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## *Brexit: The UK's withdrawal from the EU*

### *A commentary on the Only Representative Implications*

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December 2020

#### **ORO Background:**

The issue of chemical management under REACH and CLP presents a key challenge for companies in the UK, the European Union (EU) and outside the EU. The Only Representative Organization (“ORO”) represents its 34 members, more than 2,500 non-EU companies and almost 20,000 EU based importers<sup>i</sup>. The ORO is an Approved Stakeholder<sup>ii</sup> within the ECHA dialogue process and represents a particular field of competence. In addition to providing support to members, the organisation has also published a Best Practice Guide which is available through the ORO webpages<sup>iii</sup> or from ECHA<sup>iv</sup>.

Members of ORO are committed to continue to provide market access to the EU on behalf of its non-EU clients (“Principals”).

#### **ORO's main objectives:**

- Set up common Only Representatives guidance and quality standards
- Develop a common understanding of REACH requirements for Only Representatives
- Represent Only Representatives and non-EU manufacturers
- Cooperate with regulators and other stakeholders in the REACH process

#### **BREXIT Background**

Since our last statement in January 2018, the UK has formally withdrawn on 31<sup>st</sup> January 2020 from the European Union under the terms of the Withdrawal Agreement<sup>v</sup> and entered a Transition Period. During this period EU law has continued to apply in the UK, as if the UK were still a Member State. New Commission Implementing Regulations, authorisation decisions, restrictions etc. will form part of the retained UK law at the end of the Transition Period. The Transition Period will end on 31<sup>st</sup> December 2020.

There have been numerous key documents from both UK and European regulatory authorities and trade associations which are highly informative on the subject and to which we direct the reader. These were based on a worst case “no-deal” Exit scenario. However, they remain relevant under the assumption that chemicals legislation will not be addressed in the Free Trade Agreement (FTA) to be negotiated between the EU and the UK. The result of this would be similar to previously considered “no deal” Brexit scenarios in which the UK would operate its own chemicals regime. Therefore, in the absence of clarity on that point, this is currently the worst-case scenario to prepare for.

- The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019<sup>vi</sup> and subsequent amendments (No. 2)<sup>vii</sup> and (No. 3)<sup>viii</sup>. These statutory instruments (SI) will be amended during the Transition Period to ensure that the relevant transitional measures begin at the end of the transition period, not at the point that the UK left the EU.
- ECHA: How will the UK Withdrawal affect you?<sup>ix</sup> This has been adapted to present information which is role-specific. This source is highly informative, and we encourage the reader to bookmark it. Since the withdrawal of the UK from the EU, some of this information is under review to more accurately reflect the consequences of the Transition Period.

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- How to comply with REACH chemical regulations (in the UK). The UK government updated their guidance on how a UK implementation of REACH (as per the above SI) will impact UK-based businesses, and announces intended changes to registration deadlines in the UK, for those that are able to notify or grandfather<sup>x</sup>.
  - Health and Safety Executive (HSE): REACH Regulation at the end of the transition period. Advice and scenarios for stakeholders occupying a variety of supply chain roles<sup>xi</sup>
  - CEFIC-CIA briefing note: what you need to know – practical considerations to maintain trade post-Brexit<sup>xii</sup>

This document intends to build on the practical measures which actors should consider reducing the likelihood of supply chain interruption after the Transition Period has ended, and the role an Only Representative can play.

The negotiation talks are dynamic and may impact your supply chain. We would suggest you remain in close contact with ECHA and your trade groups for updates on progress as it applies to EU chemical regulations and potential UK chemical regulations.

Communicate actively with your suppliers and customers to ensure that the appropriate actions are being prepared to secure your supply chains in the event of separate UK chemicals legislation coming into effect after 31<sup>st</sup> December 2020<sup>xiii</sup>, but also in early 2021 to understand the further actions of your supply chains

### SCENARIOS

#### 1. Chemicals are not explicitly covered by a UK-EU trade deal; UK REACH enters into force on 1<sup>st</sup> January 2021

This is *the most likely scenario*.

In the event that chemicals legislation does not feature in a free trade agreement (FTA) between the EU and the UK, UK REACH will enter into force at the end of the Transition Period – 11pm 31<sup>st</sup> December 2020.

From this moment, the UK will be outside the scope of EU REACH and have no obligations under that Regulation.

It is unlikely that an FTA will enable the REACH Regulation to apply in the UK. UK Government Minister Michael Gove gave evidence to the Committee on the Future Relationship with the European Union back in March, stating that after Brexit, the UK government will not accept the jurisdiction of the European Court of Justice (ECJ) in the UK – which REACH would require<sup>xiv</sup>.

Furthermore, the UK government stated back in May that UK REACH *will* enter into force on the 1<sup>st</sup> January 2021<sup>xv</sup>.

Implications:

- Existing substance Registrations submitted by UK legal entities under REACH will become “non-existent” at the point of withdrawal.
- UK-based Only Representatives (ORs) will no longer meet the REACH Article 8 criteria and hence will cease to exist as Registrants under REACH and will not be able to fulfil obligations on behalf of EU-27/EEA importers.
- Registrations submitted by an EU-27/EEA-based OR to take over the importer registration and authorisation obligations for UK importers will no longer apply. The relationship to the UK-based importer will cease and the UK importer will no longer be regarded as a downstream user.

“UK REACH” will come into effect at the point that the transition period ends. In the first instance it will replicate EU REACH as far as possible, with some modifications where the EU REACH Regulation is inoperable e.g., where references are made to ECHA and the European Commission. This means, for example, registration will be required in the UK. However, there will also be additional transitional provisions, applicable to UK-based legal entities, that aim to help mitigate the immediate effects of UK REACH compliance.

Briefly:

- UK-based legal entities in possession of an EU REACH registration in the period between 29<sup>th</sup> March 2017 and the end of the Transition Period have a 120-day grace period to “grandfather” in their registrations – unless they transferred their registration to another UK-based legal entity during that time.
- During this grace period, they can submit ‘basic’ information – essentially equivalent to a member dossier. Doing so will grant them market access in the UK for between 2 and 6 years post-Transition, depending on tonnage band and hazard (see Figure 1 below). To remain on the market beyond this period, they must fulfil the full REACH information requirement for their tonnage band.

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

Figure 1 Registration deadlines for UK-based legal entities that successfully grandfathered within 120 days, or notified within 300 days. Source: <https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations>

- Because this provision only applies to UK based legal entities that held a registration pre-Exit, it would typically not be available to new Only Representatives appointed in the UK *after* the end of the Transition Period; they would not have previously held a registration.
- UK-based legal entities importing from the EU that were previously considered downstream users or distributors will become importers and immediately acquire a registration obligation. Affected legal entities will have a 300-day grace period to submit a relatively simple notification known as a Downstream User Importer Notification (DUIN). This will allow them to effectively maintain their downstream user/distributor status until, at the latest, 28<sup>th</sup> October 2027, again depending on tonnage band and hazard (Figure 1). After this point, they must be in possession of a full UK registration to remain on the UK market at or above 1 tonne per annum. **N.B.** This is *not* a pre-registration; to register, an inquiry dossier must first be submitted to the UK authority.
- **Importantly, a newly appointed (post-Transition) UK-based Only Representative can take on the notification (and subsequent optional registration) responsibility on behalf of UK-based downstream users by submitting a DUIN.**
- No such transitional provisions are in place for EU-based legal entities.

Actions required to maintain an existing REACH Registration currently held by an UK legal entity:

- A. To transfer the Registration to the EU-27/EEA under the REACH regime:
  - Transfer to an EU-27/EEA legal entity upon completion of a legitimate asset transfer in advance of the end of the Transition Period per the current ECHA Guidelines<sup>xvi</sup>
  - A UK Manufacturer or Formulator can appoint an EU-27/EEA-based Only Representative upon withdrawal from the EU. Although today there can be no such appointment within ECHA's REACH-IT system, ECHA outlines a concept for a suspensive clause in a contractual arrangement<sup>xvii</sup>.
- B. To retain the Registration in the UK under its equivalent legislation:
  - According to the current situation existing REACH registrations can be grandfathered into the UK's copy-paste legislation. To do this an account needs to be created within the new UK REACH-IT system and 'basic' information submitted within 120 days (i.e. by 30<sup>th</sup> April 2021). Subsequently, the full REACH information requirement (e.g., the dataset) must be fulfilled according to the timelines outlined in Figure 1, and by 28<sup>th</sup> October 2027 at the latest).

Actions to help mitigate supply chain disruption for UK-based downstream users/distributors:

- A. UK-based downstream user/distributor to notify under UK REACH:
- Once the UK REACH-IT system is live, the UK-based legal entity can create an account and submit a simple notification within 300 days (i.e., by 27<sup>th</sup> October 2021). This should be immediately followed up by a spreadsheet detailing the substances for which the legal entity was a downstream user or distributor; emailed to the Health and Safety Executive (HSE).
  - This notification is not a pre-registration. Furthermore, it does not oblige the legal entity to register in the future.
  - To remain on the market (at or above 1 tonne per year), the UK legal entity must be covered by a new full registration by 28<sup>st</sup> October 2027 at the latest, or sooner depending on tonnage band and hazard as per Figure 1. This could be submitted by themselves, or by an OR appointed by the non-UK manufacturer/formulator.
  - **N.B.** The grandfathering provisions do not apply here. A registration fee will be levied by the Agency.
- B. Manufacturers, formulators or article producer **not based in the UK** appoints an Only Representative to notify on behalf of UK-based customers:
- After the Transition Period has ended, a non-UK manufacturer or formulator can appoint a UK-based Only Representative to submit notifications on behalf of UK-based downstream users and distributors. This must be done within the 300-day notification period.
  - This Only Representative can be appointed by an EU-based manufacturer/formulator, or non-EU, non-UK manufacturer/formulator, so long as the UK-based customers that are covered can show that they were existing downstream users or distributors under EU REACH, for the substances being notified.
  - The OR notification can be completed in addition to the individual downstream user or distributor also submitting a notification, for example if they wanted to temporarily cover supply from other EU-based suppliers.
  - The Only Representative may choose to register the notified substances in the UK. This would be a full, new registration – preceded by an inquiry dossier. The grandfathering provisions do not apply. A registration fee will be levied by the Agency.

We provide a summary table in Annex I to this document to outline, in a non-exhaustive fashion, the considerations which companies may consider depending on their role within the supply chain and the location of their customers.

### 2. A UK-EU trade deal contains provisions for chemicals including some degree of regulatory alignment with EU REACH.

Given the UK's Negotiating Mandate outlining a general desire to diverge from EU regulations and for the European Court of Justice (ECJ) to have no jurisdiction in the UK, this scenario currently seems unlikely in the extreme. It is mentioned here solely to stress this fact, and to encourage you to plan for the previous scenario.

### General points relating to UK REACH

- **Transfer Costs:** No fee will be levied by the UK Agency for the grandfathering process, nor for downstream user/distributor notifications (under Article 127E and Article 127EA). Data holders may still charge extra for UK-specific Letters of Access. Transfers of assets using ECHA's REACH-IT platform, prior to the end of the Transition Period, will be subject to the standard fees as laid out in the Fees Regulation<sup>xviii</sup>.
- **IUCLID Versions:** The UK REACH-IT system will only accept dossiers in IUCLID 6 format, and above. Dossiers created in older versions of IUCLID must be converted into the latest IUCLID format. **However**, any business rules/completeness check/quality check failures that result from this change will **not** need to be addressed for the first stage of the grandfathering process (within 120 days).
- **Joint Submissions:** Because UK REACH replicates EU REACH, the provisions relating to Joint Registration remain. It is expected that a UK lead registrant will be appointed (from amongst the grandfathered registrants, and potential new registrants (inquirers)). The process for this has not yet been released by the UK Agency.

### NOTE: Northern Ireland Protocol: (Ref: ECHA Q&A)

Transfers of chemicals from Great Britain to Northern Ireland are considered as imports into the EU, and the relevant obligations for importers under REACH, CLP, BPR, PIC and POPs apply.

The IE/NI Protocol provides that REACH applies to and in the United Kingdom in respect of Northern Ireland. REACH does not apply in other parts of the United Kingdom ('Great Britain').

On a practical level this means that:

- substances manufactured in or imported to Northern Ireland need to be registered with ECHA, including substances imported from Great Britain to Northern Ireland;
- substances shipped from Northern Ireland to the EU/EEA are not considered 'imported' from the registration perspective;
- an Only Representative based in Northern Ireland is considered equal to an Only Representative in the EU/EEA;
- a manufacturer, formulator or an article producer in Northern Ireland cannot appoint an Only Representative;

The IE/NI Protocol will start to apply as of 1 January 2021.

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### Contact:

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### ANNEX I: End of transition period: Considerations for Actors depending on their role, location and customers

Selling to:	UK only	EU-27/EEA only	UK and EU-27/EEA at >1tpa
<b>Your Role:</b>			
<b>Non-EU Company with an existing UK-based OR</b>	<ul style="list-style-type: none"> <li>- Check that your OR will continue to support you</li> <li>- Check that contracts and appointments refer to UK REACH</li> <li>- Inform your customers about continuity</li> <li>- Have your OR grandfather your EU REACH Registration in the UK within 120 days after the end of the transition period</li> <li>- OR to submit remaining supporting data for the registrations by the appropriate deadline.</li> </ul>	<ul style="list-style-type: none"> <li>- Will your UK-based OR give coverage in EU-27/EEA by transferring to an EU-27/EEA affiliate legal entity?</li> <li>- If not, then find an EU-based OR and arrange for orderly transfer before the end of the transition period</li> </ul>	<ul style="list-style-type: none"> <li>- Registrations will be required in both jurisdictions. <b>N.B.</b> Your existing LoAs may not be valid for UK registrations; you may have to negotiate and pay again.</li> <li>- You will potentially require two ORs: one in the EU-27/EEA and one in the UK, therefore see recommendations for each jurisdiction (to left).</li> </ul>
<b>Non-EU Company with an existing EU-27/EEA OR</b>	<ul style="list-style-type: none"> <li>- Does the UK importer have their own Registration?</li> <li>- If so, they can grandfather; if not...</li> <li>- Will your EU-27/EEA-based OR set up a UK entity?</li> <li>- If not, find a new UK-based OR</li> <li>- Instruct EU-OR to transfer Registration to UK OR <i>before 31<sup>st</sup> December 2020.</i></li> <li>- UK-OR Grandfather the EU Registration under UK REACH within 120 days after the end of the transition period</li> <li>- UK-OR to submit remaining supporting data for the registrations by the appropriate deadline.</li> </ul>	<ul style="list-style-type: none"> <li>- No action required</li> <li>- Maybe useful and necessary to communicate to customers</li> </ul>	
<b>UK-based Manufacturer</b>	<ul style="list-style-type: none"> <li>- Registrations should already be in place, if &gt;1 tpa is manufactured</li> <li>- Grandfather the UK Registration by end April 2021 (i.e., within 120 days after the end of the transition period)</li> </ul>	<ul style="list-style-type: none"> <li>- Even though supply is to the EU only, manufacturing still occurs in UK so grandfathering of existing registration still required</li> <li>- To cover EU importers, establish an OR arrangement with an EU-27/EEA based OR using suspensive clause triggered at end of Transition.</li> <li>- Inform supply chain of intended action and confirm appointment of the OR to EU customers</li> <li>- Could consider transfer of Registration if associated</li> </ul>	<ul style="list-style-type: none"> <li>- Grandfather the existing registration(s) in the UK</li> <li>- Appoint an EU-OR and transfer registration before the end of the transition period (via suspensive clause)</li> <li>- High urgency: Consider seeking an EU-27/EEA-based OR and prepare contracts, agreements and dossier(s) ahead of withdrawal date, to be ready for submission after 31<sup>st</sup> Dec 2020. You will need to check with the Lead Registrant/Consortium Manager for LoA rights.</li> </ul>

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		<p>Manufacturing assets are transferred to EU Legal Entity transfer <b>N.B.</b> manufacturing in the UK must cease if this transfer is completed before the 31<sup>st</sup> December 2020</p>	
<p><b>UK-based Importer (from sources outside the EU-27/EEA)</b></p>	<ul style="list-style-type: none"> <li>- Registrations should already be in place, if &gt;1 tpa is imported</li> <li>- Grandfather the UK Registration by end April 2021</li> </ul>	<ul style="list-style-type: none"> <li>- Even though supply is to the EU only, import still occurs in UK so grandfathering of existing registration still required</li> <li>- If you are a formulator, establish an OR arrangement with an EU-27/EEA-based OR using suspensive clause triggered at end of Transition.</li> <li>- Non-EU supplier could appoint an EU-based OR to cover imports into the EU (see above)</li> <li>- Inform supply chain of intended action and confirm appointment of the OR to EU customers</li> <li>- Consider supply chain alteration to avoid UK import</li> <li>- Alternatively, could transfer your registration to an EU subsidiary or other EU-based importer (along with associated relevant assets)</li> </ul>	<ul style="list-style-type: none"> <li>- A combination of the two recommendations for each jurisdiction (left)</li> <li>- Grandfather the existing registration(s) in the UK</li> <li>- Either appoint an OR upon Transition date (via suspensive clause); or initiate a transfer to EU legal entity prior to the Transition date</li> <li>- Inform supply chain and customers</li> </ul>
<p><b>You become a UK-based Importer from an EU-27/EEA registrant or DU/distributor (previously you were a REACH DU or distributor)</b></p>	<ul style="list-style-type: none"> <li>- Registration obligation arises under UK chemicals legislation as soon as the 1 tonne threshold is breached</li> <li>- Submit the required UK notification within 300 days after the end of the transition period and prepare for Inquiry and Registration by the appropriate deadline (see Figure 1)</li> <li>- Seek support from non-UK manufacturer using UK-based OR</li> <li>- New UK-OR (appointed post-Transition) can notify and register on behalf of new UK importers</li> </ul>	<ul style="list-style-type: none"> <li>- Reimport principle may apply for volumes shipped back to EU-27/EEA so no EU-27/EEA registration required</li> <li>- Notify as per the left column, then prepare for UK Registration required under UK chemicals legislation by 31<sup>st</sup> Dec 2022</li> </ul>	<ul style="list-style-type: none"> <li>- EU-27/EEA customers could buy direct from the EU-27/EEA-based manufacturer/importer</li> <li>- Otherwise a combination of the two recommendations for each jurisdiction (left)</li> </ul>
<p><b>You become an EU-27/EEA-</b></p>	<ul style="list-style-type: none"> <li>- Ensure that your UK supplier will</li> </ul>	<ul style="list-style-type: none"> <li>- Check whether your UK supplier will register</li> </ul>	<ul style="list-style-type: none"> <li>- Reimport principle likely to apply for volumes shipped</li> </ul>

<p><b>based importer from a UK manufacturer</b></p>	<p>register/grandfather under UK chemicals legislation to maintain your supply</p> <ul style="list-style-type: none"> <li>- If importing at 1 tpa or more, registration must be in place prior to the end of the transition period as there are no transitional provisions in the EU.</li> <li>- Check whether your UK supplier will register under an EU-27/EEA OR arrangement or transfer their registration</li> <li>- If not, then consider registering or finding an alternative supplier.</li> <li>- Reimport principle may apply to UK customer for volumes shipped back to UK</li> <li>- transition period</li> <li>-</li> </ul>	<p>under an EU-27/EEA OR arrangement or transfer their registration</p> <ul style="list-style-type: none"> <li>- If not, then consider registering or finding an alternative supplier.</li> <li>- If importing at 1 tpa or more, registration must be in place prior to the end of the transition period as there are no transitional provisions in the EU.</li> </ul>	<p>back to UK so no UK importer registration required</p> <ul style="list-style-type: none"> <li>- Check whether your UK supplier will register under an EU-27/EEA OR arrangement.</li> <li>- If not, then consider registering or finding an alternative supplier.</li> </ul>
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<sup>i</sup> <http://www.onlyrepresentative.org/about-oro/facts-figures>

<sup>ii</sup> <https://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>

<sup>iii</sup> <http://www.onlyrepresentative.org/>

<sup>iv</sup> <https://echa.europa.eu/reach-2018/in-your-language/european-organisations>

<sup>v</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12020W/TXT&from=EN>

<sup>vi</sup> <https://www.legislation.gov.uk/ukdsi/2019/9780111178034/contents>

<sup>vii</sup> <https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-reach-etc-amendment-etc-no-2-regulations-2019>

<sup>viii</sup> <https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-reach-etc-amendment-etc-eu-exit-no-3-regulations-2019>

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

<sup>x</sup> <https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations#Tonnage-band-deadlines>

<sup>xi</sup> <https://www.hse.gov.uk/brexit/reach-guidance.htm>

<sup>xii</sup> <https://www.cia.org.uk/News/Details/Brexit-Preparing-for-a-future-UK-out-of-REACH-scenario>

<sup>xiii</sup> 31<sup>st</sup> December 2020 is the current anticipated date for the end of the Transition Period however, this date could either be brought forward or extended, depending on the progress of the negotiations between the UK and EU.

<sup>xiv</sup> <https://committees.parliament.uk/oralevidence/162/html/>

<sup>xv</sup> <https://committees.parliament.uk/publications/1277/documents/11202/default/>

<sup>xvi</sup> [https://echa.europa.eu/documents/10162/13643/pg\\_8\\_legal\\_entity\\_change\\_en.pdf/09cb0bf2-4b27-4a44-8ed1-cd0fe39171e7](https://echa.europa.eu/documents/10162/13643/pg_8_legal_entity_change_en.pdf/09cb0bf2-4b27-4a44-8ed1-cd0fe39171e7)

<sup>xvii</sup> <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1371-1372-1415-1416-1417-1418-1419-1423-1424-1425-1426-1427-1444-1445-1464-1538-1539> FAQ ID 1464

<sup>xviii</sup> [https://eur-lex.europa.eu/eli/reg\\_impl/2015/864/oj](https://eur-lex.europa.eu/eli/reg_impl/2015/864/oj)