



UK out of REACH

We are here to support you!



Current status

- ▶ The United Kingdom (UK) left the European Union (EU) on 31 January 2020 and finally exited EU jurisdiction on 31 December 2020. This precipitated significant changes in the regulatory regime for all companies who manufacture chemical substances in the UK as well as their non-UK suppliers.
- ▶ A new chemicals regulation, UK-REACH, came into force on 1 January 2021 in Great Britain (GB: England, Scotland, Wales) replacing EU-REACH. UK-REACH is administered by the UK's Health & Safety Executive (HSE), taking on the role played by the European Chemicals Agency (ECHA) for EU-REACH.
- ▶ Northern Ireland is a special case: it remains in EU-REACH but with special arrangements for trade with GB.
- ▶ UK-REACH is a very close copy of EU-REACH and it applies in a similar way to all substances manufactured in or imported into GB. For example, registration dossiers are to be submitted in IUCLID format to the HSE with same information required at same tonnage bands.
- ▶ EU-REACH and UK-REACH are not linked in any way and could diverge in future.
- ▶ The UK and EU did not reach an agreement to simplify data sharing for registrants under both EU-REACH and UK-REACH. Data access and use for each regulatory regime has to be considered separately.
- ▶ Only GB-registered companies can register under UK-REACH. Former UK downstream users become importers under UK REACH. Non-GB companies can appoint an Only Representative (OR) based in GB to undertake the responsibility for the chemical substances that they export to GB.

Practical details

- ▶ Transitional notification and registration arrangements apply to existing manufacturers and importers of chemical substances for the first few years following UK-REACH coming into force (exact timeframe for registration is dependent on substance tonnage band and other criteria; see below).
- ▶ UK-REACH legislation is written from the perspective of GB-based companies.
 - ▶ Substances previously registered under EU REACH by GB-based companies (manufacturers, importers, ORs) were eligible to be grandfathered into UK-REACH. The first step was to submit basic substance information in IUCLID format to HSE by 30 April 2021.
 - ▶ GB-based companies who are importing substances on the basis of a REACH registration held by a company based in the EEA or newly appointed "GB-based ORs" of non-GB manufacturers or formulators currently supplying GB companies must submit a Downstream User Import Notification (DUIN) containing basic substance information to HSE by 27 October 2021. Prior to registration, an Article 26 inquiry dossier needs to be submitted to HSE.
 - ▶ Following grandfathering or DUIN/inquiry submission, registration dossiers must be submitted by the following deadlines:

Deadline (Years after 28 Oct. 2021)	Tonnage per year	Hazardous Property
28 October 2023 → 2 years	>1000 tonnes	Carcinogenic, mutagenic or toxic for reproduction (CMRs) – 1 tonne or more per year
		Very toxic to aquatic organisms (acute or chronic) – 100 tonnes or more per year
		Candidate list substances (as at 31 December 2020)
28 October 2025 → 4 years	>100 tonnes	Candidate list substances (as at 27 October 2023)
28 October 2027 → 6 years	>1 tonne	



UK out of

REACH

Support from knoell

The knoell group of companies (knoell) has been an independent service provider for the agrochemical and industrial chemical industry since 1996, with currently over 600 employees at sites in Europe, Asia, Brazil and the USA. knoell has extensive experience in the area of EU-REACH and supports a variety of clients both within and outside the EEA. For example, knoell companies act as ORs, registering and otherwise maintaining substance registrations for non-EEA companies; knoell staff have prepared full technical and member (co-registrant), and inquiry dossiers in IUCLID (the software used by ECHA for EU-REACH and which is also to be used for dossier creation and submission for UK-REACH); knoell also offers post-registration support with dossier and substance evaluation etc.

knoell is ideally placed to offer support to both EEA and non-EEA suppliers to comply with UK-REACH and, particularly those who wish to appoint an Only Representative to cover their substances exported to GB or who simply need assistance with the procedures. Thus:

- ▶ As a GB-registered company, Dr. Knoell Consult Ltd. ("knoell UK") can act as your Only Representative (OR) under UK-REACH.
- ▶ knoell UK staff have been (and still are) actively engaging with UK authorities and trade bodies as UK-REACH has been developed. We participated in large-scale public meetings, discrete focus groups and testing sessions for the UK-REACH-IT systems, as well as 1-on-1 discussions with key players.
- ▶ knoell UK staff are gaining knowledge and experience with the UK-REACH-IT system, formally called "Comply with UK REACH".
- ▶ knoell UK staff are able to draw upon the experiences of colleagues in knoell Germany and knoell NL who act as OR for non-EEA clients under EU-REACH, including use of REACH-IT.
- ▶ In similar fashion to non-EEA suppliers exporting to the EEA, a non-GB manufacturer exporting to GB would appoint knoell UK as its OR to fulfil the obligations of importers under UK-REACH with respect to defined substances. Full details of these (name, CAS No., EC No.) would need to be supplied, together with additional information such as EU-REACH registration numbers and any regulatory actions taken under EU-REACH such as candidate listing, restrictions, and authorisations.
- ▶ We would require details of imported tonnages and of the GB importers and would expect cooperation of these importers as and when required.
- ▶ We can prepare Safety Data Sheets for the UK if needed.
- ▶ We worked with our lawyers to prepare a template "UK Only Representative Agreement" (UKORA) for knoell UK to act as OR for non-GB companies.

- ▶ We are, therefore, confident that we can support both, new and existing clients, with any obligations under UK-REACH, including set up in UK-REACH-IT; notification, preparation and submission of registration dossiers; liaising with UK authorities, companies, and trade bodies; and above all acting as OR in GB.
- ▶ An annual fee for the OR role under UK-REACH would ordinarily be payable in GBP, which would also cover the initial notification (DUIN) in the UK-REACH IT system. Annual fees would be charged on a sliding scale based on the number of substances. For other services which are not included in the annual fee – e.g., initial set-up of substances and products in knoell's OR data base and transfer of data as collected from GB importers; preparation of OR Coverage Certificates; other regulatory and technical tasks – knoell generally does not charge a fixed fee but, as far as possible, offers a bespoke service with tasks tailored to the client's needs and charged at an agreed hourly rate(s)¹.
- ▶ We are also confident that we can offer appropriate advice and services when required for other standalone GB chemicals-related regulations such as BPR or CLP, Plant Protection or Medical Devices.

¹ **Note:** Preparation of Safety Data Sheets, if requested, is also normally done at a fixed fee.

Contact us:

Dr. Knoell Consult Ltd., Cardiff, UK
Dr. Iain MacKinnon, imackinnon@knoell.com
Graeme Towell, gtowell@knoell.com



www.knoell.com