Brexit FAQs

With less than one year until the UK's exit from the EU, companies continue to face significant uncertainty on the decade worth of investment in EU REACH. To support companies in planning for the UK's exit, REACHReady together with the Chemical Industries Association (CIA) have identified a number of frequently asked questions focussing on REACH, Classification, Labelling and Packaging (CLP) and Biocidal Product (BPR) Regulation. Based on enquiries through our helpdesk, the questions are aimed at advising companies on any potential actions they may need to take in light of the UK withdrawal from the EU. Whilst it is important that businesses consider potential contingency measures in light of the UK decision to leave the EU, any actions companies will ultimately be required to undertake, as well as timelines involved, will depend upon the outcome of the on-going withdrawal negotiations between the UK and EU. As there is still a great level of uncertainty we will continue to update this document as further information comes to light.

For all Gold subscribers, REACHReady will continue to answer any specific questions you may have on Brexit and chemicals regulation. Further guidance will also be made available as the negotiations progress.

March 2018

REACH

Biocidal Product Regulation (BPR)

Classification, Labelling and Packaging (CLP)

REACH

1. **Can the UK stay in EU REACH?**
   This is a matter of negotiation between the EU and the UK. REACH is a measure of the EU single market and, as long as the UK leaves the EU single market, it may be unlikely that the UK remain in EU REACH post Brexit. In her latest Brexit speech, the UK Prime Minister announced that the UK intends to explore with the EU the terms on which the UK could remain part of a number of EU agencies, including ECHA. In doing so, the Prime Minister acknowledged that, through a potential "associate membership", the UK would be abiding by the rules of those agencies, respecting the remit of the European Court of Justice as well as making an appropriate financial contribution and providing technical expertise. Whilst the details of this proposal - and whether it can be agreed with the EU- are currently unknown, it is important to highlight that, whatever the UK's future relationship with the EU will be, post Brexit exports to the EU will have to continue to comply with REACH and imports from the EU into the UK will have to be compliant with any future new UK law that will be put in place.

REACH registrations

2. **Do I need to register a phase in substance by the 2018 deadline if the UK is leaving the EU in March 2019?**
   The UK will still be part of the EU in May 2018 and all existing EU regulations will continue to apply to UK companies until the UK leaves the EU. Therefore, companies manufacturing or importing substances ≥1 tonne per year must register the phase in substances by 31st May 2018.

3. **Do I need to register a non-phase in substance if the UK is leaving the EU in March 2019?**
   The UK will remain an EU Member State until the date of withdrawal on 30 March 2019. Therefore, companies manufacturing or importing substances ≥1 tonne per year must have a valid REACH registration.

4. **What will happen to my REACH registration once the UK has left the EU?**
   Currently, negotiations are still taking place and any potential future agreement between the EU and UK is still unknown. However, the REACH legal text states that registrants must be established in the EU. The UK after 30 March 2019 will no longer be a Member State of the EU. Unless agreed otherwise, this would mean that UK-based companies can no longer be a registrant under REACH. The potential consequences of this would mean that UK based companies would either continue to supply the EU on the basis of their own registration via a transfer or the EU based customers will need to register the substances themselves. Under a "UK out of EU REACH" scenario, there are different potential options depending on the company's role.

   Manufacturers:
   To relieve EU customers from potential future registration requirements, a manufacturer is likely to have two options, either relocate to the EU or to appoint an Only Representative based within the EU. If the manufacture is going to appoint an OR within the EU it is likely

that the registrations can be transferred to the OR in due course. However, in some cases the manufacturer's customers who would be the EU importer may already hold a registration for the substance. This would allow the continuation of the import of that substance but the tonnage band of registration may increase.

Importers:
A UK-based importer is likely to have to legally establish itself as an importer based within the EU. It is unlikely that importers will be able to transfer their registration to an OR based in the EU. This is because Article 8 of the REACH Regulation states that only manufacturers of substances, formulators of mixtures and producers of articles established outside the EU are able to appoint an Only Representative.

Only Representative:
The non-EU manufacturer who appointed the UK based OR will need to change the OR to an EU based company. If the UK based OR has an EU affiliate that could act as OR, the non-EU manufacturer could nominate them to act as the new OR. The transfer of an OR is already a defined process in REACH, please see *ECHA's practical guide 8: How to report changes in identity of legal entities* for further information. The UK based OR will need to help facilitate the transfer in REACH IT.

5. **When do I need to transfer my registration from UK based manufacturer to an OR based in EU and how do I complete transfer?**
While the UK is a Member State, UK companies are not able to complete the transfer as the registrations will be required by the UK companies to continue manufacturing in the UK. ECHA guidance currently provides for transfer to only be done for companies that change name or legal personality and is not for switching between entities due to other reasons. A change in legal personality is currently limited to the cases of changing between OR, partial or total asset transfer, mergers, spin-offs and splits.

In a recent update of its Brexit FAQs, ECHA clarified that UK based manufacturers will have the possibility to transfer their registrations at the time of the UK withdrawal from the EU. ECHA is currently recommending that UK manufacturers set up a contractual agreement to appoint an EU based OR and for the agreement to take effect on the date when the UK leaves the EU. The UK withdrawal is foreseen to be 30 March 2019 00:00 hours and therefore UK companies would need to notify the transfer in REACH-IT immediately ahead of the UK withdrawal. ECHA is currently putting together practical steps for this process. This answer and related timelines will be updated once we have any further information. For example, if a transition period is ultimately put in place lasting until 31 December 2020, our current assumption is that REACH would still apply to UK companies in the interim.

6. **What will happen during the transitional period, do I still need a REACH registration?**
If a transition is ultimately agreed, it is expected that during this period the UK will still follow EU regulations. Therefore REACH would still apply and companies manufacturing or importing substances ≥1 tonne per year would be required to have a REACH registration in place.

7. **Will I be charged a fee for transferring my registration as I have already paid for my registration whilst the UK is currently still part of the EU?**
   A fee is currently charged for a change in legal personality in the case of switching OR, partial or total asset transfer, mergers, spin-offs and splits. ECHA has stated that the circumstance of the UK withdrawal from the EU doesn't provide a legal basis for waiving the fees. Consequently, our current assumption is that a fee for the transfer of the registration will be charged, unless agreed otherwise.

8. **What happens if I'm the lead registrant of a REACH registration?**
   A lead registrant can either move to the EU, carry out a legal entity change to become an EU based Only Representative or the SIEF appoints a new lead registrant. If the SIEF appoints a new lead registrant the current lead registrant will need to transfer the lead registrant role before the UK leaves the EU. The current lead registrant will need to ensure that all shared data and cost sharing arrangements are transferred to the new lead registration. The transfer of lead registrant is already a defined process under REACH.

9. **Am I able to communicate with the SIEF after the UK leaves the EU?**
   After its withdrawal from the EU the UK will be seen as a third country and therefore have no obligations under REACH, unless agreed otherwise. If a UK based company have transferred their registration to an EU legal entity or EU based OR, the EU entities will become part of the SIEF. It is therefore, recommended that all discussions regarding the access to the data is concluded before the UK leaves the EU.

10. **Will I need to register my substances in the UK even if I have a valid registration under REACH?**
    The EU REACH registration is only applicable in EU countries. In the UK, through Article 50, REACH will be converted into UK law after the withdrawal from the EU. Therefore all the obligations and requirements under REACH will be in place in the UK. Registrations of substances will be likely however it is unclear at this time exactly what would be required of companies that have already registered substances under REACH.

11. **Can I use my letter of access purchased for EU REACH for use in UK registrations?**
    The conditions of use for a letter of access can vary from SIEF to SIEF and will depend on the contents of the SIEF agreement. UK companies may be able to use the letter of access for UK registrations if this is agreed upon by the rest of the SIEF members. It is therefore, recommended that companies review their letter of access and contact the SEIF if necessary.

REACH Authorisations

12. **Do I need to apply for authorisation for an Annex XIV substance with the latest application date being before the UK leaves the EU?**
    UK companies would need to have an authorisation in place if they are using a substance in Annex XIV between the substance sunset date and the date the UK leaves the EU. However, if the sunset date if after the UK withdrawal (30 March 2019) then UK companies will not have to apply for authorisation.

If a UK company has submitted an authorisation prior to the latest application date they will benefit from the transitional arrangements associated with authorisation applications (see ECHA Q&A ID 572 for further information). If REACH provisions on authorisation continue to apply in the UK after the UK has withdrawn from the EU (through UK domestic law or possible agreements with EU) companies would still be able to use the substance passed the sunset date while their application was being processed.

13. **I currently hold and/or covered by a REACH authorisation. Once the UK has left the EU will my company need to continue to adhere to the conditions of this decision?**
    Once the UK has left the EU, REACH will no longer apply to the UK unless agreed otherwise. Therefore you will not be subject to this obligation. However, you will have to comply with UK domestic law which is likely to include authorisation obligations.

14. **I'm covered by a REACH authorisation as a downstream user based in the UK. Once the UK has withdrawn from the EU will I need to comply with the authorisation decision?**
    Once the UK has left the EU the REACH regulation will no longer apply. However, companies will need to be aware of any potential authorisation obligations under UK domestic law.

15. **As a manufacturer or formulator will I be able to transfer my authorisation to an Only Representative within the EU?**
    The current status suggests that UK based companies will have the possibility to transfer their authorisations to an Only Representative once the UK has left the EU. While the UK is a Member State then the UK companies are not able to complete this transfer as the authorisations will be required by the UK companies to continue using the Annex XIV substance in the UK. ECHA is currently recommending that UK companies in this position set up a contractual agreement to appoint an EU based OR and for the agreement to take effect on the date when the UK leaves the EU. The UK withdrawal is foreseen to be 30 March 2019 00:00hours. The OR would need to adhere to all the conditions within the authorisation decision and the authorisation holder would need to notify ECHA of the transfer who in turn will forward the notification to the European Commission. ECHA is currently putting together practical steps for this process; this answer will be updated once we have any further information.

16. **Will my EU customers still be covered by my authorisation (or pending application for authorisation) once the UK has left the EU?**
    Once the UK leaves the EU the REACH regulation will no longer apply to UK companies unless agreed otherwise. The UK based companies can transfer their authorisations to an Only Representative based within the EU (see question 14). EU customers will need to rely on a supplier that holds a valid authorisation or apply for authorisation themselves.

Biocidal Product Regulation (BPR)

17. **Will active substances that have been evaluated by the UK and approved by the European Commission be affected by the UK leaving the EU?**
    The decisions on active substances are taken at European level therefore the active substance approvals of those substances evaluated by the UK will remain valid under the BPR once the UK has left the EU.

18. **The approval of our active substance is due for renewal before the UK leaves the EU and it was originally evaluated by the UK. Are we able to use a different evaluating competent authority for this renewal?**
    Article 13 of the BPR states that it is not required for the same evaluating competent authority that approved the active substance originally to be the evaluating competent authority that carries out the renewal. Please note that you need to indicate within the application of renewal the competent authority you are proposing for the evaluation and provide written confirmation that the competent authority agrees to do so.

19. **What will happen to those substances that are currently in either the notification or application phase with the UK being the evaluating competent authority?**
    Both ECHA and the European Commission are working with the Member States together on a plan for the handover of pending cases.

20. **Will I be able to still submit requests for active substance approval/inclusion of a substance on Annex I once the UK has left the EU?**
    These applications must be submitted in a Member State however, the applicants for the active substance approval aren't the "owners" of the approval. Therefore the applicants do not need to be based in the EU. Once the UK has left the EU, the UK will be a Third country but will still be able to submit these types of submissions.

21. **We hold a product authorisation in an EU Member State/Union authorisation. Will this authorisation be effected by the UK leaving the EU?**
    The Authorisation holder must be based in the EU or the following four countries: Switzerland, Iceland, Liechtenstein and Norway as stated in Article 3 of BPR. Therefore, a UK company would have to transfer the authorisation to a new holder that is based in the EU or the aforementioned four countries before the UK leaves the EU. This transfer procedure is already in place within the BPR. Companies are able to trigger the amendment of their existing authorisation through an administrative change that requires a prior notification before it is implemented. Please see Annex I to Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products for further details.

22. **Will an authorisation issued in a Member State on the basis of the recognition of UK authorisation remain valid after the UK leaves the EU?**
    The authorisations issued in a Member State on the basis of the recognition of a UK authorisation will not be affected by the UK leaving the EU and will remain valid.

23. We need to submit an application for which the UK could act as the evaluating Competent Authority. With the UK leaving the EU is it wise to choose the UK?

The UK will remain to be a Member State up until the withdrawal date (30 March 2019) therefore applicants can choose them to be their evaluating Competent Authority. However, companies need to be mindful of the UK withdrawal timeline and if the regulatory procedure they are wanting the UK competent authority to undertake can be completed within this timeline. If it is unlikely that the process will be completed in time it may be worth choosing a different evaluating Competent Authority to prevent having to change during the procedure which could create delays.

24. As a listed supplier in accordance with Article 95 once the UK has left the EU what do I need to do?

Suppliers that are listed in the Article 95 list have to be established in the EU/EEA or Switzerland, therefore UK companies would need to appoint a representative that is based in those countries. This will need to be communicated to ECHA through the "request for correction" procedure within enough time so that the list can be updated before the UK leaves the EU. If the "request for correction" procedure is not completed the UK supplier will be removed from the Article 95 list.

25. Will my authorisation I currently hold for a biocidal product under the national authorisation process for the UK remain valid once the UK leaves the EU?

The EU BPR only applies to EU Member States therefore once the UK has the EU it will no longer have any obligations under the BPR. In the UK through Article 50 the BPR will be converted into UK law after the withdrawal from the EU. Therefore all the obligations and requirements under BPR will be in place in the UK. Authorisations of products will be likely, however it is unclear at this time exactly what would be required of companies that already have a product authorisation in place.

<u>Classification, Labelling and Packaging (CLP)</u>

26. Will my company still need to classify and label products being imported to the EU and UK in accordance with the EU CLP Regulation?

UK imports

As from the date of the UK's withdrawal from the EU, UK companies will no longer be subject to the provisions of the CLP Regulation. The UK is obliged to implement classification, labelling and packaging provisions from United Nations' Global Harmonised System (GHS) and therefore UK based importers will likely be required to comply with UK regulations based on GHS.

EU imports

After the UK's withdrawal, UK companies will no longer be subject to EU CLP Regulations. As a consequence it will be the responsibility of the EU based importer to ensure the product is classified, labelled and packaged in accordance with the CLP Regulation before placing it on the EU market.

27. What will happen to my C&L notification after the UK withdrawal?

All existing notifications will remain available under the conditions of the legal notice that ECHA has published along with the inventory. ECHA has indicated that UK based companies will be able to update or remove notification using REACH-IT. Following the UK's withdrawal it will be the responsibility of the EU-based importer to submit the C&L notifications to ECHA.

28. Will my Safety Data Sheet need to be updated following the UK's withdrawal?

Substances and mixtures imported to the EU from the UK will need updated SDS with the details of the supplier responsible for placing the product on the EU market. In terms of the SDS required for the UK post Brexit, requirements will depend on the UK regulations the UK will put in place.