UK REACH additional guidance if there is no Brexit deal

We have now agreed in principle the terms of the UK's smooth and orderly exit from the EU, as set out in the Withdrawal Agreement. We have also agreed the broad terms of our future relationship as set out in the outline Political Declaration. But nothing is agreed until everything is agreed - and as such it is the duty of a responsible government to continue to prepare for all scenarios, including the unlikely event of a no-deal.

This guidance expands on, and should be read in conjunction with, the guidance document ("Technical Notice") published on 24th September 2018, to help businesses prepare for the unlikely possibility of no deal.

In the unlikely event of no deal, the EU REACH[1] Regulation will be brought into UK law by the European Union (Withdrawal) Act 2018. The Act replicates REACH in the UK whilst making the changes necessary to make it work outside of the EU. We will therefore retain the key principles of the EU REACH Regulation, including its fundamental principle of 'no data, no market', and its provision for Only Representatives (ORs). In this note, the EU REACH Regulation, as amended, is referred to as the UK REACH Regulation, and the regulatory system it creates is referred to as UK REACH.

As the UK Statutory Instrument is not yet available, references in this guidance will be to the EU REACH article numbers.

Implications for business

The role you currently undertake within EU REACH may change, in some cases significantly. It is therefore important that you undertake a review of your role(s) within the EU and UK REACH regimes. To maintain or gain access to the EU/EEA and the UK markets, there may be a number of actions you will need to take if there is no deal with the EU. For example:

For existing EU REACH registration holders

- In order to continue exporting substances or mixtures to the EU/EEA market, UK-based entities currently holding EU REACH registrations would need to transfer their registrations to an EU/EEA-based entity, or support their EU/EEA-based importers to become registrants. Further details are available on the ECHA website.
- Entities currently holding EU REACH registrations would also need a valid UK REACH registration to maintain access to the UK market.

For downstream users

[1] EU REACH (EC)1907/2006

- UK downstream users (who do not hold an EU REACH registration) currently purchasing chemicals from an EU/EEA country would need to ensure the substances they purchase are covered by a valid UK REACH registration. If purchasing over 1 tonne per year, they could either:
    - encourage the EU/EEA supplier to appoint a UK-based OR;
    - become the importer and take on the duty to register chemicals for the UK market; or
    - change source to a UK registered supplier.
- UK downstream users using a substance subject to an EU REACH authorisation would need to provide information to the UK Agency (the HSE) to continue to benefit from the authorisation.

In a no-deal scenario, the UK and the EU regulatory agencies would operate independently from each other. If companies are supplying and purchasing substances, mixtures or articles to and from the EU/EEA and the UK, they will need to ensure that the substances, or substances within a mixture/article, are registered with both agencies (ECHA and the UK Agency, i.e. the HSE) separately in order to maintain or gain access to both markets.

The following guidance sets out a number of actions that your company would need to investigate so that you can prepare for a 'no-deal' scenario. For the UK market, there will be a phased approach designed to minimise disruption and ensure continuity. Some of the proposed timeframes will be kept under review.

Scenario 1: You are a UK-based EU REACH registration holder wishing to maintain UK market access

- Your registration(s) will be legally recognised in the UK REACH system at the point that the UK leaves the EU. This recognition is called 'grandfathering'.
- This will provide continued access to the UK market after the UK leaves the EU.
- You will then need to confirm your existing registration and provide supporting information to the UK Agency (the HSE). You will need to:

    1. Open an account on the new UK REACH IT system, which will be launched by the point that the UK leaves the EU.
    2. Provide some basic information on your existing registration within 60 days of the UK leaving the EU. Full details of the information required can be found in Appendices A and B.
    3. Provide the technical information required under UK REACH for your tonnage band within 2 years of the UK leaving the EU. The information requirements for UK REACH will remain the same as they currently are for EU REACH. This timescale will be kept under review. Full details can also be found in Appendices A and B.

- Grandfathering will apply to all registrations (including intermediates) held by UK-based entities, including importers and UK-based Only Representatives (ORs), and to sole, lead or joint registrants.
- Grandfathering will apply to all registrations that exist at the time of exit, and all registrations held by UK entities at any point within the two years prior to 29th March 2019. This means that if a UK registration was transferred to an EU/EEA-based entity in the run-up to the UK leaving the EU, it will still be carried over into the UK system.
- Any ECHA decisions relevant to the registration will remain valid.
- Grandfathering will not incur any fees from the UK Agency (the HSE) for registrants: it will happen at the point that the UK leaves the EU, providing unbroken legal validity.
- Your UK REACH registration number will be issued upon submission of the initial information required within 60 days of the UK leaving the EU.
- Access to the technical information used for the ECHA registration may require renegotiating commercial contracts/letters of access which were originally put in place for EU REACH under a Substance Information Exchange Forum (SIEF). You may wish to instigate contact with SIEF members as part of your contingency planning; this may help provide an early indication of the terms that would be attached to renegotiating access to the data for UK REACH purposes.
- You may wish to contact the other UK registrants in your SIEF to prepare a joint UK REACH registration.

Scenario 2: You are a UK-based downstream user or a distributor of an EU REACH registered chemical and wish to maintain UK market access

- If the UK leaves the EU without a deal, EU/EEA countries will be in the same situation as non-EEA countries for the purposes of the UK REACH Regulation. This means that companies procuring substances and mixtures from EU/EEA suppliers either directly or in articles would become importers under UK REACH. These companies will then have an obligation to hold a UK registration as importers. However, in order to ensure continued access to the UK market and to maintain supply chains, we propose to implement a 'notification' system before full registration obligations are applied.
- If you are a downstream user or distributor of EU/EEA-imported substances, you will need to complete a 'notification' by:

    1. Opening an account on the new UK REACH IT system.
    2. Providing some information within 180 days of the UK leaving the EU. Full details of the information required can be found in Appendix C.

- Notification will not incur any fee from the UK Agency (the HSE).
- The notification does not tie you to your existing EU/EEA supply chain: you may switch suppliers temporarily or permanently, and inform the UK Agency (the HSE) of any relevant changes.

- You will need to register the substances with the UK Agency (the HSE) by providing the technical dossier appropriate to your tonnage to support your registration within two years of the UK leaving the EU, if you wish to continue importing these chemicals. This timescale will be kept under review. These will be classed as new registrations and will therefore be subject to fees payable to the Agency (the HSE).
- EU/EEA manufacturers exporting to the UK may choose to appoint a UK-based OR to take on UK REACH obligations. This would be classed as a new substance registration, and full registration duties (e.g. full data package submitted on registration) would apply and the appropriate registration fee would be charged (see 'new registrations' later in this document). This registration would need to be made within 180 days after the UK leaves the EU, in order to relieve downstream users of notification duties as UK importers.

Scenario 3: You are a UK importer of chemicals from outside the EU/EEA, or rely on a UK importer for your supply from outside the EU/EEA, and wish to maintain EU/EEA market access

- If you import substances from a non-EU/EEA country, you cannot appoint an OR under EU REACH (only a manufacturer, formulator or producer of articles can do so). This means that, as a UK-based importer, you will not have the option to transfer your registrations directly to an EU-based OR to continue selling into the EU/EEA. If you wish to continue to sell chemicals to EU/EEA customers in a no-deal scenario, you may do the following:
    - Ensure your EU/EEA customers hold a valid EU REACH registration as an importer; or
    - Ensure the non-EEA country manufacturer supplying you appoints an OR based in an EU/EEA country.
- If you rely on a UK importer of non-EEA chemicals, you should check your supplier's contingency plans, to ensure uninterrupted supply.

Scenario 4: You are a UK-based REACH authorisation holder wishing to maintain your use or the supply for a use in the UK

- If you are a UK manufacturer, importer, downstream user or an Only Representative, your existing EU authorisations before the UK leaves the EU will be carried over ('grandfathered') into the UK system. This will include the review period and any conditions attached to the authorisation. It will not incur a fee from the Agency (the HSE).
- If you are a UK holder of authorisations (i.e. where you applied and the European Commission has granted an authorisation decision), you will be required, within 60 days of the UK leaving the EU, to supply the UK Agency

(the HSE) with technical information relating to the authorisation to enable the effective management and enforcement of the authorised substance. The required technical information is:

a) the information included in the application for the authorisation;
b) any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion; and
c) 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.

Scenario 5: You are a UK downstream user of a REACH authorisation held by an EU/EEA-based company, wishing to maintain your use or the supply for a use in the UK

- If you are a UK downstream user of an EU REACH authorisation held by an EU/EEA company, you will continue to be able to use that substance in accordance with that authorisation after the UK leaves the EU, providing, within 60 days of the UK leaving the EU, that you:

1. Confirm to the UK Agency (the HSE) that you are an existing authorised downstream user under EU law in relation to the substance, and
2. Notify the UK Agency (the HSE) of:
    a) the existing EU authorisation;
    b) any conditions set out in the existing EU authorisation;
    c) the identity of the supplier of the substance.

Substances of Very High Concern and Restrictions

- The ECHA candidate list at the point that the UK leaves the EU will be carried into UK law. Annex XIV of the EU REACH Regulation and the substances listed in it will also be retained in the UK REACH Regulation.
- The restrictions currently listed in Annex XVII to the EU REACH Regulation will be carried over into the UK REACH Regulation.
- The powers to update the candidate list, Annex XIV and Annex XVII will remain in UK REACH based on the same legal conditions and criteria.

Scenario 6: You are exempt through a PPORD

- Article 9 exemptions (PPORDs) in EU REACH will be carried over into UK REACH.
- Current exemptions under EU REACH for substances imported or manufactured for purposes of product(s) and process oriented research and development (PPORDs), where the research and development concerned

takes place in the UK, will be grandfathered into UK REACH. If you are a manufacturer, importer or producer, you must, within 60 days of the UK leaving the EU:

1. Notify the Agency of the relevant information required as per Article 9(2) using the UK REACH IT system – no fee is required on compliance with this for a grandfathered PPORD;
2. Notify the UK Agency (the HSE) of the number and notification date assigned by ECHA;
3. Supply the UK Agency (the HSE) with copies of any additional necessary information given to ECHA.

- Grandfathered PPORDs will be subject to the same conditions imposed by ECHA, and existing validity periods for PPORD exemptions will be maintained e.g. five years from the agreed date with ECHA under Article 9(3) or Article 9(7), and may be extended by up to 10 years.
- Grandfathered exemptions will expire on the date that the exemption granted under the EU REACH Regulation would have expired unless you request an extension from the UK Agency (the HSE).

Scenario 7: You are awaiting an ECHA or EU Commission decision

Registrations

- If your registration under the EU REACH Regulation is in progress at the point that the UK leaves the EU, you will need to submit a separate new registration to the UK Agency (the HSE). This will incur the fee applicable to a new registration, payable to the UK Agency (the HSE).

Authorisations

- If you are a UK company that has submitted an authorisation application to ECHA but where ECHA has not finalised its opinions under Article 64(5) by the point that the UK leaves the EU, you will need to resubmit your dossier to the UK Agency (the HSE) if you want to continue placing this substance on the market or using it in the UK after the sunset date inscribed in Annex XIV of REACH.
- The authorisation process will be streamlined where your application is in its final decision stage. An application for an EU authorisation is at the final decision stage if:
  (a) ECHA has adopted its final decisions, but
  (b) the European Commission has not made a final decision granting or refusing the application.

  The Secretary of State for Defra will make a decision on the basis of the opinions ECHA sent to the European Commission. The decision will be taken subject to the consent of the Devolved Administrations where it involves matters of devolved competence.

To take advantage of this, applicants will have to:

(i) notify the Secretary of State of the existence of the application, and

(ii) give the Secretary of State copies of the application, the information included in it, and any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion in relation to the application for the authorisation.

(iii) give the Secretary of State copies of the opinions ECHA sent to the applicant.

Where the sunset date has passed, the UK applicant will still be able to manufacture, import, market or use the substance as long as the necessary information is provided to the Secretary of State within 180 days of the UK leaving the EU.

- Where an application has been made to ECHA by an EU/EEA applicant before the last application date, and ECHA has not given its final opinions the UK-based downstream users will no longer be able to benefit from that authorisation application to continue using the substance after the sunset date. Instead you will have to apply for a UK REACH authorisation. You should contact the UK agency (the HSE) to discuss the best way of achieving compliance.

UK REACH after the UK leaves the EU without a deal

New registrations

- If a business wishes to place new chemicals on both the EU/EEA and UK markets, if there's no deal with the EU, they will have to ensure that they comply with both EU REACH and UK REACH. UK REACH registrations will require the same IUCLID technical dossier format as EU REACH, for the relevant tonnage bands in the UK market. Non UK-based entities may access the UK market under UK REACH via a UK-based Only Representative, or by relying on their UK customer to register the substance.
- Registration of new chemicals for the UK market, after the UK leaves the EU without a deal, will be done directly through the UK Agency (the HSE), via the UK REACH IT system. The ECHA Fees regulation will be transposed into UK law so the fees will be similar to those currently charged by ECHA using the average exchange rate for 2017.
- New registrations will not be phased-in by tonnage bands.
- As with EU REACH, obligations would depend on tonnage band, and apply by reference to the tonnage manufactured in or imported into the UK. There would be no registration obligations for substances under one tonne.
- UK REACH will include a similar pre-registration substance inquiry system to EU REACH.
- Similar provisions on data sharing and test cost sharing will also be reflected in the UK REACH Regulation.

Authorisations

- After the UK leaves the EU without a deal, new applications for authorisations for the UK market should be made to the UK Agency (the HSE), and will incur similar administration fees as authorisations currently do under EU REACH. The Agency must obtain and use the advice of the environmental regulators across the UK (which will be coordinated centrally by the Environment Agency) when the application involves environmental issues.
- The UK REACH authorisation process would include the same provision for inviting information on alternative substances or technologies as in EU REACH.
- Decisions to grant authorisations would be taken by the Secretary of State, subject to the consent of the Devolved Administrations where they involve matters of devolved competence.

Safety Data Sheets

- The format, content and conditions under which Safety Data Sheets are required, as specified in the EU REACH Regulation and the subsequent amendments[2], will remain the same. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

Restrictions

- If there's no deal with the EU, the UK will make its own decisions on future restrictions.
- The UK system would have a similar procedure to introduce new or amended restrictions. The UK Agency (the HSE) will make assessments on any future substances that may meet the requirement for restriction under the UK REACH Regulation; issues taken into account will include (but not be limited to) regulatory developments in the EU. The Agency must obtain and use the advice of environmental regulators across the UK (which will be coordinated centrally by the Environment Agency) when the application involves environmental issues.
- The Agency will send its opinions to the Secretary of State who will decide whether to amend Annex XVII, subject to the consent of the Devolved Administrations where matters of devolved competence are involved.

PPORD Exemptions

- All new PPORD notifications after the UK leaves the EU should be made to the UK Agency (the HSE).

Only Representative provision

- The UK REACH Regulation will replicate the EU REACH Regulation's provision for Only Representatives (ORs). Third country manufacturers, formulators and producers of articles wanting to trade into the UK will be able to appoint a UK-based OR to take on their duties under the UK REACH

[2] **Regulation (EU) 2015/830** - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0830&from=EN

Regulation. This facility would therefore also be available to EU/EEA countries wanting to access the UK chemicals market.

UK REACH-IT

- An IT system mirroring EU REACH IT is being built for registrations, grandfathering and downstream user notifications to be operable from 29th March 2019.
- The system will replicate the same functionalities as the one used for EU REACH purposes. It will, for example, allow IUCLID to be used so that the same dossiers can be uploaded to UK REACH-IT.

Appendix A: Grandfathering data submission requirements

Registrants under EU REACH

This applies to all existing UK registrants under EU REACH, except for registrants of intermediates (please see appendix B for intermediates requirements).

The registrant must supply the following information to the Agency (the HSE) within 60 days of the UK's exit from the EU:

- evidence of their ECHA registration – such as ECHA registration number and date, and such other evidence as HSE may require of the EU registration.

- the information referred to in Article 10(a)(i), (ii), and (iii), and any relevant indication under Article 10(a)(viii)):

  This means the following information:
  - *Identity of manufacturer/importer (Article 10(a)(i))*
  - *Substance identity (Article 10 (a)(ii))*
  - *Information on the manufacture and use of the substance data (Article 10(a)(iii))*
  - *An indication as to which of the relevant information on manufacture and use has been reviewed by an assessor (Article 10(a)(viii))*

- notification of any ECHA decision which relates to the registration.

All of the other information submitted to ECHA in accordance with Article 10 must be submitted to the UK authority (HSE) within 2 years. This is the information referred to in Article 10(iv)-(ix) and (xi), and Article 10(b):

- *The classification and labelling of the substance (Article 10(a)(iv))*
- *Guidance on safe use of the substance (Article 10(a)(v))*
- *Study summaries (Article 10(a)(vi))*
- *Robust study summaries, if required (Article 10(a)(vii))*
- *An indication as to which of the above has been reviewed by an assessor (Article 10(a)(viii))*
- *Proposals for additional testing (Article 10(a)(ix))*
- *Exposure information for substances in the 1-10 tonnes tonnage band (Article 10(a)(x))*
- *Confidentiality request and justification, if relevant (Article 10(a)(xi))*
- *A chemical safety report when required under Article 14 (Article 10(b))*

Appendix B – Grandfathering data submission requirements for intermediates

Registrants under EU REACH

This applies to all existing UK registrants of intermediates under EU REACH.

The registrant must supply the following information to the Agency (the HSE) within 60 days of the UK's exit from the EU:

- evidence of their ECHA registration – such as ECHA registration number and date, and such other evidence as HSE may require of the EU registration; and

- for on-site isolated intermediates: the information referred to in Article 17(2)(a), and (b), (e) and (f), and the confirmation referred to in Article 17(3); or

  for transported isolated intermediates: the information referred to in Article 18(2)(a), and (b), (e) and (f), and the confirmation referred to in Article 18(4)

  This means the following information:
  - *identity of manufacturer or importer (Article 17(2)(a) or 18(2)(a))*
  - *identify of the intermediate (Article 17(2)(b) or 18(2)(b))*
  - *a brief general description of use (Article 17(2)(e) or 18(2)(e))*
  - *details of the risk management measures applied (Article 17(2)(f) or 18(2)(f))*
  - *confirmation of application of strictly controlled conditions (Article 17(3) or 18(4))*

All of the other information submitted to ECHA in accordance with Article 17 or 18 must be submitted to the UK authority (HSE) within 2 years. This is the information referred to in Article 17(2) (c) and (d) or Article 18(2)(c) and (d) and Article 18(3):

This means the following information:

- *the classification of the intermediate (Article 17(2)(c) or 18(2)(c))*
- *any available existing information on physicochemical, human health or environmental properties of the intermediate (Article 17(2)(d) or 18(2)(d))*
- *for transported isolated intermediates over 1000 tonnes the additional information on physicochemical, human health or environmental properties as specified in Annex VII (Article 18(3))*

Appendix C: Notification requirements for UK Downstream Users and Distributors of EU REACH registered chemicals

All notification information should be submitted within 180 days.

A. If the existing UK downstream user or distributor under EU REACH imports the substance into the UK in quantities of 1 to 10 tonnes per year from an EU/EEA state they must supply:

- the information referred to in Article 10(a)(i)
- the information referred to in Article 10(a)(ii) and (iv) to the extent that it is available to them
- the information referred to in Article 32(1)(a) to (d)
- the relevant registration number for the substance under EU REACH, and such other evidence as the Agency may require to support the information in Article 32(1).

  This means:
  - *Identity of manufacturers/importers*
  - *Substance identity to the extent it is available to them*
  - *Classification and labelling to the extent it is available to them*
  - *Details of any authorisations*
  - *Details of any restrictions*
  - *Any other available and relevant information necessary to enable appropriate risk management measures to be identified and applied*
  - *Registration number(s) assigned by ECHA*

B. If the existing UK downstream user or distributor under EU REACH imports the substance into the UK in quantities of 10 tonnes or more per year from an EEA state they must supply:

- the requirement of Article 10(a)(i)
- the information referred to in Article 10(a)(ii) and (iv) to the extent that it is available to them
- the information referred to in—
  - Article 14(6)
  - Article 31, and
  - Article 32(1)(a) to (d)
- The relevant registration number for the substance under EU REACH, and such other evidence that the Agency may require to support the information relating to Articles 14, 31 or 32.

  This means:
  - *Identity of manufacturers/importers*
  - *Substance identity to the extent that it is available to them*
  - *Classification and labelling to the extent that it is available to them*
  - *Identification and application of appropriate measures to control risks identified in the Chemical Safety Report*

- *Safety data sheets*
- *Details of any authorisation*
- *Details of any restriction*
- *Any other appropriate information to enable correct risk management measures to identified and applied including those resulting from additional exposure-driven testing*
- *Registration number(s) assigned by ECHA if available*