REACH AND THE CHEMICALS REGIME IN THE UK AFTER BREXIT

With only eight months to go until the UK is likely to leave the EU, the call for certainty on the future of chemicals regulation in the UK is being made loudly by the chemicals sector, in particular in relation to the EU REACH regime.

With notoriously complex supply chains, and deep branches into all other areas of manufacturing, contingency planning for this sector is made all the more difficult (but all the more necessary) by a lack of clarity on what the UK's long-term position will be. Rightly so, many companies have been considering the implications for a no-deal Brexit in which there is no agreement on a future relationship with the EU or on a transition arrangement. With the publication of the UK Government's White Paper on The Future Relationship between the UK and EU, some clarity is emerging, at least from the UK side, which suggests a softer Brexit in areas that would include chemicals regulation. This briefing considers ten questions about the UK chemicals regime post-Brexit.

A reminder of the principal elements of the REACH regime is contained in the Annex to this briefing.

Key issues

- This briefing considers ten questions about the UK chemicals regime post-Brexit focusing on the EU REACH regime
- It covers no-deal Brexit scenarios, the emerging agreement on a transition period, and the UK White Paper position on a future agreement
- We also look at next steps and what chemical and manufacturing sector companies should be doing now
- The Annex sets out a basic overview of the EU REACH regime

Following a no-deal Brexit

1. Will a REACH registration held by a UK-based company remain valid to enable products to be sent to customers in the EU-27?

It is likely that such a registration will be void under EU law following Brexit and therefore could not operate to allow imports. This interpretation is supported by the European Chemicals Agency (ECHA).

It is possible that the company might be able to keep the registration alive by:

- Transferring its registration to an EU entity prior to the date of departure of the UK from the EU (29 March 2019 is currently set as the exit date) as part of a business transfer to that entity of the assets relating to the registration; or
- Transferring the registration upon the exit date to an Only Representative (or "OR" - see Annex) based in the EU-27. This suggestion has been made by ECHA. However, while it sounds attractive, it could only apply to a UK *manufacturer* registrant (as opposed to a UK *importer* registrant) since only manufacturers can appoint an OR. Also, it is as yet unclear whether such a transfer will be legally effective. This is a point that could be usefully clarified in the Withdrawal Agreement between the UK/EU (assuming that one can be reached).

In order to continue supplying EU-27 customers going forward if the registration cannot be kept alive, the company would need either to get its EU-27 customers to make the necessary registrations for the products or arrange for another entity to do so (perhaps its EU-27 distributor), or itself set up another group subsidiary within the EU-27 for this purpose.

Unless the UK company registers or arranges registration, its EU-27 customers may well find it easier (and less costly) to source products from an alternative supplier in the EU-27 which has perhaps already registered the relevant substances.

Similar considerations would apply to a REACH authorisation or application for an authorisation.

2. Will a UK company be able to rely on its pre-Brexit REACH registrations / authorisations for compliance under a replacement UK regime?

This will depend to a large extent on the way any replacement chemicals regime is implemented in the UK following a no-deal Brexit. The recently passed European Union (Withdrawal) Act 2018 will effectively create a parallel UK REACH regime (the UK REACH Regime) subject to any changes the Government needs to make by statutory instrument to make the regime work effectively. The Government is currently considering what those changes might be (see further Question 9).

In giving evidence to the House of Lords EU Energy and Environment Sub-Committee on 18 July 2018, Environment Minister Thérèse Coffey stated that the Government is considering allowing existing REACH registrations by UK-based companies to be 'grandfathered' so that they would be valid within the UK system for manufacture in, and import into, the UK after Brexit. It is difficult to see how this would be workable without access to existing data in the ECHA databases and to REACH IT systems. Ms Coffey suggested that the Government could simply copy over the ECHA database for these purposes, but acknowledged that there may be intellectual property and commercial confidentiality issues with this approach. If there is no agreement with ECHA in this regard, the Government may require UK based companies to submit duplicate information to a new UK REACH database, or alternatively simply allow EU REACH registrations to continue to be valid for UK purposes without the data being submitted.

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REACH registration relies on a great deal of data sharing between registrants for the purposes of making and maintaining a registration. Registrants' data sharing arrangements might not be sufficiently flexible to allow data sourced from pre-Brexit EU REACH registration activities to be used for a company's ongoing compliance with the UK REACH Regime.

3. What are the implications for a UK-based customer which sources its products from EU-27 suppliers?

Currently, the UK-based customer will rely upon its EU supplier to register substances under the EU REACH regime as necessary. When the UK leaves the EU, the UK will become a third country, at which point the UK company may become liable for the first time as an "importer" under the new UK REACH Regime for making any necessary registrations. Significantly, in order to avoid a gap in the regulatory framework, the UK REACH Regime would need to be in place (with all registrations in place) by the exit date.

Although unpalatable, UK customers might consider whether they could or should begin the process of registering under the EU REACH regime or the UK REACH Regime now, but there is no clear route to do so:

- The UK customer cannot yet register under the UK REACH Regime as it does not yet exist in implementable form (and may not exist if a deal is agreed with the EU);
- The UK customer cannot register under the EU REACH regime in the expectation that the UK REACH Regime would accept that registration under 'grandfathering' arrangements because currently it is not an 'importer' under the EU REACH Regime, and therefore cannot register.

A similar issue applies for the EU customers referred to in Question 1. The Government has recognised that these issues exist, and apparently has discussed them with ECHA, but no solution has yet been identified.

4. Will a non-EU manufacturer using a UK-based OR to register under REACH be able to continue to access the EU-27 market after Brexit?

Yes, but it will need to make some changes. A UK-based OR will not be able to carry out duties under the EU REACH regime in relation to registration or authorisation of substances after the exit date. There are two main options. Either:

- The OR could relocate to be based in the EU-27, or
- the non-EU Manufacturer will need to appoint a new EU-27-based OR.

In each case, this will involve administrative changes (including on the REACH IT system) but not a new registration or authorisation.

Transition period

5. What would happen during any transition period?

The current draft of the withdrawal agreement being negotiated between the UK Government and the EU contains a transition period running from the exit date until 31 December 2020. This transition period would be intended to allow the UK and EU time to finalise an agreement on a future relationship between them and other associated arrangements, thereby avoiding a potential 'cliff edge' of regulatory chaos that might otherwise arise on the exit date. The second draft of the withdrawal agreement, published in March 2018, includes a number of key provisions relevant to the chemicals regulatory regime. These are agreed at negotiator level, although they would only take effect if, and when, there is full agreement on the document, many aspects of which remain very controversial.

Under the draft withdrawal agreement, EU law would apply to the UK during the transition period. This would mean that, to all intents and purposes, UK companies would be governed by the EU REACH regime, and the issues raised in Questions 1 to 4 above would be delayed to the end of the transition period. While this appears to give some breathing space to the chemicals sector, the possibility of there being no agreement, or that any agreement will come very late in the day in March 2019, means that this might not provide significant comfort.

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During any transition period, the draft withdrawal agreement provides that the UK will have no role in decision-making at EU level. Also, during the transition period the UK would not be able to act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union (or in situations where Member States act jointly) in relation to REACH. As such, the UK would have very little role or influence in the chemical evaluation or authorisation processes for REACH during the transition period but the UK would be subject to all of its requirements.

Softer Brexit scenarios

6. Is it possible that the UK will stay in the REACH regime? Or is some other agreement with the EU on chemical regulation likely?

The chemicals sector and major chemicals players have been clear in wanting to remain in REACH, or at least be closely aligned to it, not least to avoid the duplication of controls that would be entailed by parallel UK and EU-27 regimes co-existing with no interaction between them.

While the political situation is difficult to predict, it seems unlikely at this stage that the Government would decide to stay formally within the REACH mechanism as this would require the UK to be subject to both ECHA and ultimately Court of Justice of the EU jurisdiction – crossing one of the red lines set out by the Government for its Brexit negotiations. Certainly, the White Paper does not envisage full membership of REACH in this way (see Question 7 below).

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It is interesting to note that during its consideration of the Trade Bill on 17 July 2018, the House of Commons voted to accept an amendment which would require the UK to negotiate an agreement with the EU to allow the UK to fully participate in the European medicines regulatory framework after Brexit. It remains to be seen whether similar attempts will be made to keep the UK more fully within the EU REACH regime.

7. Has anything been agreed yet with the EU?

Beyond the provisions relating to the transition period (See Question 5 above), very little has been agreed so far relating specifically to the future relationship between the UK and the EU on chemicals regulation. The second draft withdrawal agreement provides that goods that have been lawfully "placed on the EU market or UK market" before the end of the transition period can be marketed or used either in the UK and EU in the future.

This would allow EU REACH registrations and authorisations in existence before the end of the transition period, effectively to remain alive. To give an example, a UK manufacturer that manufactured and placed a consignment of chemicals on the market in the UK before the end of the transition period under a valid REACH registration could subsequently export that substance from the UK to France after the end of the transition period without further requirements for registration upon entry into France. The manufacturer would need to be able to prove that it placed the consignment on the market before the relevant date. Goods are "placed on the market" when they have first been supplied for distribution, consumption or use on the UK or EU market. Additional provision is made for supervision of such goods on the markets to ensure compliance with relevant rules.

Note that if the withdrawal agreement is not signed in this form, or at all, these provisions would not apply and all pre-exit date EU REACH registrations and authorisations are likely to be void as per the discussions in Questions 1, 2 and 3 above.

8. What is the UK seeking under the White Paper proposals?

The White Paper sets out more detail on the Government's post-Brexit intentions for an agreement on the future relationship with the EU in many areas. These are simply the UK's aspirations for a deal; no detailed comment on the proposals in the White Paper has yet been provided by EU negotiators.

The UK and EU would maintain a "common rulebook" on regulations applying to manufactured goods covering "only those rules necessary to provide for frictionless trade at the border". This would include matters such as compliance with REACH and regulations on hazardous substances. It would seem likely that this will extend at least partially to the separate EU rules on classification and labelling of chemicals (CLP) under which the EU adopts the UN Globally Harmonised System.

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Key points in the White Paper relevant to the chemical regulatory regime are set out in the box below:

White Paper highlights for chemical regulation

- Manufacturers would only need to undergo one set of conformity tests in either market in order to place products in either market. This would create a form of "mutual recognition" arrangement.
- The UK would participate in ECHA (by way of "associate membership") for the purposes of relevant compliance activity and have access to relevant data and systems (including presumably the REACH database and REACH IT system). The UK would be willing to pay for such participation.
- Under REACH, UK businesses would be able to continue to register substances directly (presumably meaning with the UK Government rather than registering with ECHA through an EU based representative).
- The CJEU would have jurisdiction in relation to disputes over decisions of ECHA. Also the UK would accept that the CJEU would have a role in interpreting elements of EU law necessary to operate the common rulebook, and the UK would take account of EU case law on the subject.
- Parliament would pass legislation to implement the common rulebook, from which it could diverge. However, any divergence "would be in the knowledge that it would breach the UK's international obligations, and the EU could raise a dispute and ultimately impose non-compliance measures". These could include "localised rebalancing measures" such as financial compensation, or, ultimately, suspending the relevant part of the relationship.
- Arrangements would be put in place to deal with changes in laws over time affecting the common rulebook. Decisions and disputes on these would ultimately be determined by a Joint Committee established as a governing body of the future UK / EU relationship (which would be formed of UK and EU political leaders), or by an arbitration panel appointed by it, but the arbitration panel would follow CJEU decisions.
- There would be cooperation arrangements between UK and EU regulators to allow co-ordinated enforcement action. This would allow ECHA and the UK enforcement body (likely to be the HSE) to ensure that products placed on each other's markets comply with relevant registration, authorisation and restriction requirements.
- All authorisations, and approvals and agency activity undertaken before the end of the transition period would be recognised by both UK and EU authorities for the future.

It seems likely that the common rulebook for chemicals will involve the UK signing up effectively to operate a REACH regime based on EU rules. At a basic level, this is likely to mean that, after the transition period, a UK-based company would make registrations and seek authorisations from the UK regulatory body (likely the UK HSE) under the UK REACH Regime. These UK REACH registrations and authorisations would be recognised by the EU-27 and be sufficient to enable the UK company to place relevant products on the EU-27 market. EU REACH registrations and authorisations obtained by EU-27 entities, would correspondingly be accepted by UK authorities for the purposes of the UK market. This seems a useful step. Much detail would need to be filled in by the parties in the future agreement, but a number of key questions arise. By way of example:

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- What arrangements would be put in place for joint registrations by UK and EU-27 registrants; e.g. could they choose which authority to register with?
- Will the UK authorities be able to develop and operate their own Authorisation Lists or Restriction Lists? Presumably not since the creation of parallel but different lists could lead to an uneven regulatory playing field. Does this mean that the UK would simply have to adopt whatever lists are agreed from time to time by ECHA / the EU-27? Would the UK effectively therefore be signing up to remain in REACH subject to Parliament deciding to diverge from it in due course with consequent implications for access to EU markets?
- If the UK has to sign up to common lists (as above), what say would the UK have within this framework as an Associate Member of ECHA? Much of the work at EU level to decide upon the hazardous nature of chemicals currently involves co-operation between Member States, and EU institutions, e.g. in relation to evaluating chemicals, proposing substances which will be subject to authorisation or restriction. Would the UK have a full role and vote as if the UK was still a member of REACH and be able to act as lead authority in evaluating chemicals?
- Would the UK be able to grant its own REACH authorisations or would this need to be done within the framework of its participation in ECHA? The UK may very well take different view on risk assessment in this context.

Whether the UK will be able to negotiate a workable package which resembles its proposed common rulebook with the EU remains to be seen. Remarks from EU leaders more broadly rejecting a "cherry-picking" approach to access to the single market suggest that this is not going to be easy.

For a broader perspective on the White Paper, see our briefing: "Britain's Brexit Blueprint: The UK Government publishes its future relationship white paper".

Next steps

9. What happens next?

The UK Government is continuing to negotiate the withdrawal agreement with the EU. Subject to any further political turmoil on its approach to Brexit, and the view taken by EU negotiators on the White Paper, it will now seek to step up negotiations on the future agreement, including on elements relating to the common rulebook for regimes such as REACH.

The Government is also preparing the statutory instruments to make necessary changes to chemicals legislation (among many other areas). We understand that separate sets of SIs are being prepared for different scenarios, though drafts that have so far been published relate only to the first of the scenarios:

- On the assumption of a no-deal Brexit;
- Dealing with rules covering a transition period; and
- Dealing with a future agreement.

The most immediate concern is to understand what the SIs will need to cover for a no-deal Brexit. Necessary changes would include designating a UK body as competent authority for the UK REACH Regime. They would also need to cover removal of provisions dealing with the involvement of ECHA and EU-27 Member States in processes relating to registration dossier evaluation, and procedures for adding substances to an Authorisation List, granting of authorisations and approval of new restrictions. Legislation would also need to cover the establishment and operation of a new UK REACH database and IT infrastructure.

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10. What should chemical companies and others involved in the chemical supply chain be doing now?

It is tempting for chemical sector companies to delay preparations for Brexit until there is further clarity on an agreement for a transition period, and on the shape of a future agreement. However, the clock is ticking steadily towards the exit date, and concerns are growing about the likelihood of a there being no deal by that date.

The complexity of chemical and other manufacturing supply chains, and the time needed to make structural changes to these arrangements mean that contingency planning should be well underway. In any event, UK-based companies should be mapping out their supply chains and considering issues such as:

- What would happen to their registrations / authorisations (and related applications) in a no-deal scenario.
- Whether options are available to allow registrations and authorisations to remain valid after Brexit, including the possibilities for use of EU-27 based entities and representatives.
- How responsibilities for registration and authorisation may change based on a no-deal scenario, especially any new obligations on parties for registration / authorisation applicable in the UK or EU-27 which previously did not exist.

- How data sharing arrangements on registration might be affected by Brexit – e.g. can shared data be used in future for UK registrations under the UK REACH Regime.
- How relevant business contracts may need to be amended to deal with the various consequences and risks of a no-deal Brexit, or indeed for a future where the UK continues to participate in REACH in some way.
- For downstream users – understanding how their suppliers may be affected by the changes and whether they may need to take on REACH registration duties or consider the possibility of alternative suppliers, e.g. in the event that current suppliers drop out of the market or will not support new registrations or authorisations.

Of course, many other related issues will also need to be considered, such as customs formalities and payment of any tariffs, as these may have a bearing on the above issues.

Companies should also be working closely with their representative organisations and putting forward their vision of a future relationship with the EU on chemicals regulation, and the extent to which the UK should formally participate in REACH mechanisms and ECHA.

Click here to see the UK White Paper: *The Future Relationship between the United Kingdom and the European Union*.

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ANNEX

BASIC OVERVIEW OF THE EU REACH REGIME FOR CHEMICALS

REACH applies in EU member states and also territories of the European Economic Area.

Registration

In basic terms, before a company manufactures a substance in the EU, or places it on the market in the EU, at volumes of 1T/year or more, it must register that substance with the European Chemicals Agency (ECHA). Registration duties are therefore placed on EU manufacturers and EU importers of substances into the EU.

Registration is made in respect of specific uses of the substance – this entails information exchange up and down the supply chain to ensure those registering a substance know what their customers use the substance for, and can judge whether the use is safe.

In principle, only one registration is made per substance – this requires consortia of companies registering the same substance to work together, share data (and cost), and submit the registration. Significant amounts of data have to be collected and analysis performed on substance identity, characteristics, impacts and safe use. A non EU-manufacturer can employ an EU-based representative (called an Only Representative) to register a substance on its behalf in the EU.

Authorisation

Following a complex evaluation process undertaken by Member States, ECHA and the European Commission, the Commission can add substances judged to have certain harmful qualities to an Authorisation List. A company cannot use in the EU, or place on the market in the EU, a substance on the list unless that particular use of the substance has been authorised by the Commission. A downstream user (e.g. a EU customer of a UK manufacturer), can rely on the Manufacturer's authorisation as long as it covers the downstream user's use.

Restriction

Following a consultative process at EU level, harmful substances can be added to a Restriction List and are then subject to total or partial restrictions on use, or placing on the market

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