Brexit & REACH: Potential Changes to UK Chemical Regulation

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29 March 2019, the date currently fixed in United Kingdom (UK) and European Union (EU) law as when the UK will leave the EU, is now just two weeks away. At this late stage, the terms of the UK's withdrawal from the EU remain unsettled. The Withdrawal Agreement agreed in draft with the EU at the end of 2018 has now been twice rejected by the UK Parliament.

Although several outcomes are possible (including the UK Parliament's eventual approval of the Withdrawal Agreement), there is currently a significant likelihood that the UK will exit the EU without any agreed withdrawal terms – a "no-deal" or "cliff edge" Brexit. This could occur either on 29 March or, if a delay is agreed between the UK and the EU, on some as-yet unspecified later date.

While the UK Parliament voted on 13 March to reject the possibility of a "no-deal" Brexit occurring and then, on 14 March, it voted in favor of a delay to the UK's withdrawal from the EU, neither of those votes serves to definitively rule out the possibility of a "no-deal" Brexit. A "no deal" Brexit remains the default position under UK and EU law.

A "no-deal" Brexit would mean an abrupt end to the UK's membership of the EU, with the immediate cessation of UK participation in various EU institutions and regimes, including the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regime.

EU REACH Continues Under the Withdrawal Agreement

Under the Withdrawal Agreement (were it to be eventually ratified), the post-Brexit regulatory framework in the UK would stay broadly the same for a transitional period. The Withdrawal Agreement provides for that transitional period to last 21 months (assuming Brexit takes place on 29 March 2019, through to December 2021).

Under the Withdrawal Agreement, the UK would continue to participate in REACH, and:

- the process for registering new chemicals under REACH during the transitional period would remain the same:
- the UK would recognise all new registrations, approvals, authorisations and classifications granted by the EU during the transitional period; and

• registrations, approvals, authorisations, and classifications in place before the UK leaves the EU would continue to be valid during the transitional period.

The New UK REACH Under a "No-Deal" Brexit

In the event of a "no-deal" Brexit, the UK must (unless other arrangements have been made) immediately implement its own chemicals regime. In that event, 'EU REACH' will effectively be brought into UK law by the UK's *European Union (Withdrawal) Act 2018* replicating EU REACH in the UK. The new 'UK REACH' will therefore retain the key principles of EU REACH, including the principle of 'no data, no market'. New chemicals placed on the European market will therefore need two separate registrations: one for EU REACH and one for UK REACH.

The relevant UK regulatory authority, the Health and Safety Executive (HSE), has advised that UK REACH may materially impact businesses:

[t]he role you currently undertake within [REACH] may change, in some cases significantly. It is therefore important that you undertake a review of your role(s) within the EU and [the new UK replacement] regimes. To maintain or gain access to the [European] and the UK markets, there may be a number of actions you will need to take if there is no deal with the EU.

The HSE's UK REACH guidance is largely directed to UK-based businesses and is framed by reference to their current roles under EU REACH. That guidance, including applicable filing and notification deadlines, can be accessed using the following links:

- Scenario 1 UK-based REACH registrants;
- <u>Scenario 2 UK-based downstream user or a distributor of an EU REACH registered chemical;</u>
- Scenario 3 UK importers or distributors of substances from outside the EU/EEA;
- Scenario 4 UK-based REACH authorisation holders;
- Scenario 5 UK downstream users of a REACH authorisation held by an EU/EEA-based company; and
- Scenario 6 entities which are exempt for the purposes of product and process orientated research and development (PPORD).

The HSE does not provide explicit guidance for businesses operating outside of the UK, EU, or the wider European Economic Area (where REACH also applies) which provide chemical substances to customers in the UK. However, it is reasonable to assume that the HSE guidance relating to EU/EEA countries should be applicable to all businesses based outside of the UK (though, of course, businesses outside of the EU/EEA region may be less aligned with REACH).

Obligations of Non-UK Businesses Under UK REACH

Under EU REACH, non-EU/EEA businesses do not have any have direct obligations. This is because such entities are not subject to the jurisdiction of either the EU institutions or those of any EU member state. However, any chemical substances marketed to the EU/EEA become subject to REACH upon entry into the region. To avoid the need for EU-based importers to register under EU REACH in lieu of non-EU/EEA entities (which, aside from being administratively onerous, could require that EU-based importers have access to the non-EU/EEA entity's confidential business information), EU REACH allows non-EU/EEA entities to appoint an 'Only Representative' to register a substance on behalf of its non-EU/EEA principal.

Unfortunately, if and when UK REACH comes into effect, existing EU REACH registrations submitted by 'Only Representatives' will not be automatically "grandfathered" into the new UK framework. Instead, grandfathering will only apply, with some information filing obligations, to the existing EU REACH registrations or authorisations of UK-based entities (including UK-based Only Representatives). Therefore, an existing EU REACH registration held by, for example, a Netherlands-based Only Representative on behalf of a US chemical manufacturer will not be grandfathered into UK REACH.

Non-UK manufacturers exporting to the UK post-Brexit may elect to appoint a UK-based Only Representative to take on UK REACH obligations post-Brexit. If they do not, then UK-based businesses importing substances from non-UK suppliers may (subject to volume thresholds) then have an obligation to obtain and hold a UK REACH registration. Such UK importers may currently be relying on the UK REACH registrations of EU/EEA -based companies.

To ensure immediate post-Brexit continued access to the UK market and to maintain supply chains, the HSE is proposing to implement a relatively light-touch 'notification' system before full registration obligations are applied to such UK importers. The specified information – which is set out in the HSE's guidance – will have to be provided to the HSE within 180 days of UK REACH coming into effect.

Any UK REACH registration by an Only Representative on behalf of a non-UK principal within 180 days of Brexit would, however, see such UK importers regain the status of downstream users within UK REACH (and they would therefore not need to become registrants themselves). The UK importers would be relieved of their duty to notify the HSE within 180 days.

Therefore, in the example above of a US chemical manufacturer, while that entity would not have any direct obligations under UK REACH, to enable it to practically continue to import into the UK post-Brexit, its direct UK-based customers would either need to register under UK REACH (as UK importers) or the US chemical manufacturer could itself use a UK-based Only Representative to effect a UK REACH registration (which the UK importers could then rely upon).

Current UK downstream users of an EU REACH authorisation held by an EU/EEA company will continue, under UK REACH, to be able to use that substance in accordance with that authorisation after the UK leaves the EU, provided they meet certain notification requirements. That element of existing UK/EU/EEA supply chains should therefore not be materially impacted.

Importantly, EU REACH registrations and authorisations which are pending when UK REACH comes into effect will not be recognised by UK REACH: new applications will need to be made under UK REACH. Further HSE guidance is available here.

Given the continued uncertainty around Brexit, businesses should continue to closely monitor developments and seek to identify how they, or their UK-based customers, may be impacted by changing circumstances, including the potential implementation of UK REACH.

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