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registration

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UK REACH

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 and for UK-based companies who import substances as well as their non-UK suppliers.
- ▶ A stand-alone 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 end-point studies required at same tonnage bands.
- ▶ However, the two systems, 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. Therefore, data access and use for each regulatory regime is considered separately. The UK authorities are working on this issue and to allow time for potential changes the registration deadlines have been postponed (see table). In addition, a mechanism to allow simple registration of substances already registered for EU-REACH is in place. This is referred to as New Registration of Existing Substances (NRES).
- ▶ 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 EU-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 had to submit a Downstream User Import Notification (DUIN) containing basic substance information to HSE by 27 October 2021 but late submission is possible.
- ▶ Following grandfathering or DUIN submission, registration dossiers must be submitted by the following deadlines.

Deadline	Tonnage per year	Hazardous Property
27 October 2026 → previously 2023	>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)
27 October 2028 → previously 2025	>100 tonnes	Candidate list substances (as at 27 October 2023)
27 October 2030 → previously 2027	>1 tonne	



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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 650 employees at sites in Europe, Asia, 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), NRES and inquiry dossiers in IUCLID (the software used by ECHA for EU-REACH and which is also 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 prepare for UK-REACH and 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. We are often in direct dialogue with the HSE to resolve specific client-related issues.
 - knoell UK staff have gained much knowledge and experience with the UK-REACH-IT system, formally called "Comply with UK REACH".
 - 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.
- knoell UK staff working with colleagues in knoell Germany and knoell NL now have considerable experience in acting as an OR under UK-REACH, including preparation and submission of DUINs, inquiry and registration dossiers in IUCLID.
 - 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 our clients, existing and new, 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.
 - Although less well developed we also provide support for other chemicals-related regulations such as BPR and CLP, for which there are also standalone GB legislation.
 - An annual fee for the OR role would ordinarily be payable in GBP, which would also cover the initial notification (DUIN) and set up of an account in the UK-REACH IT system (Comply with UK REACH). 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 database and transfer of data as collected from GB importers; preparation of OR Coverage Certificates or Letters of Confirmation (if requested); 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.

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

Think globally, act locally. Contact us:

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