Brexit FAQs

To support companies in planning and preparing for the new trading relationship between the UK and EU, 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 relation to the above regulations. 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 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 through our dedicated helpdesk. Further guidance will also be made available as the negotiations progress.

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Note – These FAQs do not yet consider implications from any potential negotiated outcome with the EU or take yet into account the future implementation of the Ireland/Northern Ireland Protocol. The information provided may therefore help in overall business planning, but it should not be used as definitive tool at this stage.

REACH: maintaining access to the EU market

REACH: accessing UK market:

Biocidal Product Regulation (BPR): maintaining access to the EU market

BPR: maintaining access to the UK markets

Classification, Labelling and Packaging (CLP)

EU REACH: Maintaining access to the EU market

1. Can the UK stay in EU REACH?

The UK left the European Union on the 31st January 2020, moving into a transition period set to expire on the 31st December 2020. For the time being and until the end of the year, access to the UK's and EU's single markets continues as before. On chemicals regulations, UK based companies must still comply with EU regulations and responding to ECHA as before. In terms of future relationship, the UK government and the European Commission have excluded continued UK's participation in ECHA and the legislation it governs (REACH, CLP, BPR, PIC). Both negotiating positions indicate that the two parties intend to form separate legal orders at the end of the transition, including for chemicals. As things stand, we expect a separate chemicals regulatory regime in the UK at the end of the transition. How the two systems will interact is however not fully clear as the future relationship is still in the process of being worked out.

Note: The Withdrawal agreement foresees that EU chemicals regulations will continue to apply to Northern Ireland (with periodic consent of the Northern Ireland Assembly), as part of the solution agreed to avoid a hard border on the island of Ireland.

2. Do I need to register a non-phase in substance if the UK has left the EU?

The UK left the European Union on the 31st January 2020, moving into a transition period set to expire on the 31st December 2020. During this time companies wanting manufacture or import chemicals in both the EU/EEA and UK must still comply with EU regulations and responding to ECHA as before. Therefore, companies manufacturing or importing substances ≥1 tonne per year must have a valid REACH registration.

3. What will happen to my REACH registration at the end of the transition?

Registrants must be established in the EU/EEA. The consequences of this means that UK based companies would either continue to supply the EU following the transfer of their own registration to a EU/EEA legal entity or the EU/EEA based customers will need to register the substances themselves. The options available are dependent on the company's role under REACH.

Manufacturers:

To relieve EU customers from potential future registration requirements, a UK manufacturer is likely to have two options, either appoint an Only Representative based within the EU/EEA or relocate to the EU/EEA.

If the manufacture is going to appoint an OR within the EU/EEA, 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.

UK based manufacturers also have the option to transfer their existing registrations to an EU/EEA based legal entity, on the basis that the EU/EEA legal entity maintains the manufacturing role and that the transfer is the result of a legal entity change. Therefore, the transfer has to fit into one of the following situations:

- UK based manufacturer goes through an acquisition or relocation to the EU

- Intragroup transfer of the whole operations/manufacturing activity. This would be for example the transfer of the activity from a UK based mother company to an EU/EEA based daughter company.

This type of transfer would need to take place before the end of the transition and ECHA must be notified without undue delay. Notification can be done through the legal entity change function within REACH IT. Once this transfer has taken place, the UK manufacturer will no longer be able to benefit from the registration and will need to cease manufacturing the substances that the registration covers. However, once the transition ends, UK companies will no longer be covered by REACH and therefore, would be able to start manufacturing those substances again in compliance with the relevant UK law.

Importers:
UK importers can't transfer their registrations to an OR based in the EU/EEA. 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 can appoint an Only Representative.

Based on the recently updated ECHA Q&As, UK importers may consider transferring their registrations to an EU/EEA based legal entity but only if this transfer is the result of a legal entity change. For example, the importing business would need to be transferred to a legal entity in the EU. For further guidance please contact our helpdesk.

This type of transfer would need to take place before the end of the transition and ECHA must be notified without undue delay. Notification can be done through the legal entity change function within REACH IT. Once this transfer has taken place, the UK importer will no longer be able to benefit from the registration and will need to cease importing the substances that the registration covers.

However, once the transition ends, UK companies will no longer be covered by REACH and therefore, would be able to start importing those substances again in compliance with the relevant UK law.

Only Representative:
The non-EU manufacturer who appointed the UK based OR will need to change the OR to an EU/EEA 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. The OR change must take place before the transition ends.

4. When do I need to transfer my registration from UK based manufacturer to an OR based in EU and how do I complete transfer?
The UK has now left the European Union on 31st January 2020, moving into a transition period set to expire on the 31st December 2020. Based on this agreement, we understand that UK based manufacturers need to start the transfer of registrations to an OR before the end of the transition.

For companies that currently need to stay registered in the UK, the transfer can't however be fully completed until after the end of the transition.

ECHA's guidance on how to transfer you UK REACH registration provides practical instructions on how to set up the transfer within REACH IT. This process will allow substances that already have been registered by UK companies under REACH to be legally placed on the EU/EEA market after the transition ends. A few points to note include:

- ECHA opened a "Brexit window" in REACH IT which allows UK companies to transfer their registrations;
- The UK company's EU successor needs to be set up in REACH IT and share their UUID to allow the UK company to begin the process in REACH IT;
- UK companies shouldn't submit updates to their registrations any more as pending registrations such as those going through the completeness check can't be transferred;
- A transfer agreement needs to be put in place. REACHReady recommends using a **suspensive condition clause,** as the appointment of an OR can be formally enacted only when the transition ends. Please see the joint CIA and Cefic guidance for suggested wording for these contracts;
- If you use a suspensive conditional clause, make sure that the successor reviews the transfer but does not proceed to accept it yet;
- Once the transition ends, UK companies will no longer have access to registrations and notification in REACH IT. They will however maintain access to their message box where they will receive messages regarding the status of their transfer;
- After UK withdrawal, the successor needs to accept the transfer and pay the invoice for the transfer by the due date. If not, the transfer in REACH IT will automatically be undone and the registrations after UK withdrawal will be void.

5. **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 don'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.

6. **What happens if I'm the lead registrant of a REACH registration?**
   A lead registrant can either move to the EU/EEA, carry out a legal entity change to become an EU based Only Representative or the SIEF appoints a new lead registrant. If a new lead is appointed, data and cost sharing arrangements should be taken over by new lead. The transfer of lead registrant is already a defined process under REACH.

7. **Am I able to communicate with the SIEF after the UK withdrawal?**
   At the end of the transition, UK companies have no obligations under REACH. If a UK based company has transferred their registration to an EU/EEA legal entity or EU/EEA based OR, the EU/EEA entities will become part of the SIEF. It is therefore, recommended that all discussions regarding the access to the data is concluded as soon as possible.

8. **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/EEA countries. In the UK, REACH is converted into UK law for application at the end of the transition period. Therefore, all the obligations and requirements under REACH will be in place in the UK. For implications in the UK under a no deal scenario at the end of the transition, please see the relevant questions related to accessing the UK market.

9. **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 SIEF if necessary.

10. **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 end of the transition. However, if the sunset date is after the end of the transition, then UK companies will not have to apply for authorisation under EU REACH.

    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 ECHA has not finalised its opinions by the point the UK leaves the EU REACH regime, we expect that you will need to resubmit your dossier to the future UK Agency (HSE) if you want to continue to place the substance on the UK market or using it after the sunset date (see questions on UK REACH below).

11. **I currently hold and/or covered by a REACH authorisation. Once the transition ends, will my company need to continue to adhere to the conditions of this decision?**
    Once the transition ends, EU REACH will no longer apply to the UK. However, you will have to comply with UK domestic law which is will include authorisation obligations.

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

13. **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. While the UK continues to implement REACH during the transition, 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 once the transition ends. 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's new guidance on how to transfer UK REACH registration provides practical instructions on how to set up the transfer within REACH IT. This process will allow substances that already have been authorised by UK companies under REACH to be legally placed on the EU/EEA market after the UK withdrawal from the EU. A few points to note include:

- ECHA opened a "Brexit window" in REACH IT which allow UK companies to transfer their authorisations;
- The UK company's EU successor needs to be set up in REACH IT and share their UUID to allow the UK company to begin the process in REACH IT;
- A transfer agreement needs to be put in place REACHReady recommends using a **suspensive condition clause.** Please see the joint CIA and Cefic guidance for suggested wording for these contracts;
- As of the end of the transition UK companies will no longer have access to notifications in REACH IT, they will maintain access to their message box where they will receive messages regarding the status of their transfer
- The successor will need to pay the invoice for the transfer by the due date if not the transfer in REACH IT will automatically be undone and the authorisation will be returned to the UK company where after the end of the transition they will be void.

14. Will my EU customers still be covered by my authorisation (or pending application for authorisation) once the transition ends?

Once the transition ends, the REACH regulation will no longer apply to UK. UK based companies can transfer their authorisations to an Only Representative based within the EU as detailed in question 13. EU customers will need to rely on a supplier that holds a valid authorisation or apply for authorisation themselves.

REACH: <u>Accessing UK market</u>

15. Will EU REACH apply to the UK market?

Under the European Union (Withdrawal) Act, the UK converts EU law as it stands at the end of the transition into domestic law. Under this approach, EU REACH is converted into UK law and using secondary legislation technical corrections are made to correct deficiencies. The decision to covert EU law into the UK was aimed to give certainty, continuity to businesses and citizens and not to deregulate.

16. What will happen to my company's REACH registration in the UK?

The UK authority would carry across existing REACH registrations held by UK based companies directly into the UK's replacement for REACH. These registrations would be "grandfathered" into the UK regime.

17. Will my company need to tell the UK authorities that they have registrations to be "grandfathered"?

UK companies will have to validate their existing registrations with the UK Agency (HSE). They would have to do this by opening an account in the new UK IT system and they would need to

provide some basic information on their existing registration within 120 days from the end of the transition (30 April 2021).

18. Once my company's registrations have been "grandfathered" by the UK authority do I need to do anything further?

UK companies that have "grandfathered" registrations then have between 2-6 years from 28 October 2021 to provide the HSE with the data package that supported their original EU registration. Similar to EU REACH the phased registration timeframe based on tonnage and hazard properties is as follows:

Deadline Post 28 October 2021	Tonnage	Hazardous Property
27 October 2023	• 1000 tonnes or more per year	• 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	• 100 tonnes or more per year	• Candidate list substances (as at 27 October 2023)
27 October 2027	• 1 tonne or more per year	

19. Under EU REACH my company was considered a downstream user but under UK REACH the company will be an importer, what does the company need to do?

Those companies that will become importers under UK REACH will need to notify the UK authority and provide some basic information on the chemicals within 300 days from the end of the transition (27 October 2021). This is known as a Downstream User Import Notification (DUIN). A new full registration would then need to submitted to the HSE in line with the phased timeframe below for imports to continue.

Deadline Post 28 October 2021	Tonnage	Hazardous Property
27 October 2023	• 1000 tonnes or more per year	• 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)

Deadline Post 28 October 2021	Tonnage	Hazardous Property
27 October 2025	• 100 tonnes or more per year	• Candidate list substances (as at 27 October 2023)
27 October 2027	• 1 tonne or more per year	

A non-UK manufacturer may appoint a UK Only Representative to take on the notification and registration duties from the UK importer.

20. Will my REACH authorisation be valid in the UK once the transition period ends?

Existing EU authorisations held by UK manufacturers, importers and Only Representatives can be grandfathered into the UK. Those authorisation holders will need to provide the following data to the UK agency:

- the information included in the application for the authorisation
- any other information provided to ECHA for the authorisation which was material to the formation of ECHA's opinion; and
- any information required to be submitted or recorded before the point that the UK leaves the EU under any condition under which the authorisation is granted.

21. What happens if my company has submitted an authorisation application and it is still being processed when the transition ends?

If ECHA's RAC and SEAC committees have not yet submitted an opinion to the EU on the application, then the UK company would need to re-submit their dossier to the UK agency. However, if ECHA's RAC and SEAC committees have provided opinions and are awaiting a decision from the Commission, UK applicants would be required to notify the UK of the application. The UK company would also need to provide copies of the application and any other information that led to ECHA's formation of its opinion.

22. A UK company currently benefits from an upstream EU authorisation. Will the company still be able to benefit from these authorisations once the transition ends?

For a UK company to continue to benefit from these authorisations they would have to submit the following information to the UK agency

- That they are an existing authorised downstream user under EU law in relation to the substance;
- The existing EU authorisation, any conditions set out and the identity of the supplier.

<u>EU Biocidal Product Regulation (BPR)</u>

23. Will active substances that have been evaluated by the UK and approved by the European Commission be affected by the fact that the UK has left 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.

24. **The approval of an active substance was due for renewal and it was originally evaluated by the UK but the UK left the EU. What has changed since the UK left the EU?**
    During the transition period, the UK authority cannot act as evaluating competent authority for any application for approval of active substance/product-type combination. In the case of renewal of approval of active substances for which the UK was the evaluating Competent Authority, new evaluating competent authorities from EU Member have been identified. We understand that applicants have been notified of the changes.

25. **What happened to those substances that were in either the notification or application phase with the UK being the evaluating competent authority at the time the UK left the EU?**
    The European Commission and Member States agreed a plan for the handover of pending cases. For existing active substances in the Review Programme, the Commission Delegated Regulation (EU) 2019/227 applies. New evaluating competent authorities have been already appointed and responsible for the evaluation of applications since 30 March 2019.

26. **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 an EU Member State (or an EEA country or Switzerland). 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 EU/EAA countries or Switzerland. UK companies will still be able to submit these types of submissions.

27. **We hold a product authorisation in an EU Member State/Union authorisation. Will this authorisation be affected by the UK leaving the EU?**
    The Authorisation holder must be based in the EU/EEA countries or Switzerland. Therefore, a UK company would have to transfer the authorisation before the end of the transition. This transfer procedure is already in place within the BPR. Companies can 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.

28. **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. The authorisation holder must be established in a EU/EEA country, or Switzerland before the end of the transitional period.

29. **As a listed supplier in accordance with Article 95 what do I need to do in light of the UK departure from the EU?**
    Suppliers that are listed in the Article 95 list have to be established in the EU/EEA or Switzerland; UK companies would therefore need to appoint a representative that is based in those countries to continue to be on the list. 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 transition ends. If the "request for correction" procedure is not completed, the UK supplier will be removed from the Article 95 list. ECHA recommends that the request is submitted two months before the end of the transition period.

30. Will my authorisation I currently hold for a biocidal product under the national authorisation process for the UK remain valid once the transition period ends?

The EU BPR only applies to EU Member States, EEA countries and Switzerland. Therefore once the transition ends, the UK will no longer have any obligations under the EU BPR. In the UK, however, the BPR will be converted into UK law. Therefore, all the obligations and requirements under BPR will be in place in the UK. If you hold a biocidal product authorisation that is valid in the UK at the end of the transition, we expect it would remain valid in the UK. Please follow future developments in the UK as there will likely be actions to take to ensure the product remains in compliance with future UK law (see UK BPR questions).

UK BPR

31. My company holds a valid biocidal product authorisation in the UK: will it remain valid once the transition period ends?

We expect a biocidal product authorisation that is valid in the UK at the end of the transition to remain valid in the UK until its normal expiry date. After the transition ends, there may be actions that you may have to take, such as ensuring your active substance supplier meet future UK Article 95 list requirements. Authorisation holders will also need to be based in the UK.

32. My company has a biocidal product authorisation being process by the HSE at the end of the transition, what will happen?

We assume that where possible the HSE will continue to process the biocidal product to be able to grant a national authorisation. However, companies may be asked to re-submit information that was part of the original submission.

33. My company has an application being processed by another Member State for an EU wide authorisation, what do I need to do to be compliant in the UK?

The company would need to re-apply to the UK for a national authorisation. We expect the date of the original application would be recognised for the purpose of meeting any application submission deadlines.

34. My company is currently listed on the Article 95 list. Will there be a UK equivalent?

There will be a UK version of the approved active substance suppliers (Article 95 list). We expect that the companies that are already listed on the EU list at the end of the transition period will be included in the UK list. To remain on the UK list they would need to submit to the HSE the same supporting information that they submitted to ECHA. This could be for example an active substance dossier or a letter of access. Companies would also need to be established in the UK to remain on the UK list. A two-year phase in period is foreseen.

Classification, Labelling and Packaging (CLP)

35. 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

The UK is obliged to implement classification, labelling and packaging provisions from United Nations' Global Harmonised System (GHS). The UK intends to adopt the GHS system in the same way as the EU and as a consequence the UK classification and labelling system would be based on the existing EU CLP regulatory regime. UK based importers will likely be required to comply with UK CLP regulations.

EU imports

After the UK's withdrawal, UK companies will no longer be subject to EU CLP regulatory regime. 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 EU CLP Regulation before placing it on the EU market.

36. 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. A UK-based manufacturer or importer can transfer the C&L notification to an EU legal entity using the legal entity change (LEC) module in REACH-IT. The transfer of UK-based notifications to EU/EEA legal entities can take place at any point in time, prior to the end of the transition period. However, if you are a UK based manufacturer, and intend to appoint an Only Representative (OR), the C&L notification cannot be transferred to the OR. In this case the newly appointed OR will need to submit a new group C&L notification on behalf of the EU importers, or the EU based importers will need to submit their own C&L notification to ECHA.

37. Will I need to make a classification and labelling notification for substances and mixtures placed on the UK market?

If you are currently a UK-importer (i.e. you obtain substances or mixtures from outside of the EU) or a UK manufacturer and you have already submitted a notification to ECHA in accordance with Articles 39 and 40 of CLP, our assumption is that you will not have to submit another notification in the UK for those substances. However, if a party becomes an importer after the end of the transition or imports a substance(s) that they have not notified in accordance with Articles 39 and 40 of CLP before the end of the transition, we believe they will have a duty to notify substances in the UK where the relevant criteria are met in the UK CLP regulations. This would also apply to UK-based distributors who currently obtain substances and/or mixtures from EU-based suppliers as these 'distributors' will become new importers in the UK after the end of the transition.

38. Will I need to submit a poison centre notification when placing mixtures on the UK market?

In terms of UK's approach, at the end of the transition period, Annex VIII of the CLP Regulation (which is currently scheduled apply from 1st January 2021) is only expected to apply in the EU. As

a consequence, UK-based importers and downstream users are expected to continue with voluntary submission in the form of Safety Data Sheets (SDS) to the NPIS.

39. 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. Similarly, SDS for substances and mixtures placed imported to the UK will need to be updated with details of the supplier responsible for placing the product on the UK market.

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