

## The Impact of Brexit on the Chemical Industry

January 16, 2020

**Following the referendum in 2016, the United Kingdom (UK) had been due to leave the European Union (EU) on 29th of March 2019. A delay until 31st of October 2019 was subsequently agreed and a further extension was granted until 31 January 2020 to allow the UK Parliament to approve a deal for an orderly exit. This step has now been completed following the recent general election.**

This deal, which will see the UK formally leave the EU on 31 January 2020, includes provision of a transition period until the end of 2020. It is understood that during this transition period the UK will continue to follow EU regulations, including REACH.

Chemical control in EU countries fall under the EU REACH Regulation, which is managed by the European Chemicals Agency (ECHA). Once the transition period concludes after the UK leaves the EU, the REACH regulation will most likely no longer apply in the UK.<sup>1</sup> The UK government is expected to put in place a new "UK REACH" system immediately after the end of the transition period. This effective duplication of the REACH system will increase the regulatory burden for companies that manufacture or import chemicals into Europe.

This article will discuss the regulatory impact of separate REACH systems and the anticipated effect on data access. It will also discuss strategies that chemical companies can deploy now to maintain compliance and supply, including the use of a service provider who can support both UK and EU REACH registrations.

### Regulatory Impact of Separate REACH Systems

Following Brexit, chemical companies will need to consider compliance under both the EU REACH and UK REACH systems. UK companies will no longer be able to hold EU REACH registrations even if they currently have them. Consequently, a UK entity will no longer be able to act as an "Only Representative Registrant" (ORR) on behalf of non-EU manufacturers under EU REACH and non-EU manufacturers would need to appoint a new, EU-based ORR to make sure they are covered for both EU REACH and UK REACH.

Furthermore, UK companies who currently hold an EU REACH registration will need to "grandfather" their regulatory compliance status into the new UK REACH scheme to allow them to continue to manufacture in or import those substances into the UK. UK manufacturers who hold an EU REACH registration will need to appoint an ORR in the EU and transfer their registration to make sure their exports to the EU are covered under the EU REACH scheme.

<sup>1</sup> <https://echa.europa.eu/uk-withdrawal-from-the-eu>

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## Negotiation of Additional Data Access

The implementation of a new regulatory scheme in the UK is expected to pose both an administrative and financial burden on chemical companies. This is due in part to anticipated data access costs associated with registration under both regulatory systems.

EU REACH requires chemical manufacturers to submit test data to regulatory authorities commensurate to the tonnage level of a substance. The higher the tonnage, the more test data to be provided and the costlier the exercise. The UK government has indicated that the data requirements for UK REACH will be comparable to those for EU REACH. This means that companies who complete testing for EU REACH can use the same study data for UK REACH.

Unfortunately, most existing data sharing agreements between lead registrants and co-registrants are specific to EU REACH and will not cover access to support UK REACH registration. Co-registrants will need to negotiate with lead companies for a UK Letter of Access (LoA) to data, an exercise that may come at an additional price. While the EU REACH currently provides guidance for LoA pricing, similar guidance does not currently exist for UK REACH. The latter's price could be a proportion of the fee already paid for the EU LoA, or it could be determined in a different manner. It will be interesting to see if an industry standard develops for the price of this additional access over time.

Whilst a basic set of company specific information will be due within 120 days of the end of the transition period following the UK leaving the EU, the UK government has indicated that companies already registered under EU REACH will have to up to two years to arrange access to the rest of the data and submit a new registration for UK REACH. Data negotiations between lead registrants and co-registrants for UK REACH registration must, therefore, be finalized and a complete registration dossier submitted within that two-year timeframe.

## Proactive Strategies to Maintain Compliance and Supply

Chemical companies can deploy a number of strategies now to help maintain compliance and supply post-Brexit. This includes making an up-to-date inventory of substances supplied in the UK and the rest of the EU, as well as an up-to-date list of importers in the UK and EU. Companies can then determine the supply level in the UK and EU separately with the objective of determining which substances require registrations in either or both systems. UK REACH is expected to mirror EU REACH's one tonne per year limit for triggering registration.

Once the above steps have been taken, a company can make a commercial decision on how to proceed. This may be based in part on the cost associated with the UK LoA. For instance, if a company imports just over one tonne of a low-profit-margin substance into the UK, it may choose not to purchase a separate UK registration for financial reasons and voluntarily restrict supply to the UK, avoiding the regulatory burden.

Finally, it is important for non-EU companies to understand the often complex supply chain of substances which move from the UK to the EU and vice versa to ensure that they understand the regulatory obligations of themselves and their customers.

## Use of a Technical/Regulatory Service Provider to Navigate Complexities

Those companies seeking help with their compliance strategy should consider engaging a service provider who can support both UK and EU REACH registrations. Our team at Exponent offers full services to support both EU REACH and UK REACH, including regulatory strategy, preparation of EU and UK REACH registrations and negotiations with respect to data access.

Exponent is currently supporting many non-EU manufacturers and have registered hundreds of substances as an Only Representative under EU REACH. As an ORR, our registrations cover the whole of the intended EU supply chains of our non-EU clients, allowing multiple importers for each substance to be covered by a single registration. In preparation for UK REACH, we have also been working with our non-European clients to collate tonnage data to identify those substances that will require registration in the UK to aid with the commercial decisions regarding their paths forward. After Brexit, Exponent will continue to support many clients with both their UK and EU27 REACH regulatory obligations to ensure registrations across Europe are maintained as necessary.

Our team is also partnering with UK manufacturers to ensure that they can continue to manufacture chemicals in the UK and that their EU obligations will be met after Brexit. When EU REACH and UK REACH are separate, EU companies who purchase chemicals from UK suppliers and vice versa will no longer be considered downstream users. Instead, they will have registration requirements of their own. Our role includes helping UK manufacturers give advice to their customers as to the registration requirements that they will have post-Brexit or helping our clients meet their obligations by acting as a newly appointed ORR from our offices in the EU. On behalf of these UK chemical producers we are also taking steps to grandfather the manufacture of these chemicals into the new UK scheme.

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## Exponent's Expertise

Exponent offers a one-stop-shop that covers all technical and regulatory aspects of chemical regulation throughout Europe and worldwide. Specific to Brexit, our multidisciplinary team of regulatory experts and scientists can help chemical manufacturers set and/or negotiate data access prices, evaluate, summarize and submit data for EU and/or UK REACH registration, and ensure registrations are maintained as necessary.



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