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

CONTENTS

ECHA PROPOSES TO RESTRICT MICROPLASTICS

Small pieces of plastic called microplastics are intentionally added to a variety of products. From these products, they may be released to the environment, where they are likely to persist for thousands of years. Their potential effects on human health and the environment are not well understood. As part of the EU's strategy on plastics, ECHA has recently proposed to restrict their use. Below is an explanation of the most important aspects of the proposal.

In November 2017, the European Commission requested ECHA to assess whether the use of intentionally added microplastics in consumer and professional products should be restricted. ECHA published the findings of its assessment in January 2019. After ECHA's scientific committees have provided their opinions on the proposal, it will be sent to the European Commission for it to decide on the regulatory actions needed at EU level.

WHY MICROPLASTICS ARE A CAUSE FOR CONCERN

Microplastics are small, typically microscopic, synthetic polymer particles that resist degradation. They can form when larger pieces of plastic that have not been disposed of or recycled properly gradually break down in the environment. They can also be deliberately manufactured and intentionally added to products for a specific purpose. When these products are used, the microplastics may then be released to the environment.

Once released to the environment, microplastics are practically impossible to remove, and it is difficult to assess their long-term effects. They have been found in the oceans and rivers, as well as in sewage treatment plants and systems. They are also added to agricultural land through the use of sewage sludge as a fertilizer.

Due to their small size, microplastics can also be easily ingested by animals and thereby enter the food chain. In the environment, microplastics may eventually be broken down further to become nanoplastics, about which the potential effects are even less known.

There is currently not enough information to establish a safe level for microplastics in the environment or food. Due to the concerns for human health and the environment, several EU Member States have already restricted the use of microplastics in certain types of products at the national level.

SCOPE OF ECHA'S PROPOSAL

In its assessment, ECHA found that the risks arising from the intentional use of microplastics are not adequately controlled. The Agency is proposing to restrict the use of intentionally added microplastics in products where their use results in the release of microplastics to the environment.

The proposed restriction would impact microplastics used in various consumer, professional, agricultural and industrial products, preventing their use in:

- cosmetic products – both rinse-off and leave-on products;
- detergents and maintenance products – for example, for the encapsulation of fragrances in laundry detergents and cleaning products; and
- agricultural and horticultural products – such as fertilizers and plant protection products.

Furthermore, the proposal suggests labelling requirements for a range of products containing microplastics in a variety of sectors to minimize their potential release during use, including:

- paints, inks and coatings – both for professional and consumer use;
- chemicals used in the oil and gas sector;
- construction products – such as fibre-reinforced cement and adhesives; and
- medicinal products and medical devices.

The restriction proposal does not cover naturally occurring polymers such as cellulose, polymers that meet the proposed interim biodegradability criteria, or fertilizing products in the EU, for which the requirements will be set in the soon to be adopted Fertilizing Products Regulation.

ECHA has proposed that the restriction would take effect in a step-by-step manner, to give industry time to reformulate their products and develop suitable, more environmentally friendly alternatives to microplastics. The first phase of the restriction, if adopted, is expected to enter into force in 2021.

The restriction proposal is based on current scientific knowledge and available information on the intentional uses and risks of microplastics. As scientific understanding will continue to evolve, ECHA's proposal also requires that further information is collected on the uses of microplastics. This way, if additional measures are needed in the future, they would be based on the best possible information.

ECHA also recommends for a review of the restriction to be carried out five years after its entry into force. This is needed to assess how the market has adapted to the restriction, how well biodegradable polymers perform in the context of the intended use, and what additional information has become available on the impacts of microplastics on the environment and human health.

NEXT STEPS

ECHA's Committee for Risk Assessment and Committee for Socio-economic Analysis are currently checking the conformity of the restriction proposal and are expected to formulate their opinions in the coming months. To give stakeholders enough time to prepare for the six-month public consultation scheduled to start in March, the restriction proposal was published on ECHA's website on 30 January 2019.

Source: ECHA

AUTHORIZATIONS GRANTED FOR FOUR USES OF TWO SUBSTANCES

The European Commission has granted authorizations for four uses related to two substances. The authorizations and the expiry date of review period are for:

- Formaldehyde oligomeric reaction products with aniline (technical MDA) (EC 500-036-1, CAS 25214-70-4), granted to Polynt Composites France.
  Authorized use: Formulation of an epoxy resin hardener containing technical MDA. Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilizing spent ion exchange resins in a high containment matrix
  Date of expiry: 21 August 2029
- 1,2 –dichloroethane (EDC) (EC 203-458-1, CAS 107-06-2), granted to Eli Lilly Kinsale Limited.
  Authorized use: Use as a reaction medium and a solvating agent in mediating subsequent chemical transformation reactions leading to the manufacture of an active pharmaceutical ingredient, Raloxifene Hydrochloride.
  Date of expiry: 22 November 2029
- 1,2 –dichloroethane (EDC) (EC 203-458-1, CAS 107-06-2), granted to Bayer Pharma AG.
  Authorized use: Use of 1,2-dichloroethane as an industrial solvent in the manufacture of the high-grade pure final intermediate of Iopromide, the active pharmaceutical ingredient for the X-ray contrast medium Ultravist®.
  Date of expiry: 22 November 2029

Source: European Commission

FRENCH INDUSTRY COMMITS TO ELIMINATE CHEMICALS OF CONCERN FROM NAPPIES

French manufacturers of baby nappies have pledged to remove fragrance allergens in the products within three months, the French environment ministry has said. They will also analyze their supply and distribution channels to identify possible contamination with substances of concern.

The commitment comes after the country's Agency for Food, Environment and Occupational Health and Safety (Anses) published a report on 23 January showing unsafe levels of hazardous chemicals in baby nappies.

These included the fragrances butylphenyl methylpropional and hydroxyisohexyl 3-cyclohexene carboxaldehyde, as well as polycyclic aromatic hydrocarbons (PAHs). Dioxins and furans were also detected.

It also found traces of other fragrances, glyphosate, volatile organic compounds (VOCs) and formaldehyde, but these substances did not exceed the limits.

Anses called for "urgent action to be implemented by manufacturers" to limit children's exposure to these fragrances.

On the same day the Anses report was published, the health and economy ministries met with industry and asked them to present "corrective measures" within 15 days.

Manufacturers and distributors put forward their pledges on 8 February in a meeting with the French government. During talks, industry representatives also presented details of actions already taken since 2017 to improve the manufacturing processes and information flow.

The French ministry also stated that manufacturers will need to improve online information on product composition within three months and include dedicated labels on the product within six months.

COMPLIANCE CHECKING

The French Directorate-General for Competition, Consumer Affairs and Fraud Control will be carrying out inspections to check industry compliance with the new rules.

It has already started these in order to understand the impact that measures, already taken by industry since 2017, have had on the market. This year it is "strengthening its controls and will draw up a report in six months", a press release from the economy minister added.

France is also taking steps to introduce specific measures at European level to restrict or ban the presence of chemicals of concern in nappies.

Source: French Ministry of Ecological and Solidarity Transition

ECHA STRATEGIC PLAN SUMMARY

The ECHA has released a summary of its strategic plan for 2019–2023. In this plan ECHA says it "will ensure safer chemicals use in Europe by improving the basis of the data, disseminating and checking it and taking regulatory actions when needed." To achieve its goals, it spells out three priorities:

Priority 1 – Identify substances of concern and manage risks

Objective

- Accelerate data generation and the identification of substances of concern.
- Accelerate regulatory action on substances of concern

Priority 2 – Safe and sustainable use of chemicals by industry

Objective

- Effective communication along the supply chain becomes mainstream

Priority 3 – Manage chemicals sustainably by applying EU legislation

Objective

ECHA's information, knowledge and competences support the implementation of EU legislation.

The ECHA state that by implementing the EU's legislation on chemicals together with national authorities and the Commission, ECHA is:

- helping industry to comply with legal requirements;
- advancing the safe use of chemicals;
- addressing chemicals of concern; and
- providing information on chemicals.

Full details on the 2019–2023 strategic plan can be found on ECHA's website.

Source: ECHA

SWEDEN BEGINS A NATIONWIDE CHEMICALS COMPLIANCE PROJECT

Consumers have a right to know if there are some hazardous chemicals in products sold in stores. During 2019 inspectors from over 60 Swedish municipalities, in cooperation with the Swedish Chemicals Agency (Kemi) will check how companies follow the rules.

"To have control of chemicals is crucial for a sustainable society. Anyone who sells goods needs to provide information to its customers about the goods containing especially dangerous substances. To protect health and the environment, it is important that companies are aware of and comply with the requirements for information on hazardous substances and labelling of processed goods. Through our collaborative projects with the municipalities to increase awareness among businesses we will investigate how the law is respected," said Frida Ramström an inspector at Kemi.

The nationwide enforcement project will check if product suppliers are complying with the REACH Article 33 requirement to provide recipients with information on hazardous chemicals in articles.

Surveyors from more than 60 municipalities and from the Swedish Chemicals Agency will in 2019, among other things, will carry out analysis of

the chemical content of products and check the labels. Municipalities will make checks in their local stores while the Swedish Chemicals Agency focuses on manufacturers, importers and retail chains.

Article 33 stipulates that suppliers will provide recipients of articles containing substances of very high concern (SVHCs) with information to allow their safe use. This includes every article incorporated as a component of a complex product. They are also obliged to give the same information, free of charge, to consumers within 45 days of receiving a request.

Kemi stresses that consumers do not need to be concerned about hazardous substances in articles, because in most cases there are no acute risks of using individual products.

"For the most part, there is no major risk for consumers to use products containing hazardous substances, but the total amount of hazardous substances from many different sources can eventually cause health and environmental problems," said Frida Ramström.

Source: Cision News

DRAFT DECISION FOR THE IDENTIFICATION OF 4-TERT-BUTYLPHENOL (PTBP) AS A SUBSTANCE OF VERY HIGH CONCERN (SVHC)

This draft Commission Decision published on 7 February aims at identifying 4-tert-butylphenol as a substance of very high concern.

4-tert-butylphenol (PTBP) (EC No 202-679-0, CAS No. 98-54-4) is identified as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No. 1907/2006 due to its endocrine disrupting properties with probable, serious effects to the environment, which give rise to an equivalent level of concern according to Article 57(f)) of that Regulation. Final date for comments on the draft decision is 8 April 2019.

Source: European Commission

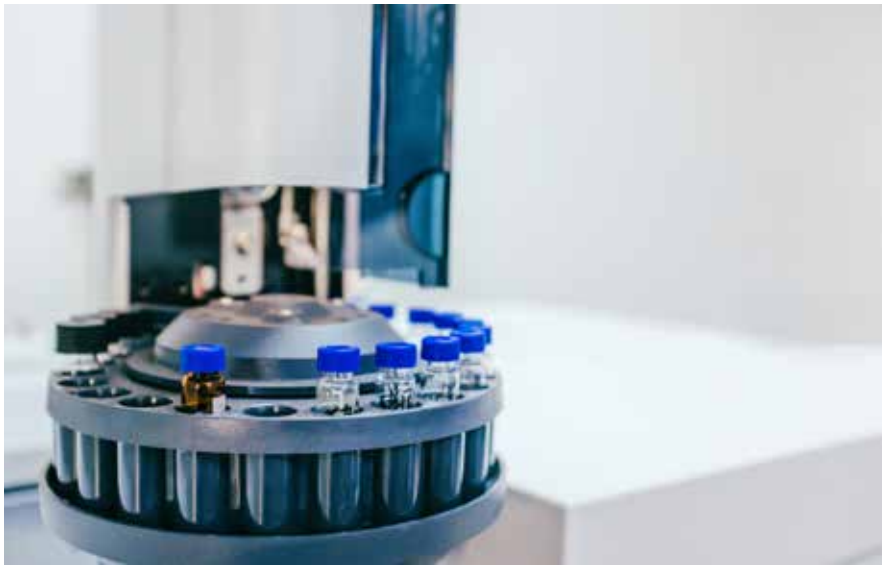
EU ANNOUNCES 12 SUBSTANCES TO BE ADDED TO THE AUTHORISATION LIST

On 15 February the European Commission notified the WTO of its intention of its aim to amend Annex XIV of the REACH Regulation. The objective of this draft Regulation is to subject 12 substances of very high concern to the authorization requirement laid down in the REACH Regulation. According to Article 55 of REACH, the aim of the authorization provisions is "to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."

Their inclusion, which the Commission has proposed for October 2019, would increase the number of substances in the Annex from 43 to 55.

The draft proposes to include 12 additional substances in that Annex, namely:

- 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear;
- dihexyl phthalate;
- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate;
- trixylyl phosphate;
- sodium perborate, perboric acid, sodium salt;
- sodium peroxometaborate;



- 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] (covering any of the individual stereoisomers of [1] and [2] or any combination thereof) ('karanal group');
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328);
- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327);
- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350);
- 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320);
- diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA).

Once the regulation is adopted and enters into force, the placing on the market and the use of those substances in the EU will only be possible, after the date specified for each substance ("sunset date"), for those operators who have been granted an authorization in accordance with Articles 60-64 of REACH.

According to the WTO notification the proposed date of adoption is October 2019. The EU Executive last updated Annex XIV in June 2017 when it added 12 substances to the authorization list, before that, it had a three-year moratorium on such additions.

Source: European Commission

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

WHEN YOU NEED TO BE SURE

SGS