REACH E-NEWSLETTER



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

CHEMICALS REMAIN EU'S SECOND HIGHEST PRODUCT RISK

For a second year running, hazardous chemicals in products, such as toys and clothing, have remained the second biggest risk to health and safety on the EU and EEA market.

Risks related to chemicals comprised 22% of all notifications last year, according to a European Commission report on the EU's Rapid Alert System for dangerous products (Rapex). This was down 1% on the 2016 notifications. Chemical risk was the number one risk notified in 2015.

Injury from use of a product again led the risk categories in 2017 at 28%.

In total, there were 544 alerts about chemicals in products and chemicals represented the most common risk notified in:

- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- Greece
- Italy
- Lithuania
- The Netherlands
- Norway
- Romania
- Slovenia

Unlike previous years, the Commission's latest report does not include a breakdown of which notified products contained hazardous chemicals.

The five most notified products were:

- Toys (29%)
- Motor vehicles (20%)
- Clothing, textiles, and fashion items (12%)
- Electrical appliances and equipment (6%)
- Childcare articles and children's equipment (5%)

The number of notifications grew from 2,044 in 2016 to 2,201 alerts last year.

The largest number of total Rapex notifications came from Germany with 354 alerts (16%), Spain with 222 (10%) and France with 191 alerts (9%).

China remained the number one product country of origin, accounting for 52.4% of notifications.

FOLLOW-UP ACTIONS

National authorities have an obligation to follow up on the information circulated in Rapex. If they find the same product on their own market, they should take measures and send this information through the system so it is also circulated.

They carried out 4,000 follow ups in 2017. These fell into the following categories:

- Motor vehicles (79%)
- Toys (6%)
- Childcare articles and children's equipment (3%)
- Clothing, textiles and fashion items (3%)
- Electrical appliances and equipment (1%)

While in the risk categories, chemicals only comprised 6% of follow ups, fire represented 10% and injuries topped the list with 72%.

Article source: ChemicalWatch.com

2018 REACH DOSSIER SUBMISSIONS HIGHER THAN EXPECTED - ECHA

With less than three months to go before the final REACH registration deadline on 31 May, ECHA says it has received a total of 16,175 dossiers; 17% more than it had anticipated by this time.

Companies have submitted dossiers for 6,875 substances; 4,508 of which have been registered for the first time, the agency has said.

The number of companies submitting new registrations has reached 2,966, and SMEs have submitted 17% of all registrations, it added.

The agency had estimated that by the 2018 deadline up to 60,000 registrations would be prepared for up to 25,000 substances; three times more than for either of the previous deadlines in 2010 and 2013.

Article source: ChemicalWatch.com

CALL FOR EVIDENCE: RESTRICTION OF OXO-DEGRADABLE PLASTICS

The purpose of the call for evidence is to collect information to assess the impacts of a possible restriction on oxo-degradable plastics. The deadline for comments is 11 May 2018, 23:59 (Helsinki time).

The call is in response to the European Commission's request for ECHA to prepare an Annex XV restriction dossier regarding the placing on the market and use of oxo-degradable plastics due to concerns on their potential risk to the environment that may arise from their use. The restriction may potentially focus on the use or placing on the market of the additives used in these types of plastics to promote their oxidation.

ECHA is inviting interested parties to submit any information they have related to these plastics to help with the preparation of the dossier.

Article source: European Chemicals Agency

TEN YEARS OF REACH: MAKING CHEMICALS SAFER FOR CONSUMERS, WORKERS AND THE ENVIRONMENT

The European Commission has issued the following press release concerning the effects of the REACH regulation.

"For the last 10 years, the key EU law on chemicals (REACH) has significantly enhanced the protection of human health and the environment and promoted alternatives to animal testing. Building on this, the Commission proposes actions to further facilitate its implementation.

Chemicals are present in every aspect of our lives, at work but also in consumer goods such as clothes, toys, furniture and electrical appliances. They are essential to our daily lives but certain substances may pose risks to human health and the environment. The REACH review recently published shows that thanks to the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) EU companies and authorities are ensuring the safe use of chemicals and the phase-out of dangerous substances.

Internal Market and Industry Commissioner Elżbieta Bieńkowska said: "REACH is the most advanced and comprehensive chemical legislation in the world, and many other jurisdictions have followed the EU's lead in regulating chemicals. EU industry now makes chemicals safer for citizens and the environment. We need to build on this success and ensure that EU manufacturers do not face competitive disadvantages compared to non-EU manufacturers, notably by making sure that imported goods comply with EU rules on chemicals."

Environment Commissioner Karmenu Vella said: "A majority of Europeans are worried about being exposed to hazardous chemicals. Through REACH, the EU is successfully addressing their concerns, generating knowledge about chemicals and banning harmful ones on the EU market. REACH is already inspiring chemical legislation in other countries and further improvements will allow us to protect our citizens' health and the environment even better."

REACH keeps delivering concrete results to Europeans with:

- Safer products for consumers, workers and the environment. Under REACH, the EU has made progress in restricting or banning the use of certain chemicals that may be harmful to human health or the environment and driving their replacement by safer alternatives. Some examples are:
- Banning harmful chemicals: 18 restrictions have been issued for different groups of substances such as chromium, nickel and lead in consumer products; bisphenol A, an endocrine disruptor, in cash register receipts and also nonylphenol compounds, toxic to the aquatic environment, in textile articles.
- Replacing the most dangerous substances ("substances of very high concern") with safer alternatives: So far, 181 chemicals that can have serious effects on human health and the environment have been identified as such and 43 are included in the "REACH authorisation list", which means that companies need to get an authorisation to use them and that they are being gradually phased out as suitable alternatives become available.
- Non-animal testing: REACH promotes alternative, non-animal methods for the hazard assessment of chemicals, reducing the need for tests on animals. The Commission provided around €40 million per year to support research on alternative methods between 2012 and 2016.
- A comprehensive data set for chemical safety on the EU Single Market: So far, the REACH registration procedure has gathered information on more than 17,000 substances in 65,000 registration dossiers of the main chemicals manufactured and used in the EU. This has improved communication and transparency in the supply chain, allowing Europe to better address risks linked to chemicals and further harmonise the internal market for chemicals.

For better protection of consumers, workers and the environment, the European Commission is proposing several concrete actions to improve the implementation of REACH. These measures are put forward to improve the quality of registration dossiers submitted by the companies, to simplify the overall authorisation process and to ensure a level playing field between the EU and non-EU companies. The Commission wants to further support SMEs in their compliance and enhance enforcement by national authorities.

The Commission also wishes to improve the coherence of REACH with worker protection and waste legislation".

NEXT STEPS

The Commission will discuss the outcomes and follow-up actions of the second REACH review with the European Parliament, Member States and stakeholders at a public conference, planned for June 2018.

Article source: ECHA.europa.eu

EUROPEAN TOY INDUSTRY SEEKS EXCLUSIONS FROM PAH GUIDELINE

Rubber and plastic components of some toys and children's articles such as bikes, scooters and baby walkers should be excluded from an EU guideline on the restriction on polycyclic aromatic hydrocarbons, an industry association has said.

In comments circulated at a recent meeting of the Competent Authorities for REACH and CLP (Caracal), Toy Industries Europe (TIE) also said the definition of synthetic textiles as rubber and plastic was "overly broad" and would lead to "unnecessary additional testing costs for SMEs".

ECHA published the draft guideline on the scope of the Annex XVII restriction on PAHs in January last year. It then updated it following a stakeholder consultation. A final guideline is expected in the near future, an ECHA spokesperson said.

The restriction applies to articles intended for general public use, if any of the rubber or plastic components that come into "direct as well as prolonged contact or short-term repetitive contact" with the skin or the mouth contain more than 1 mg/kg of any of eight identified PAHs.

Toys and childcare articles fall within the scope of the restriction, but the concentration limit is lower at 0.5 mg/kg.

However, TIE says that some components of children's articles such as the wheels of bikes "should be clearly excluded" as children do not have "prolonged or short-term repetitive contact" with them.

Articles with components that TIE says should be excluded are:

- Run bikes, children's bikes, toy mower and toy scooters
- High chairs, baby walkers, walking frames and stationary walkers for indoor and terrace use

An official at TIE later clarified that it was not asking for an exemption, "but rather the appropriate interpretation of the legislative text through clarification".

On textiles, TIE says that major European testing laboratories do not consider synthetic textiles under the scope of the restriction and including them via the guideline "would mean that compliance is immediately required".

DRAFT GUIDELINE

The European Commission in 2014 asked ECHA to develop a practical guideline for PAH restriction, which kicked off in December 2015. PAHs are suspected carcinogens.

ECHA published the first draft last year, and then revised it after the consultation. The first draft of the guideline says that it is not possible to develop an exhaustive list of all the articles that may fulfil the criterion of "direct" contact, however examples include masks, balloons, bracelets, handles, grips, hand tools, gloves and diving suits.

Regarding "prolonged" contact, ECHA says there is not enough scientific evidence for a definition, but that it is understood as an "extended duration of contact", for example from "carrying an article, sitting on it, leaning towards it, holding on to it, wearing it or keeping in the mouth for an extended and uninterrupted length of time."

Examples include carrying handles of mobile devices, camera cases, cigarette lighters, headphones and whistles, it says.

For "short-term repetitive" contact, the guideline mentions items such as Frisbees, shuttlecocks, balloons and thermos bottles.

The guideline provides an indicative list of examples of articles that fall within the scope, including:

- Sport equipment: bicycles, kick scooters, boxing gloves, yoga mats, swimming aids, ski goggles, snorkelling/fishing equipment
- Household utensils, trolleys, walking frames: cookware, handheld game consoles, PC mouse, remote controls, tablet computers, plastic drinking bottles
- Tools for domestic use: hammers, measuring tapes, power drills
- Clothing, footwear, gloves and sportswear: flip-flops, underwear, prints of T-shirts, wet suits, flippers, gloves, socks
- Watch-straps, wrist-bands, masks, head-bands: sun glasses, head torches, sex articles, musical instruments, tooth brushes, stress balls
- Miscellaneous: colouring/painting articles, tweezers, manicure/pedicure tools, shavers, textiles, tiles/mats used in playgrounds
- Toys and childcare articles: toy cars and trains, run bikes and toy scooters, baby walkers, loom bands, toy guns, balloons, teething rings

Article source: ChemicalWatch.com

IRELAND PLANS OVER 1,000 CHEMICAL LEGISLATION INSPECTIONS IN 2018

Ireland is planning to carry out a total of 1,285 inspections and audits in relation to chemicals legislation this year, including 200 on REACH and CLP.

Outlining its work programme for 2018, the Irish Health and Safety Authority (HSA) says it will determine compliance with regulations through onsite visits and desk-based assessments.

It will conduct REACH and CLP inspections as part of the occupational hygiene and control of major accident hazards (Comah) programmes, the Irish competent authority says. It will give emphasis to registration duties and to compliance with safety data sheets, authorisation and restriction requirements.

Other highlighted enforcement activities include a follow up on ECHA's communications to Irish companies, regarding decisions on:

- REACH Article 36 – obligation to keep information for ten years;
- Article 40(3) – examination of testing proposals
- Article 41(3) – compliance check of registrations

Inspections will also focus on the classification and labelling of chemicals in accordance with CLP, the HSA says.

It aims to complete five REACH registration audits and ten REACH/CLP audits, as well as 15 assessments of substances subject to authorisation.

REACH ACTIVITIES

The Irish authority plans to complete an awareness-raising campaign in the run up to the May 2018 REACH registration deadline, with SMEs the main focus. It says it will provide support to individual companies through the helpdesk.

Other REACH-related work includes a follow up on ECHA's decision on substances evaluated from the 2015 Community Rolling Action Plan (Corap), the HSA says.

For market surveillance, it will check 150 products "to ensure chemicals classified as carcinogenic, mutagenic or reprotoxic (CMR) are not available for sale to the general public".

Within this group, 20 detergent products will be assessed for compliance with the EU detergents Regulation. Regarding the Rotterdam Convention on the trade of dangerous substances, it will complete "information-gathering" on companies which may have duties under the regulations for follow-up assessment, it says.

Its activities will include screening of 20 articles for compliance with REACH restrictions. Non-compliant products are to be notified to the European Commission's market surveillance database.

In addition, the HSA will monitor the EU rapid alert system for dangerous products (Rapex) and assess 10% of relevant alerts for availability on the Irish market.

Article source: ChemicalWatch.com

NEW 'CHEMICALS IN OUR LIFE' WEBSITE INFORMS CONSUMERS ABOUT CHEMICALS

ECHA has launched a new dedicated website to make consumers more aware of the benefits and risks of chemicals in their everyday lives.

Are the chemicals used in tattoos safe? Will I get an allergic reaction if I dye my hair? Many consumers in Europe are concerned about the possible risks posed by chemicals in their lives – a 2016 Eurobarometer study of almost 28 000 people in 28 countries showed that 65 % of respondents were concerned about being exposed to hazardous chemicals.

To specifically address consumers with information on chemicals, ECHA has on World Consumer Rights Day, launched the Chemicals in our life website. The website, available in 23 EU languages, provides useful information on the benefits and risks of using chemicals and explains how the EU legislation on chemicals protects us.

The website has a Trending section for topical news and is connected to ECHA's chemicals database; the world's largest database of its kind.

Users can also explore parts of the European Observatory for Nanomaterials. Several articles on nanomaterials related to health, the workplace and consumer products are available. Readers can navigate through a 360-degree interactive apartment, which shows where and why nanomaterials are used in our lives.

This is a very comprehensive website with lots of information and leads to other areas.

Article source: ECHA.europa.eu

PUBLIC CONSULTATION ON 8 POTENTIAL SVHC'S

On March 8, 2018, European Chemical Agency (ECHA) opened the first 2018 public consultation on eight potential Substances of Very High Concern (SVHCs)

If these proposals are accepted the Candidate List will expand to 189. Interested parties have until April 23, 2018 to submit comments and further information on use, exposure, alternatives and risks of the substances to ECHA.

THE EIGHT POTENTIAL SVHC PROPOSALS

Eight proposals are published for comments in the 2018 first SVHC consultation list, among which three potential SVHCs are cyclic polydimethylsiloxanes - octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane (i.e. D4, D5 and D6 respectively), which are considered to have PBT and vPvB properties. These cyclic polydimethylsiloxanes have various applications including, but not limited to, silicone polymer production, in washing and cleaning products, cosmetics and personal care products, polishes and waxes. Recently, the EU published regulations on D4 and D5 in wash-off cosmetic products with a limit of 0.1% by weight and the restriction will be effective from 1 February, 2020.

One SVHC proposal is Benzo[ghi] perylene, which belongs to family of polyaromatic hydrocarbons (PAHs) and is also considered for inclusion owing to its classification as having PBT and vPvB properties. It is not produced intentionally but occurs together with other PAHs as a constituent of coal and petroleum stream UVCB substances.

Terphenyl hydrogenated is another vPvB substance on the consultation list. It is a UVCB substance used in coatings, adhesives, sealants, heat transfer fluid and as additive in plastic applications.

One proposed SVHC is a respiratory sensitiser - ethylenediamine which is used in epoxy, PU, adhesives, coatings and other polymers, as well as processing aid agents, scavenging agents in refinery streams and corrosion inhibitors.

The remaining two substances are lead and disodium octaborate, which are both classified as toxic for reproduction. Lead is mainly used in lead-acid batteries and in lead sheets used in the construction industry. Lead is also used as shots and bullets for ammunition and for alloying steel, in soldering alloys, cable sheathing and for the production of oxides, pigments, stabilizers and other lead compounds. Lead is strictly restricted in jewellery and accessible parts of articles under REACH Annex XVII. Meanwhile, there are two restriction proposals on regulating lead in shot for shooting in wetland and its compounds in PVC articles as stabilizers. Disodium octaborate has wide dispersive use in the manufacturing industry, the building sector, in refractory mixtures, as micronutrient fertilizers, and for indoor and outdoor facilities.

The substances and examples of their uses are:

- Octamethylcyclotetrasiloxane (D4) (EC 209-136-7) - used in washing and cleaning products, cosmetics and personal care products and polishes and waxes
- Decamethylcyclopentasiloxane (D5) (EC 208-764-9) - used in cosmetics and personal care products, polishes and waxes, washing and cleaning products and textile treatment products and dyes
- Dodecamethylcyclohexasiloxane (D6) (EC 208-762-8) - used in polishes and waxes, washing and cleaning products, and cosmetics and personal care products
- Ethylenediamine (EC 203-468-6) - used in adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, and pH regulators and water treatment products
- Terphenyl hydrogenated (EC 262-967-7) - used as plastic additive, as solvent, in coatings/inks, in adhesives and sealants
- Lead (EC 231-100-4) - used in metals, welding and soldering products, metal surface treatment products, polymers and heat transfer fluids
- Disodium octaborate (EC 234-541-0) - used in antifreeze products, heat transfer fluids, lubricants and greases and washing and cleaning products
- Benzo[ghi]perylene (EC 205-883-8) - not registered under REACH; normally not produced intentionally, but rather occurs as a constituent or impurity in other substances

ABBREVIATIONS

PBT: Persistent, bioaccumulative and toxic

vPvB: Very persistent and very bioaccumulative

UVCBs: Substance of unknown or variable composition, complex reaction products or biological materials

Article souce: ECHA.europa.eu

PRIME MINISTER: UK TO SEEK 'ASSOCIATE MEMBERSHIP' OF ECHA

The British government is to seek "associate membership" of ECHA and other European agencies as part of the EU withdrawal negotiations, UK prime minister Theresa May has told an audience in London.

In her third major address on Brexit, Ms May said the country will "want to explore with the EU the terms on which the UK could remain part of EU agencies, such as those that are critical for the chemicals, medicines and aerospace industries – the European Medicines Agency, the European Chemicals Agency, and the European Aviation Safety Agency".

The UK would accept, she told a Mansion House audience, that "this would mean abiding by the rules of those agencies and making an appropriate financial contribution".

Ms May went on to outline what she believed to be the benefits of an associate membership approach for both Britain and the trade bloc:

- It is "the only way", she said, to meet the country's objective of ensuring that products in these sectors only need to undergo one series of approvals in one country. To achieve this a "comprehensive system of mutual recognition" will be needed.
- These agencies play a critical role in setting and enforcing relevant rules and the UK could "continue to provide our technical expertise".
- UK firms could resolve certain challenges related to the agencies through UK courts rather than the European Court of Justice (ECJ).

In the case of REACH registrations, it is unclear whether this single approval is to be granted by ECHA or by a new UK chemicals agency and then be 'mutually recognised' by ECHA.

Article source: ChemicalWatch.com

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

WHEN YOU NEED TO BE SURE

SGS