REACH E-NEWSLETTER

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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 the European Chemicals Agency (ECHA) and government sources (HSE, DEFRA etc.). Each of our articles are linked back to source for further reading.

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GENEVA MEETING AGREES GLOBAL BAN ON PFOA, WITH EXEMPTIONS

International chemical regulators at the meeting of the UN Conference of the Parties in Geneva unanimously approved a global ban on the use of perfluorooctanoic acid (PFOA). PFOA is widely used in industrial sectors and manufacturing processes for its resistance to water and oil. PFOA-related compounds are used as surfactants and surface treatment agents in textiles, papers, paints and firefighting foams. The substance has been identified as persistent, bioaccumulative and reprotoxic by the EU.

Participating governments in the Stockholm Convention on Persistent Organic Pollutants agreed to list the chemical in Annex A of the treaty at a recent United Nations Conference of the Parties meeting in Geneva. Under Annex A of the Stockholm Convention, governments must take measures to "eliminate the production and use" of PFOA, which is linked to diseases, including kidney cancer, testicular cancer, thyroid disease, ulcerative colitis and pregnancy-induced hypertension.

The majority of the countries that approved the May 3 decision have 12 months to fully implement the ban. Some members of the Stockholm Convention are permitted to have a longer implementation time frame to complete their domestic ratification process.



EXEMPTIONS GRANTED

Various international industry groups succeeded in lobbying for exemptions and extended implementation timelines for certain PFOA products. Several five-year exemptions to the ban were approved for the chemical, including in:

- · firefighting foam;
- photolithography or etch processes in semiconductor manufacturing;
- photographic coatings applied to films;
- textiles for oil-and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety;

- invasive and implantable medical devices;
- manufacturing fluorinated polymers;
- manufacturing plastic accessories for car interior parts; and
- manufacturing electrical wires.

The use of PFOS in firefighting foams was given a five-year deadline, and its production, export or import and use in training was disallowed.

Some firefighting groups said they were disappointed that governments agreed to grant an exemption for fluorinated firefighting foams, noting there are cost-affordable fluorine-free alternatives available

Source: Bloomberg Environment

COUNCIL OF MINISTERS ADOPTS DIRECTIVE TO RESTRICT SINGLE-USE PLASTICS

The EU is cracking down on plastic pollution. On 21 May the Council adopted a directive that introduces new restrictions on certain single-use plastic products.

The formal adoption of the new rules by the Council is the final step in the procedure.

The single-use plastics directive builds on the EU's existing waste legislation but goes further by setting stricter rules for those types of products and packaging that are among the top ten most frequently found items polluting European beaches. The new rules ban the use of certain throwaway plastic products for which alternatives exist. In addition, specific measures are introduced to reduce the use of the most frequently littered plastic products.

Single-use plastic products are made wholly or partly of plastic and are typically intended to be used just once or for a short period of time before they are thrown away. One of the main purposes of this directive is to reduce

the amount of plastic waste that we create. Under the new rules, single-use plastic plates, cutlery, straws, balloon sticks and cotton buds will be banned by 2021.

Member states have agreed to achieve a 90% collection target for plastic bottles by 2029, and plastic bottles will have to contain at least 25% of recycled content by 2025 and 30% by 2030.

BACKGROUND

The Commission presented its proposal for a directive in May 2018. The Council reached its position on 31 October 2018. Negotiations with the European Parliament started on 6 November 2018 and ended in a provisional agreement on 19 December 2018, which was confirmed by EU ambassadors of the member states on 18 January 2019.

The formal adoption of the new rules by the Council on 21 May is the final step in the procedure.

Source: European Council



IMPROVING SUBSTANCE REGISTRATION COMPLIANCE IS ECHA'S KEY PRIORITY

REACH places the burden of proof on industry to make sure that their chemicals are safe to use. By law, ECHA needs to check the compliance of at least 5% of registrations. In 10 years of evaluation, ECHA has checked more than 2,700 dossiers for compliance. For high-volume substances, the checks cover 25% of the substances. This has led to improved knowledge and safer use of chemicals.

However, ECHA does not have the legal mandate to revoke market access based on its compliance checks. If companies do not provide the necessary safety information, national authorities are responsible for enforcing the law.

ECHA has said "improving compliance with the law is our key priority". Through its annual evaluation reports, the Agency

has consistently highlighted the issue of non-compliant information and given registrants recommendations on how to improve.

As a next step, ECHA is preparing an action plan with the Commission to increase their actions for compliance checks: raising the percentage of dossiers to be checked and increasing efficiency. The Agency is committed to screening all registered substances by 2027 and checking compliance of all substances that need it. This can be for several reasons – for example, substances that have hazardous properties or where more data needs to be generated to conclude a potential risk. The plan will be published before the summer.

Source: ECHA



NEW INTENTION TO IDENTIFY A SUBSTANCE OF VERY HIGH CONCERN

A new intention has been received by ECHA for identification of diisohexyl phthalate (EC 276-090-2, CAS 71850-09-4) as a substance of very high concern from Sweden. The expected date for the dossier submission is 5 August 2019.

Sweden has identified diisohexyl phthalate as meeting the requirements for classification as toxic for reproduction.

Source: ECHA



ECHA CONSULTATIONS

PUBLIC CONSULTATIONS ON APPLICATIONS FOR AUTHORIZATION

ECHA is looking for comments on 11 applications for authorization covering 18 uses of:

- Chromium VI compounds used in surface treatments and as an anticorrosion and reaction stabilizing agent;
- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-Nonylphenol, branched and linear, ethoxylated (EC -, CAS -), used in the production of various medical devices (e.g. in vitro diagnostic) and medicinal products;
- Pitch, coal tar, high-temp. (EC 266-028-2, CAS 65996-93-2), used in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts for aerospace launchers.

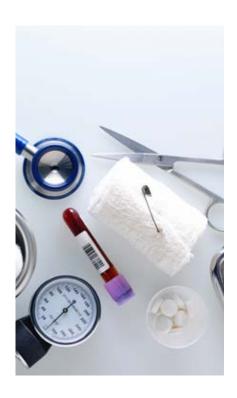
The deadline for comments is 17 July 2019. Details can be found here:

- ► ECHA
- ► ECHA Weekly

PUBLIC CONSULTATIONS ON OCCUPATIONAL EXPOSURE LIMITS

ECHA has launched calls for evidence on lead and its compounds, and on diisocyanates for setting occupational exposure limit (OEL) values. The purpose of the calls is to gather information (for example on uses, exposure, health effects), to help ECHA draft reports relating to health-based exposure limits at the workplace. The deadline for comments is 30 June 2019. Details can be found at:

- ► ECHA
- ► ECHA Weekly



SEAC CONCLUDES TO RESTRICT HAZARDOUS SUBSTANCES IN TATTOO INKS

SEAC (ECHA's Committee for Socioeconomic Analysis) has adopted its final opinion supporting the proposal by Denmark, Italy, Norway and ECHA to restrict the placing on the market of tattoo inks and permanent makeup. Substances within the scope of the restriction include carcinogenic, mutagenic and reprotoxic (CMR) substances, skin sensitizers or irritants, substances corrosive or damaging to the eye, metals as well as other substances regulated in cosmetic products.

The proposal includes concentration limits for the substances within its scope. The aim of the restriction is to make inks for tattooing safer and protect people from serious health problems or effects. Twelve per cent of Europeans – over 60 million people – have tattoos or permanent make-up.

SEAC concluded that the proposed restriction is the most appropriate measure to control the risks posed by these substances, and that it is proportionate to the risk because it will bring significant benefits to society (i.e. avoided adverse skin effects and other health impacts), while not imposing significant economic impacts on supply chains. Suppliers of tattoo inks may have to reformulate their inks within 12 months of the restriction entering into effect.



Tattoo ink's main components are a colourant and water, but they may contain surfactants, polymeric binding agents, fillers like silica or barium sulphate, and alcohol preservatives. A 2017 Joint Research Council report identified 67 azo compounds in tattoo inks, around half of which can produce carcinogenic aromatic amines as they break down in the skin.

NEXT STEPS

Following SEAC's adoption of its final opinion, according to the procedure envisaged in the REACH Regulation,

the opinions of RAC and SEAC will be forwarded to the European Commission for a draft regulation and possible amendment of Annex XVII to REACH. If the restriction is adopted in its currently proposed format, the requirements for tattoo inks and permanent makeup will enter into effect one year after their publication of the measure in the Official Journal of the European Union. However, further changes during the subsequent steps are still possible.

Source: ECHA

SWITZERLAND NOTIFIES WTO OF REACH RESTRICTIONS ALIGNMENT

On 1 May 2019, the World Trade Organization (WTO) circulated a notification from the Swiss Federal Office for the Environment (FOEN) announcing a proposal to revise its Ordinance on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance, ORRChem). The draft amendment (the 'Order'), in French, German or Italian and attached to WTO document number 19-2977, would align the Swiss Ordinance with many of the recently adopted restrictions from Annex XVII of Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in the European Union (EU).

New restrictions on the marketing of certain hazardous substances are due to be introduced in several ORRChem annexes to align it with EU REACH.

They include proposed provisions on:

- DecaBDE, used as a flame retardant; prohibited in articles or parts thereof unless its presence is an unavoidable impurity
- PFOA, its salts and precursors
- DEHP, DBP, DIBP and BBP in articles; less than 0.1% in plasticized materials of an article

- D4 and D5 in cosmetics; no more than 0.1% in rinse-off cosmetics
- Nonylphenol ethoxylates (NPEOs) in textiles; no more than 0.01% in textile articles that can be cleaned with water
- Ammonium salts in cellulose insulation mixtures
- Methanol in windscreen fluids; no more than 0.6% in windscreen washing or de-icing fluids

Note: entry 67 to Annex XVII of EU REACH restricts Deca-BDE to less than 0.1% in articles or parts thereof (Regulation (EU) 2017/227).

Additionally, to fulfil the requirements of the Kigali Amendment to the Montreal Protocol, it will also modify the existing regulation on fluorinated greenhouse gases.

According to the draft amendment, the 'Order' enters into force on 1 June 2019. Certain amended provisions/restrictions to ORRChem will become effective during 1 December 2019 to 1 June 2024.

Source: World Trade Organization



UK AUDIT COMMITTEE LAUNCHES CONSUMER SURVEY ON HAZARDOUS CHEMICALS

The UK's Environmental Audit Committee has launched a consumer survey to ascertain the level of public awareness and concern about the presence of harmful chemicals in everyday consumer products.

The survey is part of an inquiry the committee started in February to establish whether "ministers are doing enough" to protect public health and the environment from exposure to toxic chemicals in products such as furniture, food and toys.

The survey comprises 12 questions, including whether participants have sufficient knowledge about potentially harmful chemicals in products to make informed purchasing decisions, if more knowledge would change their purchasing behaviour and how information should be made available to them.

Among the issues the committee is addressing in the inquiry is how substances of very high concern (SVHC) should be regulated in the UK if and when it leaves the EU. The government

promised to tackle chemicals "of national concern" in a 25-year environment plan released a year ago.

The first oral evidence session took place on 30 April, with witnesses including Rick Mumford, deputy director and head of science at the Food Standards Agency; Anna Stec from the Centre for Fire and Hazards science at the University of Central Lancashire; and Michael Warhurst, executive director at the NGO CHEM Trust.

The next session, held on the 14 May, heard evidence from Daniel Kingdon, director of compliance and safety for EMEA at Amazon; Gemma Brierley, sustainability director, offer and supply chain at Kingfisher; Therese Lilliebladh, product requirements manager at IKEA in Sweden; and Jonathan Hindle, chairman of the British Furniture Confederation, among others.

Source: UK Parliament



WHICH PIECES OF EU LEGISLATION APPLY TO YOUR SUBSTANCES?

The European Union Chemical Legislation Finder (EUCLEF) is an upcoming online service that will enable companies to find out how their substances are being regulated in the EU and what legal obligations they have. Work is under way and ECHA is planning to launch the service, which will initially cover 40 pieces of EU legislation, in 2020.

MAKING LEGISLATIVE INFORMATION EASIER TO FIND

If you manufacture, use, distribute or sell chemicals in the EU, you have to comply with relevant EU law – which may comprise several pieces of legislation. EUCLEF will help companies – especially SMEs – identify which ones apply to their substances by collecting information from different pieces of legislation and regulatory processes in one place.

ECHA's website currently contains information on chemical substances managed by the Agency under the REACH, CLP, BPR and PIC regulations, and the Chemical Agents (CAD) and Carcinogens and Mutagens (CMD) directives. Through EUCLEF, companies will have access to a much wider range of legislative information on areas such as:

- cosmetic products;
- pesticides;
- waste;
- toy safety; and
- food safety and food contact materials.



EUCLEF will also support the work of the European Commission and national authorities, as it will help them identify substances for which there may be regulatory overlaps or gaps.

HOW WILL EUCLEF WORK?

Information on other pieces of chemical legislation will be seamlessly integrated in ECHA's Information on Chemicals portal. You will be able to search for substances by their names or by their EC or CAS numbers.

Just like now, a search will provide you with an Infocard whenever one is available with information on your substance, such as details on its classification and labelling (if applicable), manufacture, import and uses. But once EUCLEF is launched, the search result will also show any pieces of legislation relevant to your substance and covered by the service.

The current plan is to also create a EUCLEF landing page on ECHA's website.

This page will list the pieces of legislation covered by the service and not managed by ECHA – 35 at first – and give you access to an overview of the scope of the legislation, exemptions, regulatory activities, obligations and substance lists.

ADDING MORE INFORMATION IN THE COMING YEARS

ECHA plans to continue developing the service over the next few years, adding further pieces of EU legislation and enriching the kind of information that can be accessed through ECHA's web pages. For example, there are plans to integrate information on national occupational exposure limits and emission limit values from individual member states to the service at a later stage.

Further developments of the service will depend on the available budget and resources.

Source: ECHA

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 97,000 employees, SGS operates a network of over 2,600 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.

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