October 16, 2020

UK REACh Regulatory Alert

EXECUTIVE SUMMARY

The United Kingdom (UK) left the European Union (EU) on 31 January 2020 and is no longer a Member State of the EU. The post-exit transition period ends on 31 December 2020, at which point EU chemical legislation will no longer apply in the UK, except in Northern Ireland which continues to be subject to EU REACh in accordance with the Northern Ireland Protocol.

During the transition period chemical regulation in the UK continues on the same terms as before. This alert summarizes not only the new REACh obligations in the UK and how supply chains, substance registrants, authorisation holders and downstream users in both the UK & EU are affected under two parallel chemical regimes during and after this transition period.

REACh During the transition period

- EU REACh continues to apply in the UK during the transition period, including EU REACh candidate list, authorisation list and restrictions, which continue to apply in the UK.
- UK REACh obligations do not yet apply.
- REACh Registrations, Applications for Authorisation (AfAs), and Authorisation decisions in EU REACh continue to be valid in the UK, and those held by UK companies will still be recognized in the EU.
- Importers & exporters of chemicals, substance registrants, authorisation holders and downstream users under both chemical regimes need to prepare and take action to mitigate potential chemical supply chain disruption.

UK REACh Comes into Force on 1 January 2021

UK REACh will come into force at the end of the transition period on 1st January 2021. However, EU REACh will continue to apply in Northern Ireland.

The UK Health and Safety Executive (HSE) will take over the functions of the European Chemicals Agency (ECHA) in respect to UK REACh, and a database of UK chemicals registrations will be established.

Links to Regulation:

Original Statutory Instrument: **Statutory Instrument 2019 No. 758 -** ensures the UK has an effective system of chemicals regulation after leaving the EU.

Note, this regulation amends the existing EU Regulation as its basis and therefore it needs to be read alongside EU REACh.

In addition, current UK Guidance makes provision for registration extension dates beyond those currently provided in the UK Statutory Instruments listed here. Additional Statutory Instruments are envisaged.

Amendments:

- **Statutory Instrument 2019 No. 858** – (1) substitutes a new Article 127E to clarify that pre-exit UK downstream users and distributors are to continue to be regarded as UK downstream users and distributors depending on whether there is a protected transitional import of the substance by the UK user or distributor and (2) a new provision [article 127EA] to accommodate the appointment of an Only Representative where article 127E applies.

- **Statutory Instrument 2019 No. 1144** - inserts a new transitional provision [article 127GA] relating to applications for authorisations to use chemical substances of very high concern between 27 March 2017 and end of Implementation Phase where no EU REACh substance Authorisation has been granted for a submitted AfA.

Guidance:

UK Guidance: how to comply with REACh chemical regulations

UK REACh OVERVIEW

The principles of EU REACh, including its fundamental principle of "no data, no market" and its provision for Only Representative (OR) roles are retained in UK REACh.

To help the UK industry and their supply chains, the UK government has established certain "transitional arrangements", governing chemical regulations during the transition period.

UK REACh Transitional Arrangements

Registration

Transferring existing UK registrations into the UK REACh system:

- EU REACh registrations held by UK–based companies, including those held by UK–based ORs, will be grandfathered into the UK regime and any registration that has a relevant past connection with the UK (article 127A) will also be recognized in the UK;
- Grandfathering will be on the basis of notification in the short term (120 days), with full registration required in a 2-, 4- or 6-year timescale depending on volume and, in certain cases, the hazardous properties of the substance in order that high volume and particularly hazardous substances are registered first.

Companies that import chemicals from European Economic Area (EEA) countries will have new obligations for Registration:

- Such companies continue to be regarded as downstream users (DU) for a period of time, provided that they notify UK authorities by 26 October 2021, by making a Downstream User Import Notification (DUIN).
- Full registration for imports > 1 tonne pa is required in a timescale of up to an additional 6 years depending on volume and, in certain cases, the hazardous properties of the substance.
- An Only Representative (OR) in the UK may be appointed by an EEA producer, formulator or article manufacturer for the purpose of fulfilling importer obligations, including making Downstream User Import Notifications (DUINs).

Authorisation

EU REACh

- Granted Authorisations held by UK companies will be recognised in the UK.
- Granted Authorisations held by upstream suppliers in the EU will continue to be in recognized in the UK.
- Authorisations applied for by UK companies but not yet granted must be re-submitted to UK authorities and will be processed through the UK authorities for review and approval.

Where a UK user is dependent upon an upstream Authorisation application that has been applied for in the EU before the relevant Latest Application Date but not yet granted, then new Authorisation Latest Application Dates (LADs) and Sunset dates (SDs) will apply, and both will be set to 30 June 2022.

- The applicable LAD and SD will be 18 months after the end of the transition period, provided that an application for authorisation (AfA) for the use has been submitted to ECHA prior to the original LAD but not yet decided by the European Commission (EC) at the end of the transition period.
- This arrangement will allow continued use by UK DUs for 18 months after the transition period.
- Use after the 18-month period will require a new UK authorisation to be submitted by either the UK DU, another UK upstream applicant or a UK OR on behalf of the EU supplier, by 30 June 2022.

Further Details

UK REACh Registration

UK REACh Registration will be required for substances manufactured or imported into the UK in quantities of 1 tonne or more per year, whether they are substances on their own, in mixtures, or in articles (if the substance is intended to be released during normal and reasonable conditions of use).

- UK REACh does not mandate joint registration through Substance Information Exchange Fora (SIEFs), but does retain the EU REACh 'One Substance, One registration' principle;
- Inquiry is required for new substances before Registration to ensure they were not registered previously.
- New registrations will be phased-in by tonnage bands, similar to EU REACh.

The Registration Deadlines are:

Deadline	Tonnage and Substance Properties
28 October 2023	• 1000 tonnes or more per year • Very toxic to aquatic organisms: 100 tonnes or more per year • Carcinogens, Mutagens & Reprotoxins (CMRs) for and Substances on UK Candidate List substances as at 31 December 2020: 1 tonne or more per year
28 October 2025	• 100 tonnes or more per year • Substances on UK Candidate List substances as at 27 October 2023: 1 tonne or more per year
28 October 2027	• 1 tonne or more per year

Substances excluded from Registration Requirements are the same as EU REACh

Radioactive substances, substances under customs supervision, the transport of substances through the UK that do not enter the UK customs territory, non-isolated intermediates, waste, and some naturally occurring low-hazard substances will be excluded from the scope of UK REACh, as they are from EU REACh.

Authorisation and Restrictions

- The ECHA candidate list as of 31 December 2020 will be transposed into the UK candidate list.
- The Authorisation List (Annex XIV) of the EU REACh Regulation as of 31 December 2020 including all substances, sunset dates and latest application dates listed in it will be transposed into UK REACh Regulation.
- Restrictions listed in Annex XVII to the EU REACh Regulation as of 31 December 2020 will be transposed into the UK REACh Regulation.
- Updates to the Candidate List, Annex XIV and Annex XVII in UK REACh will be based on the same legal conditions and criteria as EU REACh.
- There are no obligations or commitments to maintain alignment with EU REACh after UK REACh comes into force. Whilst the principles of operation are the same, some divergence should be expected.

RELEVANT DATES

UK REACh REGISTRATION TIMELINE ACTIONS		Phase 1 Action	Phase 2 Action
Users of Substances Registered in EU Countries	Companies procuring substances on their own, in mixtures or in articles for intended release from EU/EEA suppliers will become importers under UK REACh. Downstream users of such substances in the UK importing > 1 tonne per year will need to complete Downstream User Import Notifications (DUINs) based on information available in the Safety Data Sheet. Full registration will also be needed. This notification provision also applies to Imports from 3rd countries coming to the UK directly, if covered by an OR based in another EU/EEA country. See Article 127E	Complete DUIN by 27 Oct 2021	Full registration within 2,4 or 6 years post 28 Oct 2021 depending on tonnage band/hazardous properties of substance: • As an importer submit full UK- REACh Registration, or; • Get the EU/EEA exporter to submit a full Registration via a UK-based OR, or; • Switch to a UK supplier with their own UK registration or; • Lower import below 1 tonne/year.
UK-based holders of EU Registrations	***Grandfathering*** *a*pplies to all Registrations (including intermediate) held by UK-based EU REACh registration holders, whether as Manufacturer, Importer or Only Representative.	***Notify by April 30th 2021***	Within 2,4 or 6 years post 28 Oct 2021 depending on tonnage band, provide full registration data under UK REACh

*Importers of mixtures from the EEA will only be required to submit information for the substances which they have been informed are contained in the mixtures.

*Grandfathering will not apply to registrations held by entities established outside of the UK, regardless of whether they are part of a group of companies which also has a presence in the UK, unless they have been transferred to a UK-based entity before the UK leaves the EU.

REACh AUTHORISATION – UK Authorisation Applications

Role	Compliance Requirements	Notes
A UK-based REACh Authorisation Holder where the European Commission has granted an authorisation decision	**By 1 March 2021 (i.e. 60 days)** Provide UK Health and Safety Executive (HSE) with the technical information relating to the Authorisation	Any conditions of use and review period for an existing authorisation will be carried over into UK REACh. Article 127 F
A UK Downstream User of the above applicant	By 1 March 2021, notify use to HSE. Refer to UK Guidance in Executive Summary on method to notify (not yet available).	Art 127 H applies

If you are a UK-based company that has submitted an Authorisation Application where ECHA has adopted its final opinions BUT the *European Commission has not made a final decision. Art 127G*	**By 30 June 2021,** notify UK Department for Environment, Food and Rural Affairs (Defra) Secretary of State of the Application Refer to UK Guidance in Executive Summary on how to notify (not yet available)	1. Notify Defra Secretary of State of the Application; 2. Provide copies of the application, the information included in it, and any other information provided to ECHA by the applicant of the Authorisation for the Authorisation which was material to the formation of ECHA's opinions; 3. Provide the final opinions ECHA sent to the applicant
A UK Downstream User of the above applicant	No action	Use may continue pending UK decision
An EU Downstream user of the above applicant	Consult upstream applicant or supplier urgently	**Your EU use is no longer covered by the UK application**
If you are a UK company that has submitted an Application for Authorisation (AfA) where ***ECHA has not adopted final opinions under Article 64(5)*** ***Art 127GA***	By 30 June 2022 ***resubmit your application to UK HSE*** Refer to UK Guidance in Executive Summary on how to notify (not yet available)	Resubmit your application to UK HSE based on modified sunset date
A UK Downstream User of the above applicant	No action	Use may continue pending UK decision
An EU Downstream User of the above applicant	Consult upstream applicant or supplier urgently	**Your use is no longer covered by the UK application**

REACh AUTHORISATION – EU Authorisation Applications

Role	Action
A UK Downstream User of a substance covered by an EU/EEA-based upstream authorisation	By 1 March 2021 Notify HSE Art 127 H applies New UK Authorisation required 18 months before the end of the authorisation review period by the Downstream User, or by a UK Importer, or by OR of the EEA supplier.
A EU-based company supplying the UK that has submitted an Application for Authorisation (AfA) where ECHA has adopted its final opinions BUT the European Commission has not made a final decision	Maintain supply for use in the UK. Apply to the UK HSE for a UK REACh Authorisation via a UK-based OR, or through UK -based importer or affiliate by 30 June 2022

A UK Downstream User of the above applicant	Maintain your use in the UK beyond 18 months after end of Implementation Phase. Either you or an upstream supplier must apply to UK HSE for a UK REACh Authorisation within 18 months of end of Implementation Phase, i.e. by 30 June 2022.

RISKS

Business Risk: Potential chemical obsolescence issues

Risks come from two sources:

1) New obligations in the UK (except for Northern Ireland)
2) Changes to existing EU obligations applying to supply from UK (except Northern Ireland) into the EU (including Northern Ireland).

The key risks are:

- Re-registration costs in either UK or EU;
    - Access to data from existing EU SIEFs may be costly to registrants, and require significant negotiation
    - Downstream users may not have the capacity to act as importers and take on the burden associated with UK registration obligations.

- Supply chain disruption;
    - Overall costs for EU manufacturers may not be justified by the size of the UK market alone, resulting in substance withdrawal
    - Lack of transparency in registration intentions leads to supply chain impacts
    - Downstream users (formulators) failure/inability to act as importers and register substances may impact on the availability of mixtures of mixtures (i.e. secondary, tertiary and quaternary mixtures) on the market
    - Delays in gaining authorisations creates business uncertainty and/or unwillingness of EU manufacturer to support the burden and costs of preparing a UK Authorisation

- Costs of managing obligations and diverging lists in the two jurisdictions;
    - Managing authorisations in 2 jurisdictions with different review periods
    - Potential for different decision outcomes (i.e. on an Application for Authorisation) under the two regimes.

- Confusion due to parallel similar but not identical regimes.
    - Due to differences in time frames and processes for decision making under UK REACh on Applications for Authorisation
    - Due to differences in interpretation of science and to scope.

Disclaimer: