

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 government sources (HSE, DEFRA etc.). Each of our articles are linked back to source for further reading.

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COMMISSION ADOPTS EU PHTHALATES RESTRICTION DECISION

On 18 December 2018 the European Commission adopted a decision to amend the REACH Regulation and restrict the use of the phthalates, DEHP, BBP, DBP and DIBP in consumer products on the EU market.

The restriction, which will take effect from June 2020, was unanimously agreed by member states back in July and has been undergoing scrutiny from the European Parliament and Council of Ministers.

The restriction follows the scientific and technical recommendations by the European Chemicals Agency, and will come into effect as of June 2020. The four substances will be restricted to a concentration equal to or below 0.1% by weight individually or in any combination in any plasticized material in articles used by consumers or in indoor areas. The four phthalates can be present in plasticized materials in a wide variety of everyday products, from cables and coated fabrics to sport equipment. Consumers can be exposed to phthalates through oral or skin exposure or by breathing dust particles containing such substances.



The substances are on the REACH candidate list of SVHCs for their reprotoxic as well as endocrine disrupting properties. The Commission said its adoption will “complement” the existing restriction on three other phthalates – DINP, DIDP and DNOP – in toys and childcare articles (entry 52).

The legislation also lists certain categories of articles that are exempt from this restriction. In addition, new definitions have been given for “plasticized material”, “childcare article” and “prolonged contact with human skin”, making the interpretation of the restriction easier and less ambiguous.

ECHA has recently begun consulting on a draft recommendation to amend the REACH Authorisation List (Annex XIV) entries for the same four phthalates to include their endocrine-disrupting properties (see separate article).

Changes to the restriction are summarized in the table below.

| ENTRY 51 TO ANNEX XVII OF REACH | | |
|---------------------------------|--|---------------------------|
| | REGULATION (EU) 2018/2005 AMENDING REGULATION (EC) 1907/2006 | REGULATION (EC) 1907/2006 |
| Phthalate | DEHP, DBP, BBP and DIBP | DEHP, DBP and BBP |
| Scope (plasticized material) | (i) Used as substances or in mixtures in toys and childcare articles (ii) Placing toys and childcare articles on the market (iii) Placing articles on the market | |
| Requirement | < 0.1% (individually or in combination) | ≤ 0.1% (sum) |
| Effective date | 7 January 2019 for DEHP, DBP, BBP and DIBP for scope (i) above 7 January 2019 for DEHP, DBP and BBP for scope (ii) above 7 July 2020 for DEHP, DBP, BBP and DIBP for scopes (ii) and (iii) above | In force |

Source: *European Commission*

CONSUMER GROUPS WANT EU COMMISSION TO TAKE ACTION ON 'SLIME'

In a letter sent on 14 December to Mr Stefano Soro at the European Commission, the consumer groups Anec and Beuc said it is "urgently necessary" that the European Commission takes on a "coordinating role" to ensure illegal products on the single market will "reliably" be removed by member states before more consumers buy them.

The letter explains that such a role is "essential" because "only 18 alerts" about dangerous slime toys have been uploaded to the EU rapid alert system (Rapex) – since the beginning of 2018.

The appeal follows recent tests carried out by consumer associations from eight European countries, which found illegal levels of boron in over four pots of slime out of ten.

Manufacturers use boron to give slime a gelatinous texture. The substance is classified as an SVHC owing to its reprotoxic qualities and has potential hormone-disrupting effects.

The most extreme cases showed levels of boron 14 times above the EU safety limit in samples on sale in France and Spain. In France out of thirteen products tested in September, three were found to be non-compliant, while Spain detected illegal levels of boron in two products out of ten tested in June.

In the UK in December, consumer association Which? tested 13 toy slimes and putties from high street and online



retailers. It discovered 40% failed to meet the EU safety standard for toys, EN71-3 (boron) in slime <math><300\text{mg/kg}</math> and in toy putties <math><1200\text{mg/kg}</math>.

In a previous test Which? found that eight out of eleven slime toys it examined exceeded the EU safety limit.

Recent analysis from NGO the European Environmental Bureau showed that there have been more warnings for toys concerning chemical safety than any other product type this year. The EU rapid alert system (Rapex) reported warnings for 290 toys that contained substances above limits set by EU authorities.

Most (250) were issued for plastic toys, 150 were for plastic dolls, 21 for modelling clays or slimes and 31 for balloons or balls.

More toys failed chemical checks than any other type of product, including clothing (42), cosmetics (91), jewellery (51) and even protective equipment (5), according to the analysis.

Of the 1,996 products of all types checked for all risks, 563 failed chemical tests, the NGO's analysis found.

Source: The European Consumer Organisation

ECHA'S FUTURE STRATEGIC PLAN – MAKING THE BEST USE OF INFORMATION ON CHEMICALS IN EUROPE

ECHA's current multi-annual work programme ends in 2018, the same year that marked the third registration deadline under REACH. ECHA has engaged in an open and collaborative process with its partners and stakeholders to define its future strategy for the 2019–2023 period, which resulted in its adoption during the December Management Board meeting. The new strategy also contains ECHA's new mission and vision.

ECHA's MISSION: We, together with our partners, work for the safe use of chemicals.

ECHA's VISION: To be the centre of knowledge on the sustainable management of chemicals, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment.

Sharon McGuinness, the Chair of the Management Board said: "This strategy goes a long way in preparing ECHA for the next five years but also for the long-term future – with many challenges ahead such as the new Financial Framework of the EU and the UK withdrawal from the Union. We are entering a period where ECHA will play a key role in implementing the recommendations of the Commission's REACH Refit evaluation, as well as take on new tasks. It is very important to have clarity on our mission and have the



right priorities in place, so that all our stakeholders can rely on them."

The new strategy identifies three strategic priorities:

1. Identification and risk management of substances of concern.
2. Safe and sustainable use of chemicals by industry.
3. Sustainable management of chemicals through the implementation of EU legislation.

Bjorn Hansen, ECHA's Executive Director said: "Our new strategic priorities lead us to making the best use

of our unique source of information on chemicals in Europe and to focus our efforts where we can provide the most impact. This also means an increased focus on ensuring compliance with EU chemicals legislation. We have the right competences to respond to challenges. We aim to become more efficient in the next five years, which will also be supported by the new organizational set-up of ECHA, to be effective from January onwards."

Source: [ECHA](#)

PUBLIC CONSULTATION LAUNCHED ON RESTRICTING SUBSTANCES IN **TATTOO INKS**

ECHA is looking for comments on the draft opinion of the Committee for Socio-economic Analysis (SEAC) on the proposed restriction of hazardous substances in tattoo inks and permanent make-up.

The consultation focuses on the technical feasibility of the concentration limits for the substances in the scope of the proposed restriction and the need for a derogation on Pigment Blue 15:3 and Pigment Green 7.

The deadline for submitting comments is 11 February 2019.

Source: [ECHA](#)



PUBLIC CONSULTATION ON **FOUR PHTHALATES** FOR AMENDING THEIR AUTHORISATION LIST ENTRIES

ECHA has prepared a draft recommendation for amending the Authorisation List (Annex XIV) entries for four phthalates to include their endocrine-disrupting properties. The phthalates are:

- **bis(2-ethylhexyl) phthalate (DEHP)**, EC 204-211-0, CAS 117-81-7);
- **dibutyl phthalate (DBP)**, EC 201-557-4, CAS 84-74-2);
- **benzyl butyl phthalate (BBP)**, EC 201-622-7, CAS 85-68-7); and
- **diisobutyl phthalate (DIBP)**, EC 201-553-2, CAS 84-69-5).

As some currently exempted uses of these phthalates may require authorization due to the amendment, the consultation is specifically addressed to operators concerned with these uses (e.g. use in mixtures in concentrations between 0.1 and 0.3%, use of DEHP in food contact materials or in medical devices).

The deadline for comments is **12 March 2019**.

Source: [ECHA](#)



TWO PUBLIC CONSULTATIONS LAUNCHED ON PROPOSED RESTRICTIONS OF FIVE COBALT SALTS AND OF N,N-DIMETHYLFORMAMIDE

ECHA has submitted a proposal to restrict the manufacture, placing on the market and use of five cobalt salts: cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate).

The proposal applies to the manufacture, placing on the market and use of the five cobalt salts as substances on their own or in mixtures in a concentration equal to or above 0.01% by weight in industrial and professional applications. The use of the five cobalt salts as an additive in feeding stuffs within the scope of Regulation (EC) no. 1831/2003 on additives for use in animal nutrition is exempted from the proposal.

Italy has submitted a proposal to restrict N,N-dimethylformamide (EC 200-679-5; CAS 68-12-2).

The dossier proposes the restriction to apply to the manufacturing and all industrial and professional uses of N,N-dimethylformamide whatever its purity, in concentrations higher than 0.3%.

According to the restriction proposal, DMF may only be manufactured and used in industrial and professional settings in concentrations at or above



0.3% if under normal operating conditions the exposure will remain below the derived no effect levels (DNEL) calculated for workers for long-term inhalation exposure of 3.2 mg/m³ and for dermal exposure of 0.79 mg/kg bw/day. Both DNEL values have been derived according to the relevant ECHA REACH Guidance.

Both consultations are open from 19 December 2018 to 19 June 2019, 23:59 Helsinki time. ECHA's scientific committees welcome early comments by 1 March 2019 to assist them in the first discussions on the proposals in March 2019.

Source: [ECHA](#)

UK REACH ADDITIONAL NO-DEAL GUIDANCE

The Department for Environment, Food and Rural Affairs has released additional guidance, published on HSE's Brexit webpages, on how chemical businesses and other stakeholders will be affected in the event of a no-deal outcome.

This guidance expands on, and should be read in conjunction with, the Technical Notice published on 24 September 2018. These documents are designed to help businesses make informed plans and preparations.

Details published includes information on Substances of Very High Concern (SVHCs) and Substance Restrictions (Annex XVII). Some highlights are:

- The ECHA candidate list at the point that the UK leaves the EU will be carried into UK law. Annex XIV of the EU REACH Regulation and the substances listed in it will also be retained in the UK REACH Regulation
- The restrictions currently listed in Annex XVII to the EU REACH Regulation will be carried over into the UK REACH Regulation
- The powers to update the candidate list, Annex XIV and Annex XVII will remain in UK REACH based on the same legal conditions and criteria



The full additional guidance can be viewed on the HSE website.

Source: *HSE*

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.

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WHEN YOU NEED TO BE SURE

