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

CONTENTS

CHEMICALS AND THE EU EXIT

The following technical notices concerning the regulation of chemicals in the UK in a no-deal scenario were published on 12 October 2018 by the government:

- Classification, Labelling and Packaging (CLP) regulation – 'Classifying, labelling and packaging chemicals if there's no Brexit deal'
- Biocidal Products Regulation (BPR) – 'Regulating biocidal products if there's no Brexit deal'
- Plant Protection Products (PPP) regulation – 'Regulating pesticides if there's no Brexit deal'
- Prior Informed Consent (PIC) regulation – 'Export and import of hazardous chemicals if there's no Brexit deal'
- Regulation on mercury – 'Control on mercury if there's no Brexit deal'
- Regulating Persistent Organic Pollutants (POPs) – 'Control on Persistent Organic Pollutants if there's no Brexit deal'

A technical notice relating to the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) was also published on 24 September 2018 and given the importance of this document it is published in full in this newsletter. Please see" DEFRA note on No Brexit deal".

These technical notices set out information to allow businesses and citizens to understand what they would need to do in the unlikely event that the UK leaves the EU without an agreement ('no deal'), so they can make informed plans and preparations.

The government remains committed to securing a negotiated outcome. Following the publication of the white paper for

the future relationship on 12 July 2018, negotiations are continuing at pace to agree the terms of this future relationship alongside the withdrawal agreement. The HSE is supporting this activity.

Source: Health and Safety Executive

DEFRA GUIDANCE NOTE ON A NO-DEAL SCENARIO

1. PURPOSE

This technical notice published by HM Government on 24 September is part of a series and sets out how businesses producing, registering, importing or exporting chemicals would be affected if the UK leaves the EU in March 2019 with no deal.

2. BEFORE 29 MARCH 2019

There is a large body of existing EU law relating to chemicals which protects human health and the environment, as well as enabling products to be placed on the market.

The UK chemicals industry is regulated through a framework largely based on EU legislation. The European Chemicals Agency (ECHA) is the lead body in implementing this framework. The main piece of legislation is REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). REACH requires EU companies to register chemicals with ECHA before placing them on the market and puts in place additional regulatory controls on hazardous chemicals.

Companies producing and exporting chemicals from outside the European Economic Area (EEA) must comply with REACH by ensuring the EEA-based importer they supply fulfils the requirements of the regulation or procuring the services of an Only Representative (OR). An OR is based in the EEA and acts as an agent to carry out the tasks and responsibilities of importers to comply with REACH. This can simplify access to the EEA market for products from companies outside the EEA, secure the supply and reduce responsibilities for importers.

3. AFTER MARCH 2019 IF THERE IS NO DEAL

In the unlikely event of a no deal, the UK would ensure UK legislation replaces EU legislation via the EU Withdrawal Act, establish a UK regulatory framework and build domestic capacity to deliver the functions currently performed by ECHA. The legislation would preserve REACH as far as possible, while making technical changes that would need to be made because the UK has left the EU.

By doing this the UK would continue to be able to monitor and evaluate chemicals in the UK to reduce the risk posed to human health and the environment. It would also minimise disruption to the supply in chemicals. Existing standards of protection of human health and the environment would be maintained. The Health and Safety Executive (HSE) would act as the lead UK regulatory authority, from the day the UK leaves the EU, building on its existing capacity and capability.

The new regulatory framework would: enable the registration of new chemicals through a UK IT system that is similar to the existing EU IT system; provide specialist capacity to evaluate the impact of chemicals on health and the environment; ensure sufficient regulatory and enforcement capacity in the HSE, the Environment Agency (EA) and other regulators, enabling them to recommend controls in response to the hazards and risks of substances; and provide for an appropriate policy function in the Department for Environment, Food & Rural Affairs (Defra) and the devolved administrations.

In a 'no-deal' scenario the UK would not be legally committed to medium – or long-term regulatory alignment with the EEA.

4. IMPLICATIONS

In the unlikely event that the UK leaves the EU without a deal, this would mean:

- Companies registered with REACH would no longer be able to sell into the EEA market without transferring their registrations to an EEA-based organisation. Companies would therefore need to take action to preserve their EEA market access.
- UK downstream users currently importing chemicals from an EEA country would face new registration requirements. Under the UK's replacement for REACH, importers would have a duty to register chemicals. Similarly, UK downstream users of authorisations would no longer be able to rely on authorisation decisions addressed to companies in the remaining EEA countries.

5. ENSURING CONTINUED ACCESS TO THE UK MARKET AND MAINTAINING EXISTING STANDARDS OF PROTECTION FOR HUMAN HEALTH AND THE ENVIRONMENT

The approach set out below is designed to maximise continuity in as light a touch way as possible, consistent with the requirements of REACH that are being brought into UK law through the EU Withdrawal Act. It provides a transition period before full obligations would fall on the importers who would otherwise be most affected.

To ensure continuity for business we would:

- Carry across existing REACH registrations held by UK-based companies directly into the UK's replacement for REACH, legally 'grandfathering' the registrations into the UK regime.
- Set up a transitional light-touch notification process for UK companies importing chemicals from the EEA before the UK leaves the EU that do not hold a REACH registration. This would reduce the risk of interruption in supply chains for companies currently relying on a registration held by an EEA-based company. This would mean that those UK companies could continue to buy those chemicals from the EEA without any break.
- Carry into the UK system all existing authorisations to continue using higher-risk chemicals held by UK companies.

To ensure we have the information needed to regulate the safe use of chemicals, UK firms would need to take the following action:

- Businesses with existing EU REACH registrations being automatically grandfathered into the UK regime or authorisations would have to validate their existing registration with the UK authority (the HSE), opening an account on the new UK IT system and providing some basic information on their existing registration within 60 days of the UK leaving the EU. This IT system is being tested with a range of different users so that it is ready to support registrations of chemicals in the UK from March 2019.
- Companies with grandfathered registrations would have two years from the day the UK leaves the EU to provide the UK authority (the HSE) with the full data package that supported their original EU registration and is held on the ECHA IT system.
- Businesses that imported chemicals from the EEA before the UK leaves the EU (but who did not have an EU REACH registration), would need to notify the UK authority and provide some basic data on the chemicals within 180 days of the UK leaving the EU, instead of having to undertake a full registration immediately. This would be an interim arrangement for those importers and they would need to move to full registration at a later date following a review of this approach.
- Importing businesses would be responsible for identifying appropriate risk management measures and recommending them to their customers.
- If a business wished to place new chemicals on both the EEA and UK markets, in a 'no-deal' scenario, they would have to make two separate registrations, one to ECHA and one to the UK. The information and data package needed would be the same for both.

6. MAINTAINING OR SECURING EEA MARKET ACCESS

UK companies with existing REACH registrations wishing to maintain EEA market access would need to refer to guidance on the ECHA website on the steps they would need to take. Existing UK registrants would, for example, need to transfer their registrations to an appropriate EEA-based entity (such as an affiliate or an OR) or develop new working relationships with their EEA customers. This would require action before the UK leaves the EU.

UK companies wishing to register new chemicals for the EEA market after the UK leaves the EU would need to register those with ECHA as they do now, but would need to do so via their EU customers or an OR. Further guidance on how to do this can be found on the ECHA website.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North – South cooperation between Northern Ireland and Ireland, which we are committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government has indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU Member States. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK – EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we will take full account of the unique circumstances of Northern Ireland.

Norway, Iceland and Liechtenstein are party to the Agreement on the European Economic Area and participate in other EU arrangements. As such, in many areas, these countries adopt EU rules. Where this is the case, these technical notices may also apply to them, and EEA businesses and citizens should consider whether they need to take any steps to prepare for a 'no-deal' scenario.

Source: Department for Environment Food & Rural Affairs

ILLEGAL SUPPLY OF LEAD-CONTAINING SOLDER TO THE GENERAL PUBLIC

The HSE have been made aware that a number of retailers have been supplying solders containing lead to the general public.

A harmonised classification for lead was agreed and published in 2016 [Regulation (EU) 2016/1179] and this came into effect on 1 March 2018.

As a consequence, the sale of metallic lead or mixtures containing lead (at greater than or equal to 0.3%) to the general public is prohibited [Article 67 of REACH; and Restriction 30 in Annex XVII].

Such products can still be supplied to professional users, however, it should be noted that the restriction also requires that the products be marked visibly, legibly and indelibly as: 'Restricted to professional users.'

The impact of the harmonisation of the classification of lead metal was highlighted by the Lead REACH consortium in their news article earlier this year. This is given below and provides further detail that you may find useful.

RESTRICTIONS ON SUPPLY TO CONSUMERS

Lead metal is already restricted in specified uses as set out in Entry 63 of REACH Annex XVII. In light of the classification as a Category 1A reproductive toxicant, additional restrictions on the supply of lead metal to consumers will take effect under REACH on 1 March 2018.

Annex XVII lists the substances and groups of substances subject to REACH Restriction. Entries 28, 29 and 30 prohibit the supply to the general public of substances classified as carcinogenic, mutagenic or reproductive toxicant, Category 1A or 1B. The substances affected by these restrictions are listed in Appendices 1 to 6 of Annex XVII; lead metal is included in Appendix 5 by Regulation (EU) 2017/1510 from 1 March 2018.

From that date, supply to consumers is prohibited for lead metal as a substance, and in mixtures – including solders and other alloys – when the individual concentration is equal to or greater than 0.03% for mixtures containing lead metal powder, and 0.3% for mixtures containing lead metal in massive form.

This supply prohibition will not apply to architectural lead sheet, lead-based batteries, lead ammunition or other articles containing lead, unless they are otherwise restricted by Entry 63 of REACH Annex XVII or other legislation.

Lead producers should take all reasonable steps to remind their customers of this REACH restriction to ensure any affected products are not supplied to consumers after 1 March 2018.

Suppliers of lead as a substance and mixtures containing lead above the relevant concentration limits must ensure before placing those products on the market that the packaging is marked visibly, legibly and indelibly as: 'Restricted to professional users'.

Source: Health and Safety Executive

RESTRICTION PROPOSAL AVAILABLE ON FIVE SOLUBLE COBALT SALTS AND ON DMF

The two restriction proposals were submitted on 5 October and are now available on ECHA`s website.

The restriction proposal for five soluble cobalt salts seeks to decrease the individual excess cancer risk levels and resulting number of cancer cases arising from occupational exposure to these salts through inhalation. It requires registrants and downstream users to implement a reference exposure value of 0.01 µg/m3 in their chemical safety assessments. ECHA considers this the most appropriate Union-wide measure to ensure a high level of protection of workers reducing the risk of cancer linked to exposure to cobalt salts.

The restriction for N,N-dimethylformamide (DMF; EC 200-679-5, CAS 68-12-2) requires registrants and downstream users of DMF on its own or in mixtures in a concentration equal to or greater than 0.3 % to use in their chemical safety assessment and safety data sheets a harmonised long-term derived no-effect level (DNEL) value of 3.2 mg/m3 for inhalation and of 0.79 mg/kg bw/day for dermal exposure.

ECHA's scientific committees are currently performing a conformity check on the dossiers. The dossiers will be published on ECHA's website shortly to increase transparency and to help stakeholders prepare for the six-month public consultations on the dossiers, which are expected to be launched in mid-December if the dossiers pass conformity.

Source: ECHA

THE EU TAKES ACTION AGAINST HAZARDOUS CHEMICALS IN CLOTHING, TEXTILES AND FOOTWEAR

On Wednesday 10 October, the European Commission adopted new restrictions for 33 substances known to cause cancer and reproductive health problems (CMR substances) for their use in clothing, footwear and other textile products. The new rules have been adopted by amending the list of substances restricted under REACH. The restrictions will apply to companies from October 2020 onwards.

The substances restricted may occur in these articles either as impurities or to give specific properties, such as to prevent shrinkage or make fabric crease-resistant. Consumers can be exposed to these hazardous substances through skin contact, inhalation or unintentional ingestion of dust released from the textile fibres. The most vulnerable to exposure from them these substances are pregnant women and small children.

These new rules set maximum concentration limits for the use of CMR substances in clothing and textiles and prohibit products exceeding these limits from being placed on the EU market, regardless of their origin of production. The new restriction was prepared on the basis of a technical assessment by the European Chemicals Agency, followed by broad discussions with

relevant stakeholders, in particular citizens, public authorities, industry and trade associations, NGOs, academic and research, workers and Member States' representatives.

The restriction includes maximum concentration limits established either for individual substances or for groups of substances, such as certain azo dyes and carcinogenic aromatic amines; impurities, mainly polycyclic aromatic hydrocarbons (PAHs); metals: arsenic, cadmium, chromium, lead and their compounds as well as organic compounds: formaldehyde, chlorinated aromatic hydrocarbons, benzene, phthalates, quinolone and polar aprotic solvents.

Restrictions are regulatory measures to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction can apply to any substance on its own, in a mixture or in an article, including those that do not require registration. Restrictions setting out conditions for the placing on the market of substances apply to both domestic production and imports.

An explanatory guide to this new restriction is under preparation.

Source: European Commission

BREXIT – GUIDANCE TO STAKEHOLDERS ON IMPACT IN THE FIELD OF DETERGENTS

Preparing for Brexit is not just a matter for EU and national authorities, but also for private parties. Businesses are reminded of legal repercussions that need to be considered when the United Kingdom ceases to be a member of the EU.

The guidance document published on 28 September 2018 analyses the legal consequences of the United Kingdom's withdrawal on detergents.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, economic operators in the field of detergents are reminded of the legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of detergents, in particular Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents no longer apply to the United Kingdom. This has particular consequences for detergents placed on the EU market as of the withdrawal date.

The report identifies three areas of concern that need to be considered:

- Responsibilities for importers
- Labelling
- Approved laboratories

The report can be found here ►

Source: European Commission

ECHA INCREASES VISIBILITY OF AUTHORITY ACTIVITIES

The scope of the Public Activities Coordination Tool (PACT) has been extended to also cover substances under dossier and substance evaluation, as well as substances in the registry of intentions for harmonised classification and labelling, substance of very high concern identification or restriction.

The PACT offers companies an overview of information on substances that are on an authority's radar for potential regulatory risk management. Users can find a summary of each activity per substance, and be directed to process-specific lists, which give information on all the substances subject to a particular process. The advance notice enables companies to consider their business strategy and gives all stakeholders more time to prepare their contributions to the public consultations that are run during the formal risk management processes.

The first version of the PACT listed only substances under regulatory management option analysis (RMOA) and substances under informal hazard assessment for persistent, bioaccumulative and toxic (PBT) and/or very persistent and very bioaccumulative (vPvB) properties or endocrine-disrupting properties.

The new PACT now also includes:

- Dossier evaluation (compliance check and testing proposals)
- Substance evaluation
- Registry of CLH intentions until outcome
- Registry of restriction intentions
- Registry of SVHC intentions

Three new standalone lists for RMOA, PBT/vPvB assessment and endocrine disruption assessment activities have also been released.

In addition, the dossier evaluation web page hosting the non-confidential versions of adopted decisions has been revamped and now provides information on the type, scope and status of the assessment undertaken for a given dossier.

The PACT supports ECHA's Integrated Regulatory Strategy, which brings together the REACH and CLP processes to achieve the aims of these regulations, and contributes to meeting the 2020 goals of the World Summit on Sustainable Development.

The PACT tool can be found here ►

Source: ECHA

EU NOTIFIES WTO OF DRAFT NEW REGULATION FOR TCFAs FOR INCLUSION IN ANNEX XVII OF REACH

Submitted by Denmark the restriction covers use of a combination of perfluorinated silanes and one or more organic solvents in sprays used for the general public.

Objective and rationale, including the nature of urgent problems where applicable: The exposure to (3, 3, 4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di-or tri-O-(alkyl) derivatives (TDFAs) with organic solvents in a concentration, individually or in any combination, equal to or greater than 2 ppb by weight of the mixtures poses a risk to human health, in particular a risk of severe lung injury.

The aim of the restriction is to prevent the occurence of the serious lung injury when used by the general public for spraying / impregnating applications.

The 18 months of transitional period before the application of the proposed restriction will allow stakeholders sufficient time to comply with the proposed restriction and to ensure adequate communication within the supply chain.

Closure for comments is on 2 December 2018.

Source: ECHA

HOW TO PREPARE AND SUBMIT INFORMATION TO POISON CENTRES

ECHA has published a new guidance document for the submission of information to poison centres and provides key information for companies submitting information on hazardous mixtures and for the Member State appointed bodies receiving the information.

Up until 1 January 2020, information submitted for the purposes of making an emergency health response may vary from Member State to Member State. The introduction of the new PCN format harmonises and reduces inconsistencies in the information made available to medical personnel in different Member States.

The Poison Centres notification (PCN) portal is the online tool for industry to both prepare and submit information on hazardous mixtures that can be used by poison centres to help make an emergency health response. The information to be submitted through the PCN portal is based on the harmonised PCN format that defines the information requirements established in Annex VIII to the CLP Regulation.

Source: EU Publications

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 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.

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

WHEN YOU NEED TO BE SURE