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 the European Chemicals Agency (ECHA) and government sources (HSE, DEFRA etc.)

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SIX NEW SUBSTANCES ADDED TO THE CANDIDATE LIST

On 15 January 2019 ECHA added five new substances to the Candidate List due to the carcinogenic, toxic to reproduction, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties of the substances. One further substance was added under the "Equivalent level of concern" category.

Four of the new SVHCs added are benzo[k]fluoranthene (BkFA), fluoranthene, phenanthrene and pyrene – which belong to the family of polyaromatic hydrocarbons (PAHs). These PAHs are not produced intentionally but occur together with other PAHs as constituents of coal and petroleum stream UVCB substances.

The fifth, 2,2-bis(4'-hydroxyphenyl)-4-methylpentane is structurally similar to bisphenol A (BPA) and therefore is considered as an alternative to BPA in the manufacture of thermal paper. It is mainly used in polymer manufacturing and its minor uses include surface coatings, inks and adhesives.

The remaining SVHC candidate is 3-benzylidene camphor and has been included because of its endocrine disrupting properties for probable serious effects to the environment. It was used as UV filter in cosmetics and sun screen products; however, its use in cosmetic products was prohibited in 2015 by Regulation (EU) No 2015/1298.

The potential uses of these potential SVHCs are summarized in Table 1.

NO.	SUBSTANCE	CAS NO./ EC NO.	CLASSIFICATION	POTENTIAL USES
1	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6/ 401-720-1	Repr. 1B	• Manufacture of polymer • Use in thermal paper, surface coatings, inks and adhesives
2	Benzo[k]fluoranthene	207-08-9/ 205-916-6	Carc. 1B, PBT, vPvB	• Not produced intentionally but occurs together with other PAHs as a constituent of coal and petroleum stream UVCB substances
3	Fluoranthene	206-44-0/ 205-912-4	PBT, vPvB	• Not produced intentionally but occurs together with other PAHs as a constituent of coal and petroleum stream UVCB substances
4	Phenanthrene	85-01-8/ 201-581-5	vPvB	• Not produced intentionally but occurs together with other PAHs as a constituent of coal and petroleum stream UVCB substances
5	Pyrene	129-00-0/ 204-927-3	PBT, vPvB	• Not produced intentionally but occurs together with other PAHs as a constituent of coal and petroleum stream UVCB substances
6	1,7,7-trimethyl-3-(phenylmethylene) bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8/ 239-139-9	EQC	• Used as UV filter in cosmetics and sun protection agents

Source: ECHA

BACKGROUND

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 and are candidates for eventual 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. In particular, 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 (15 January 2019) to notify ECHA.

SVHCs may be introduced into various consumer products due to the complexities of both the supply chain and production process. Identifying high risk products or materials, or having a test strategy, can also be a smart way to ensure compliance and save costs. If you would like to learn more about how SGS can support your REACH compliance activities please contact us at gb.reach@sgs.com.

COMPANIES TO PROVIDE MORE INFORMATION ON NANOMATERIALS

A specific revision of the REACH information requirements for nanomaterials has now been adopted by the European Commission. The amendments clarify what information companies placing substances in nanoform on the market need to provide in their registration dossiers. The new rules apply as of 1 January 2020.

The new requirements will enable both companies and authorities to systematically assess the hazardous properties of nanomaterials, how they are used safely, and what risks they may pose to our health and the environment. This information will help authorities in the EU to identify if further risk management measures are needed.

Companies now have to assess whether the new information requirements apply to their substances. The changes are relevant for companies manufacturing or importing nanoforms of substances that fall within the scope of REACH. Nanoforms of substances are those covered by the European Commission's recommendation for a definition of a nanomaterial.

ECHA strongly encourages registrants of nanoform substances to familiarize themselves with the amendments and assess what action they need to take to comply. ECHA is also currently assessing the need to update existing guidance or issue new guidance to help registrants comply with the new requirements.

BACKGROUND

Nanomaterials are chemical substances in a particular form with special features at the nanoscale, between 1 nm and 100 nm. They can be used in many different ways, for example, in catalysts, electronics, solar panels and batteries, and in materials science and biomedical applications. Similar to conventional forms of substances, some nanomaterials are hazardous, and others are not. Scientific evidence shows that the toxicity of nanoforms as well as their effects on the environment may differ from the conventional substance.

The European Union Observatory for Nanomaterials (EUON) provides information about the safety, innovation, research and uses of nanomaterials on the EU market. It is funded by the European Commission and hosted and maintained by ECHA.

Source: ECHA

ECOLABEL RULES ON HAZARDOUS CHEMICALS IN PAPER ENTER INTO FORCE

EU Commission decision (EU) 2019/70 of 11 January 2019 establishing the EU Ecolabel criteria for graphic paper and the EU Ecolabel criteria for tissue paper and tissue products has entered into force.

Aims of the Ecolabel criteria. The criteria aim to reduce discharges of toxic or eutrophic substances into waters and environmental damage or risks related to the use of energy (climate change, acidification, ozone depletion, depletion of non-renewable resources). To this end, the criteria aim to:

- reduce energy consumption and related emissions to air,
- reduce environmental damage by reducing emissions to water and waste creation,
- reduce environmental damage or risks related to the use of hazardous chemicals, and
- safeguard forests by requiring recycled fibres or virgin fibres to be sourced from forests and areas that are managed in a sustainable manner.

The new rules in this decision, forbid the use of substances of very high concern (SVHC) and a range of other harmful chemicals classified under the CLP Regulation, and will remain valid until the end of 2024, according to the Commission Decision.

The criteria also ban metal-based pigments and dyes in paper products.

They apply to the following:

- graphic paper: sheets or reels of not converted, unprinted blank paper or board, whether plain or coloured, made from pulp and fit to be used for writing, printing or conversion purposes;
- tissue paper: sheets or reels of not converted tissue paper for conversion into tissue products listed below; and
- tissue products: fit for use for personal hygiene, absorption of liquids or the cleaning of surfaces, or for a combination of those purposes. They include handkerchiefs, toilet tissues, facial tissues, kitchen or household towels, hand towels, table napkins, mats and industrial wipes.

To allow for a transition, producers should be able to submit applications based on either the new or the old criteria "for a limited period", according to the Decision. However, products bearing the label based on the old criteria may be used only until 31 December 2019.

Source: Official Journal of the European Union

ECHA PROPOSES TO RESTRICT INTENTIONALLY ADDED MICROPLASTICS

ECHA has submitted a restriction proposal for microplastic particles that are intentionally added to mixtures used by consumers or professionals. If adopted, the restriction could reduce the amount of microplastics released to the environment in the EU by about 400 thousand tonnes over 20 years.

ECHA's assessment found that intentionally added microplastics are most likely to accumulate in terrestrial environments, as the particles concentrate in sewage sludge that is frequently applied as fertilizer. A much smaller proportion of these microplastics is released directly to the aquatic environment.

The persistence and the potential for adverse effects or bioaccumulation of microplastics is a cause for concern. Once released, they can be extremely persistent in the environment, lasting thousands of years, and practically impossible to remove. Currently it is not possible to determine the impact of such long-term exposure on the environment.

Data available on effects is limited, particularly for the terrestrial environment, which makes risk assessment difficult. Due to their small size, microplastics and nanoplastics – even smaller particles that are created from the further degradation of microplastics – may be readily ingested and thereby enter the food chain. The potential effects on human health are, though, still not well understood.

Overall, the use of microplastics in products that result in release to the environment are not adequately controlled.

ECHA's proposed restriction targets intentionally added microplastics in products from which they will inevitably be released to the environment. The definition of microplastic is wide, covering small, typically microscopic (less than 5mm), synthetic polymer particles that resist (bio)degradation. The scope covers a wide range of uses in consumer and professional products in multiple sectors, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medicinal products, as well as various products used in agriculture and horticulture and in the oil and gas sectors.

ECHA has assessed the socio-economic impact of the proposed restriction and is aware that the restriction is likely to result in different costs depending on the type of product affected. However, implementing the restriction is expected to be cost-effective in all sectors, including the agricultural sector, identified in the proposal as the biggest source of intentionally added microplastics.

Several EU Member States have already introduced bans on the use of microplastics in certain types of products, largely concerning wash-off cosmetic products.

ECHA has published the restriction proposal on microplastics at the same time as its restriction proposals for formaldehyde and for siloxanes D4, D5 and D6.

THE RESTRICTION PROPOSAL PUBLISHED ON 30 JANUARY 2019 DETAILS THE FOLLOWING:	
Details on the scope of restriction	Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.
Reason for restriction	The Commission has requested ECHA to prepare an Annex XV restriction dossier concerning the use of intentionally added microplastic particles to consumer or professional use products of any kind.

Source: ECHA

INTRODUCTORY GUIDANCE ON THE CLP REGULATION UPDATED

ECHA has published an updated version of its Introductory Guidance on the CLP Regulation (version 3.0).

The update takes into account the changes to the regulation brought by the latest Adaptations to Technical and Scientific Progress (ATPs), including the 12th ATP. Outdated information has also been deleted.

This document provides guidance on basic features and procedures laid down in the Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

Source: ECHA

NEW RESTRICTION PROPOSALS SUBMITTED

On 11 January 2019 ECHA submitted proposals to restrict:

- microplastics (EC -) see separate article in this e-bulletin.
- formaldehyde and formaldehyde releasers (EC/CAS -)
- octamethylcyclotetrasiloxane (D4) (EC 208-764-9), and decamethylcyclopentasiloxane (D5) (EC 209-136-7) and dodecamethylcyclohexasiloxane (D6) (EC 208-762-8.)

ECHA's committees are currently performing conformity checks on the dossiers. The dossiers will be published on ECHA's website on 30 January, to ensure transparency and that stakeholders have enough time to prepare for the six-month public consultations. The public consultations will start in April 2019 if the dossiers pass conformity.

FORMALDEHYDE RESTRICTION PROPOSAL

DETAILS ON THE SCOPE OF RESTRICTION

Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses.

REASON FOR RESTRICTION

The Commission has requested ECHA to assess the risk of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses.

THE PROPOSAL EXPANDS THE SCOPE OF RESTRICTION FOR D4/D5 AND ADDS NEW ONE FOR D6

REMARKS

The Commission updated request on 5 February 2018 to include D6 to the previous restriction scope.

DETAILS ON THE SCOPE OF RESTRICTION

Leave on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1% shall not be placed on the market. In addition, wash-off and rinse-off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market.

REASON FOR RESTRICTION

Commission request to ECHA

Expands the scope of restriction for D4/D5 and adds new one for D6.

Source: ECHA

ADVICE ON THE CLASSIFICATION, LABELLING AND PACKAGING REGULATIONS (CLP) REGARDING BREXIT FROM THE HSE

The following additional guidance has been published and concerns chemicals regulation in the event that the UK leaves the EU on 29 March 2019 with no deal.

This guidance summarizes the legal requirements included in the Biocidal Products Regulation, Classification Labelling and Packaging and Prior Informed Consent regulations as retained in UK law, using powers in the EU Withdrawal Act 2018. The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (EU Exit) (Amendment etc.) Regulations 2019 will make amendments to this retained law to ensure that UK chemicals and Genetically Modified Organisms regulations will continue to operate effectively at the point at which the UK leaves the EU.

This Statutory Instrument (SI) and supporting Explanatory Memorandum was laid in draft in Parliament on 21 January 2019 for consideration under the affirmative process and will be debated by both Houses in due course. The SI is available to view online here.

You are advised to read these updates and take note of any deadlines that may apply to you.

- Biocidal Products Regulation (BPR)
- Classification Labelling and Packaging (CLP)
- Prior Informed Consent (PIC)

Source: Health and Safety Executive

UPCOMING INSPECTIONS TO CHECK COMPLIANCE WITH REACH REGISTRATION OBLIGATIONS

Inspectors, working together with customs authorities, have started checking the compliance of importers and manufacturers with REACH registration obligations as part of an EU-wide Forum enforcement project.

The inspections are part of Forum's seventh coordinated REACH enforcement project (REF-7) involving all 31 EU and EEA countries during which cooperation with customs authorities to check imports of substances is expected.

The project aims to ensure EU-wide enforcement of the obligations of importers and manufacturers to register their substances, given that the last registration deadline passed in 2018. Checks will cover imported and manufactured substances in all tonnage bands, the main focus being on substances imported or manufactured in quantities of 1–100 tonnes per year. The inspections will also include a check of parts of the registration dossier and of other duties related to registration, for example, whether the registrant is compliant with the duty to update a registration dossier.

Inspectors in Member States will verify whether substances registered as intermediates meet the definition of intermediates and are manufactured and used under strictly controlled conditions. In addition, substances registered as monomers in polymers will be checked.

ECHA's Forum finalized the preparations for the REF-7 project at the end of 2018. The inspection activities will continue throughout 2019. A report on the results of the inspections will be available in the fourth quarter of 2020.

BACKGROUND

The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of the REACH, CLP and PIC regulations and the BPR in the EU, Norway, Iceland and Liechtenstein.

Source: Health and Safety Executive

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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