Brexit: Preparing for a future «UK out of REACH scenario»

What you need to know - Practical considerations to maintain trade post Brexit

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Introduction

The European chemical industry is convinced that the best guarantee against market disruptions is the UK remaining in the REACH legislation, including their activity within ECHA. Due to the highly interconnected nature of chemicals supply chains, Brexit will have important implications in the area of chemicals regulations for companies both in the UK and in the EU27/EEA countries. If the UK is leaving REACH, UK businesses will become “non-EU entities”. In case of the worst case “no-deal” scenario REACH will stop applying to the UK already from 30 March 2019 at 0h CET, 29 March 2019 23h UK time. Through the EU (Withdrawal) Act, the UK Government will convert REACH into UK law on UK exit day. This approach means that similar regulatory requirements to manufacture and import chemical products in the UK will apply on the UK exit day and beyond. Registration, evaluation, authorisation and restrictions will remain key elements of a UK REACH scheme. For the time being and whilst REACH applies to the UK, UK businesses are considered “EU legal entities” under EU regulation.

This briefing note is aimed at supporting business across Europe in preparing for the potential effects Brexit may have on compliance with either chemical law. The advice provided in this document is based on the assumption that the UK would be leaving REACH as result of Brexit. If this scenario materialises, as industry bodies we will continue to engage with authorities both in the UK and in the EU27/EEA with the aim to ensure the challenges companies both in the EU27/EEA and in the UK will face to maintain REACH compliance are minimised.

Note: This document addresses the impact of Brexit on REACH registration compliance as “licence” to operate in the single market. Similar considerations should be made on other aspects of REACH compliance as well as for other chemicals regulations such as CLP, BPR and PIC. From a trade perspective, impact on potential tariffs, IPR (Trademarks), Rules of Origin, Incoterms, VAT systems migration should also be taken into account as part of companies’ strategies and planning for the upcoming UK departure from the EU.

The issues

- Many EU27/EEA and UK based downstream users are currently relying on the 21,000 plus substances registered under REACH by their upstream supply chain.
- With UK leaving the scope of EU REACH, downstream users may become importers under the regulations overnight and consequently would need to complete their own registration or rely on their third country suppliers to appoint an Only Representative (OR).
- As no import into the EU27/EEA can take place until registration of the substance (as such or in mixture or intended release from articles) is complete (requiring several months), the above mentioned situation creates the risk of losing the supply of chemicals, requiring registration under REACH (as such or some ingredients), and is likely to impact industrial value chains. Moreover, different as in the UK (see below), no transition period to allow for the continuity of the supply chain is foreseen on the EU side.
- Following Brexit, EU27/EEA sales to the UK will have to comply with the relevant UK legislation (UK REACH) under extremely tight and challenging timescales. To not discontinue the import for several months, a transition period for registration is defined if the substances to be registered under UK-REACH are notified within 180 days after Brexit. (At the moment, no equivalent notification scheme is foreseen at EU side.)
• Beyond registrations similar disruptions are expected for existing REACH authorisation holders and their related supply chains (e.g. component manufacturers, chemical formulators) who will no longer be able to rely upon authorisations granted to UK based companies.

• Performing studies, providing and gaining legal access rights to data for registration is likely to be a time consuming and expensive part of registering substances, requiring early alignment of registrants in the UK.

1. Maintaining access to EU single market: considerations for UK-based businesses

Impact of Brexit on UK-based companies who trade with the EU27/EEA depends on their specific role under REACH. In order to continue to trade with the EU27/EEA post Brexit, companies should be mindful that the following scenario will apply from the date REACH stops applying in the UK:

• UK-based chemical manufacturers will not be able to register directly under REACH, but will need to appoint EU27/EEA-based only representatives (ORs) for their substances - such as companies’ affiliates or consultants, or to relocate their manufacturing activities to the EU27/EEA or to rely on EU27/EEA based importers to register under REACH;

• UK-based importers and traders would need to establish themselves or transfer their business to a company in the EU27/EEA, as they won’t be able to appoint EU27/EEA-based ORs. Under REACH, only non-EU27/EEA manufacturers of substances, formulators of mixtures and manufacturers of articles can appoint an OR;

• UK-based companies currently acting as OR under REACH, on behalf of non-EU27/EEA manufacturers, won’t be able to continue in that role. The non-EU27/EEA manufacturer will need to appoint a new OR based in the EU27/EEA to continue to supply to the EU27/EEA. The change of OR must take place in REACH-IT, during the Brexit window from 12 to 29 March, 24:00 hours CET (11 p.m. UK time). Only complete registrations can be transferred. A follow-up will be needed by the successor after the transfer. This is explained in the new ECHA step-by-step guidance (https://echa.europa.eu/documents/10162/13552/how_to_transfer_uk_reach_registrations_en.pdf/1fb443ce-79de-6596-aae5-3f1033f1a5fb)

Practical considerations to ensure continued validity of existing REACH registrations in the EU

✓ It is important to identify substances/mixtures impacted by Brexit and your company’s role in the supply chain. Special attention should be given to the list of 1181 substances that are only registered by UK LE’s, as published on the ECHA website.

✓ If a substance is manufactured by a UK legal entity as well as by an EU27/EEA legal entity of the same company and both hold valid registrations, the EU27/EEA entity could act as importer of the UK product. In this case, the EU27/EEA legal entity’s existing registration would need to be updated to indicate the additional volume being imported in the dossier. Please be mindful that higher tonnage bands may be reached and further testing required as a consequence. An OR would not need to be appointed in this case and transfer of registrations would not be required.

✓ The scenario of transferring of registrations is already envisaged under specific circumstances that are not necessarily related to Brexit, e.g. for changing OR, partial or total asset transfer, mergers, spin-offs, splits (please see ECHA guidance for further information).

✓ UK manufacturers and importers will need to maintain their registrations in the UK to be able to continue to manufacture/import in the UK until REACH stops to apply to the UK.

✓ The ECHA website currently states that a possibility to transfer existing registrations “immediately” before the withdrawal date will be put in place in the case of registrations hold by UK
manufacturers and practical steps will be clarified in due course. As part of your contingency planning, please assume that REACH IT UK accounts will be deactivated from the date REACH stops applying in the UK, so transfer of registrations should be initiated before the BREXIT date and can be completed by payment of the registration fees after the UK leaves the EU REACH regime. Companies are advised to follow ECHA news alerts as new information will emerge in due course.

✓ ECHA is currently advising to set up a contractual agreement to appoint an OR, which contains a suspensive conditional clause stipulating that the appointment takes effect on the date when the UK withdrawal from the EU takes effect. A text template for contracts with ORs is provided below.

In order to overcome the current uncertainties as regards the exact BREXIT date in the contract with ORs, Cefic suggests using the following suspensive clause:

“By this agreement company [XX] established in the United Kingdom appoints company [YY] as its Only Representative pursuant to Article 8 of Regulation (EC) No 1907/2006 (“REACH regulation”) to undertake all activities necessary subject to the REACH Regulation.

The agreement shall take effect at the time of signature of the present agreement by both parties. The appointment of the Only Representative shall take effect at the time of the UK’s withdrawal from the EU (i.e., at 00.00 hours CET on 30 March 2019; 11 p.m. UK time on 29 March 2019) or at a later date in case of an extension of the withdrawal date in accordance with Article 50(3) of the Treaty on the European Union [suspensive clause] or, if the Withdrawal Agreement concluded between the EU and the UK is ratified and thereby establishes a transition arrangement, at the time of the end of the transition period (i.e., at 00.00 hours CET on 1 January 2021; 11 p.m. UK time on 31 December 2020 – subject to any changes resulting from waiving the use of summer time within the EU or at later date in case of an extension of the transition period in accordance with Article 132 of the Withdrawal Agreement) [conditional clause]”

✓ In the case of UK importer registrations according to ECHA “it is not possible to transfer a registration of a UK importer to a newly appointed Only Representative. In this case, non-EU manufacturers may appoint an EU27/EEA-based Only Representative of the substance. However, the EU27/EEA-based Only Representative would then need to submit a new registration for the substance”. According to ECHA Brexit Q&A 1539, UK-based importers will be able to transfer before the UK withdrawal individual registrations to EU27/EEA legal entities that would replace them as importers post Brexit, if this transfer is the result of a legal entity change, i.e. the actual importing business is transferred to a legal entity in the EU27/EEA.

✓ If not already done, please review your contractual conditions of SIEF/consortia agreements in order to prepare for the potential future transfer of rights to refer to data to an EU27/EEA subsidiary or representatives so they can take over the EU27/EEA registration. The Cefic SIEF agreement template, for example, allows for the right to transfer the non-Lead Registrant’s rights and obligation in the case of legal entity change without obtaining the renewed consent from the SIEF Lead Registrant, subject to acceptance by the assignee of the terms of the SIEF agreement, to be notified to the Lead Registrant without undue delay. This is foreseen in the template agreement only in case of transfer to a company’s affiliate (please check definition of affiliate), or to a legal successor in ownership in the event e.g. of a sale or merger of the business relevant to the substance. In other cases you may have to check with the lead registrant before the transfer can take place.

✓Registrations that are transferred in REACH-IT may require a subsequent dossier update (subject to conditions specified in Art. 22 of REACH) to include the legal entity’s details where registrations are transferred to. The EU27/EEA successor would then need to complete an update of the dossier for all the registrations it receives from the UK, if e.g. the role of the registrant (e.g. manufacturer to OR) or the tonnage band change.
✓ In the case of mixtures, UK formulators may need to track raw materials imported from the EU27/EEA to confirm future “re-import” to EU27/EEA status (REACH registration exemption, Art. 2.7).

NOTE: UK based companies should also bear in mind that under a “UK out of REACH scenario” manufacturing and import will be subject to UK legislation in future (see section 3).

2. Considerations for EU-based companies with UK supply and trade relationship

Post Brexit, imports into the EU will continue to be subject to REACH. Once the UK leaves the EU REACH regime, EU27/EEA businesses relying on REACH registrations from UK suppliers will become importers under EU REACH and in this case are subject to registration requirements, unless they can purchase the substance from suppliers in the EU27/EEA who have a REACH registration or are covered by EU27/EEA-based ORs appointed from UK companies.

✓ Check the list of your actual suppliers and approved suppliers of your substances and mixtures;
✓ Identify substances and mixtures that are sourced from UK suppliers through an inventory;
✓ Please bear in mind that registrations are per legal entity, not per company;
✓ Check whether UK suppliers plan to appoint an EU27/EEA legal entity that will act as EU27/EEA based OR post Brexit to ensure continued supply in the EU27/EEA or if there is or will be another EU27/EEA importer;
✓ If you are yourself already importing a substance and at the same time you have a registration under your company name, you can continue to be supplied from the UK source as you can be covered by your own registration. Your dossier would need to be updated in due course once the UK leaves REACH to indicate the additional volume being imported in the dossier. Please be mindful that higher tonnage bands may be reached and further testing required as a consequence.
✓ If there are other suppliers in the EU27/EEA countries, or other non-EU27/EEA suppliers covered by an OR in the EU27/EEA, they may be able to support you. If they are not approved yet by your company, you may have to initiate the process of approval of a new supplier, which may be rather cumbersome and time consuming in some cases (finding another supplier for a catalyst as an example will be more cumbersome than finding a replacement for a solvent like acetone).
✓ If the other options are not available or you are not sure, you have to reflect on whether registering substances on their own or in mixtures as EU27/EEA importer post Brexit may be a way forward (if import into the EU27/EEA reaches 1 tonne or more per year). A registration as importer would allow to import from different non-EU27/EEA sources if the substance is the same and if allowed by your quality system and your requirements for approving new suppliers. However, the EU27/EEA importer can only start importing once ECHA has confirmed the completeness of the registration, or three weeks after the submission date, if there is no indication to the contrary from ECHA.
✓ Please remember that in the case of mixtures, a EU27/EEA supplier of a mixture may also be dependent on a UK supplier for a substance or for a mixture in a mixture.
✓ If your supplier of a mixture can confirm to you that their suppliers of the substances used for the mixture are situated in the EU27/EEA then no problems are expected. In all other cases there may be a risk of potential supply chain disruption if no action is taken in future.
✓ Substances in stock, registered by the manufacturer/importer/Only Representative located in the UK, placed on the market of the EU27/EEA before the withdrawal date, can continue to be placed on the EU27/EEA market and be used after the withdrawal date. However, any consignment of a
substance imported into the EU27/EEA market as of the withdrawal date has to be registered in accordance with the EU rules, i.e. it requires the registrant/Only Representative to be established in the EU27/EEA.

NOTE: If your company sells chemical products in the UK, please take into consideration that imports into the UK from the EU27/EEA will be subject to UK legislation in future (see section 3)

3. Implications of a future UK REACH for UK and EU27/EEA companies

Under a future UK REACH, registration of substances will likely be required under almost identical conditions as those under REACH. This will include requirements for data based on tonnage bands. Under a no-deal scenario, the UK REACH legal instrument is expected to be effective as of 30 March 2019. The time periods foreseen in UK REACH to submit a full registration are time-limited (2 years). Substances registered after the respective deadlines are considered to be “new chemicals” and need to be registered before import or manufacture. It should be noted, that most chemical products are mixtures of several substances. Suppliers of chemical products therefore have to ensure that all substances, including the ones they purchase, are duly registered under the respective legislation.

As with REACH, non-UK legal entities who are manufacturers of a substance on its own, in mixtures or in articles, formulators of mixtures or producers of an article and importing into the UK, will be able to appoint UK based ORs if they wish to relieve UK customers from registration obligations under a UK REACH. Existing UK downstream users currently relying on their EU27/EEA supplier appoints a UK OR, gains the legal right to use existing data for UK-REACH and manages new registrations within 6 months. However, if the UK downstream user or UK distributor submits a “notification” within 6 months to the UK Agency, the appointed UK OR will have 2 years to submit the registration. Companies are advised to identify all products that are exported to the UK market.

In the event of a no deal outcome the following actions arise and should be considered as a result of a UK REACH need to be considered.

- UK-based companies with REACH registrations valid at least until 29 March 2019 need to notify the UK authority within 120 days from 30 March 2019 at 0h CET, 29 March 2019 23h UK time and then resubmit registration data in the UK within 2 years (by 30 March 2021) for products already registered under REACH.

- UK companies (currently downstream users) that source products from EU27/EEA suppliers will become UK importers under UK REACH and will be subject to UK REACH registration obligations. A notification within 180 days from 30 March 2019 at 0h CET, 29 March 2019 23h UK time is required as interim arrangement with full registration expected at a later date. It is important to identify all substances manufactured and imported into the UK that may be subject to a UK REACH and check if you have any information available about these substances. If your EU27/EEA supplier plans to appoint a UK OR the initial notification you make to UK authorities will allow a longer timeframe to submit a registration by the appointed OR.

- Manufacturers of a substance on its own, in mixtures or in articles, formulators of mixtures or producers of an article imported in the UK, based outside the UK (including EU27/EEA businesses) will be in the position to appoint UK based only representatives if they wish to relieve UK customers from registration obligations under a UK REACH. REACH only representative provisions under Article 8 will be transposed into UK legislation.
• Placing chemicals on both the EU27/EEA and UK markets in a ‘no deal’ scenario would mean two separate registrations, one to ECHA and one to the UK Agency, are required with a similar or ideally the same data package. Therefore, SIEF participants should verify the scope of their usage rights in relation to the information contained in the REACH registration dossier – and, as the case may be – seek adjustment of existing contracts, based upon their respective contracts.

• As in EU REACH, UK REACH will likely require registrants to hold the rights to refer to substance-specific data contained in the registration dossier submitted under UK law. Study data are usually owned by an individual entity or a consortium of companies. Lead registrants are usually granted a sub-licensing right by the respective data-owners, and co-registrants receive a Letter of Access as proof that they have the right to refer to the data in order to fulfill their registration obligations.

When being the joint data owners, consortium members will be asked determine the conditions under which existing studies may be used for UK REACH purposes. REACH requires the registrant to either own or have a right to refer to studies summarised for the purpose of registration with ECHA. Such rights are granted for the validity area of REACH, i.e., for the time being EU28 plus Norway, Iceland, and Liechtenstein (EEA). This naturally includes the United Kingdom. After a Brexit, registrants based in the UK or wanting to appoint an OR located in the UK will require a separate right to refer to fulfil local registration requirements.

Various systems may exist, for example, owners of rights to refer for EEA including EU28 could in addition receive a separate right with equal scope (same tonnage band) for the United Kingdom with or without financial compensation. Rationale for it being at no additional fees: the compensation for the right to refer had been paid with the aim to be able to act in EEA including EU28. This interest persists unchanged after a Brexit. As the change of the legal situation was not created intentionally by any of the contract partners, there is no reason to require an additional compensation then. At the same time, enormous additional administrative efforts are avoided. However, it is for each contract partners, to decide, based on their own decision-making process, on best to organise for this, including on the financial side.

• Registrants in the UK are advised to form consortia and nominate a lead registrant as early as possible. They should try to leverage as much as possible of the lead dossier provided under REACH.

A technical notice on regulating chemicals under no-deal scenario published by the UK Government is available here. The technical notice is complemented by additional guidance on UK REACH in case no deal Brexit.
Further information:

**ECHA**

**Commissions webpage**

**UK Government**
- [https://www.gov.uk/government/brexit](https://www.gov.uk/government/brexit)

**Industry positions (CIA/Cefic)**
- [https://www.cia.org.uk/Policy/Our-positions](https://www.cia.org.uk/Policy/Our-positions)
- [http://www.cefic.org/newsroom/News/](http://www.cefic.org/newsroom/News/)

**Brexit milestones and expected timelines**

23 June 2016: the UK voted to leave the EU

29 March 2017: UK’s notification to leave the EU sent; 2 year negotiation period started

25 November 2018: Brexit negotiations finalised. EU Council agreed UK’s EU Withdrawal Agreement and political declaration on future relationship framework

15 January 2019: EU Withdrawal agreement rejected by British Parliament

29 March 2019: UK leaves the EU at 11pm UK time

30 March 2019: UK leaves the EU at 0h CET

UK leaves REACH on 29 March 2019, 11 pm UK time/30 March 2019, 0h CET, unless a transition is ultimately agreed.

Only if withdrawal agreement, including the transition period, is concluded: 31 December 2020. An extension of the transition period by one or two years is then possible. REACH will no longer be part of the UK legal system at the latest at the end of the transition period.

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