Brexit FAQs

To support companies with regards to 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.

For all Gold subscribers, REACHReady will continue to answer any specific questions you may have on Brexit and chemicals regulation through our dedicated helpdesk.

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REACH: maintaining access to the EU market

REACH: accessing GB market:

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

BPR: maintaining access to GB market

Classification, Labelling and Packaging (CLP)

EU REACH: Maintaining access to the EU market

1. Has the UK left EU REACH?

The UK left the European Union on the 31st January 2020 and moved into a transition period that expired on 31st December 2020. EU REACH has stopped applying to Great Britain and has been converted into a separate regulatory regime for chemicals (UKREACH). 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).

Note: The Withdrawal agreement foresees that EU chemicals regulations continues 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. Qualifying businesses based in Northern Ireland are also set to maintain unfettered access to the GB market under specific arrangements. Further guidance is available on HSE's website.

2. What happened to my REACH registration at the end of the transition?

Registrants must be established in the EU/EEA. The consequences of this means that GB 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 need to register the substances themselves. The options available were dependent on the company's role under REACH. The ECHA transfer window is now closed.

Manufacturers:

To relieve EU customers from registration requirements, a GB manufacturer had the option to transfer its registrations to an Only Representative (OR) based within the EU/EEA. In some cases, the manufacturer's customers who would be the EU importer may already have hold a registration for the substance. This allows the continuation of the import of that substance, but the tonnage band of registration may increase. GB based manufacturers had also 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, for example:

- GB based manufacturer went 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 GB based mother company to an EU/EEA based daughter company.

Importers:

GB importers did not have the possibility to 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.

GB importers had the possibility to transfer their registrations to an EU/EEA based legal entity but only if this transfer was the result of a legal entity change. For example, the importing business had to be transferred to a legal entity in the EU.

Only Representative:

The non-EU manufacturer who appointed a GB based OR had to consider changing the OR to an EU/EEA based company. If the GB based OR has an EU affiliate that could act as OR the non-EU manufacturer had the option to nominate them to act as the new OR. The transfer of an OR was 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 GB based OR had to help facilitate the transfer in REACH IT. The OR change had to take place before the end of the transition.

3. **When do I need to transfer my registration from GB based manufacturer to an OR based in EU and how do I complete transfer?**

   The process of transferring registrations is now closed. Companies had to start the transfer of registrations before the end of the transition. ECHA's guidance on how to transfer your UK REACH registrations provided practical instructions on how to set up the transfer within REACH IT. This process allowed substances that were already registered by GB companies under REACH to be legally placed on the EU/EEA market after the end of the transition period. A few points to note we include:

   - ECHA opened a "Brexit window" in REACH IT which allows GB companies to transfer their registrations;
   - The GB company's EU successor had to set up in REACH IT and share their UUID to allow the GB company to begin the process in REACH IT;
   - GB companies were advised not to submit updates to their registrations any more as pending registrations such as those going through the completeness check couldn't be transferred;
   - REACHReady recommended using a **suspensive condition clause,** as the appointment of an OR could be formally enacted only when the transition ended. In this case, the successor reviewed the transfer but did not proceed to accept it yet;
   - After UK withdrawal, the successor had to accept the transfer and pay the invoice for the transfer by the due date. If not, the registration has become void.
   - GB companies no longer have access to registrations and notification in REACH IT. They however maintained access to their message box.

4. **Was there a fee for transferring my registration as I have already paid for my registration whilst the UK was currently part of the EU?**

   Yes, a fee is 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.

5. **Will I need to register my substances in GB even if I had a valid registration under REACH?**

   The EU REACH registration is only applicable in EU/EEA countries. In GB, REACH has been converted into UK law for application at the end of the transition period. Therefore, all the obligations and requirements under REACH are in place in GB. For implications in GB, please see the relevant questions related to accessing the GB market.

6. **Can I use my letter of access purchased for EU REACH for use in GB 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. GB companies may be able to use the letter of access for GB 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.

7. **Do I need to apply for authorisation for an Annex XIV substance with the latest application date being before the UK left EU REACH?**
   GB companies needed 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 GB companies cannot apply for authorisation under EU REACH.

   If a GB company had submitted an authorisation prior to the latest application date they could 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, you would need to resubmit your dossier to the future UK Agency (HSE) if you want to continue to place the substance on the GB market or using it after the sunset date (see questions on UK REACH below).

8. **I held and/or was covered by a EU REACH authorisation. As the transition ended, does my company need to continue to adhere to the conditions of this decision?**
   EU REACH no longer applies to GB. However, you have to comply with UK domestic law which is includes authorisation obligations.

9. **I was covered by a REACH authorisation as a downstream user based in the GB. As the transition ended, do I need to comply with the authorisation decision?**
   EU REACH no longer applies to GB. However, companies need to be aware of any potential authorisation obligations under UK domestic law.

10. **As a manufacturer or formulator can I transfer my authorisation to an Only Representative within the EU?**
    The process of transferring UK authorisations is now closed. GB based companies had the possibility to transfer their authorisations to an Only Representative. GB companies have been advised to set up a contractual agreement to appoint an EU based OR and for the agreement to take effect once the transition ended. The OR needs to adhere to all the conditions within the authorisation decision.

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

11. **Does EU REACH apply to the GB market?**
    No. Under the European Union (Withdrawal) Act, the UK government converted EU law as it was at the end of the transition into domestic law. Under this approach, EU REACH was converted into UK law and using secondary legislation technical corrections were 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.

12. **What happens to my company's EU REACH registration in the GB?**

The UK authority has allowed to carry across EU REACH registrations held by GB based companies directly into the UK's replacement for REACH. These registrations have been "grandfathered" into the UK regime.

13. Does my company need to tell the UK authorities that we have registrations to be "grandfathered"?

GB companies had the option to validate their registrations with the UK Agency (HSE). They had to do this by opening an account in the new UK IT system and they had to provide some basic information on their existing registration within 120 days from the end of the transition (30 April 2021). For queries on late grandfathered registrations, please contact HSE.

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

GB 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 Category 1A,1B) - 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	

15. 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 become importers under UK REACH 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 Category 1A,1B) - 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	

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

16. Will my REACH authorisation be valid in GB after the transition period ?

Existing EU authorisations held by GB manufacturers, importers and Only Representatives had the opportunity to grandfather into GB within 60 days from the end of the transition. Those authorisation holders had 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 EU REACH under any condition under which the authorisation was granted.

17. What happens if my company has submitted an authorisation application and it was still being processed when the transition ended?

If ECHA's RAC and SEAC committees did not submit an opinion to the EU on the application, then the GB 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, GB applicants would be required to notify the UK of the application within 180 days from the end of the transition. The GB company would also need to provide copies of the application and any other information that led to ECHA's formation of its opinion.

18. A GB company was benefitting from an upstream EU authorisation. Can the company still be able to benefit from these authorisations?

For a GB company to continue to benefit from these authorisations, they had to submit the following information to the UK agency within 60 days from the end of the transition:

- That they were 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.

EU Biocidal Product Regulation (BPR)

19. **Are active substances that have been evaluated by the UK and approved by the European Commission 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 remain valid under the BPR.

20. **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 coudn't 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 were identified. We understand that applicants were notified of the changes.

21. **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 were appointed and responsible for the evaluation of applications since 30 March 2019.

22. **Will I be able to still submit requests for active substance approval/inclusion of a substance on Annex I as 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. GB companies will still be able to submit these types of submissions.

23. **We held a product authorisation in an EU Member State/Union authorisation. Is 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 GB company would have had to transfer the authorisation before the end of the transition. This transfer procedure was already in place within the BPR. Companies had to trigger the amendment of their existing authorisation through an administrative change that requires a prior notification before it is implemented. Annex I to Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products provided further details.

24. 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 have been established in a EU/EEA country, or Switzerland before the end of the transitional period.

25. What listed suppliers in accordance with Article 95 had to do in light of the UK departure from the EU?

Suppliers that were listed in the Article 95 list have to be established in the EU/EEA or Switzerland; GB companies were requested to appoint a representative that is based in those countries to continue to be on the list. This had to be communicated to ECHA through the "request for correction" procedure within enough time so that the list could have been updated before the transition ended. If the "request for correction" procedure was not completed, the GB supplier could not remain on the Article 95 list. ECHA recommended that the request was submitted two months before the end of the transition period.

26. Will my authorisation I held for a biocidal product under the national authorisation process for GB remain valid after the end of the transition period?

The EU BPR only applies to EU Member States, EEA countries and Switzerland. GB no longer have any obligations under the EU BPR. In GB however, the BPR was converted into UK law. Therefore, all the obligations and requirements under BPR are in place in GB. If you held a biocidal product authorisation that is valid in GB at the end of the transition, it would remain valid. (please see GB BPR questions).

<u>GB BPR</u>

27. My company held a valid biocidal product authorisation in GB: does it remain valid after the end of the transition period?

We understand that a biocidal product authorisation that is valid in GB at the end of the transition remains valid until its normal expiry date. There may be actions that you may have to take, such as ensuring your active substance supplier meet future GB Article 95 list requirements. Establishments rules also apply.

28. My company had a biocidal product authorisation being process by the HSE at the end of the transition, what happens?

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

29. 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 GB?

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

30. My company was listed on the Article 95 list. Will there be a GB equivalent?

There is a GB version of the approved active substance suppliers (Article 95 list). Companies that were already listed on the EU list at the end of the transition period are included in the GB list. To remain on the GB 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 GB list. A two-year phase in period is foreseen.

Please check the HSE factsheets for specific scenarios that may apply to your company

Classification, Labelling and Packaging (CLP)

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

GB imports

GB is obliged to implement classification, labelling and packaging provisions from United Nations' Global Harmonised System (GHS). GB has adopted the GHS system in the same way as the EU and as a consequence the GB classification and labelling system is based on the existing EU CLP regulatory regime. GB based importers are required to comply with GB CLP regulations.

EU imports

After the UK's withdrawal, GB 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.

32. 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. Following the UK's withdrawal, it will be the responsibility of the EU-based importer to submit the C&L notifications to ECHA.

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

If you are currently a GB-importer (i.e. you obtain substances or mixtures from outside of the EU) or a GB manufacturer and you have already submitted a notification to ECHA in accordance with Articles 39 and 40 of CLP, before the transition period you donot have to submit another notification in GB for those substances. We understand from the UK authority that where the new GB importer was part of an EU to GB supply chain (as a downstream user or a distributor) that was in place on 31 December 2020, and the information already notified to ECHA by the manufacturer or importer elsewhere in that supply chain can be relied on as accurate, no re-notification is needed to HSE. However, the legal obligation to demonstrate that the hazard information and labelling is correct will rest with the new importer if challenged by an enforcing authority. Where new supply chains are established from 1 January 2021, notification to HSE will

be needed by GB based manufacturers and importers. Where the hazard information changes, a new notification to HSE will be needed.

34. **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 (for which harmonised notifications for consumer and professional uses applied from 1st January 2021) is only expected to apply in the EU and Northern Ireland. As a consequence, GB-based importers and downstream users are expected to continue with voluntary submission in the form of Safety Data Sheets (SDS) to the NPIS.

35. **Will my Safety Data Sheet need to be updated following the UK's withdrawal?**
substances and mixtures imported to the EU from GB 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 imported into GB will need to be updated with details of the supplier responsible for placing the product on the GB market.

36. **Is the proposed GB mandatory classification and labelling (MCL) list an exact copy of Annex VI of the CLP regulation (EC 1272/2008 as amended?**
The GB mandatory classification and labelling list carried over all EU harmonised classification and labelling, in force, on 31 December 2020. Since 1 January 2021, the HSE has noted that the new GB MCL List will now be amended annually to keep the entries up to date with scientific and technical developments which do not necessarily mirror the EU harmonised classification and labelling list.

37. **Has the 15th ATP to CLP, which was officially published in the transition period been taken into account for GB CLP? What about the 16th and 17th ATP?**
The 15th ATP to EU CLP had entered into force by the end of the transition period therefore, it forms part of the retained legislation. The application date for GB mandatory classification and labelling for the 15th ATP substances is 1 March 2022. The 16th and 17th ATP did not come into force before the end of the transition period. Therefore, both the 16th and 17th entries will not be included in the GB MCL list.

38. **Can an Only representative (OR) fulfil the CLP notification requirements on behalf of the non-GB manufacturer?**
Under article 8 of UK REACH, a non-GB manufacturer/formulator/producer of articles can appoint a GB-based Only Representative to fulfil the obligations of the GB-based importers. Under GB CLP however, there is no reference to Only Representative (OR) and therefore no option to use an OR to fulfil the obligations on importers under GB CLP including fulfilling CLP notification requirements.

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