAT COMPANIES CAN DO

All companies placing chemical products or articles on the EU market must comply with REACH restrictions. This means that the suppliers of products in all steps of the supply chain are responsible. So, if you place products on the market, you should be aware of the chemicals they contain and how they are supplied and by whom.

This may mean proactively testing the

products and establishing agreements with suppliers to make sure that the chemical composition of the products in the supply chain is in line with chemicals legislation. Companies should also put systems in place in case a non-compliant substance, mixture or article is found in their portfolio, so they can quickly act to correct the situation.

Companies could also check the RAPEX alert system – an EU portal of products found on the market that pose a serious risk to health or the environment – to get information on non-compliant products found on the market. Restrictions are put in place so that the risks from substances that are harmful for human health and the environment are under control.

Preventing these risks is a legislative and moral responsibility and should be taken seriously at every step of the supply chain. Given the findings of the project report, however, there still seems to be a lot to be done.

Article source: [European Chemicals Agency](#)

BUSINESS IMPACTS OF NOT REGISTERING FOR REACH ON TIME

The final registration deadline is looming, with serious consequences to not meeting it by 31 May 2018.

At the start of the year, ECHA was still expecting about 25,000 unique substances covered by some 60,000 registrations, to be submitted by the last REACH deadline of 31 May 2018, for substances in the 1-100 tonnes/year band. However, the numbers at that point were about 6,500 and 15,000 respectively, meaning there is a large gap to be filled during the remaining months.

This begs two questions. What will happen to the substances that are not registered by the deadline? And what will the business impact be on would-be registrants and downstream users?

From 1 June, the REACH Regulation will have reached a business-as-usual state where no further transitional schemes will apply for substances that require registration - that is, those manufactured in or imported into the EU and EEA at one tonne/year or more and not exempt from REACH or the registration requirement. Therefore, companies will have either:

1. Successfully registered their substances; submitted registrations but, for whatever reason, had them rejected and not resubmitted them in time;
2. Had an additional extension granted by ECHA to complement an inadequate submitted dossier; or
3. Not registered at all, due to negligence, wilful intent not to register or unawareness of the obligation.



SUMMARY: OPTIONS FOR LATE REGISTRANTS

If the volume is one tonne per year or more and the business does not wish to cease its commerce involving the substance, then you must stop manufacture and/or import of the substance immediately and do the following:

1. For substances where a joint submission is available, contact the LR (Lead Registrant) or consortium for access to it (usually via LoA (Letter of Access) purchase). If not, you need to become the LR.

2. Submit an inquiry to ECHA with information on the substance identity and await acceptance before submitting the registration dossier for the substance.
3. Submit the required registration dossier to ECHA and pay the registration fee.
4. Await acceptance of registration dossier and issuance of a registration number, before continuing manufacture or import of the substance.

If you need your substances registering please contact GB.REACH@sgs.com

Article source: ChemicalWatch.com

DANISH DIY RETAILERS FAILING TO COMPLY WITH REACH ARTICLE 33

The Danish EPA says DIY retailers are failing to comply with Article 33, the REACH information obligation.

The agency tested 41 products – purchased from eight DIY retail chain stores - for the presence of 18 phthalates, 13 of which are on the REACH candidate list of substances of very high concern (SVHCs). The tests showed that 13 of the products – which focused on plastic, ranging from protective PVC clothing to pet toys – contained more than 0.1% by weight of the listed phthalates.

The EPA said it focused mainly on plastic products and phthalates because articles consisting of PVC and soft plastic materials often contain substances from this chemical group.

The agency requested from the supplier's information on whether the articles contained any SVHCs. Article 33 of REACH requires companies to respond to a request for information if a product contains any above a concentration of 0.1%. They must provide the information free of charge and within 45 days.

Suppliers of five of the 13 products did not respond to the EPA's request. Six replied, but provided incorrect information. Of the remaining two, both acknowledged and gave details on the content of the candidate list phthalate, DEHP, in their product. But one product also contained more than 0.1% of DIBP, which the company concerned did not disclose. DIBP was added to the REACH Authorisation List in 2012.

"Even though it is a random check, one must say that there is room for major improvements among this market in relation to compliance with the duty of information," says Jane Pedersen, EPA function manager.

The DIY retail stores that did not correctly comply received formal letters explaining their obligations under the Article.



A WIDER PROBLEM

A year ago, Denmark's Environment and Food Minister, Esben Lunde Larsen, called on retailers to be proactive in sourcing information from their suppliers about harmful substances in products. His call followed a similar inspection that found phthalates – including those on the REACH candidate list – in products at DIY stores.

A study in 2016, commissioned by the European Commission's DG Environment, found many companies selling construction materials in the EU are not responding to REACH Article 33 requests.

And last year, the European Commission's DG Environment commissioned a study reviewing the available tools that support the management and communication of hazardous substances in articles, with an aim of improving the implementation and enforcement of Article 33 of REACH.

These followed the European Court of Justice (ECJ) 2015 ruling on the 0.1% threshold for notifying SVHCs in articles. Some organisations said REACH information obligations would become extremely difficult and called for a review of Article 33 in the wake of the decision.

In addition, some NGOs have launched smartphone apps that allow consumers to quickly send Article 33 requests to product suppliers, with an EU-wide app currently being developed.

During the consultation on the Commission's five-year REACH Review, which is expected to be published "within weeks", some have commented on the need for a review of Article 33.

Article source: ChemicalWatch.com

DANISH TEST FINDS SVHC IN DETERGENT FOR WHITE LAUNDRY

Tests in Denmark on 38 detergents used to wash white laundry, have revealed one product containing a substance of very high concern (SVHC) and four with allergenic preservatives.

The work, carried out by the Danish Consumer Council's 'Think Chemicals' initiative, found the SVHC sodium borate in one liquid detergent. The substance is on the REACH candidate list and its classification under the CLP Regulation says it "may damage fertility or the unborn child and causes serious eye irritation".

And the tests found that four other liquid detergents contained benzisothiazolinone, a preservative similar to the very allergenic methylisothiazolinone. Perfume, another cause of allergy, was found in many products.

Twenty-one of the products tested did not contain any harmful chemicals, and none of the detergents in powder form had problematic preservatives.



LABELLING

Think Chemicals points out that only some ingredients must be listed on a detergent's packaging. However, the law requires that information on all ingredients should be accessible on a website listed on the label. The organisation says that while many producers make the information available, there are quite a few that are missing or incorrect.

It would also be a benefit for the consumers to have access to the full list without consulting a website, it says.

The Think Chemicals programme carries out independent testing of products, aimed at helping consumers avoid chemicals of concern.

Article source: ChemicalWatch.com

EU FLAME RETARDANT EXPORTS BANNED UNDER PIC AMENDMENTS

The EU is to ban exports of four brominated flame retardants and three other substances, under amendments made to legislation controlling the trade of very hazardous chemicals.

All seven substances have been included in Part 1 of Annex V of the prior informed consent Regulation (Pic) – a list of persistent organic pollutants (POPs) that are subject to export ban.

The changes, published on 6 February in the EU's Official Journal, will become effective on 1 April.

From that date, brominated flame retardants (tetra-, penta-, hexa- and heptabromodiphenyl ethers) at concentrations of 0.1% or more when produced partially or fully from recycled materials may not be exported, the Commission says.

The ban will help the EU fulfil its obligations under the 2004 UN Stockholm Convention – a global treaty to control and phase out POPs.

The substances are used in a wide array of products such as building materials, electronics and textiles.

Other substances to be banned, in accordance with the convention, are:

- The solvent hexachlorobutadiene – a possible carcinogen;
- Polychlorinated naphthalenes (PCN) – a largely phased out electrical insulator; and
- The flame retardant hexabromocyclododecane (HBCDD).

HBCDD, which is on the REACH authorisation list for persistent bioaccumulative and toxic (PBT) properties, was added to the Stockholm Convention in 2013. Hexachlorobutadiene and PCN were added in 2015.



Five other chemicals identified as substances of very high concern (SVHCs) under REACH were added to both Part 1 and Part 2 of Annex I. This requires exporters to notify the appropriate member state authority and also obtain the explicit consent of the importing country. The substances and their SVHC properties are:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)– vPvB (very persistent and very bioaccumulative);
- Benzyl butyl phthalate (BBP) – toxic for reproduction and endocrine disrupting chemical (EDC);
- Diisobutyl phthalate – reprotoxic and EDC;
- Diarsenic pentaoxide – carcinogenic; and
- Tris (2-chloroethyl) phosphate – reprotoxic.

The Commission said the substances are subject to authorisation under REACH. However, "since no authorisations were granted, those substances are severely restricted for industrial use".

Musk xylene is a "perfume fixative" used in some cosmetics and fragrances, but has explosive and carcinogenic hazards under CLP. It has been on the REACH candidate list since 2008.

Plasticiser BBP and diarsenic pentaoxide, an arsenic compound, have been on the candidate list since 2008. Diisobutyl phthalate, another plasticiser, and flame retardant and additive plasticiser tris (2-chloro diisobutyl phthalate thyl) phosphate were placed on the list in 2010.

Triclosan has also been added to Part 1 and Part 2 of Annex I. It is not approved for use in biocidal products, but used as a preservative and antimicrobial agent in cosmetics, drugs and natural health products.

The Pic Regulation governs the import and export of very hazardous chemicals between the EU and other countries. There are currently 22 substances in Part 1 of Annex V; and 186 chemicals in Part 1 and 87 in Part 2 of Annex 1.

Article source: ChemicalWatch.com

EU PRIORITISES SEVEN NEW SUBSTANCES FOR AUTHORISATION

The European Chemicals Agency (ECHA) has recommended seven new substances of very high concern (SVHCs) to be added to the REACH Authorisation List. They have been prioritised from the Candidate list because of their intrinsic properties in addition to high volume and widespread usage.

Some of these substances are not currently used in the EU but could be substituted for substances already on the Authorisation List or recommended for it. These new recommendations are therefore to avoid poor substitutions.

If you are using or intending to use one of these substances, you should be aware that you may at some point require an authorisation to do so. This

can be obtained by your supplier on your behalf as long as that authorisation covers the way you use the substance. You should also be aware that authorisations are time limited.

Of the seven substances put forward by ECHA, two are harmful to reproduction and five are either Persistent, Bioaccumulative and Toxic (PBT) or very Persistent, very Bioaccumulative (vPvB).

The final decision on the inclusion of the substances in the Authorisation List and on the dates by which companies will need to apply for authorisation to ECHA will be taken by the European Commission in collaboration with the Member States and the European Parliament.

Article source: ECHA.europa.eu



SUBSTANCE	REASON FOR INCLUSION ON THE CANDIDATE LIST	POSSIBLE USES
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group) EC: n/a CAS: n/a	vPvB	Fragrance in soaps and detergents.
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) EC: 7-384-8 CAS: 25973-55-1	PBT, vPvB	UV stabiliser in plastic products and rubber coatings.
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) EC: 223-383-8 CAS: 3864-99-1	vPvB	No registered uses.
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) EC: 253-037-1 CAS: 36437-37-3	vPvB	No registered uses.
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) EC: 223-346-6 CAS: 3846-71-7	PBT, vPvB	No registered uses.
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC 201-559-5) EC: 271-094-0 EC: 272-013-1 CAS: 68515-51-5 CAS: 68648-93-1	Toxic for reproduction.	Plasticiser in PVC compounds and adhesive.
1-methyl-2-pyrrolidone (NMP) EC: 212-828-1 CAS: 872-50-4	Toxic for reproduction.	Widely used solvent in cleaning agents, coatings, functional fluids etc.

EU PUBLISHES REGULATION ON BPA IN FCM VARNISHES, COATINGS

The European Commission has published its amending Regulation on the use of bisphenol A in varnishes and coatings intended to come into contact with food that sets a migration limit of 0.05mg of BPA per kg of food.

This Regulation enters into force 20 days after its publication in the EU Official Journal and applies from 6 September.

Materials and articles on the market before that date can be sold until stocks are exhausted.

MEPs voted to reject a motion that had called for a total ban on BPA in FCMs at the beginning of the year.

Article source: ChemicalWatch.com



INSPECTORS BEGIN CONTROLS OF CLASSIFICATION AND LABELLING OF MIXTURES

Inspections in EU and EEA Member States will check whether the classification and labelling of a mixture corresponds to the information presented in the safety data sheet for the mixture. The controls began in January 2018 under the enforcement project REACH-EN-FORCE-6 (REF-6). Altogether, 31 European countries will participate in the project.

Member States may also include additional modules in their inspections. The additional modules cover: exemptions concerning labelling and packaging requirements, the obligation to apply harmonised classification and labelling (CLH), the specific requirements of the CLP Regulation for liquid laundry detergent capsules (LLDCs), and the authorisation and labelling of biocidal products.

The REF-6 module on biocidal products is the first project undertaken jointly by the Forum for Exchange of Information on Enforcement (Forum) and the Forum's Biocidal Products Regulation Subgroup (BPRS). This module is also the first enforcement project that the BPRS is participating in – the subgroup was founded in March 2017.

The REF-6 project was adopted by the Forum at the end of 2016. The inspection activities will continue throughout 2018. A report on the results of the inspections will be available in the fourth quarter of 2019.

Article source: ECHA.europa.eu



UK OPENS PRODUCT SAFETY OFFICE

The UK has established a new office to provide scientific and technical expertise in areas including chemicals in products, and to coordinate the response to national product safety incidents.

The new body – Office for Products Safety and Standards – will support trading standards teams around the country, work with the British Standards Institution (BSI) on product recalls, and help manufacturers conduct product research, according to a government statement.

It is not, however, set up with the intention of replacing existing surveillance authorities or mechanisms as Britain prepares to leave the European Union, a spokesperson at the Department for Business, Energy and Industrial Strategy (Beis) said.

The UK reports to the European Commission's Rapid Alert System for dangerous products (Rapex), which includes information on hazardous chemicals found in products, the risks identified and the measures taken in order to prevent or restrict their marketing or use across the EU.



The government is exploring how to continue its access to Rapex, once it leaves the EU next year.

The government statement says the new office "coordinates the response to national product safety incidents, including product recalls and repairs" and "can provide advice on chemical composition where that is a relevant factor in the safety of a product".

It adds that there will be no changes to the enforcement of REACH, which remains the responsibility of the Health and Safety Executive (HSE).

Article source: ChemicalWatch.com

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 95,000 employees, SGS operates a network of over 2,400 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.

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WHEN YOU NEED TO BE SURE

