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 European Chemicals Agency (ECHA) and Chemical Watch. Each of our articles are linked back to source for further reading.

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ENFORCEMENT PROJECT TO CHECK COMPLIANCE WITH THE OBLIGATIONS OF SUBSTANCES IN ARTICLES



ECHA's Enforcement Forum has started work on a pilot project to verify compliance with the notification and communication obligations of substances in articles in REACH. It will specifically target seven substances, or groups of substances, including flame retardants and phthalates.

The project is being launched as a result of national enforcement actions, reports from authorities and NGOs, and the low number of notifications being made to ECHA indicate that industry is failing to meet its obligations.

The pilot was first announced in November 2015, two months after the European Court of Justice (ECJ) ruling that the 0.1% threshold for notifying SVHCs in articles applies to each component of a complex product rather than the entire product.

The project aims to:

- check compliance of producers, importers and suppliers of articles with their obligations (REACH Articles 7 and 33);
- raise awareness and understanding of legal obligations and the level of compliance among duty holders;

- build a better picture of the actual level of compliance by suppliers of articles;
- identify reasons for non-compliance and decide whether ECHA, the Commission and/or member states competent authorities need to do more, such as providing support to duty holders; and
- gather experience and establish enforcement methods for a potential future large-scale check of these obligations.

The target groups for inspection are article distributors and producers or importers of articles. Articles that are likely to contain Candidate List substances to which consumers may be exposed are a particular focus point. Examples of consumer articles that may be inspected are electrical products, building materials and interior articles. The substances, or groups of substances, that it will focus on are:

- brominated flame retardants;
- phosphorous flame retardants;
- short-chain chloroparaffins;
- phthalates;

- aprotic polar solvents;
- perfluorinated substances; and
- phenolic benzotriazoles.

The project runs from October 2017 to June 2018. A report of the results is expected by the end of next November.

At the end of June, ECHA published the long-awaited revision of its guidance on substances in articles. The agency said the "comprehensive update", which was expected in 2016, gives more clarity on communication and notification obligations when articles contain SVHCs. It includes new examples, which it says are in line with the judgement of the ECJ ruling.

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AUTHORISATION – DRIVING THE SUBSTITUTION OF HARMFUL CHEMICALS AND REDUCING RISKS

To continue using hazardous substances included in the Authorisation List, you must apply for authorisation. To date, ECHA has received 120 applications for authorisation for 22 substances of very high concern. A stocktaking conference held in November 2017 highlighted how authorisation has positively impacted European businesses, workers and the general public by stimulating substitution and reducing the risks of hazardous chemicals.

Scientific opinions have been given by ECHA's Committees for Risk Assessment (RAC) and Socio-economic analysis (SEAC) for more than 160 uses of substances requiring authorisation.

Based on these opinions, the European Commission has so far granted authorisations to all applicants whose applications have gone through the decision-making process.

With data now available from these authorisation cases, ECHA and the Commission have both taken a closer look at how the REACH authorisation system is working. In September, ECHA published a report concluding that even though it is difficult to quantify the direct impact of the granted authorisations, the benefits of authorisation generally outweigh the remaining risks. Why is that?

PUTTING ADDITIONAL RISK MANAGEMENT MEASURES IN PLACE?

To reduce the risks from continuing to use substances of very high concern, RAC has recommended additional requirements for more than 70% of the uses applied for.

These requirements aim to primarily protect workers, but also members of the general public who may be exposed to the substance through the environment.

Stricter conditions of use, and monitoring and reviewing the risk management measures are among these additional requirements. "It is quite typical for authorisation holders to be asked to regularly measure occupational exposure of workers involved in such uses and, in addition, the emissions to the environment. This information is used to review

how effective the risk management measures and operational conditions are and will help authorisation holders take action if needed," says Dr Tim Bowmer, the Chairman of RAC.

In other cases, authorisation holders are required to implement additional risk management measures, such as glove boxes to isolate sensitive materials, automatic sampling systems or local exhaust ventilation to protect their employees from being exposed to the substance of very high concern (SVHC).

SHORTER REVIEW PERIODS

Each authorisation granted by the European Commission comes with a review period – the time during which the authorisation is valid.

If a company has not found a suitable alternative and needs to continue using the substance after this period, it must submit a review report to ECHA and to justify an extension of the authorisation.

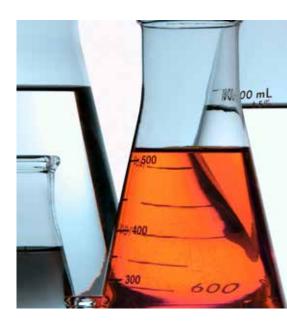
RAC and SEAC have often recommended shorter review periods than what applicants have proposed. On average, the applicants have provided justifications for the review period to be about 11 years, but the recommended period has been around two and a half years shorter.

The first review periods have already or are soon about to expire and ECHA has so far received two review reports. By contrast, about 20 authorisation holders have not submitted review reports for five substances and 10 uses in total.

PROMOTING SUBSTITUTION

But, it is not only the stricter conditions of use and other risk management measures that have led to the safer use of harmful substances on the European market – the authorisation process itself has encouraged companies to look for safer alternatives.

Preliminary findings of an ongoing study on the impacts of authorisation were presented in November at the stocktaking conference of the implementation of REACH authorisation. Based on the study, authorisation is seen as a major, although not the only, driver of substitution of SVHCs.



Most substitution activities seem to be triggered when substances are added to the Candidate List.

This is closely followed by inclusion of substances in the Authorisation List. Many applications for authorisation have also reported promising substitution activities

"This study has shown that some benefits of authorisation are starting to show: SVHCs are being substituted where their use is not essential and, if they cannot be replaced, companies make an effort to improve the risk management measures and to reduce exposure. I think that the comments heard in the early days of authorisation that it was a burden with no added value, can now be dismissed," Ms Valentina Bertato, the project manager at the European Commission, explains.

There are several reasons to choose substitution if it is technically possible. Some of them are related to the changes on the market after the substance is added to the Candidate List, others are related more to reputational issues.

For example, companies commonly state that they want to avoid the stigma of using SVHCs, costs of regulation and uncertainty associated with having to apply for authorisation and whether it is granted to them.

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HIGH REACH REGISTRATION COST 'MAIN STUMBLING BLOCK' TO REGISTRATION

Small and Medium Enterprises' (SMEs') awareness of the impending REACH registration deadline is "not the problem any longer", ECHA head Geert Dancet has said. Instead, one of the main concerns is the cost of registration "being too high", particularly in the lower tonnages.

A commissioned study, conducted by consulting firm RPA and published in August, concluded that over 95% of the SMEs consulted were aware of their duties. "Enough has been done" to make sure they register by 31 May, Mr Dancet said in a recent interview.

Now at the top of the agenda for the REACH Directors' Contact Group (DCG) meeting this month is a discussion on how to bring down the cost of registration for SMEs, manufacturing one to ten tonnes a year.

The DCG is an informal group of directors from the European Commission, ECHA and industry associations. It was set up to respond to concerns arising from companies' REACH registration obligations.

"The first thing people in ministries say is that their SMEs are complaining that Siefs [Substance Information Exchange Forum] and lead registrants are asking too much money for letters of access" and they complain it is "disproportionate", Mr Dancet said.

This topic is "the main stumbling block" when it comes to REACH registration, he added. To date, only 17% of SMEs have registered - far below the expected 40%. "We see SMEs have not yet registered in high numbers and are potentially waiting for a resolution to this cost issue."

Many are considering withdrawing from the market or going to volumes below one tonne, Mr Dancet said. "There is a risk that important substances will disappear from the market unexpectedly - that is an issue we want to avoid."

Certain substances, or the bulk production of them, are supplied only by SMEs, and if they withdraw it will be "problematic".

Article source: ChemicalWatch.com

DENMARK TO SCRAP TAX ON PVC AND PHTHALATES

The Danish government has decided to scrap a tax on products containing phthalates and PVC.

The tax, which covers tape, binders, gloves, aprons, rainwear and protective suits, entered into force in June 2000 and will end on 1 January 2019. The tax rate, which has not changed since its inception, is DKR2 (€0.3) per kilogram of PVC and DKR7 (€0.9) per kilogram of phthalate.

An official report by the Danish government says that the tax is no longer considered to have any "significant behavioural effect on health or the environment"

This, it says, is because of the declining use of phthalates – a result of many being classified by the EU as dangerous for reproduction. Certain phthalates have been added to the REACH authorisation list, while others have restrictions in place for specific articles, such as children's products. And in 2015, four phthalates – DEHP, BBP, DBP and DiBP – were added to the EU Directive on the restriction of hazardous substances (RoHS2) in electrical and electronic equipment.

The report also argues that because the tax rate remains the same, regardless of the concentration and type of phthalates and PVC in the product, there is no incentive for companies to reduce the level in a taxable product or to switch to "less problematic" ones.

However, scrapping the tax is expected to lead to "permanent administrative easing" for affected companies, saving them about DKR8m (€1.75m) annually, according to the government report. The repeal is part of a government initiative, in which several other taxes are to be scrapped. The aim is to "improve business conditions" in order to strengthen Denmark's long-term economic future.

COMPETITIVE ADVANTAGE

However, the Danish Ecological Council said the tax repeal is "completely incomprehensible from an environmental and health perspective".

"PVC plastic and phthalate softeners are environmentally harmful products that do not belong in a modern society and can be avoided for the vast majority of applications. If you abolish the tax you will give PVC and phthalate products a competitive advantage, while taxpayers will pay for the environmental damage," said Christian Ege, secretary leader at the Ecological Council.

"The tax on PVC and phthalates made the more environmentally friendly products more competitive. Now, instead, the competitiveness of the 'black' products is strengthened."



According to the NGO, the Danish Ministry of Taxation — which recommended the repeal — argued that the tax discriminated against the products covered. "This is because the tax has been dealt with moderately for a number of years and should have been expanded to cover other major product groups," the Ecological Council said.

Last month, the Danish Chemical Forum, comprising industry, NGOs and the government, launched a new set of initiatives to ensure consumers "do not bring home" four phthalates that are being phased out in the EU:

- Butylbenzyl phthalate (BBP);
- Di(2-ethylhexyl) phthalate (DEHP);
- Dibutyl phthalate (DBP); and
- Diisobutyl phthalate (DIBP).

The campaign, co-signed by the minister for environment and food, Esben Lunde Larsen, is targeted at products imported from non-EU countries.

ECHA CLARIFIES POST-BREXIT REACH 'PAPER REGISTRATION' RULES

Simply having an address in an EU member state will not be enough for UK companies to transfer their REACH registrations after Brexit, according to a new Q&A released by ECHA.

"A mere address or letter box is not sufficient and may lead to legal consequences being taken by enforcement authorities or ECHA," the agency says.

"Responsible staff and relevant documentation" must be available for inspection at the premises of every registrant, ECHA adds. Every company is responsible for its registrations and the substances they cover, and only representatives (ORs) must adhere to the requirements in Article 8(2) of REACH.

The Q&A is one of two recently added about REACH registration on its webpage, dedicated to Brexit regulatory concerns. The other covers what a UK-based company should consider when appointing an OR in an EU27 country.



James Dancy, from the UK's Department of the Environment, Food and Rural Affairs (Defra), recently said that the option of ORs registering in the UK or deciding to set up in another member state are still both possible at this stage.

And speaking in September, the Only Representative Organisation (ORO) said it is sticking to its position that a 'defensive switch' – where companies with an only representative (OR) based in the UK should consider moving to one based elsewhere in the EU following Brexit – is not necessary.

ECHA's webpage explains by means of 17 Q & A statements what will happen to the regulatory obligations of UK entities and EU member states, as well as agency operations, following the UK's withdrawal from the Union on 30 March 2019.

Article source: ChemicalWatch.com

EFFORTS TO BAN PFHxS GLOBALLY MOVE FORWARD

A UN expert panel has agreed to progress the evaluation of the fluorinated substance perfluorohexane sulfonic acid (PFHxS), its salts and related compounds, for action under the Stockholm Convention on persistent organic pollutants (POPs).

At its meeting in Rome last month, the UN's POP review committee concluded that the substance – which was nominated by Norway in June – meets the treaty's screening criteria for persistence, bioaccumulation, longrange transport and adverse effects.

The committee will now invite parties of the convention and observers to submit information on production, use and releases of the substance, as well as information on socio-economic considerations, including available alternatives and the efficacy of possible

control measures in meeting risk reduction goals. This stage, known as the risk management evaluation phase, is where exemptions are proposed.

If agreed, the POPRC (Persistent Organic Pollutants Review Committee) will then recommend whether the chemical should be considered by the Conference of the Parties for listing in Annexes A (elimination), B (restriction) and/or C (unintentional production).

The substance is used in textiles, carpet protectors, leather, papermaking, pesticides, electroplating, firefighting foams, photosensitive material and some synthetic materials. It has also been found in printing inks, sealants and in non-stick cookware.



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EU COMMISSION SUGGESTS MEASURES TO CLARIFY REACH CUSTOMS RULES

The European Commission has suggested regulatory measures, as well as recommendations and guidelines, to clarify the role of the customs authorities in enforcing REACH, and to promote a harmonised approach to goods entering the trade bloc.

Harmful substances entering the European Union as part of imported articles, which are not in themselves within the scope of REACH, have been underlined as one of the major failings of EU chemicals legislation.

The Commission says customs authorities "can and should" ensure compliance with REACH in line with Article 3(c) of the Union Customs Code (UCC). This calls for them to put in place measures, aimed at "the security and safety of the Union and its residents, and the protection of the environment".

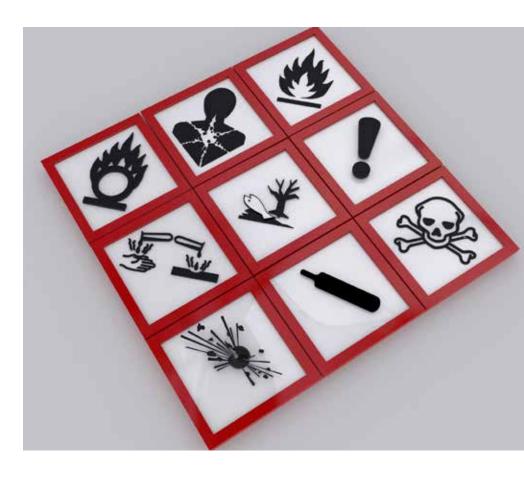
Article 46 of UCC gives the customs authorities general powers to verify REACH compliance of goods, the Commission says in a report. A member state can confer specific enforcement powers on its REACH authorities, but this does not supersede the customs authorities' powers under customs law

The Commission has suggested the introduction of implementing measures:

- to ensure uniform application of customs controls, including common risk criteria and standards on the basis of Article 50 UCC;
- on the roles of the customs authorities for REACH enforcement on the basis of Article 132 of REACH; and
- adopted in the framework of the future Market Surveillance Regulation.

The Competent Authorities for REACH and CLP (Caracal) will consider these at their meeting on 15-16 November.

In addition, the ECHA Forum for harmonised REACH enforcement may carry out recommendations, training and pilot projects and produce guidance documents in cooperation with the Commission and customs authorities, the report says.



Member states can empower REACH authorities and/or customs authorities to detain and seize substances, and ensure close cooperation between them, it adds. Both types of authorities would "probably need to exchange relevant data and there may be a need for specific criteria on risk management."

REQUEST FOR CLARIFICATION

The report comes in response to several requests from member states asking Brussels to clarify the role of customs.

The objectives of REACH and customs legislation differ fundamentally in that customs law focuses on the external aspects of the internal market, whereas REACH aims at the free circulation of substances within it.

However, the report emphasises that "customs controls are not limited to the enforcement of customs legislation", while REACH also "applies

to substances placed under various customs procedures and even to temporary storage", where specific conditions of an exemption are not fulfilled.

The issue of hazardous chemicals in imported articles is also likely to be considered as part of the EU's nontoxic strategy, expected to be finalised next year.

And last year German environment agency the UBA said extending REACH authorisation to substances of very high concern (SVHCs) in imported articles would not violate WTO rules, and that the issue would be on the table in the Commission's second REACH Review, due to be concluded in January.

FORUM FOR ENFORCEMENT REVIEWS RESULTS OF ITS RESTRICTION PROJECT AND AGREES ON NEW ACTIONS

At the meeting on 16 November, the Enforcement Forum endorsed the preliminary results of its fourth major enforcement project, REF-4, focusing on the control of compliance with the conditions set out for selected restrictions in Annex XVII to REACH.

REF-4 RESULTS

Inspectors checked 5,625 chemical products, of which, 18% did not comply with the conditions laid down in the restriction. The most frequently detected breaches were the presence of phthalates in toys (19.7%), cadmium in brazing fillers above the allowed concentration (14.1%) and asbestos fibres in products (13.6%). The products containing asbestos were mostly second-hand, and produced before the restriction came into force. Inspectors also frequently found overly high concentrations of chromium VI in leather articles and cadmium in jewellery.

At its next meeting in March 2018, the Forum will discuss the REF-4 project report, which will be published before year end. The Forum will also consider how to address the relatively high degree of infringements found.



NORWAY FINDS ONLINE RETAILERS FAILING TO INFORM ON HAZARDOUS CHEMICALS

Norway's Environment Directorate found that 11 out of 15 online retailers that it inspected, did not adequately inform customers about hazardous chemicals contained in their products. The companies are subject to the same regulations as high street retailers.

The random check was part of increased oversight of the retailers by the directorate. Its director Bjørn Bjørnstad said: "It is worrying that most online stores broke the regulations.

"They have now been corrected so that they provide consumers with information about the hazardous properties of the chemicals. This shows the importance of following up on the e-commerce market."

For online sales, information on hazardous chemicals should be stated on the website, so it is clearly visible to the consumer before they buy.

Article source: ChemicalWatch.com



PUBLIC CONSULTATION ON THE FIRST REVIEW REPORTS OF REACH AUTHORISATION

ECHA has launched a public consultation on the first two review reports received in the REACH authorisation process. The review period for two uses of DEHP (EC 204-211-0) contained in recycled soft PVC expires on 21 February 2019. Two out of three authorisation holders, both waste recycling companies, submitted review reports with the aim to allow continued use of DEHP contained in recycled soft PVC. Vinyloop Ferrara has requested a review period of 7 years while Plastic Planet have requested a review period of 12 years.

Additionally, a public consultation has started also on the two uses of pentazinc chromate octahydroxide (EC 256-418-0). Applications for authorisation have been received from Indestructible Paint Ltd, Birmingham, UK.

More information about the use applied for, including the description of the function of the substance, exposure scenarios, possible alternatives identified by the applicants, together with socioeconomic information can be found on the ECHA website.

For information: a review report is submitted by a company whose products have previously been granted authorisation and they wish to extend the authorisation period beyond that originally granted.

Comments can be submitted using a form on ECHA's website until 10 January 2018 (23:59 Helsinki time).

UK GOVERNMENT WANTS BREXIT DEAL VALIDITY FOR REACH REGISTRATIONS

The UK government has reaffirmed its position that it wants existing REACH registrations and authorisations to remain valid in both the EU and UK markets after Brexit.

And, according to a government spokesperson, the matter has been a key topic of the opening phase of Brexit negotiations.

The comments were due to be made in a speech by Steve Baker, a junior minister in the Department for Exiting the European Union at a recent Brexit conference, which was hosted by the Chemical Industries Association (CIA). Mr Baker was forced to pull out at the last minute but supplied his speaker's notes to the organisation.

"The UK's position is clear," the notes say. "We want existing registrations, authorisations and approvals to remain valid in both the EU and UK markets. Clearly, this is in the interests of businesses in the UK and the EU. [The government] recognises the complex compliance activity that takes place through supply chains.

"We understand the concerns of businesses regarding the validity of their REACH registrations, as well as the costs that industry have already invested to comply with REACH," he says. "We have been listening to what businesses and others have been telling us about their concerns for the future and the potential impacts and opportunities of EU Exit. We will continue do this.

"I can assure you that this matter has been a key topic of the opening phase of negotiations. Our position paper on this in August sets out the UK's principles for ensuring goods continue to be available on UK and EU markets."

Industry trade organisations the CBA, CIA and Cefic have all called for regulatory consistency and for the country to remain in REACH. Failure to do so, they say, might result in British registrations and authorisation applications becoming invalid.



CONTINUITY

In the short-term, Mr Baker's notes say, the EU Withdrawal Bill will provide "continuity" for the chemicals sector, because it is "designed to ensure" that the UK exits the Union with "certainty, continuity and control".

According to the notes, the UK wants:

- high standards of protection of human health and the environment;
- to make sure it can respond to emerging risks; and
- to make sure it can minimise barriers to trade.

Britain and the EU start from "the unique position" of regulatory alignment, Mr Baker says. "So the question for us now, in building a new economic partnership, is not how we bring our rules and regulations closer together, but how we manage our interdependence in a way that maintains the balance of rights and obligations that flow from this regulatory relationship."

It is in the "mutual interests" of the UK and EU chemicals industries to agree a deal that allows the greatest possible tariff-free and barrier-free trade in chemicals.

In the "unlikely scenario" that no mutually satisfactory agreement can be reached, the government will "make sure we continue to have a functioning chemicals regulatory and enforcement system".

Earlier this month, CIA and Cefic said failure to secure a transition period and a new UK/EU trade agreement after Brexit could cost the chemicals industry an extra €1.5bn a year.

COLLABORATION

The chemicals sector, Mr Baker's notes say, is "the industry of industries", and one of the UK's "core objectives" is to continue to collaborate with European partners on major science, research and technology initiatives.

"The UK will look to build on its unique relationship with the EU and establish an agreement on science and innovation that ensures the valuable research links between us continue to grow."

And the notes say "stakeholder engagement is a central element" of the government's plan to build its negotiating positions.

Industry and NGOs have both called for business to "speak up" for a better Brexit, through cooperation and more visibly communicating their concerns.

UK TO CONSULT ON POST-BREXIT ENVIRONMENTAL STANDARDS BODY

Early next year the UK will consult on plans for a new independent body to oversee environmental standards after Brexit, the country's environment secretary Michael Gove said.

The consultation will seek input into the specific powers and scope of the body, which will "advise and challenge government and potentially other public bodies" on environmental legislation and enforce standards, Mr Gove said

Currently, environmental decisions made in the UK are overseen by the European Commission, which monitors targets, scrutinises new legislation and takes action against illegal behaviour. This will change when the country leaves the European Union in March 2019.

This current system is underpinned by a number of "environmental principles", such as sustainable development and the polluter pays principle, which puts the onus on polluting individuals or businesses to pay to repair damage, Mr Gove said.

"Although these principles are already central to government environmental policy, they are not set out in one place besides the EU treaties," he said. One of the key questions, he said, is whether the devolved administrations of Scotland, Wales and Northern Ireland wish to take a different or similar approach.

"We will deliver a green Brexit, where environmental standards are not only maintained but enhanced," he said.

Article source: ChemicalWatch.com



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 90,000 employees, SGS operates a network of over 2,000 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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