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EU Exit & Chemicals Regulation

5 December 2018



Preparations for EU Exit



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- Joint Defra/HSE EU Exit Chemicals Programme
- **Defra policy lead** – REACH, PPP, MRLs, Detergents, POPs, Mercury
- **HSE policy lead** – CLP, PIC, BPR
- **HSE** is the regulator for CLP, REACH (with Environment Agency), PIC, BPR, PPP, MRLs, Detergents

Planning for all scenarios



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- Leave EU March 2019 with 'no deal', or
- Withdrawal Agreement ratified - leave EU March 2019 & enter implementation period (to Dec 2020)

At the end of the implementation period:

- Future Economic Partnership with EU', or
- UK leaves the EU with 'no deal'

Implementation Period



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- Time-limited between 29 March 2019 – 31 December 2020
- Common rules will remain in place, **with EU law continuing to apply in the UK** subject to the terms set out in the Withdrawal Agreement
- HSE no longer able to act as a ‘lead authority’
- Limited participation in EU institutions, agencies and bodies
- No UK vote in EU decision making

Future Economic Partnership (FEP) (1/2)



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- UK Government would like FEP to start at end of Implementation Period – from January 2021
- White Paper published in July 2018 – sets out UK Government proposal for future economic relationship with EU
- Close alignment on goods, including chemicals and agri-foods
- Less close alignment on services

Future Economic Partnership (2/2)

- Common rulebook for goods including agri-food
 - expectation of some form of alignment with relevant EU rules but detail to be sorted out in negotiations
- Participation by the UK in work of EU agencies ‘that provide authorisations for goods in highly regulated sectors’
 - includes ECHA
 - is silent on EFSA

No deal: Contingency planning



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- The EU (Withdrawal) Act became law in June 2018
- Will convert EU Chemicals regulation to UK domestic law – retained EU law
- Allows for Government to make regulations to correct deficiencies
- Statutory Instruments (SIs) correct deficiencies to ensure that regulations are operable for the UK

CLP - in a 'no deal' scenario



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- An independent UK system – but would adopt the UN GHS in the same way as now
- Recognise existing harmonised (mandatory) classification and labelling for listed substances which would continue to apply
- Require UK manufacturers and importers to notify details of their classification to HSE
- UK mandatory classification and labelling list (of substances) and a UK notification database

BPR/PPP - in a 'no deal' scenario



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- An independent UK system for the biocidal and plant protection products regimes
- Applications would be needed to UK (HSE) for UK specific approval/authorisation
- HSE would perform ECHA/EFSA functions where still relevant in the UK after exit
- Existing active substance approvals, authorisations, and MRLs would remain valid

What action do businesses need to take?



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- Consider your current and future pipeline of applications and renewals for both EU and UK
- Keep in touch with HSE
- Let us know if you have important questions

REACH No Deal contingency planning work is underway

In the event of a no deal, the UK would:

- Ensure UK legislation replaces EU legislation.
- Bring REACH into UK law, while making technical changes that would need to be made because the UK has left the EU.
- Establish a UK regulatory framework and build domestic capacity to deliver the functions currently performed by ECHA.

New functions and additional capacity being set up



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The new regulatory framework would mean that:

- 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.
- We enable the registration of new chemicals to the UK market through a new UK IT system, similar to the existing EU IT system.
- We put in place specialist capacity to evaluate the impact of chemicals on health and the environment.
- We ensure sufficient regulatory and enforcement capacity in the HSE, the Environment Agency (EA) and other regulators.
- We put in place an appropriate policy function in Defra and the devolved administrations.

UK Government approach aims to minimise disruption and prioritise stability



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We are working to ensure that:

- New UK regulatory systems will mirror the existing EU systems as far as possible in order to minimise costs to industry.
- We minimise disruption to integrated supply chains for chemicals.
- The UK continues to be able to monitor and evaluate chemicals in the UK to reduce the risk posed to human health and the environment.
- Existing standards of protection of human health and the environment would be maintained.
- Businesses are aware of what they need to do.

Business will have to engage with UK and EU regulatory systems

Businesses looking to operate in both UK and EU markets will need to deal with two regulatory systems.

- There are unavoidable impacts on industry.
- There are actions business would need to take.

To maintain access to the EEA market:

- UK REACH registration holders will need to transfer their registrations to an EEA-based organisation (such as an affiliate, an importer or an Only Representative).
- The ECHA website provides some guidance on this (with more updates promised).

Access to the UK market – existing registrations held by UK businesses



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- UK Government will **grandfather** existing UK EU REACH registrations into UK REACH. Registrations and authorisations in place on the day of exit would **continue to be valid for UK trade.**
- A new IT system is being built so that it is ready to support registrations of chemicals in the UK from March 2019.

Access to the UK market – existing registrations held by UK businesses



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To maintain UK market access existing UK based REACH registrants would need to:

- Open an account and provide some basic information on their existing registration on the new UK IT system in the first **60 days** of the UK leaving the EU.
- Supporting data packages (identical to those for supplied to ECHA) would need to be submitted within **two years** of the UK leaving the EU.

Access to the UK market – actions for importers or downstream users



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New requirements on UK based importers importing REACH registered chemicals from EEA.

- UK importers would have a duty to register chemicals. This would apply to those companies who don't currently hold a REACH registration but import REACH registered chemicals from the EEA.

This would mean that UK based importers would need to:

- Notify the UK authority and provide some basic data in the first **180 days after EU exit** before undertaking a full registration within two years of the UK leaving the EU.

EEA businesses could choose to appoint a UK-based 'OR' to access the UK market, full registration would also be required.

New REACH registrations



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To register a new chemical for the EU and UK market industry would need to:

For the EEA market, UK companies must register with ECHA via an EEA based customer or Only Representative.

For the UK market, UK companies set up an account on UK REACH IT and register the new chemical.

- Registration requirements will be as close to ECHA's current system as possible to reduce burden on industry.
- For example, UK REACH will require exactly the same IUCLID dossier as ECHA, so industry would send the same information to both agencies.

EEA companies would need to register via a UK-based customer or appoint a UK-based Only Representative

Authorisations and Restrictions



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- Applications for authorisations would need to be submitted to the UK Regulator as well as ECHA
- Existing EU authorisations held by UK manufacturers, importers and Only Representatives will be grandfathered into the UK. Authorisation holders will need to provide some information to the UK Agency.
- UK companies that have submitted authorisation applications to ECHA, and where ECHA have not yet submitted an opinion to the EU, would need to resubmit their dossier to the UK Agency.
- For authorisation applications awaiting EU decision following ECHA, and ECHA's (RAC/SEAC) opinion, applicants will be required to notify the UK Agency of the application and provide copies of the application and any other information that led to ECHA's formation of its opinion.

Authorisations and Restrictions: Importers

- After Exit, there will be “upstream” authorisations held by an EU-27 company upon which UK downstream users are dependent. These authorisations will not be grandfathered into UK REACH.
- To allow UK downstream users to continue benefit from these authorisations. The UK downstream user would be required to notify the UK Agency:
 - They are an existing authorised downstream user under EU law in relation to the substance.
 - The existing EU authorisation, any conditions set out and the identity of the supplier.
- All existing EU REACH Restrictions will continue to stand in UK REACH.

Next steps



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- We have published further guidance on ‘no-deal scenario’ to allow you to prepare. See:

<http://www.hse.gov.uk/brexit/uk-reach-additional-guidance.pdf>

- We would like your feedback to inform further guidance, for example:
 - What do you not understand from the Technical Notice?
 - Has the new REACH guidance answered your questions?
 - How can we work together to get these messages out to the sector and downstream users?