UK REACH – Post-Brexit & Chemicals Regulatory Compliance FAQs

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What's this about?

"Full" Brexit has taken place as it were as of 1 January 2021 affecting most regulatory areas including chemicals regulatory compliance. These FAQs are about the UK's post-Brexit chemicals regulatory compliance regime.

What's EU REACH?

The EU's chemicals regulatory regime is called REACH (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **CH**emicals) which entered into force on 1 June 2007, with a phased implementation over a decade – an enormous amount of compliance work has been undertaken by organisations affected by it. Post-Brexit the UK is no longer part of EU REACH.

What's UK REACH?

The UK now has its own REACH chemicals regulatory compliance regime called UK REACH, which started on 1 January 2021. Any business which make, sell or distribute chemicals into the UK will need to follow this (along with some other chemicals regulations). UK REACH is a registration oriented process.

The key principles of EU REACH have been retained in UK REACH, which include:

- The "no data, no market" principle;
- The "last resort" principle on animal testing;
- Access to information for workers; and,
- The so-called "precautionary principle".

Businesses supplying and purchasing substances, mixtures or articles to and from the EU/EEA/Northern Ireland and Great Britain (England, Scotland and Wales) will need to ensure that the relevant obligations are met under both EU and UK REACH – note that these are highly detailed. Under the so-called (Brexit) "Northern Ireland Protocol" EU REACH continues to apply to Northern Ireland, while UK REACH provides the regulatory framework for chemicals in Great Britain.

UK REACH applies to most chemical substances including common household products, e.g. cleaning products and paints, and also to articles containing chemicals substances e.g. clothes, furniture and electrical appliances.

The aims of UK REACH include the following:

- To provide a high level of protection of human health and the environment from the use of chemicals;
- To make the people who place chemicals on the market (manufacturers and importers) responsible for understanding and managing the risks associated with their use; and,
- To promote the use of alternative methods for the assessment of the hazardous properties of substances e.g. so-called quantitative structure-activity relationships ("QSAR") and "read across".

Under UK REACH the burden of proof is on businesses:

- They have to identify and manage risks presented by substances they manufacture and market in Great Britain; and,
- They must be able to demonstrate how the substance can be used safely and they must communicate the risk management measures to users.

What's "Comply with UK REACH"?

A new IT system has been developed for UK REACH called “Comply with UK REACH” for businesses to:

- Validate existing GB-held EU registrations (so-called “grandfathering” – for more see later below);
- Submit “Downstream User Import Notifications” (“DUINs” – for more see later below);
- Submit new substance registrations; and,
- Submit new product and process orientated research and development (“PPORD”) notifications.

To find out how to register with “Comply with UK REACH” see here https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956503/register-a-business-or-organisation-for-the-Comply-with-UK-REACH-service.odt. To sign into “Comply with UK REACH” businesses will need to create a so-called “Government Gateway” account. If a business acts on behalf of other legal entities, e.g. as a so-called “Only Representative”(for more see below), the business will need to set up a “parent” account for itself and “child” accounts for those legal entities the business represents once the business has signed into the service. Businesses should check that the substance information is in the correct format – the service only accepts substance registrations and other submissions as i6z dossier files – IUCLID 6 can be used or a later version to create the files.

Businesses will also need to contact the UK’s chemicals regulator the Health and Safety Executive to ensure that they:

- Validate existing UK-held product and process orientated research and development (“PPORDs”); and,
- Provide information on any “Authorisation” matter (for more see later below), including new authorisation application, “grandfathering” of existing authorisations, and downstream user notifications of authorised uses.

What is an “Only Representative”?

Under UK REACH, a non-GB manufacturer/formulator/producer of articles can appoint a GB-based “Only Representative” to fulfil the obligations of the GB-based importers. This may help maintain access to the GB market for their substances by reducing the responsibilities for importers. “Only Representatives” must be:

- A natural or legal person established in Great Britain;
- Equipped with sufficient background in the practical handling of substances and the information related to them;
- Appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside Great Britain; and,
- Responsible for complying with the legal requirements for importers under UK REACH.

What about GB held registrations and “grandfathering”?

EU REACH registrations held by GB-based businesses have been carried across directly into UK REACH, legally “grandfathering” the registrations into UK REACH. GB-based holders of existing EU REACH registrations need to complete the “grandfathering” process by providing basic information to the Health and Safety Executive by **30 April 2021**, through “Comply with UK REACH” as explained earlier above.

What about EU held registrations and GB downstream users?

GB downstream users (who do not hold an EU REACH registration) who currently import chemicals from an EU or EEA country must ensure that the substances they purchase are covered by a valid UK REACH registration.

Businesses that relied on a registration held by an EU or EEA-based company before 1 January 2021 can continue to import chemical substances as they did before. However, they will need to make sure that the chemical is registered for UK REACH purposes. To find out how GB downstream users can notify the Health and Safety Executive using a “Downstream User Import Notification” (“DUIN”) of their intention to continue importing

substances from the EU or EEA by **27 October 2021** see here https://www.hse.gov.uk/reach/duin.htm.

A new registration must then be submitted to the Health and Safety Executive within 2, 4 or 6 years of **28 October 2021**. Alternatively, GB downstream users can encourage their EU or EEA supplier to appoint a GB-based "Only Representative", or change their source to a GB registered supplier.

It's possible to submit "DUINs" if a chemical is covered by a registration held by an EU or EEA-based "Only Representative", and then sold into GB.

New registrants include anyone who wants to manufacture or import for the first time, and needs to submit a full registration.

After completing the substance inquiry process, new registrants can view contact details of other members within "Comply with UK REACH" and start negotiating data access.

An individual registering a new substance that has never been registered under UK REACH will become the so-called "Lead Registrant" and need to submit a lead dossier for that substance. This will make joint registration available for any future registrants (for more see later below). If multiple businesses want to register the same substance for the first time, they will be placed in a substance group together and a joint registration should be submitted.

Under UK REACH, new registrants are able to request any information from existing registrants if it's needed for their registration. However, they must request information if it involves tests on animals.

What about tonnage band deadlines?

Under UK REACH, deadlines for the full submission of data to underpin registration dossiers will be staggered over a period of 6 years. These deadlines start from **28 October 2021**, the end of the "DUIN" submission period. To find out about tonnage band deadlines and hazard profiles see here https://www.hse.gov.uk/reach/duin.htm.

What about EU market access for GB businesses?

GB-based businesses previously registered with EU REACH can no longer sell into the EEA market unless they have transferred their registrations to an EU or EEA-based organisation. GB businesses who have not done so are able to appoint an "Only Representative" to assume registration obligations under EU REACH or support their EU or EEA-based importers to become registrants. They will also need a valid UK REACH registration to maintain access to the GB market.

What about importing from the EU to GB?

EU or EEA based businesses who import chemicals into GB must ensure that they are covered by a valid UK REACH registration. These businesses can register the substance under UK REACH either through a GB-based "Only Representative", or an affiliate GB importer.

What's joint registration?

Joint registrations are a way for businesses to reduced costs and avoid testing on animals. Registrants share data to ensure the information needed for a registration is submitted to the Health and Safety Executive. They must share data on a substance's properties in a fair, transparent and non-discriminatory way. "Comply with UK REACH" enables data-sharing through setting up substance groups. Registrants under UK REACH should jointly submit information on the intrinsic properties of the substance in a lead dossier. The information in the lead dossier will support the registrations of all members of the joint registration and contain the full information requirement for the group's highest tonnage band. All members of the group will need to submit a separate member dossier containing certain information. The "Lead Registrant" is responsible for approving members into the joint registration group in 'Comply with UK REACH'. This links their member dossier to the lead dossier.

What about substance groups?

Substance groups are the way that “Comply with UK REACH” organises registrants. They are made up of multiple businesses that all want to submit a registration for the same substance. Members of the group are able to contact each other to start the data-sharing process. Registrants of the same substance are automatically matched and put in a substance group. This is done after either:

- Submitting the initial substance identification information – in the case of “grandfathered” registrations; and,
- Submitting a substance inquiry if a business is a new registrant – including those who wish to register, having submitted a “DUIN”.

Once a substance group is formed, members of the group can access each other’s contact details to organise a registration strategy, a cost-sharing model and group data sharing. A lead registrant should be appointed by the group to submit the joint registration dossier for that substance on behalf of all group members. The lead registrant role should be claimed on “Comply with UK REACH” once the dossier is ready to be submitted. If a substance group is already formed, new registrants should communicate directly with the lead registrant to negotiate data sharing. If the group is still forming, new registrants should communicate with the group as a whole.

What’s data-sharing?

Sharing the data needed to submit a joint registration is an important task for substance groups. If the substance group is in the process of forming, members must:

- Find out what studies are available;
- Assess any data gaps within the group;
- Consider other publicly available data.

If a study is not available in the group, members will need to agree how to get the missing data. The group members need to agree how they will share the costs for both existing and new studies. Businesses should agree on a process for sharing data before doing so. If members of the substance group are data owners, they may want a non-disclosure agreement. A legal agreement or a so-called “Letter of Access” can formalise the data-sharing agreement and give co-registrants and new members access rights to the data to be used in the lead dossier, for the purpose of completing their registration. All parties must make every effort to reach an agreement on data-sharing and to ensure the costs are determined in a fair, transparent and non-discriminatory way. It is very important that in this data-sharing process registrants comply with competition law rules (otherwise they may face severe sanctions).

Is there a dispute-resolution process?

UK REACH includes a dispute-resolution process to help resolve issues around data-sharing. Businesses can lodge a dispute with the Health and Safety Executive as a last resort when negotiations over data access have failed. The party submitting the dispute must provide evidence to demonstrate those negotiations took place in good faith and were fully pursued. The party the claim is being made against will also be asked to provide evidence. The Health and Safety Executive will assess this evidence and decide whether both parties have made every effort to reach a negotiated settlement. This decision will not be based on the issue of cost. Parties can appeal the decision to the UK’s First-tier Tribunal.

Can I opt out?

A registrant can opt out of submitting certain information within a joint registration and do so separately. There are three scenarios where this is possible, as follows:

- Where the costs of submitting information jointly would be too costly;
- Where submitting the information jointly would disclose commercially sensitive information and is likely to cause substantial commercial detriment; and,

- If there is a disagreement over the selection of information to be submitted in the lead dossier.

If any of these scenarios apply, businesses must submit, along with the dossier, an explanation of why that is the case.

What about Authorisation?

“Authorisation” is the process under UK REACH that phases out the use of particularly hazardous substances. It allows the use of the substance to continue in specific circumstances, where it’s deemed necessary. The UK government will make decisions to add substances to the authorisation list and grant authorisations. These decisions will be based on the scientific opinion of the Health and Safety Executive, which will be published.

What about Restrictions?

UK REACH uses a “Restriction” process to regulate the manufacture, placing on the market or use of dangerous substances, either on their own or in mixtures or articles, within GB. Such activities may be limited or banned, if they pose an unacceptable risk to human health or the environment. The “Restriction” process is designed to manage risks that are not addressed by the other UK REACH processes or by other legislation. The UK government will make decisions to restrict substances. These will be based on the scientific opinion of the Health and Safety Executive, which will be published.

Where can I get official UK guidance?

Detailed UK REACH guidance is available on the Health and Safety Executive website here https://www.hse.gov.uk/reach/brexit.htm

We report about compliance issues here https://www.corderycompliance.com/news/.

For more information please contact André Bywater or Jonathan Armstrong who are commercial lawyers with Cordery in London where their focus is on compliance issues.

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