

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

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. As the EU/UK transition period comes to an end, REACH will stop applying to the UK on 1 January 2021 at 0h CET, 31 December 2020 23h UK time. Through the EU (Withdrawal) Act, the UK Government will convert REACH into UK law at the end of the transition. This approach means that similar regulatory requirements to manufacture and import chemical products in the UK will apply once the transition period ends and beyond. Registration, evaluation, authorisation and restrictions will remain key elements of the UK-REACH scheme. For the time being and whilst EU-REACH continues to apply, 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 EU-REACH at the end of the transition period with no agreement in place on future EU/UK cooperation on chemicals. 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 future UK/EU relationship.

Please also note that the document doesn’t yet address any potential negotiated outcome with the EU or take yet into account the future implementation of the Ireland/Northern Ireland Protocol. This document is for general guidance only and cannot serve as substitute for legal advice.

The issues

- Many EU27/EEA and UK based downstream users are currently relying on the 23,000 plus substances registered under EU-REACH by their upstream supply chain.
- With UK leaving the scope of EU-REACH, EU27 and UK downstream users may become importers under both EU and UK-REACH respectively 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, differently to the UK (see below), no transition period to allow for the continuity of the supply chain for EU27 downstream users becoming importers is foreseen on the EU side.
- Following the UK departure from EU-REACH, 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 of substances for several months, a transition for registration is

envisaged if substances to be registered under UK-REACH are notified. (At the moment, no equivalent notification scheme is foreseen on the EU side).

- Complex value chains supplying chemical substances and mixtures from the EU to the UK and vice versa will be put into question with decisions taking place at each level of the value chain as to whether or not the efforts to meet duplicative compliance obligations are justified.
- 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

The impact of Brexit on UK-based companies who trade with the EU27/EEA depends on their specific role under EU-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 EU-REACH stops applying in the UK:

- UK-based chemical manufacturers will not be able to register directly under EU-REACH, but will need to appoint EU27/EEA-based 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 EU-REACH;
- UK-based importers and traders of substances from outside the EU (who do not further formulate) would need to establish themselves or transfer their business to a company in the EU27/EEA if they don't wish to rely on EU importers to register, as they won't be able to appoint EU27/EEA-based ORs. Under EU-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 EU-REACH, on behalf of non-EU27/EEA companies, 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 before the end of the transition period. Only complete registrations can be transferred. The successor will need to accept the transfer before the end of the transition. This is explained in the [ECHA step-by-step guidance](#) on how to transfer UK registrations.

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 substances that are only registered by UK legal entities, 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 substance. 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 need to maintain their registrations in the UK to be able to continue to manufacture/import in the UK until EU-REACH stops applying in the UK.
- ✓ A possibility to transfer existing registrations “immediately” before the end of the transition period is envisaged in the case of registrations held by UK manufacturers. As part of your contingency planning, please consider that UK companies will no longer have full access to the REACH IT accounts once the transition period ends, so transfer of registrations should be initiated before the end of the transition and can be completed by payment of the ECHA registration fees after the UK leaves the EU-REACH regime. Companies are advised to continue to follow ECHA news alerts.
- ✓ ECHA is currently advising to set up a contractual agreement in order to appoint an OR, which contains a suspensive conditional clause stipulating that the appointment takes effect on the date when the UK withdrawal from EU-REACH takes effect. 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 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) [conditional clause]”
- ✓ UK-based importers can transfer before the end of the transition period 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. UK importers cannot appoint an OR in the EU/EEA. However, if they act as a formulator (i.e. import a substance into the UK, and include the substance in a mixture that is exported to the EU27/EEA), they can appoint an OR for the quantities of the substance that they formulate into a mixture that they export to the EU27/EEA (ECHA Q&A 1539).
- ✓ 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 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 also complete an update of the dossier for all the registrations it receives from the UK based company, 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 (registration exemption, Art. 2.7).

<p>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 (see section 3).</p>
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2. Considerations for EU-based companies with UK supply and trade relationship

Imports into the EU will continue to be subject to EU-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 to ensure continued supply in the EU27/EEA or if there is, or will be, another EU27/EEA importer or manufacturer that you can source from;
- ✓ 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 EU-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 supply 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 and consideration of material equivalency may be an issue).
- ✓ 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 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, an 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 transition period ends, can continue to be placed on the EU27/EEA market and used afterwards. However, any consignment of a substance imported into the EU27/EEA market following the end of the transition has to be registered in accordance with the EU rules, i.e. by a registrant/Only Representative 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 (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 EU-REACH. This will include requirements for data based on tonnage bands. The UK-REACH legal instrument is expected to be effective as of 1 January 2021 at 0h CET, 31 December 2020 23h UK time and will require companies to resubmit a full registration according to transitional arrangements. 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.

In absence of a specific agreement between the EU and the UK on REACH, the following actions are expected to arise and should be considered as a result of UK-REACH starting to apply to the UK.

- UK-based companies with existing EU-REACH registrations need to grandfather them with the UK authority within 120 days from 1 January 2021 (i.e. by 30 April 2021) and then submit full registrations in the UK within 2, 4 or 6 years of 28 October 2021, depending on their tonnage band and hazardous properties (see Fig .1)
- Manufacturers of a substance on its own, in mixtures or in articles, formulators of mixtures or producers of an article imported into the UK, based outside the UK (including EU27/EEA businesses) will be in the position to appoint UK based ORs if they wish to relieve UK customers from notification and registration obligations under a UK REACH. REACH OR provisions under Article 8 will be transposed into UK legislation.
- UK companies (currently downstream users) that source products from EU27/EEA suppliers will become UK importers under UK-REACH and may be subject to UK-REACH registration obligations. A notification within 300 days from 1 January 2021 (i.e. by 27 October 2021) is expected to be required as interim arrangement with full registration expected within 2, 4 or 6 years of 28 October 2021, depending on tonnage band (see Fig.1). It is important to identify all substances manufactured and imported into the UK that may be subject to UK-REACH and check if you have any information available about these substances. UK-based ORs that will be appointed by EU27/EEA suppliers will be able to make notifications for imports sourced by existing UK downstream users and distributors. If the notification is completed by an OR within the proposed 300 days from 1 January 2021 (i.e. by 27 October 2021), the downstream user or distributor would not need to notify. Companies are advised to identify all products that are exported to the UK market.

Deadline Post 28 October 2021	Tonnage	Hazardous Property
27 October 2023	<ul style="list-style-type: none"> • 1000 tonnes or more per year 	<ul style="list-style-type: none"> • carcinogenic, mutagenic or toxic for reproduction (CMRs) - 1 tonne or more per year • Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year • Candidate list substances (as at 31 December 2020)
27 October 2025	<ul style="list-style-type: none"> • 100 tonnes or more per year 	<ul style="list-style-type: none"> • Candidate list substances (as at 27 October 2023)
27 October 2027	<ul style="list-style-type: none"> • 1 tonne or more per year 	

Fig 1. Proposed tonnage band deadlines under UK-REACH (subject to scrutiny by parliament and the devolved administrations)

- Companies that may wish to manufacture or import chemicals in the UK for the first time after the end of the transition would need to register before manufacture or import into the UK reaches 1 tonne per year.
- Placing chemicals on both the EU27/EEA and UK markets means 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 fulfil their registration obligations.

When being the joint data owners, consortium members will be asked to determine the conditions under which existing studies may be used for UK-REACH purposes. EU-REACH requires the registrant to either own or have a right to refer to studies summarised for the purpose of registration. Such rights are granted for the validity area of EU-REACH, i.e., for the time being EU28 plus Norway, Iceland, and Liechtenstein (EEA). This naturally includes the United Kingdom. After the end of the transition, 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, it could be considered that there is no reason to require additional compensation. At the same time, this could reduce additional administrative efforts. However, it is for each contract partner, 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.
- More information on UK-REACH is available [here](#) .

Further information:

ECHA

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

Commissions webpage

https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership_en

UK Government

<https://www.gov.uk/transition>

<https://www.gov.uk/government/publications/our-approach-to-the-future-relationship-with-the-eu>

<https://www.hse.gov.uk/brexit/index.htm>

Industry positions and guidance (CIA/Cefic)

<https://cefic.org/policy-matters/industrial-policy/brexit/>

<https://www.cia.org.uk/>

<https://www.cia.org.uk/reachready/> (FAQs and Brexit navigator)

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

29 January 2020: Withdrawal agreement ratified

31 January 2020: UK left the EU at 11pm UK time, transition period started

1 January 2021 at 0h CET, 31 December 2020 23h UK time: End of the transition. REACH to stop applying to the UK and to be replaced by UKREACH.

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