

UK REACH Roadmap

Are You Ready For The New UK Chemical Regulation?

UK, Europe – September 2020

At the end of the transitional period, on 31 December 2020, the chemical regulation EU REACH will cease to apply in the UK. This will automatically invalidate EU REACH registrations and authorisations held by UK companies. A stand-alone UK chemical regulation UK REACH will replace EU REACH in the UK.

In September 2020, the gov.uk guidance on <u>How to comply with REACH chemical regulations</u> was updated with further details of the new chemical regulatory regime that will apply in the UK with effect from January 2021. A number of important changes have been included in the updated guidance from previous proposals.

There will be a new stand-alone UK chemicals regime (UK REACH). This will be in the form that was planned in the context of a no-deal Brexit, but now with longer phase-in dates than originally proposed.

The regime will replicate EU REACH in the UK, and all companies who manufacture or import chemicals into the UK, or export chemicals to the EU from the UK, will need to take steps to maintain EU REACH compliance and EU market access, as well as to secure UK compliance and market access.

UK REACH

The European Union (Withdrawal) Act 2018 will convert EU REACH into UK domestic law on 31 December 2020, and create UK REACH. Therefore, UK REACH will place equivalent responsibilities and standards on UK companies as it has under EU REACH. However, a large number of associated issues need to be addressed in order for UK REACH to actually function, and to take account of transitional measures required.

The REACH etc. (EU Exit) Regulations 2019 will need to be amended in light of the September 2020 updates to phase-in dates to deal with "inoperabilities", such as changing references to the European Chemicals Agency (ECHA) and member states. Crucially, they also put in place substantial transitional measures. The transitional measures are needed to ensure that companies can continue to operate in the UK without having to duplicate the whole EU REACH process on exit day.

However, a number of actions will need to be taken promptly after exit day, and full UK REACH dossiers will need to be submitted in due course.

UK REACH will also impose obligations on some companies that did not previously have to register under EU REACH. Companies that buy chemicals from EU companies will be considered importers under UK REACH, and will face associated registration obligations.



Maintaining Compliance With EU REACH

The legal text of EU REACH will not change, but with effect from 1 January 2021, UK companies will no longer be considered EU legal entities and so will no longer fulfil one of the essential criteria to be able to hold an EU REACH registration or authorisation. This would invalidate EU REACH registrations and authorisations held by UK companies, and significantly impact their ability to sell products into the EU/EEA.

UK-based EU REACH registrants, therefore, need to transfer their registrations and authorisations to an EU-27/EEA legal entity, if they want to retain them.

This gives rise to a number of challenges because the EU REACH legal text does not provide for transfers without the transfer of an associated business. ECHA has, therefore, opened a "Brexit window" in its REACH-IT system, which will allow UK manufacturers to transfer their registrations/authorisations to an EU-27/EEA legal entity that will act as their "only representative" (OR). These transfers must be initiated in REACH-IT before the end of the transitional period, but can be set up to take effect on 1 January 2021. Companies will also need to put in place associated contractual arrangements with their ORs, and notify customers. Note that this OR transfer route is only available to UK manufacturers and formulators, not to UK importers of chemicals. Importers will need to transfer their import business to an EU/EEA entity in order to be able to transfer their associated EU REACH registrations/authorisations.

Key Issues and Challenges

Know your supply chains – The change to UK REACH will impact different supply chains in different ways, and the best solutions will also be very specific to those supply chains, for example, whether an OR will be appointed to remove the burden from new UK importers. All potentially affected companies should review supply chains to identify the possible roles to be played by each "actor"; under UK and EU REACH to ensure the supply chain can continue to function smoothly and/or what adjustments may be necessary, or commercially sensible.

Check if you have access to data – EU REACH registrations work on the basis of joint registrations that share data. Therefore, many EU REACH registrants will not own the data contained in their EU REACH registrations, and, of course, new UK importers will not have any pre-exiting access rights to EU-REACH dossier data. Current EU REACH registrants need to establish if they have sufficient rights to exiting data to use it in UK REACH, and if not, to investigate securing such rights.

New importers will need to investigate how they can access the data they would need for a UK REACH registration (or encourage the non-UK manufacturer/formulator to appoint a UK OR). Securing access to the necessary data for UK REACH registration is one of the anticipated major costs for UK companies in complying with the regime, and it has been estimated that the cost to the UK chemical industry could be more than £1 billion unless an arrangement can be reached between the UK and EU regarding sharing of EU REACH data.

Do not miss the initial UK REACH deadlines – These give rise to longer phase-in times and dates for making initial notifications, which, if missed, can mean facing immediate full registration obligations.

UK Reach Roadmap

The implications and associated actions for companies are dependent upon the activities carried out and their role in the supply chain.



UK REACH comes into force



Deadline for UK holders of existing EU REACH registrations to provide basic information to HSE



Deadline for UK importers who were downstream users under EU REACH to notify HSE using a Downstream User Import Notification (DUIN)



Deadline for submission of full registration dossier for manufacturers and importers of:

- Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMRs) ≥ 1 tonne p.a.
- Substances classified as very toxic to aquatic organisms (acute or chronic) ≥ 100 tonnes p.a.
- Substances on the EU candidate list (proposed for authorisation) as at 31 December 2020
- All other substances ≥ 1000 tonnes p.a.



Deadline for submission of full registration dossier for manufacturers and importers of:

- Substances on the (UK's) candidate list (proposed for authorisation) as at 27 October 2023
- All other substances ≥ 100 tonnes p.a.



Deadline for submission of full registration dossier for manufacturers and importers of all other substances ≥ 1 tonne p.a.

Obligations and Key Dates

Under EU REACH, EU/EEA manufacturers and importers must register substances. Unless – in the case of importers – a non-EU/EEA manufacturer appoints an OR in the EU/EEA to take on the importers' obligations. Companies that use substances that are subject to authorisation under EU REACH or place them on the market also need to obtain authorisations, or ensure these are obtained further up their supply chain.

UK Companies Holding EU REACH Registrations

Manufacturers, importers or ORs will be subject to "grandfathering", so their existing registrations will be carried across into UK REACH (regardless of whether they have been/are being transferred to an EU entity to be retained under EU REACH).

Companies should provide basic information to HSE by 30 April 2021 (broadly equivalent to the previously proposed 120-day deadline) about the registered substances.

Full registration dossiers need to be submitted by the relevant phase-in date. This is the major change of the updated guidance, because previous proposals required full registrations in all cases within two years. There are now more gradual phase-in dates ranging from two, four and six years from 28 October 2021, so the registration period now extends to October 2025 for the lowest quantity (and less concerning) substances.

Key Dates

- 30 April 2021 Basic information to HSE
- 27 October 2021 27 October 2025 Full registration dossier to HSE actual deadline dependent on quantity and hazardous properties (see roadmap)

UK Companies Importing Substances and Mixtures From EU/EEA

Companies that were previously downstream users under EU REACH, without registration obligations, are now importers, so there are two main options here:

- 1. The UK company submits a DUIN to the HSE by 27 October 2021. It will then have to submit a full registration dossier for each substance according to the same timetable as existing EU REACH registrants (see Roadmap).
- 2. The non-UK manufacturer/formulator may, instead, appoint a UK OR to take on the registration duties of importers, in which case the OR will need to make the DIUN and then submit the registration. (Note that this is not addressed in the updated gov.uk guidance, but was permissible under the no-deal proposed regime, so we assume this will still be the case).

Key Dates

Option 1

- 27 October 2021 DUIN submitted by importer to the HSE
- 27 October 2021 27 October 2025 Full registration dossier to HSE actual deadline dependent on quantity and hazardous properties (see roadmap)

Option 2

- 27 October 2021 OR to make and submit the DUIN to the HSE
- 27 October 2021 27 October 2025 Full registration dossier to HSE actual deadline dependent on quantity and hazardous properties (see roadmap)



UK Companies Importing Into UK Under OR Arrangements

Where there is a UK-based OR with an EU REACH registration, that would be grandfathered and carried across into UK REACH. However, the importer should check that the OR has taken necessary actions.

Key Dates

- 30 April 2021 OR submits basic information to HSE
- **27 October 2021 27 October 2025** Full registration dossier to HSE actual deadline dependent on quantity and hazardous properties (see roadmap)
- However, if the OR is not based in the UK, the company should follow the DUIN
 process as noted above, either itself or relying on a new OR appointed in the UK by the
 manufacturer.
- 30 April 2021 OR submits basic information to HSE
- 27 October 2021 27 October 2025 Full registration dossier to HSE actual deadline dependent on quantity and hazardous properties (see roadmap)

UK Companies Holding or Relying on EU REACH Authorisations

Companies will still be able to rely on these, because all existing authorisations that have gone through the full authorisation process (and have a review date) will be recognised by UK REACH. Under the no-deal proposed regime, companies were required to notify HSE within 60 days; it is not clear if that is still going to be the case because this is not mentioned in the updated guidance.

UK Companies Who Do Not Fit Into the Above Categories

Companies that do not fit into the above categories but are involved in chemical supply chains should review those supply chains to check that raw material suppliers have taken the necessary steps, and that other aspects of UK and EU REACH, such as restrictions, are being satisfied where applicable.

UK manufacturers of articles will also need to make sure they comply with UK REACH, and EU REACH if supplying to the EU/EEA, as regards restricted substances, and when supplying articles containing any substances of very high concern.

How We Can Help

We have developed a UK REACH legal audit to help companies identify and take the necessary steps to maintain compliance with EU REACH and comply with UK REACH.

This audit will map relevant substances and supply chains, and identify the necessary steps, and options where applicable, that need to be taken by the relevant companies.

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