Please note: The advice contained in this document should not be taken as a definitive statement of the law or its interpretation. Only the courts can decide on the definitive interpretation of the law.

Q&A FROM 2 AND 12 NOVEMBER 2020 CHEMICALS AND REACH/CLP WEBINARS

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General

1. **I understand that the EA and DEFRA and BEIS can all employ new people to deal with all the changes but smaller companies like us cannot. Directing us to websites and papers is great but we are resource strapped therefore in the same way as UK gov has given £millions out in furlough payments, none of which we took like a number of other chemical companies, you should be considering a help fund of similar magnitude to support us coping with all these changes. I am not sure you understand the magnitude of the work involved in managing all these changes. Sounds simple on slides but implementing is very very significant.**

   Does the government acknowledge the significant extra costs to perform all this work?

   - The UK does not seek to remain part of the Single Market or Customs Union, and we recognise there will be adjustments to supply chains as a consequence and new obligations and costs to businesses that trade between the UK and the EU.

   - However, we are keeping the transition to UK REACH as simple as possible, avoiding change for change's sake.

   - For example, in building the Comply with UK REACH IT system we have made sure it will work very much like the ECHA owned REACH-IT, including the same software requirements and many of the processes that businesses have been using and understand.

   - We have put in place 'grace period provisions' of 'Grandfathering' and 'Downstream User Import Notifications' to minimise the costs for businesses and maintain market access to both the EU and GB market.

   - Following concerns raised about the current timelines for supplying data to the GB regulator, we have decided to extend these deadlines which would enable industry to mitigate costs without reducing important environmental and health protections.

2. **All I see are costs and bureaucracy. So what are the opportunities for UK Chemical Companies?**

   - The UK does not seek to remain part of the Single Market or Customs Union, and we recognise there will be adjustments to supply chains as a consequence and new obligations and costs to businesses that trade between the UK and the EU.

   - Leaving the EU means we can control our own laws, and ensure our regulatory system is smart and efficient, and continues to deliver high standards of protection for the environment and human health.

   - UK chemicals businesses will have the opportunity to benefit from future trade deals that we sign with countries around the world.

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3. **Who can I have a phone conversation with?**

- The UK Chemicals Helpline will support the 'Comply with UK REACH' service once it goes live at the end of the Transition Period.

- You are also strongly encouraged to firstly read the guidance at www.transition.gov.uk and also at www.hse.gov.uk/brexit/chemicals-brexit-guidance, before reviewing the answers to commonly-asked questions below.

- If you cannot find the information you need, you can contact the following helpdesks:
  - UK REACH Policy: REACH-IT@defra.gov.uk
  - UK REACH Operations: UKREACHCA@hse.gov.uk
  - EU REACH: contact ECHA
  - CLP, Biocides, PIC and PPP: EU-Exitchemicals@hse.gov.uk
  - UK customs queries (HMRC):
    - Import/export general enquiries - 0300 200 3700
    - speak to an adviser online about general import and export queries
    - send a question about imports, exports and customs reliefs

- If you still cannot find an answer to your question, please contact the BEIS chemicals sector team, who will seek to help you find the relevant guidance: heather.thomas@beis.gov.uk.

4. **When is there more hands-on guidance available (e.g. on formats etc)?**

- Updated UK REACH user guidance was published on the HSE website on 26 October 2020 and is regularly reviewed.

- Defra have assessed existing guidance and are working to produce further public facing material before the end of the transition period as additional support for businesses in their preparations for UK REACH.

- If you have further queries please contact:
  - UK REACH Policy: REACH-IT@defra.gov.uk
  - UK REACH Operations: UKREACHCA@hse.gov.uk

5. **Is more guidance on UK REACH expected? It would be helpful to have guidance published in pdf format rather than webpages.**

- Updated UK REACH user guidance was published on the HSE website on 26 October 2020 and is regularly reviewed.

- Defra have assessed existing guidance and are working to produce further public facing material before the end of the transition period as additional support for businesses in their preparations for UK REACH.

- If you have further queries please contact:
  - UK REACH Policy: REACH-IT@defra.gov.uk
  - UK REACH Operations: UKREACHCA@hse.gov.uk

6. **Is it possible for DEFRA and the HSE to start to use plain language and simple practical examples in their materials? Most of the people that are trying to be reached are not experts at all but know how to run a business day to day.**

- Updated UK REACH user guidance was published on the HSE website on 26 October 2020 and is regularly reviewed.

- Defra have assessed existing guidance and are working to produce further public facing material before the end of the transition period as additional support for businesses in their preparations for UK REACH.

- If you have further queries please contact:
  - UK REACH Policy: REACH-IT@defra.gov.uk
  - UK REACH Operations: UKREACHCA@hse.gov.uk

REACH

'Grandfathering' existing EU REACH registrations into the UK system

7. **Is there a minimum time that a REACH registration has to be held by a UK entity in order for that registration to be grandfathered into UK REACH?**

- Grandfathering is the process of carrying across existing EU REACH registrations held by GB-based companies into UK REACH in order to ensure continuity for business. 'Grandfathered' registrations will be legally recognised by UK REACH from day 1. Businesses then need to take further action to confirm their registration within 120 days followed by submission of the full technical information supporting their registration within either 2,4 or 6 years, depending on tonnage band and hazard profile.

- Grandfathering will apply to all registrations (including intermediates) held by GB-based entities, including importers and Only Representatives (ORs) based in Great Britain, and to sole, lead or joint registrants.

- All GB-based registrations that exist at the end of the transition period, and all registrations held by GB entities at any point since 29 March 2017 will be grandfathered. This means that if a UK REACH registration was transferred to an EU/EEA/NI-based entity in the run-up to the end of the transition period, it will still be grandfathered into UK REACH.

- Grandfathering will not apply to registrations held by entities established outside of Great Britain, regardless of whether they are part of a group of companies which also has a presence in Great Britain. Those registrations will not be grandfathered, unless they have been transferred to a GB entity before the end of the transition period. Before transferring any registrations, you should consider how this would affect your operations in the EU/EEA and Northern Ireland, and your ability to access the EU/EEA and NI markets in future.

8. **If a substance is grandfathered into UK REACH but a UK company would like to upgrade the tonnage band under UK REACH, at what stage should this be done? Would this have to be done during the 2, 4 or 6 years registration of the grandfathered substances?**

- Government recently announced a phased approach to implementation of UK REACH. 'Grandfathered' registrations will be legally recognised by UK REACH from day 1. Businesses then need to take further action to confirm their registration within 120 days. For GB downstream users, you will need to notify the HSE, using a Downstream User Import Notification (DUIN), of your intention to continue importing substances from the EU/EEA within 300 days, i.e. by 27 October 2021. Full data (for grandfathered registrations) and new registration (for downstream users) obligations will be phased in over the subsequent 2, 4 or 6 years, after the initial 300 days, depending on volume and hazard.

- If your business activity requires you to upgrade your tonnage band of a grandfathered registration, you will need to be mindful that this may push you into an earlier compliance timeframe, and additional data may also be required as a consequence.

9. **After grandfathering REACH across for a product, is full registration still required to be completed if you cease manufacturing before the deadline?**

- If you cease manufacturing before the relevant compliance deadline, submission of full data will no longer be required; your grandfathered registration will automatically lapse if you do not fulfil the full data requirements by the relevant deadline.

10. **For REACH, when will practice directions be published for the First Tier Tribunal (for data sharing disputes)?**

- Response to follow.

11. **If an EU company opens a UK office before the end of the Transition period, are they able to 'grandfather' their EU REACH registration into UK REACH?**

- Grandfathering will not apply to registrations held by entities established outside of Great Britain, regardless of whether they are part of a group of companies which also has a presence in Great Britain. However, if those registrations have been transferred to a GB entity before the end of the transition period, they will be grandfathered into UK REACH. Before transferring any registrations, you should consider how this would affect your operations in the EU/EEA and Northern Ireland, and your ability to access the EU/EEA and NI markets in future.

12. **What are the specific info requirements for notification within 120 days under UK REACH (ref grandfathering of EU REACH registration)?**

- Business will need to provide some initial information on their grandfathered registrations within 120 days of end of the transition period. Please visit this page for details of the information you need to provide: What data to submit.

13. **During the 120 day grandfathering process, can the current REACH registration dossiers be submitted?**

- Yes. Full data to support grandfathered registrations (or new registrations for imported substances) can be submitted at any time before the relevant compliance deadline. The phased timeframes for full data and registration obligations provide industry with more time only if they need it.

14. **Will the 2-year look back from March 2019 still apply for grandfathering registrations into UK REACH that were originally submitted by a UK manufacturer, importer, or only representative but are moved to an EU legal entity before the end of the transition period?**

Can we transfer manufacturing registration today but still assume covered in the UK? Regarding grandfathering of UK-held EU registrations: Can I do both, grandfather and transfer to EU entity?

Will the existing UK based EU-REACH registrations that were transferred to an EU affiliate to ensure continuity of Business in the EU/EEA be grandfathered under UK-REACH?

- All GB-based registrations that exist at the end of the transition period, and all registrations held by GB entities at any point since 29 March 2017 will be grandfathered. This means that if a UK REACH registration was transferred to an EU/EEA/NI-based entity in the run-up to the end of the transition period, it will still be grandfathered into UK REACH.

15. **We currently hold a REACH Registration for raw material imported into the UK. Am I correct in assuming I just need to Re-Register this through the HSE? When can I start to do this and where can I locate the registration process / forms etc?**

- You will need to check that the registration was held under EU REACH by a GB-based entity.

- Grandfathering will apply to all registrations (including intermediates) held by GB-based entities, including importers and Only Representatives (ORs) based in Great Britain, and to sole, lead or joint registrants.

- All GB-based registrations that exist at the end of the transition period, and all registrations held by GB entities at any point since 29 March 2017 will be grandfathered. This means that if a UK REACH registration was transferred to an EU/EEA/NI-based entity in the run-up to the end of the transition period, it will still be grandfathered into UK REACH.

- Grandfathering will not apply to registrations held by entities established outside of Great Britain, regardless of whether they are part of a group of companies which also has a presence in Great Britain. Those registrations will not be grandfathered, unless they have been transferred to a GB entity before the end of the transition period.

- 'Grandfathered' registrations will be legally recognised by UK REACH from day 1. Businesses then need to take further action to confirm their registration within 120 days.

- Please visit this page for details of the information you need to provide: What data to submit.

- You will be able to submit this information using the Comply with UK REACH IT system which is due to go live at the point of transition.

16. **Does grandfathering apply to chemicals currently covered under an EU registration where we are not lead registrant but a participant. At exit we will be an importer with no access to data but considered a new importer of the same material. Does grandfathering still apply? If not why not?**

- Grandfathering will only apply to all registrations (including intermediates) held by GB-based entities, including importers and Only Representatives (ORs) based in Great Britain, and to sole, lead or joint registrants, that exist at the end of the transition period.

- EU-27 held REACH registrations will not be legally recognised ("grandfathered") automatically under the UK REACH system in the same way as registrations held by GB based entities. This is because we will not have jurisdiction over EU-27 based companies and therefore will be unable to enforce those duties required under REACH. Those registrations will not be grandfathered, unless they have been transferred to a GB entity before the end of the transition period.

- However, to ensure supply chains are not disrupted, businesses currently relying on a registration held by an EU/EEA-based company can continue importing substances as they do now on 1 January 2021. They will need to take subsequent actions to ensure that the chemical is registered for UK REACH purposes.

- Find out how UK downstream users can notify the HSE using a Downstream User Import Notification (DUIN) of their intention to continue importing substances from the EU/EEA by 27 October 2021.

- A new registration must then be submitted to the HSE within 2, 4 or 6 years after 27 2021. Alternatively, UK downstream users can encourage their EU/EEA supplier to appoint a UK-based Only Representative (OR), or change their source to a UK registered supplier.

17. **In what format the data for grandfathering will be submitted? Manual add in the system?**

- Dossiers will still need to be submitted in IUCLID. The Comply with UK REACH IT system will operate using the same software as the current REACH IT system.

- The Comply with UK REACH IT system which is due to go live at the point of transition.

18. **As an importer of materials from outside of the EU/EEA our registrations have been with an EU affiliate. Our UK entities have never held the registrations but will have to import directly into UK after the transition period. Can we make use of the grandfathering process?**

- Grandfathering will only apply to all registrations (including intermediates) held by GB-based entities, including importers and Only Representatives (ORs) based in Great Britain, and to sole, lead or joint registrants, that exist at the end of the transition period.

- Grandfathering will not apply to registrations held by entities established outside of Great Britain, regardless of whether they are part of a group of companies which also has a

presence in Great Britain. Those registrations will not be grandfathered, unless they have been transferred to a GB entity before the end of the transition period.

Importers / downstream user import notifications (DUINs)

19. **Under UK REACH if a new chemical is imported for the first time after Jan 1st 2021 can this be imported using a DUIN?**

- The downstream user import notification provision is intended to enable existing supply chains to continue unbroken and provide time for businesses to comply with their new obligations as an importer under UK REACH.

- The measure will therefore apply only to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance (and who did not have an EU REACH registration).

- From 1 January 2021, GB companies wishing to register new chemicals for the GB market would need to register those with HSE using the Comply with UK REACH IT system.

20. **Can you confirm that a distributor is not a downstream user, it's the end user that is the downstream user? both for substances and mixtures?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer.

- You are a distributor under REACH and CLP if you source a chemical substance or a mixture within GB, store it and then place it on the market for someone else (also under your own brand without changing its chemical composition in any way). For example, retailers and wholesalers are distributors under REACH and CLP.

- You are not a distributor if you buy chemicals from outside GB and place them straight on the market in GB - you are an importer.

- If you buy chemicals within GB and mix them with other chemicals, dilute them or (re)fill containers, before supplying them to others, you are a downstream user.

21. **Are you only classed as an importer if you purchase directly from the EU? If products come from the EU purchased from a GB based distributer are they the importer not us?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. All of the current exemptions in EU REACH will be carried into UK REACH. They will also apply to the notification requirements.

- As with EU REACH, under UK REACH you can have specific obligations for each individual substance you manufacture, import or use. Your obligations depend on your role in the supply chain for the specific substance.

- If you buy a chemical product directly from a supplier based outside GB and bring it into GB territory you are an importer and must comply directly with UK REACH obligations, unless your non-GB supplier has appointed a GB-based "Only Representative" to register the substance, in which case you are regarded as a downstream user under UK REACH.

- You are not a manufacturer under UK REACH if you only blend substances into mixtures or use chemicals to produce articles. In that case you are a downstream user and you have to fulfil downstream user requirements.

22. **Under REACH, what are my obligations as an end user of chemical products (I don't place them on the UK market, just use them in my manufacturing process) which are supplied directly from a company based in Belgium?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer not with the end-user. You will need to check there is an upstream UK REACH notification which is followed by a new registration in order to maintain your status in the supply chain as a downstream user.

- Downstream users have important responsibilities. For example, when downstream users receive a safety data sheet (SDS), they need to identify and apply appropriate measures to adequately control the risks. When it is an extended SDS, they must additionally check whether the exposure scenario covers their own use of the substance and their conditions of use or take alternative action.

23. **Once a substance is landed in UK under an importer do we then need a registration to purchase that substance?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer not with the end-user.

24. **If our EU supplier submits a notification for the chemical they supply to us via their Only Representative (OR) in the UK, do we still need to submit a DUIN?**

- GB based ORs are able to assume registration obligations on behalf of their GB downstream users thereby relieving them of the need to submit DUINs or complete full registrations.

25. **If an EU manufacturer registers in UK REACH, does the importer need to register it as well?**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK.

- The import will require a notification within 300 days (by 27 October 2021 - please visit this page for more details - https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details - https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

- If a EU/EEA manufacturer's GB-based OR registers within the relevant deadlines (300 days plus 2, 4 or 6 years), the GB importer would be treated as a downstream user under UK REACH, and would therefore not need to become registrants themselves. If the OR submits a notification of import or registers within 300 days of the end of the Transition Period, this would relieve their GB customer of the duty to notify the HSE within 300 days.

26. **We are classed as a downstream user under REACH - will we have to register these chemicals under UK REACH if they come direct from the EU? and will we have to register chemicals that come from the EU via a GB based company?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer.

- If you have acquired importer obligations under UK REACH as a previous downstream user of a substance covered by an EU-based registration you are able to make use of the notification provision to ensure continuity of supply. This notification will be required within 300 days (by 27 October 2021 - please visit this page for more details - https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details - https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

- EU/EEA based exporters may choose to register the substance under UK REACH through a GB-based Only Representative or an affiliate GB importer.

- GB Downstream users may make use of the notification process to ensure compliance in the interim between the end of the transition period and registration obligations being taken up by the EU/EEA supplier's GB-based entity.

- If the EEA exporter takes on registration obligations via a GB-based entity, their GB customers will retain their downstream user status.

27. **Will UK retailers who import finished products direct from the EU need to notify or can their suppliers (based in the EU) do this for them?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer.

- EU/EEA based exporters may choose to register the substance under UK REACH through a GB-based Only Representative or an affiliate GB importer.

- GB Downstream users may make use of the notification process to ensure compliance in the interim between the end of the transition period and registration obligations being taken up by the EU/EEA supplier's GB-based entity.

- If the EEA exporter takes on registration obligations via a GB-based entity, their GB customers will retain their downstream user status.

28. **Will it be possible to notify lists of substances or only single substances one after another?**

- Downstream user import notifications can be uploaded in bulk to the Comply with UK REACH IT system on an excel file. The final design of the spreadsheet is not yet publicly available. However, full details of the information requirements involved can be found here.

29. **What information must the customer provide as part of the Downstream User Import Notification? Will it be possible for a supplier to keep the composition of his product secret?**

- Full details of the information requirements involved for downstream user import notifications can be found here.

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

30. **What information do I need to provide to HSE in my initial notification within 300 days (i.e. before 27 October 2021), including what information do we need to gather at this stage from our EU suppliers?**

- Full details of the information requirements involved for downstream user import notifications can be found here.

31. **I use chemicals in my business. What should I be asking my suppliers?**

- Full details of the information requirements involved for downstream user import notifications can be found here.

- However, more broadly, you could ask your supplier about their intentions for UK REACH compliance, e.g. whether they intend to appoint a GB Only Representative (OR) to take on notification and registration obligations on behalf of their GB customers.

32. **For UK-REACH, is there an order to submit the inquiry to HSE and notify the DUIN (inquiry first then DUIN or vice versa or both at the same time)?**

- Downstream users and importers will be added to substance specific groups once they have provided their initial information within 300 days to the HSE, and subsequently undertaken an Article 26 substance inquiry.

33. **As a current downstream user under REACH, because I use chemicals registered under EU-REACH, I'll become an importer under UK-REACH and will have registration obligations. Apart from the DUIN do I also need to submit an Inquiry dossier before I can proceed to registration?**

- Downstream users and importers will be added to substance specific groups once they have provided their initial information within 300 days to the HSE, and subsequently undertaken an Article 26 substance inquiry.

- Successful inquirers will then be able to access the substance page in the system and be able to view contact details of those who are already grandfathered for that substance so that data sharing can be organised.

- We have designed the process for claiming the lead to only be available after the grandfathering stage has been completed, after 120 days. The contact details of the substance group members will be available from 'Comply with UK REACH' and we anticipate the group members will hold conversations to identify and agree a suitable lead.

34. **Is late DUIN a possibility if we place a substance on the market after 27 October 2021? Or will the UK market remain effectively frozen for up to 6 years?**

- It will not be possible to submit a late DUIN. However the market will not remain frozen for up to 6 years. To import the substance after this point, you would need to submit an Article 26 substance inquiry followed by a new registration to HSE using the Comply with UK REACH IT system.

- For substances that are registered under EU REACH, which you are now intending to manufacture or import into the UK, you will be required to submit a registration. It may be possible to defer the submission of the full information requirement so that you are able to share data and participate in the joint registration with the grandfathered registrants. You will be informed if this applies to you after successfully submitting an Article 26 substance inquiry.

35. **If a product has been registered under UK REACH by another company is there a requirement for us to submit another REACH registration? Previously a downstream user and now an importer we would not have complete breakdown of the mixtures and all of the data required.**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer not with the end-user.

- If you have acquired importer obligations under UK REACH as a previous downstream user of a substance covered by an EU-based registration you are able to make use of the notification provision to ensure continuity of supply. This notification will be required within 300 days (by 27 October 2021 - please visit this page for more details - https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details - https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

36. **For GB-based downstream users or distributors of EU REACH registered chemicals sourced from the EU/EEA, the DUIN guidance on the HSE website is still at a high level reflecting the text in the statutory instrument.**

- Updated UK REACH user guidance was published on the HSE website on 26 October 2020 and is regularly reviewed.

- Defra have assessed existing guidance and are working to produce further public facing material before the end of the transition period as additional support for businesses in their preparations for UK REACH.

- If you have further queries please contact:
  - UK REACH Policy: REACH-IT@defra.gov.uk
  - UK REACH Operations: UKREACHCA@hse.gov.uk

37. **If an EU/EEA supplier to the UK puts in place an Only Representative in UK REACH, assume the UK company (the current downstream user) would remain a downstream user?**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into GB.

- The import will require a notification within 300 days (by 27 October 2021 – please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details – https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

- If the EU/EEA manufacturer's GB-based OR registers within the relevant deadlines (300 days plus 2, 4 or 6 years), the GB importer would be treated as a downstream user under UK REACH, and would therefore not need to become registrants themselves. If the OR submits a notification of import or registers within 300 days of the end of the Transition Period, this would relieve their GB customer of the duty to notify the HSE within 300 days.

38. **With 300d+6y phase-in, how will free-riding be managed and controlled? A company could appoint a UK-OR and start importing a substance into the UK based on a previous EU Registration, and be allowed more time to submit full and complete dossiers for substances that have been notified using the DUIN process (and for grandfathered substances). While 2, 4 or 6 years from the 28th Oct 2021 is welcomed by the majority of industry, this is something of a double-edged sword because it provides a period of almost 7 years of free-riding by companies that have no real intention of making the investment necessary to present a full UK REACH dossier. Such companies will only have to complete a DUIN spreadsheet. What measures are planned to limit the scope of this kind of free-riding?**

- The purpose of the downstream user import notification provision is to enable existing supply chains to continue unbroken and provide time for businesses to comply with their new obligations as an importer under UK REACH.

- The measure applies to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance (and who did not have an EU REACH registration).

- While there may be some businesses that do not follow up with a complete registration by the relevant compliance deadline, the only other alternative would be to impose earlier deadlines for full data packages and complete registrations.

- The key challenge of moving from an EU regime to a UK equivalent has been how to transition existing EU REACH registrations held by UK companies into the UK system and accommodate those who currently source chemicals from the EU.

- We want to do this is in a way that minimises risks to supply chains and gives industry time to adjust, while ensuring we still have the confidence that industry has the information it needs to manage risks from chemicals and that our regulator has the information it needs on chemicals being placed on the GB market to support enforcement and regulatory action to protect health and the environment.

- The extension to the deadlines for data submission allows industry more time to adapt and comply with UK REACH. This is particularly beneficial to SMEs who are more likely to have smaller tonnages, giving them up to 6 years + 300 days to comply. If the extra time does not enable industry to agree data access at lower cost, it will enable the costs to be spread over a longer period and reduce the need for companies to redirect resources onto REACH compliance.

39. **If a supplier gains EU REACH registration after the end of transition but before Oct 27th 2021, can it still be notified under UK REACH and still have 6 years before UK registration [if it is in the 1mt band]?**

- No. The DUIN measure only applies to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance (and who did not have an EU REACH registration).

40. **As an importer of Chemicals from the EU do I need to advise the basic information within 60 days or 300 days?**

- If you are the importer, the import will require a notification to HSE within 300 days (by 27 October 2021 – please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details – https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

41. **How is an importer to register a substance they haven't previously imported from 2021 onwards under the one substance one registration principle if there will be other registrants who have 6 years to submit their registration data as they have submitted a DUIN? There will likely at that point be no dossier to gain access to?**

- From 1 January 2021, GB companies wishing to register new chemicals for the GB market would need to register those with HSE using the Comply with UK REACH IT system.

- For substances that are registered under EU REACH, which you are now intending to manufacture or import into the UK, you will be required to submit a registration. It may be possible to defer the submission of the full information requirement so that you are able to share data and participate in the joint registration with the grandfathered registrants. You will be informed if this applies to you after successfully submitting an Article 26 substance inquiry.

42. **The REACH Statutory Instrument (SI) requires that to submit a DUIN, an importer must have imported within the previous 2 years. Is this going to be required?**

- The measure applies to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance (and who did not have an EU REACH registration).

Only Representatives / legal entities

43. **Could you provide information on Only Representative (OR) requirements for non-UK manufacturers/formulators and respective timelines?**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK.

- The notification and registration deadlines do not differ for ORs. The import will require a notification within 300 days (by 27 October 2021 – please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details – https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

44. **If a non-EU manufacturer has an EU REACH registration through an Only Representative (OR) in the EU, will they be able to then appoint a UK-based OR for UK REACH and notify in the 300 day window to support UK customers?**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- ORs are able to make use of the grandfathering and notification transitional provisions.

- Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK. The import will require a notification, before the submission of a full UK REACH registration. Please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm.

45. **GB Only Representatives (ORs) – if you are being supplied from an EU supplier who is not the manufacturer, I understand that it's not the supplier but the manufacturer who would be required to establish a GB OR. If we do not have a direct relationship with the manufacturer how are we supposed to get the manufacturer to establish an OR, especially if there are not alternative GB sources?**

- If you have acquired importer obligations under UK REACH as a previous downstream user of a substance covered by an EU-based registration you are able to make use of the notification provision to ensure continuity of supply. This notification will be required within 300 days (by 27 October 2021 - please visit this page for more details - https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details - https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

46. **Can you please explain the role of an Only Representative acting on behalf of UK manufacturer sitting inside EU?**

- GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA market. Alternatively, GB companies could support their EU/EEA-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website.

- GB companies wishing to register new chemicals for the EU/EEA market after the end of the transition period would need to register those with ECHA as they do now, but would need to do so via their EU customers, or an affiliate or OR in the EU/EEA. Further guidance on how to do this can be found on the ECHA website.

- EU REACH will continue to apply in Northern Ireland, as such there will be no change for NI manufacturers wishing to access the EU/EEA market.

47. **What if one Only Representative (OR) makes the notifications/registrations under UK REACH for an EU company, and then the company transfers these to an new OR? Would there be a fee for the transfer?**

- As with EU REACH, if you decide to change your Only Representative, your previous representative needs to accept the transfer of asset(s) (registration, notification, etc.) to your new representative in REACH-IT. When you hire Only Representatives or consultants, you should remember to include clauses in your agreement on how to handle these situations.

- It is worth also clarifying that registrations and notifications under the REACH and CLP regulations cannot be traded. They can however be transferred in the same way as physical assets (such as production facilities or staff) when companies merge or split.

48. **We are a UK 100% owned subsidiary of EU company, can the UK entity act as an OR for UK Reach?**

- Yes. In so doing the UK entity acquires full registration obligations on behalf of its downstream GB customers.

49. **Can a non-UK manufacturer appoint a UK-OR and take advantage of the 300 day notification period and 6 year registration timetable? And can then UK DU take advantage of this to avoid registering chemicals they use? It's not clear from your guidance that this is the case.**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK.

- The import will require a notification within 300 days (by 27 October 2021 – please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details – https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

- If the EU/EEA manufacturer's GB-based OR registers within the relevant deadlines (300 days plus 2, 4 or 6 years), the GB importer would be treated as a downstream user under UK REACH, and would therefore not need to become registrants themselves. If the OR submits a

notification of import or registers within 300 days of the end of the Transition Period, this would relieve their GB customer of the duty to notify the HSE within 300 days.

50. **Can an EU distributor appoint a UK Only Representative (OR), or is this the same as with EU REACH Art. 8, where only manufacturers and formulators can appoint an OR?**

- At the end of the Transition Period, the European Union (Withdrawal) Act 2018 (as amended by the European Union (Withdrawal Agreement) Act 2020) will convert directly applicable EU law into domestic law, including the REACH Regulation. The UK Government will use the powers given to it by that Act to amend the REACH Regulation, as well as other related chemicals legislation, to ensure it operates effectively in a domestic context.

- As part of this process the provisions set out under Article 8 of EU REACH will also be retained.

- This means that the limitations on which actors in a supply chain are able to appoint ORs will also apply under UK REACH.

51. **Has the government taken into account the considerable additional costs to appoint a EU OR and manage each obligated substance? – we are looking at extra costs of nearly £9000 a year.**

- The UK does not seek to remain part of the Single Market or Customs Union, and we recognise there will be adjustments to supply chains as a consequence and new obligations and costs to businesses that trade between the UK and the EU.

- Under UK REACH we have tried to limit additional cost to industry where possible. SMEs will continue to receive significant discounts for all applicable charges under UK REACH, which will reduce fees by up to 90% while existing EU registrations grandfathered into the UK system will not pay the registration fee.

52. **REACH – can the EU legal entity representative (incl. Northern Ireland) contact be based in GB?**

- No. After the end of the transition period the UK and EU will both operate REACH, but the two will not be linked in any way. As such it will not be possible for an entity based in GB to act as an OR under EU REACH.

- However, under the terms of the Northern Ireland Protocol EU REACH will continue to apply in NI. This means that NO entities will be able to facilitate EU market access as set out here.

53. **Can a store in NI be considered as a 'legal entity' if the head office is in GB?**

- A legal entity is defined as a natural or legal person established physically in the EEA (incl. NI) with rights and obligations under REACH and CLP.

- Crucially, the legal entity has to be equipped with sufficient knowledge in the practical handling of the substances and information related to them, and is responsible for complying with the legal requirements for importers under EU REACH.

EU exporters to the UK

54. **Can an EU-based company submit a DUIN via a GB-based only representative? / Can DUIN be submitted by an appointed UK OR after the transitional period?**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- GB based ORs are able to assume registration obligations on behalf of their GB downstream users thereby relieving them of the need to submit DUINs or complete full registrations.

55. **May any EU/EEA based business, as an exporter, appoint an UK based OR to maintain their business to the UK and take away pressure from their UK based downstream users/ business partners?**

- Yes. UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR.

- GB based ORs are able to assume registration obligations on behalf of their GB downstream users thereby relieving them of the need to submit DUINs or complete full registrations.

56. **When you talk about EU/EEA suppliers, do you mean those with an existing EU REACH registration? Some producers are based outside the EU/EEA.**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR. Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into GB. The import will require a notification, before the submission of a UK REACH registration. Please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm.

ROW exporters to the UK

57. **Please explain what the process to follow is for a non-EU manufacturer that holds an EU-REACH registration through a OR to register under UK REACH.**

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR. Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK. The import will require a notification, before the submission of a UK REACH registration. Please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm.

58. **As a non EU and non UK located manufacture (of plastic pellets) – would we need to appoint a UK only representative to deal with the monomers notifications and registration or that our UK based customers would need to do some procedures?**

- Yes, monomers imported into the UK which are subject to registration will need to be registered with the HSE.

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR. Non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their monomer is covered by a registration held by an EU/EEA-based OR and then sold into the UK.

- Imports to Great Britain coming directly from a third country that are covered by a registration held by an OR based in the EU/EEA, or Northern Ireland in the case of non-qualifying Northern Ireland good (QNIG), will require a notification as above, before the submission of a UK REACH registration. Please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm.

59. **What should a UK importer supplying chemicals from a manufacturer outside of EU & UK expect from its supplier? If that manufacturer/supplier has previously registered its chemicals by an EU OR, will this import be treated similar to imports from EEA?**

- Imports to Great Britain coming directly from a third country that are covered by a registration held by an OR based in the EU/EEA, or Northern Ireland in the case of non-qualifying Northern Ireland good (QNIG), will be eligible for the GB downstream user import notification (DUIN) measure.

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR to submit DUINs under UK REACH, before the submission of a UK REACH registration.

- Or the importer can submit the DUIN, before the submission of a UK REACH registration. You may choose to submit a DUIN as a precaution, in case your supplier does not submit the DUIN or does not complete the subsequent registration requirements. There is no option to submit a late DUIN after the 300 day deadline has expired.

- Please visit this page for more details, including details of the information that is required to submit a DUIN – https://www.hse.gov.uk/brexit/scenario2.htm.

Data obligations

60. **Will a Letter of Access obtained for EU REACH Registration be valid for UK REACH registration?**

- This is unlikely because a letter of access to Consortium data for the purposes of EU REACH Registration only, i.e. an LoA holder does not have the right to use Consortium data in the joint registration dossier for other purposes, including REACH Authorisation and compliance with non-EU legislation. This also means that HSE would not be able to access the data that is referenced in the LoA.

- To access the data needed for UK REACH, companies will need to renegotiate access to the data packages and the consortia may (but not in all cases) charge for this.

- Government has recently extended the registration deadlines for submitting full data packages to two, four or six years, according to tonnage bands and hazard profile of the chemical. This should mean industry can spread costs over a longer period without reducing important environmental and health protections.

- Downstream users with little or no REACH experience will then have the opportunity to join up and share data costs with grandfathering registrants who are REACH 'experienced'.

61. **Will the use of EU REACH data for UK REACH registrations be acceptable by the EU?**

- A letter of access to Consortium data is for the purposes of EU REACH Registration only, i.e. an LoA holder does not have the right to use Consortium data in the joint registration dossier for other purposes, including REACH Authorisation and compliance with non-EU legislation. This also means that HSE would not be able to access the data that is referenced in the LoA.

- To access the data needed for UK REACH, companies will need to renegotiate access to the data packages and the consortia may (but not in all cases) charge for this.

62. **For SMEs who have previously relied on manufacturer's EU REACH registrations and were downstream users but who now find themselves as importers, how do you propose we afford all of the costs of providing the data if there is no agreement to share data and testing results that have already been done for ECHA and EU registrations – the costs are going to be massively prohibitive and basically put many SME's out of business as the UK market is considerably smaller and there will be fewer companies sharing the cost of that data so there is no way that companies will be able to afford to do all of the testing again if there is no way to share the current information held by ECHA – it will just not work.**

- Government is aware of industry's concerns about the issue of access to data and the costs this may involve to comply with UK REACH.

- We are keeping the transition to UK REACH as simple as possible, avoiding change for change's sake. For example, in building the Comply with UK REACH IT system we have made sure it will work very much like the ECHA owned REACH-IT, including the same software requirements and many of the processes that businesses have been using and understand.

- We have put in place 'grace period provisions' of 'Grandfathering' and 'Downstream User Import Notifications' to minimise the costs for businesses to maintain market access to both the EU and UK market.

- Following concerns that were nonetheless raised about the timelines for supplying data to the UK regulator, we have extended these deadlines. This allows industry more time to adapt and comply with UK REACH and be particularly beneficial to SMEs who are more likely to have smaller tonnages, giving them up to 6 years + 300 days to comply. If the extra time does not enable industry to agree data access at lower cost, it will enable the costs to be spread over a longer period and reduce the need for companies to redirect resources onto REACH compliance.

63. **How will data owning and sharing be handled if the current EU REACh lead registrant and data owner is based in the UK and decides to leave the joined EU registration after 2020?**

- This question relates to EU REACH and is therefore a matter for ECHA to advise on.

64. **We have registered some substances part of a full registration, the data is not ours, we only have permission to refer under EU REACH. Will the authorities help us to pay to use the data for UK REACH? How is UK expecting for us to pay?**

- We have kept the transition process to UK REACH under review and have listened to industry's concerns about the previous timelines for supplying data to the UK regulator.

- As a result we have extended the deadlines set in legislation from 180 to 300 days for GB importers of goods from the EU. We also extended the full registration deadline from 2yrs to a phased approach across 2, 4 & 6yrs (+300 days).

- This allows industry more time to adapt and comply with UK REACH. This is particularly beneficial to SMEs who are more likely to have smaller tonnages, giving them up to 6 years + 300 days to comply.

- If the extra time does not enable industry to agree data access at lower cost, it will enable the costs to be spread over a longer period and reduce the need for companies to redirect resources onto REACH compliance.

- As necessary, Government will continue to explore ways in which it can support businesses.

65. **As a non-lead REACH registrant, what data do we need to obtain from ECHA and/or the lead registrant in order for our registration to be 'grandfathered' into the new UK system? I'm assuming guidance will be made available to current UK ECHA registrants before access to the ECHA REACH-IT system is lost. Am I also correct in assuming that should the lead registrant decide not to register in the UK, that one of the co registrants will become lead? If so, is the lead registrant obligated to share all data with the co registrants?**

- Business will need to provide some initial information on their grandfathered registrations within 120 days of end of the transition period followed by full data packages within two, four or six years of 27 October 2021, according to tonnage bands and hazard profile of the chemical. Please visit this page for details of the information you need to provide: What data to submit.

66. **Will there be the potential to set up a joint EU-UK system to allow for joint REACH submissions, helping as the data would only need to be submitted on one portal?**

- The UK is not seeking to remain part of EU REACH. From 1 January 2021, UK REACH will operate independently of EU REACH and businesses will need to comply separately with both regimes.

- In February, the Government published our approach to negotiating our future relationship with the EU. That includes a proposal for a chemicals annex as part of the EU Free Trade Agreement.

- The chemicals Annex includes provisions to share data and information between the UK and EU and could mitigate the need for industry to provide full data packages to the HSE.

67. **Will the HSE have a copy of the REACH registration data for all UK Legal Entity at the point of the UK leaving the EU on 31st December 2020? If so, does the HSE already have an idea of how many SIEF are currently working with the UK (as these are likely to be still applicable in the new regime.)?**

- After 1 January 2021, GB will not be permitted to access confidential information held by the European Commission or the European Chemical Agency and hence any data/information previously submitted via these processes would not be available for the Health and Safety Executive (HSE) to refer to.

- The data are not 'owned' by the European Chemicals Agency (ECHA); the data supporting each substance registration are owned by a commercial consortium of companies. To access the data for the UK regime, companies will need to renegotiate access to the data packages.

68. **Can you clarify that the 2/4/6yr deadlines for UK REACH substance registrations is straight after the transition period (1st Jan 2021) or after the 300 day period for importer registrations?**

- UK REACH transitional provisions provide a period of 120 days for existing UK based REACH registrants and 300 days from 1 January 2021 for downstream users (i.e. those importing from the EU who have not previously had REACH registration responsibilities) to provide initial information to the HSE (so we know who is using what chemicals in the UK).

- Full data packages or complete new registrations will not then required within a two-year, four-year or six-year period after the initial 300 days (commencing from 1 January 2021), depending on tonnage and/or hazard profile of substances.

69. **UK REACH will necessarily be based on smaller tonnage volumes (1 jurisdiction, compared to 27 jurisdictions in EU). Therefore, many substance registrations are likely to be at lower tonnage volumes, and therefore LESS DATA will be required. How will the UK ensure equal levels of protection to human health and the environment, when basing decisions on less data? Are equal levels of safety intrinsically based on a data sharing deal in the trade negotiations?**

- The information requirements for registration under UK REACH will remain the same as the current EU regime.

70. **ECHA cost sharing disputes only rule on whether reasonable effort has been made to address the co-registrants concerns but it sounds like the UK FTT would potentially be able to rule on whether the cost-sharing calculations are "correct"?**

- The data dispute system under REACH will only address the efforts of both parties involved in making every effort to negotiate in a fair and transparent manner. The HSE will not offer onions nor base decisions on the costs of data access.

EU trade deal

71. **Is there agreement on the UK's proposal for a Chemical Annex as part of a trade deal? In other words, if a trade deal is struck, can we expect a chemicals annex to be part of that deal and ensure access to EU data?**

- The UK proposed a chemicals annex which includes a provision to share registration data that would avoid costs for businesses. This reflected what industry, including in the chemicals supply chain, had been asking for.

- The UK has pushed hard for its inclusion and believes a chemicals annex is in the interests of UK and EU businesses, but the EU will need to engage on the proposal for it to be part of the agreement.

72. **Are the UK/EU still working together to try and make current data available to share (from REACH perspective?)**

- In February, the Government published our approach to negotiating our future relationship with the EU. That included a proposal for a chemicals annex as part of the EU Free Trade Agreement.

- The UK-proposed chemicals annex includes a provision to share registration data that would avoid costs for businesses. This reflected what industry, including in the chemicals supply chain, had been asking for.

- The UK has pushed hard for its inclusion and believes a chemicals annex is in the interests of UK and EU businesses, but the EU will need to engage on the proposal for it to be part of the agreement.

Animal testing

73. **Can you give any example where extra animal testing may have to take place, on existing products/substances which already exist in EU REACH?**

- The UK has been in the forefront in opposing animal tests where alternative approaches could be used – the "last-resort principle" - and we will retain that principle moving forward, enshrining it in the Environment Bill.

- We will recognise the validity of any animal testing that has already been undertaken and so avoid the need for further testing.

- The grandfathering of all existing UK-held REACH registrations into the UK system will further avoid the need to duplicate animal testing associated with re-registration.

74. **Will new Testing be needed for already registered substances under EU REACH for UK REACH?**

- The UK has been in the forefront in opposing animal tests where alternative approaches could be used – the "last-resort principle" - and we will retain that principle moving forward, enshrining it in the Environment Bill.

- We will recognise the validity of any animal testing that has already been undertaken and so avoid the need for further testing.

- The grandfathering of all existing UK-held REACH registrations into the UK system will further avoid the need to duplicate animal testing associated with re-registration.

75. **Will you insist on new animal testing data for substances where this is no longer available for UK REACH? This will have a significant impact particularly on cosmetic ingredients?**

- The UK has been in the forefront in opposing animal tests where alternative approaches could be used – the "last-resort principle" - and we will retain that principle moving forward, enshrining it in the Environment Bill.

- We will recognise the validity of any animal testing that has already been undertaken and so avoid the need for further testing.

- The grandfathering of all existing UK-held REACH registrations into the UK system will further avoid the need to duplicate animal testing associated with re-registration.

76. **Unnecessary animal testing must be avoided, such testing has already been carried out to generate the existing information contained in the registration/test data pack. If EU/UK govs insist on duplicating this same testing to get the same data, then social media general media and the general public will be abhorred by this and rightly so. What are you doing to ensure we do not go down this track, it would be very negative for our industry and morally wrong?**

- The UK has been in the forefront in opposing animal tests where alternative approaches could be used – the "last-resort principle" - and we will retain that principle moving forward, enshrining it in the Environment Bill.

- We will recognise the validity of any animal testing that has already been undertaken and so avoid the need for further testing.

- The grandfathering of all existing UK-held REACH registrations into the UK system will further avoid the need to duplicate animal testing associated with re-registration.

Articles and mixtures

Context - REACH is very wide in its scope covering all substances whether manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles, unless they are radioactive, subject to customs supervision, or are non-isolated intermediates. Waste is specifically exempted. Food is not subject to REACH as it is not a substance, preparation or article. Substances used in the interests of defence may be exempted. Other substances are exempted from parts of REACH, where other equivalent legislation applies.

As the EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations, the same provisions relating to articles and mixtures applies and ECHA guidance on this is still helpful for GB businesses.

On mixtures, for example, a cleaning company importing 10 tonnes of a chemical mixture a year to fill bottles for individuals cleaning buildings would need to register each substance in the mixture that is imported at a tonne or more (if the company is not importing, it holds the status of a downstream user). Whereas a cleaner using those sprays in quantities of less than a tonne a year has no REACH obligations.

On articles, an article is defined as "*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*". And the key consideration is whether the article contains a Candidate List substance.

77. **Will UK Importers of products (such as a bottle of shampoo) containing chemicals also be classed as an importer under UK REACH?**

- The definition and registration requirements of articles under UK REACH will mirror that of EU REACH. If you are producing or importing an article, you need to register each individual substance in an article: if the substance is present in the article in quantities of over one tonne per year; and if the substance is intended to be released under normal conditions of use, for example a t-shirt containing a fragrance. If the substance in your article has already been registered for the same use, you do not need to register it as well.

78. **If our materials don't contain EU REACH Substances of Very High Concern (SVHCs) above the threshold level of 0,1% weight by weight (w/w), do we have any obligations under UK REACH? I assume not but want to be sure.**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. All of the current exemptions in EU REACH will be carried into UK REACH. They will also apply to the notification requirements.

- As with EU REACH, obligations under GB will 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.

- If you are producing or importing a substance in GB in quantities of over one tonne per year then it must be registered under UK REACH

- In relation to SVHCs, suppliers of articles containing substances that appear on the Candidate List may need to submit a notification to the HSE, but only when the following conditions are met:
  i. The substance has been included on the candidate list
  ii. The substance is present in the articles above a concentration of above 0.1% weight by weight (w/w) and
  iii. The total amount of the substance in the articles exceeds one tonne per producer or importer per year and
  iv. The substance has not been registered for that specific use.

79. **If you are now an importer of mixtures, do we need to do anything about the EU registered substances used within that mixture?**

- The definition and registration requirements of articles under UK REACH will mirror that of EU REACH. If you are producing or importing an article in GB, you need to register each individual substance in an article under UK REACH: if the substance is present in the article in quantities of over one tonne per year; and if the substance is intended to be released under normal conditions of use, for example a t-shirt containing a fragrance. If the substance in

your article has already been registered for the same use, you do not need to register it as well.

80. **If we are importing a mixture as a Downstream user, how can we register the mixture (individual substances) if some of those ingredients are trade secrets?**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

81. **Where you are importing a mixture of chemicals and you are not aware of the full composition – only what is disclosed on the SDS, due to it being a trade secret do you only include the parts of the composition that you are aware of in your notification?**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

82. **Please can you clarify the situation for importers of finished formulated products for resale into UK industry. How should we register as all the information seems to be about substances- raw materials – not formulated products that we do not have formulation information in any detail as it is intellectual property. Please clarify.**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

83. **If you import a mixture, and you don't know all the substances, how do we submit DUINs? Do we submit the mixture name or?**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

84. **It is still unclear how importers of formulated products that are then resold on the UK market should register. The manufacturer of the product will not give full details of the product materials and formulation as it is intellectual property, so how can the importer/distributor register the product? So far all the information seems to cover raw materials and nothing about complex formulated products imported and resold to UK industry. Can this scenario be explained please?**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).

85. **Will articles under EU REACH be treated the same as articles in UK REACH?**

- The definition and registration requirements of articles under UK REACH will mirror that of EU REACH. If you are producing or importing an article, you need to register each individual substance in an article: if the substance is present in the article in quantities of over one tonne per year; and if the substance is intended to be released under normal conditions of use, for example a t-shirt containing a fragrance. If the substance in your article has already been registered for the same use, you do not need to register it as well.

86. **We import finished cosmetic products from outside the E.U. They use chemical from both the U.K., E.U. and worldwide to make up the products. Our products are E.U. REACH compliant. What do I need to do?**

- The definition and registration requirements of articles under UK REACH will mirror that of EU REACH. If you are producing or importing an article, you need to register each individual substance in an article: if the substance is present in the article in quantities of over one tonne per year. The same is true for cosmetic articles. Based on the concentration of the substance in the imported product and the volume of product you import, you must calculate the total annual quantity of imported substance.

- Depending on your role in the supply chain you may be able to make use of the transitional provisions developed to support industry in the switch to UK REACH. Details can be found here.

- If you import the chemical in a quantity larger than 10 tonnes per year, you must ensure that the REACH registration dossier contains a Chemical Safety Report (CSR). The risk to human health of end users caused by the use of the substance in your cosmetic product does not need to be addressed in the CSR, as this aspect is covered by the cosmetic Product Safety Report. It must, however, include the environmental and occupational aspects of this use.

- You can find information on cosmetics regulations in Great Britain and Northern Ireland after 1 January 2021 by clicking through the relevant links from here.

87. **Buying EU REACH registered raw materials for blending what are the obligations for raw materials post transition and the blend?**

- While you are not a manufacturer under UK REACH if you only blend substances into mixtures or use chemicals to produce articles (in that case you are a downstream user), as with EU REACH, under UK REACH your obligations depend on your role in the supply chain for the specific substance meaning you can have specific obligations for each individual substance you manufacture, import or use. Therefore, if you buy a chemical product directly from a supplier based outside GB and bring it into GB territory you are an importer and must comply directly with UK REACH obligations, unless your non-GB supplier has appointed a GB-based "Only Representative" to register the substance, in which case you are regarded as a downstream user under UK REACH.

88. **It is not clear how we register for Reach as an importer of mixtures for resale on the UK market.**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present).
- Information is available here on how UK downstream users can notify the HSE using a Downstream User Import Notification (DUIN) by 27 October 2021.
- A new registration will then be required within the subsequent 2, 4 or 6 years, after the initial 300 days, depending on volume and hazard. Alternatively, you can encourage your EU/EEA supplier to appoint a UK-based Only Representative (OR), or change their source to a GB registered supplier.
- Note these measures only apply to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance (and who did not have an EU REACH registration).
- From 1 January 2021, GB companies wishing to register new chemicals for the GB market would need to register those with HSE using the Comply with UK REACH IT system.

89. **For complex mixtures imported from EU does each chemical need to reg in UK REACh?**

- If you are importing mixtures, you will only need to supply details of the substances in the mixture to the extent that they are available to you (where you import 1 tonne or more of the substance per year, taking account of all the mixtures where the substance is present). In practice this means that if you hold the details of the substance in a mixture then you are required to notify based on that information.

90. **If you formulate products that are a mixture of raw materials used in >1 tonne and they end up going to both GB and the EU, how are we expected to manage the reimport of our product to the EU when there may be multiple suppliers? This is without giving confidential information to our customer, who may want the product in a European location. Can we just use a certificate of compliance if the raw materials are both EU and UK REACH registered?**

- Answer to follow.

91. **We will be importing from the EU some mixtures for temporary storage in the UK before re-exporting to EU customers. Do we need to comply/register with REACH UK for these stocks?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per calendar year. Under Article 3 of UK REACH, an import is defined as '*the physical introduction into the customs territory of Great Britain'.* Therefore, UK REACH will apply only if this is the case.

92. **We manufacture blended products with chemicals that come from Europe, partly. Do we need to register directly with reach?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

93. **Are there actions needed to import treated textiles (from EU) into GB? For example: does the active substance needs to be registered or not?**

- The definition and registration requirements of articles under UK REACH will mirror that of EU REACH. If you are producing or importing an article, you need to register each individual substance in an article: if the substance is present in the article in quantities of over one tonne per year; and if the substance is intended to be released under normal conditions of use, for example a t-shirt containing a fragrance. If the substance in your article has already been registered for the same use, you do not need to register it as well.

94. **In terms of Downstream User Import Notifications of polymers; will they be exempt from testing after the 27 October deadline?**

- The exemption to the registration of polymers which apply under Article 2 (9) of REACH has been carried over into UK REACH and will apply after the transition period.

95. **Do you need to register the monomers?**

- Monomers imported into the UK which are subject to registration will need to be registered with the UK Agency. If UK businesses wish to export monomers to the EU which are subject to EU registration, they would need to register with the European Chemical Agency (ECHA).

Northern Ireland

96. **When there is divergence between EU and UK regulations and outcomes after 1st January will the automatic authorisation for NI (who will presumably continue to follow EU regulation) still apply?**

- Businesses based in Northern Ireland will retain their roles under EU REACH with respect to EU/EEA and NI market access. EU REACH authorisations for NI businesses will not be recognised under UK REACH. Business seeking to bring a Substance of Very High Concern (SVHC) into GB from NI will still have to seek an authorisation from HSE that reflects the particular environment, workplace or consumer conditions in GB.

97. **If you import from EU you have to register for UK REACH. If you are a retailer with a central distribution, and then export to NI, do you also have to register for EU REACH?**

- EU REACH will continue to apply in Northern Ireland. As a result, a valid EU REACH registration will be required for any substances placed on the NI market.

98. **How import/export between EU and NI? Is it like between EU and UK or like NI is still within EU?**

- For the duration of the Protocol, NI will remain part of EU regulatory systems for chemicals (whereas UK REACH will regulate the GB market) to ensure frictionless movement of goods within the island of Ireland, whilst remaining within the UK customs territory.

- This means that Northern Ireland will have access to the Single Market but can also be part of UK trade deals negotiated around the world.

- If you are a NI business, while there will be no change in how you can place chemical substances on the EU/EEA market, there are still actions that you will need to take. If you purchase a chemical substance covered by a GB-based EU REACH registration, you will no longer be able to rely on the substance being legally registered in the EU/NI after the transition period ends.

- For the substance to remain legally registered, the GB-based manufacturer from which you bought the chemical will need to appoint an only representative established in one of the EU or EEA countries. Alternatively, you can choose to register the substance yourself as an importer.

- If your company purchases a mixture from a GB-based supplier to be placed on the EU market, you will become an importer of that mixture into the EU. You will have to fulfil all the CLP obligations for that mixture. This applies even if you do not change the composition of the mixture.

- If your GB-based supplier is currently an importer of the chemical from outside the EU/EEA, they have the option of moving their importing activity to the EU or EEA. Otherwise, you will need to register the substance as the EU-importer.

- If you wish to move products from NI to GB your GB customer will be required to submit some basic information to the HSE. Alternatively, the NI supplier is able to do so on their behalf. Details of this process can be found here.

99. **Has the EU agreed that any NI business can still participate in EU REACH as the guidance on the ECHA website doesn't seem to refer to this?**

- ECHA's website sets out the following "If your company is based in Northern Ireland, REACH, CLP, the BPR, PIC and POPs regulations continue to apply to you also after the end of the transition period. As a company located in Northern Ireland, you will therefore continue to have access to several of ECHA's IT tools needed to fulfil your obligations. However, in certain situations concerning poison centre notifications and biocidal products, IT systems provided by the UK authorities need to be used. For more information, see the Q&As.'

- "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.'

- "This information is based on the Protocol on Ireland and Northern Ireland which is part of the Withdrawal Agreement and applies as from 1 January 2021." Please see https://echa.europa.eu/uk-company-based-in-northern-ireland

- This means that Northern Ireland will have access to the Single Market but can also be part of UK trade deals negotiated around the world.

100. **The Northern Ireland Protocol currently exempts Supermarkets, does this mean that Supermarkets trading in Northern Ireland do not have to register Chemicals with the EU?**

- Government guidance set out here explains that the Protocol obliges both the UK and EU to seek to streamline trade between Great Britain and Northern Ireland, and to avoid controls at Northern Ireland ports as far as possible. In line with that obligation, discussions are ongoing about the process by which controls are conducted, and their frequency. The guidance will be updated to take account of those discussions.

- Specifically, the UK Government recognises the unique position of authorised traders, such as supermarkets, with stable supply chains, and comprehensive oversight of warehousing and distribution operations, moving pre-packaged products for retail sale solely in Northern Ireland. We are continuing to pursue specific solutions for this trade, and this guidance does not therefore apply to this trade.

- Specifically in relation to EU REACH, registration obligations rest with the importer. While there will be no change for NI businesses in how they interact with EU REACH, there are still actions that a supermarket should take. If the supermarket is an importer buying a chemical substance from a GB-based company that registered a substance under REACH, it will no longer be able to rely on the substance being legally registered after the transition period ends.

- The NI supermarket will need to check there is an upstream EU REACH registration in order to maintain its status in the supply chain as a downstream user.

101. **Simon has said that to maintain EU/EEA market access, UK registration holders would need to transfer their registrations to an EU27/EEA legal entity. Does this mean that UK-UK REACH registration holders can transfer their registrations to an NI legal entity to maintain EU/EEA market access?**

- Yes. For GB businesses wanting to place products on the NI market, they will need to comply with EU REACH. GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA/NI market; this includes entities based in NI. Alternatively, GB companies could support their EU/EEA/NI-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website - https://echa.europa.eu/uk-withdrawal-from-the-eu.

102. **From Northern Ireland protocol, Northern Ireland will remain under the EU REACH. Is that right? For how long?**

- As part of the revised protocol to the Withdrawal Agreement agreed by the United Kingdom and the European Union, EU REACH will continue to apply in Northern Ireland after the transition period ends.

- The Protocol is a practical solution to avoid a hard border with Ireland whilst ensuring the UK, including Northern Ireland, leaves the EU as a whole, enabling the entire UK to benefit from future Free Trade Agreements (FTAs). There will be special provisions which apply only in Northern Ireland while the Protocol is in force.

- The Protocol is not codified as a permanent solution: it is designed to address a particular set of problems in a way that upholds the Belfast (Good Friday) Agreement and ensures the UK, including Northern Ireland, leaves the EU as a whole. It can do so only for as long as it has the consent of the people of Northern Ireland. That is why it is for the elected institutions in Northern Ireland to decide what happens to the Protocol's alignment provisions in a consent vote that can take place every four years, with the first vote taking place in 2024.

103. **I believe it was Simon that mentioned that NI will no longer accept EU registrations from UK based companies. I do not understand this.**

- As part of the revised protocol to the Withdrawal Agreement agreed by the United Kingdom and the European Union, EU REACH will continue to apply in Northern Ireland after the transition period ends.

- Northern Ireland-based businesses will retain their current role and obligations under EU REACH in respect to access to the EU/EEA and NI markets.

- From 1 January 2021, UK REACH will operate independently of EU REACH and businesses will need to comply separately with both regimes. As such, after the transition period ends, Northern Ireland-based businesses will no longer be able to rely on EU REACH registrations held by Great Britain-based businesses.

- For GB businesses wanting to place products on the NI market, they will need to comply with EU REACH. GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA/NI-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA/NI market. Alternatively, GB companies could support their EU/EEA/NI-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website.

104. **We understand that NI will follow EU law regarding CLP, REACH, Biocides and Cosmetics regulations etc.**
   - **Who will be the competent authorities for these regulations in NI & do they already have the necessary infrastructure in place?**
   - **Will they have access the relevant EU databases and decision making processes?**
   - **Will they 'inherit' all of the UK's past decisions and approvals?**

- As part of the revised protocol to the Withdrawal Agreement agreed by the United Kingdom and the European Union, EU REACH will continue to apply in Northern Ireland after the transition period ends. HSE Northern Ireland (HSENI) will be the competent authority for EU CLP, REACH, Biocides and Cosmetic Regulations. As NI will remain part of EU REACH, no new infrastructure, e.g. REACH IT, is required.

- HSE NI are the competent authority.

- Discussions are ongoing with the EU on access to EU databases to enable Northern Ireland to deploy its responsibilities as competent authority under the Northern Ireland Protocol.

- Authorisations already issued by the UK will have been considered under the EU regulatory regimes. These authorisations will remain valid until their expiry date in GB.

- Businesses based in Northern Ireland will retain their roles under EU regulations with respect to EU/EEA and NI market access. As such, EU registrations and authorisations will continue to be recognised under EU regulatory regimes.

Exporting to the EEA

105. **If I transfer my REACH registration to the EU, am I still covered for UK REACH?**

- Yes. Grandfathering will apply to all registrations (including intermediates) held by GB-based entities, including importers and Only Representatives (ORs) based in Great Britain, and to sole, lead or joint registrants.

- All GB-based registrations that exist at the end of the transition period, and all registrations held by GB entities at any point since 29 March 2017 will be grandfathered. This means that if a UK REACH registration was transferred to an EU/EEA/NI-based entity in the run-up to the end of the transition period, it will still be grandfathered into UK REACH.

106. **If a product is manufactured in the UK for export to EU and is currently registered under EU REACH, does it also have to be registered under UK REACH?**

- Yes a UK REACH registration would be required. For existing substances, you will need to check whether the registration was held under EU REACH by a GB-based entity. If so, GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA market. Alternatively, GB companies could support their EU/EEA-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website.

- However, if the EU REACH registrations is held by a GB-based entity, including importers and Only Representatives (ORs) based in Great Britain, grandfathering will apply.

- All GB-based registrations that exist at the end of the transition period, and all registrations held by GB entities at any point since 29 March 2017 will be grandfathered. This means that if a UK REACH registration was transferred to an EU/EEA/NI-based entity in the run-up to the end of the transition period, it will still be grandfathered into UK REACH.

107. **Can a UK company still benefit from the EU REACH re-import rule if the UK company imports a substance from the EU into the UK before 1 January 2021, then imports the same substance into the EU after 1 January?**

- This relates to EU REACH and is therefore for ECHA to advise on. ECHA advice on re-importing is contained here https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1076. It states that substances which have been registered, exported and then re-imported are exempted from registration under certain conditions.

- To benefit from this exemption, the EU business will need to document that the following conditions are fulfilled:

    1. The substance must have been registered before it was exported from the EU.
    2. The substance already registered and exported must be the same, as the substance being re-imported.
    3. The substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered.
    4. The re-importer must have been provided with information on the exported substance as required by REACH (e.g. safety data sheet).

- There is also an ECHA help page if you want to submit a specific question for advice – https://comments.echa.europa.eu/comments_cms/Contact_REACH.aspx.

108. **In regards to EU REACH and the re-import exemption – could you confirm that when an order is placed with an EU REACH registered Company but that the source material is rest of the world whether the re-import exemption would apply? The example is that the order is placed with a German company so is processed by an EU company but the material is shipped from America for products manufactured in the UK but sold into the EU.**

- This question relates to EU REACH and it is therefore for ECHA to advise. However the advice at the following link may be helpful - https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1076.

- It states that "Substances which have been registered, exported and then re-imported are exempted from registration under certain conditions.'

- "To benefit from this exemption, you need to document that the following conditions are fulfilled:
    1. The substance must have been registered before it was exported from the EU.
    2. The substance already registered and exported must be the same, as the substance being re-imported.

3. The substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered.
4. The re-importer must have been provided with information on the exported substance as required by REACH (e.g. safety data sheet).'

- "For further information, see chapter 2.2.3.6 "Re-imported substance" in the Guidance on registration: http://echa.europa.eu/documents/10162/13632/registration_en.pdf"

109. **For UK businesses exporting chemicals to the EU, do we need to have EU REACH Only Representative (OR) certificates in place by Jan 1st 2020, or just show that our suppliers have moved their registrations to an EU legal entity?**

- GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA market. CEFIC has issued advice on suspensive clauses to facilitate transfers, see https://echa.europa.eu/documents/10162/13552/how_to_transfer_uk_reach_registrations_en.pdf/1fb443ce-79de-6596-aae5-3f1033f1a5fb.

- Alternatively, GB companies could support their EU/EEA-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website, see https://echa.europa.eu/uk-withdrawal-from-the-eu.

- GB companies wishing to register new chemicals for the EU/EEA market after the UK leaves the EU would need to register those with ECHA as they do now, but would need to do so via their EU customers, or an affiliate or OR in the EU/EEA. Further guidance on how to do this can be found on the ECHA website.

110. **We have heard that the ECHA 'window' for transferring REACH registrations to an EU entity will close on 15 December. Are you able to confirm this?**

- Yes – ECHA has confirmed that the window for transferring UK-held EU REACH registrations to EU/EEA/NI-based entities will be open until 15 December 2020 - https://chemicalconvention.org/wp-content/uploads/2020/10/Brexit-ECHA-pdf.pdf.

111. **Can GB mainland companies transfer their EU dossiers to a company in Northern Ireland in order to maintain access to the EU market?**

- Yes. GB businesses wanting to place products on the NI market will need to comply with EU REACH. GB-based entities currently holding EU REACH registrations would need to transfer their registrations to an EEA-based entity (such as an affiliate or an OR) in order to continue exporting substances or mixtures to the EU/EEA/NI market; this includes entities based in NI. Alternatively, GB companies could support their EU/EEA/NI-based importers to ensure that they comply with EU REACH. Further details are available on the ECHA website - https://echa.europa.eu/uk-withdrawal-from-the-eu.

112. **Will UK based consultancy firms be able to have access to ECHA IT tools?**

- No. From 1 January 2021, UK REACH will operate independently of EU REACH and businesses will need to comply separately with both regimes. As such, after 1 January 2021, GB-based businesses will no longer have access to ECHA IT tools like REACH-IT, R4BP, or the ECHA Submission portal.

113. **When supplying mixtures of already EU registered substances back into the EU, will our EU customers have any REACH obligations as importers?**

- This relates to EU REACH and is therefore for ECHA to advise. However, EU REACH obligations rest with the importer. The EU importer will need to check there is an upstream EU REACH registration in order for the importer to maintain its status in the supply chain as a downstream user. ECHA guidance for importers can be found here https://echa.europa.eu/support/getting-started/importer.

114. **Regarding transfers – Defra and the HSE continue to present as if all UK held EU REACH registrations can be transferred to EU Legal entities – THIS IS NOT THE CASE. There are only a few acceptable situations where transfers can take place as per ECHA Feb 2019 guidance (https://echa.europa.eu/documents/10162/13552/how_to_transfer_uk_reach_registrations_en.pdf/). Please can you clarify where transfers are possible and more clearly communicate this, I have had a number of clients say DEFRA says we can transfer our UK reg to EU!**

- Response to follow.

115. **For UK registration holders needing to transfer registration to EU legal entity, will there be a grace period after 1 January 2021?**

- Information published by ECHA states that the window for transferring UK-held EU REACH registrations to EU/EEA/NI-based entities will be open only until 15 December 2020 - https://chemicalconvention.org/wp-content/uploads/2020/10/Brexit-ECHA-pdf.pdf.

New substance registrations / new imports

116. **If a GB company imports a new substance from outside GB (with no EU Registration) in 2021, is it possible to do a notification to HSE and benefit from the transition period of 2, 4 or 6 years?**

AND – If you are currently importing material from EU then there are going to be staged timings depending on tonnage for provision of data, if you then want to bring in a new product for the first time after 1 January 2021, are you still able to do this over the staged timings?

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. As such, for new substances being placed on the GB market for the first time from 1 January 2021, a new registration will be required.

- The downstream user import notification provisions are intended to enable existing supply chains to continue unbroken and provide time for businesses to comply with their new obligations as an importer under UK REACH.

- For substances that are registered under EU REACH, which you are now intending to manufacture or import into the UK, you will be required to submit a registration. It may be possible to defer the submission of the full information requirement so that you are able to share data and participate in the joint registration with the grandfathered registrants. You will be informed if this applies to you after successfully submitting an Article 26 substance inquiry.

117. **What is the REACH registration timeline for new substances for which we are not an owner of a EU REACH registration or a downstream user?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. As such, for new substances being placed on the GB market for the first time, a new registration will be required.

- Before any registration is submitted, an Article 26 substance inquiry must be sent to the UK Agency, the Health and Safety Executive, to determine whether there has been a previous registration or inquiry for the same substance. Successful inquirers will then be able to access the substance page in the system and be able to view contact details of those who are already grandfathered, from EU REACH, for that substance so that data sharing can be organised.

- We have designed the process for claiming the lead to only be available after the grandfathering stage has been completed, after 120 days. The contact details of the substance group members will be available from 'Comply with UK REACH' and we anticipate the group members will hold conversations to identify and agree a suitable lead.

118. **If we begin to import a new substance in early 2021 so we do not benefit from the registration deadlines, will we be forced to take on the Lead Registrant role and complete the registration before the grandfathering or DUIN deadlines?**

- For substances that are registered under EU REACH, which you are now intending to manufacture or import into the UK, you will be required to submit a registration. It may be possible to defer the submission of the full information requirement so that you are able to share data and participate in the joint registration with the grandfathered registrants. You will be informed if this applies to you after successfully submitting an Article 26 substance inquiry.

119. **Will there be a pre-registration system for products under one tonne?**

- Pre-registration was a feature of EU REACH. Manufacturers and importers (or an 'Only Representative') were required to pre-register substances (manufactures or imported in volumes of one tonne or more per annum) that were already on the EU market (phase-in substances) if they wanted to benefit from transitional arrangements (as a new EU Regulation) that allowed registering them at a later stage.

- After pre-registration, potential registrants had until December 2010, June 2013 or June 2018 (depending on tonnage per year and the hazardous properties of the substances) to register.

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. As the final registration date under EU REACH has passed for pre-registered substances, pre-registration no longer exists in EU REACH and will therefore not be carried over into UK REACH.

- Registration obligations apply under UK REACH for substances manufactured or imported in GB in quantities of a tonne or more per year.

120. **If we identify the need to register a substance under UK REACH in 2021 due to import of the substance from a non-EEA country, how do we know whom we have to contact for data sharing, etc.? Will the 2, 4, 6-year deadlines also apply to us or do we have to register right away once we start importing >1 tpa? As far as our understanding goes, the DUIN are only applicable if importing substances from within the EEA to the UK. Is this correct?**

- For substances that are registered under EU REACH, which you are now intending to manufacture or import into the UK, you will be required to submit a registration. It may be possible to defer the submission of the full information requirement so that you are able to share data and participate in the joint registration with the grandfathered registrants. You will be informed if this applies to you after successfully submitting an Article 26 substance inquiry.

Authorisations & restrictions

121. **Will the UK HSE be undertaking dossier evaluations?**

- Yes. HSE will take on all of the functions currently performed by ECHA. That includes evaluating the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. This focuses on:
  - Examination of testing proposals submitted by registrants
  - Compliance check of the dossiers submitted by registrants
  - Substance evaluation

- Once the evaluation is done, registrants may be required to submit further information on the substance.

- HSE will also carry out evaluation of authorisation applications. You will need to submit an application for approval under the GB only regime. All active substance evaluations will continue to be subject to independent scientific advice via a UK based body. There will be a GB list of approved active substances.

- An approval granted by HSE after 1 January 2021 would be GB specific and authorised under the GB regime.

122. **Is there a person appointed to charge of UK REACH at HSE?**

- The Work and Pensions Secretary has overall responsibility for HSE and therefore for HSE's responsibilities under UK REACH.

123. **EU REACH has Substances that are of Very High Concern or those that require authorisations. Will UK REACH transfer these over? What about future authorisations, will the UK make its own decisions and possibly diverge from the EU REACH?**

- All existing EU REACH authorisations and restrictions will be carried over at the point UK REACH comes into force so there will be no change in protection from dangerous chemicals that are currently prohibited from use.

- The UK is setting-up processes for evaluation, authorisation and restriction under UK REACH. These processes will mirror the processes established in EU REACH.

- The UK will use the processes for evaluation, authorisation and restriction to assess and manage the risks from chemicals in the same way that currently occurs under EU REACH.

- We will not take divergent decisions for the sake of it.

- Now we have left the EU the decisions we make will reflect what is best for the UK and the environment. The decisions we will take will be based on the best available evidence, including looking at approaches taken by chemical regimes across the world.

124. **After publication of updated SVHC candidate list under EU REACH, how would it be implemented/ published in UK REACH? Also, with respect to plastic in contact with food- EC 10/2011- would this regulation be replicated and amended under UK local rules?**

- The ECHA candidate list at the point the transition period ends 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 UK REACH candidate list will therefore include every substance that is on the EU REACH candidate list on 1 January 2021. After this point, the full process of SVHC identification under UK REACH is required to add a substance to the UK REACH candidate list.

- Regulation EC 10/2011 comes under the Materials and Articles in Contact with Food Regulations. After the end of the transition period responsibility will fall to the FSA, to take on the role of risk assessing substances that may be used in specific food contact materials for the UK market. This will also include recycled plastic processes. It will reflect the current EU requirements. Further information can be found at the following links:

  - https://www.food.gov.uk/business-guidance/requirements-for-regulated-product-applications-from-1-january-2021
  - https://www.food.gov.uk/business-guidance/submitting-a-regulated-product-authorisation-application-from-1-january-2021

125. **Will EU REACh annex XVII be implemented into UK REACh?**

- The restrictions listed under Annex XVII will be carried across as part of retained EU law. UK REACH will have a similar procedure to introduce new or amended restrictions.

- 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 HSE must obtain and use the advice of environmental regulators across GB (which will be coordinated centrally by the Environment Agency) when the application involves environmental issues.

126. **Application for Authorisation by CTAC (The Chromium Trioxide consortium) was approved by written vote a week ago, so the last hurdle is the final publishing in the EU Official Journal. If this doesn't occur before 31st December will it still transition to UK REACH?**

Please can DEFRA/HSE confirm the status of the CTACSub authorisation. It is believed that this has undergone all the necessary EU ECHA agreement procedures and now just needs to be published in the OJ. As a consequence will this granted EU ECHA authorisation be grandfathered into UK REACH?

- Ongoing GB applications awaiting a Commission decision will have to reapply for authorisations under UK REACH. However, if ECHA have already adopted its opinion, then it will move to the latter application stages of UK REACH for a final decision by the Defra Secretary of State. Further information can be found in our guidance.

- On the other hand, if the authorisation decision has already been taken and you are a UK downstream user of the 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, 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.

127. **If an authorisation is UK based but being transfer to an EU based OR at the end of the transition period will this be classed as a UK based authorisation or an EU based authorisation?**

- ECHA advises (https://echa.europa.eu/uk-based-authorisation-holder-under-reach) that "after the end of the transition period, EU legislation will no longer apply to GB…… Authorisations granted to GB-based companies will no longer exist, so EU-based companies relying on such authorisations will need to find suppliers with valid authorisations in the EU/EEA, or apply for new authorisations themselves.'

- "A GB-based company can transfer its application or authorisation e.g. to an only representative in the EU. We recommend that you make a formal agreement with the only representative that takes effect at the same time as the transition period expires. The

transfer shall be notified in REACH-IT as early as possible following the instructions in the 'How to transfer your UK REACH registrations prior to the UK withdrawal from the EU' guide."

- On the other hand, for UK REACH, 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, 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.

128. **Are there any plans to reduce the limits of SVHCs in articles under UK REACH?**

- Defra is considering how best to address the identification and tracking of chemicals in articles across supply chains to reduce barriers to reuse and recycling. We will be engaging with stakeholders in 2021 to help inform this work.

- We are committed to the safe and effective management of chemicals, including the use of SVHCs.

129. **The UK REACH Regs. carry over into the UK the 'safeguard clause' of REACH (Art. 129) . This allows Scotland to take unilateral action to restrict chemicals not yet restricted in the UK. Will these powers be used to stimulate the UK to stay aligned with new EU restrictions?**

- An appropriate authority (Defra, Scottish Government or Welsh Government) may introduce a provisional restriction via the safeguard clause, but only if it has justifiable grounds for believing that urgent action is essential to protect human health and the environment. Officials from Defra are working closely with officials from HSE, EA and the Devolved Administrations to coordinate activity under UK REACH.

Fees

130. **For a grandfathered registration there is no registration fee under UK REACH. But if I subsequently wish to upgrade to a higher tonnage, will I then incur a fee?**

- No, there is no fee to update the registration within the same tonnage band, however fees would be incurred to change tonnage band.

- If your business activity requires you to upgrade your tonnage band of a grandfathered registration, you will also need to be mindful that this may push you into an earlier compliance timeframe, and additional data may also be required as a consequence.

131. **What will the fees / fee structure be for registering substances with UK REACH? Will they be similar to fees paid earlier during EU REACH registration or this will be nominal fee?**

- The ECHA Fees regulation (Commission Regulation (EC) 340/2008) will be transposed into UK law at the point of exit meaning UK REACH fees will echo those currently charged by ECHA using the average exchange rate for 2017.
- These fees are charged proportionally, under the same basis as EU-REACH. The fee structure for registrations would therefore be determined by both the size of the registrant company and the tonnage band. SMEs will continue to receive discounts for all applicable charges under UK REACH, meaning in some instances reductions of up to 90%.

132. **How can the same/similar fees be charged for UK REACH registration as EU REACH when the market is so much smaller?**

- Whether the fees should be lower for the administration of a regulation in a single market, i.e., the UK, than for its administration in the markets of 27 EU Member States is only part of the picture.

- The fees are intended to contribute to the costs of HSE activities as the new UK REACH regulatory body, ensuring that it has the appropriate resources to fulfil its obligations as set out in legislation.

REACH IT

133. **All reach registered chemicals have a EU REACH number, will the UK REACH numbering system follow the same format or will chemicals have new numbers?**

- A new UK REACH registration number will be issued for substances under the new regime.

134. **In what format will the data be submitted? IUCLID dossier?**

- Under the UK REACH regime, we have ensured the technical information and data package requirements, would be the same as under EU REACH. This will extend to Safety Data Sheets and use of the IUCLID technical dossier format. The Comply with UK REACH IT system will therefore operate using the same software as the current REACH IT system.

135. **Will both IUCLID 5 and IUCLID 6 dossiers be accepted for Grandfathering notifications?**

- The UK REACH IT system, Comply with UK REACH, will use the IUCLID 6 dossier format.

136. **From HSE website and the SI, it appears that the information to be submitted in a DUIN is more or less identical to that in an inquiry dossier. Just the format is different: Excel versus IUCLID. Why this needless duplication?**

- Submission of DUINs is required to ensure the HSE is aware of the import of substances into GB that meet the registration requirements set out under UK REACH. However, article 26 substance inquiries are required for those individuals who intend to submit full registrations

for a given substance, thereby allowing others to have submitted DUINs to retain their downstream user status.

137. **If we have never had to use IUCLID or had to do anything to do with REACH then how can we get access to the system that is needed to do these registrations or equivalent of pre-registrations?**

- UK REACH IT will go live on 1 January 2021 at the same point as the UK REACH regulation. Further guidance will follow shortly on the Comply with UK REACH IT system.

138. **What part will IUCLID play in the UK chemicals regulatory regime? ECHA has just released v65, and backwards compatibility is poor / non-existent. How will UK keep up with the ridiculous complexity introduced by these IUCLID updates?**

- Under the UK REACH regime, we have ensured the technical information and data package requirements, would be the same as under EU REACH. This will extend to Safety Data Sheets and use of the IUCLID technical dossier format. The UK REACH IT system, Comply with UK REACH will use the IUCLID 6 dossier format.

139. **Will UK REACH IT be accessible from abroad or must we physically sit in the UK to use the system?**

- The UK REACH IT system, Comply with UK REACH, will be accessible from abroad.

140. **If I have an existing registration on the ECHA-IT system, exactly which files do you need to resubmit your registration into the UK IT-REACH system?**

Would a no-deal scenario impact access to ECHA data? Would we still be able to use this data to derive dose descriptors for risk assessments i.e. for consumer products?

- From 1 January 2021, UK REACH will operate independently of EU REACH and businesses will need to comply separately with both regimes. As such neither GB based businesses nor HSE will no longer have access to ECHA IT tools like REACH-IT, R4BP, the ECHA Submission portal, or to the data which is held by ECHA.

- Under the UK REACH regime, we have ensured the technical information and data package requirements, would be the same as under EU REACH. This will extend to Safety Data Sheets and use of the IUCLID technical dossier format. Therefore any data you own or still have access to after the end of the transition, can be used to support UK REACH compliance. The UK REACH IT system, Comply with UK REACH will use the IUCLID 6 dossier format.

141. **So it is only possible to open a REACH IT account under UK REACH by a GB based entity from 1.1.2021 not before to handle DUIN and Grandfathering requirements?**

- Yes, The UK REACH IT system, Comply with UK REACH, can only go live on 1 January 2021 at the same point as the UK REACH regulation.

142. **Is the new UK-REACH IT system going to be made available before 31st Dec for viewing or is it all going to be a surprise in the new year?**

The UK REACH IT system, Comply with UK REACH, can only go live on 1 January 2021 at the same point as the UK REACH regulation. Further guidance will follow shortly on the Comply with UK REACH IT system.

143. **When will the UK Reach IT system become functional? We want to register as an importer of formulated products for resale on the UK market, but cannot see anywhere that we can register.**

- The UK REACH IT system, Comply with UK REACH can only go live on 1 January 2021 at the same point as the UK REACH regulation.

REACH SI (Statutory Instrument) / clarifying regulatory requirements

144. **When is UK-REACH planned to be approved by parliament?**

- The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 SI was laid in Parliament on 15 October.

- This SI is seeking to address two issues. It makes changes to reflect the Northern Ireland (NI) Protocol, for example providing for access to GB markets. It also amends the existing deadlines for UK businesses to submit their preliminary information, and eventually their data dossiers.

- The SI is expected to clear Parliamentary process in time to come into force on 1 January 2021.

145. **You mention a new SI coming into effect from January 1st, if we don't know what it is and how it is impacts us how can we prepare to comply and why so late in the day?**

- UK REACH will come into force on 1 January 2021. The UK REACH SI was made on the 29th March 2019. There have been subsequent SIs but the core foundations of UK REACH have not changed.

- We have the secondary legislation in place to make the necessary changes to EU REACH to facilitate an independent UK regime.

- The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 SI was laid in Parliament on 15 October.

- This SI is seeking to address two issues. It makes changes to reflect the Northern Ireland (NI) Protocol, for example providing for access to GB markets. It also amends the existing deadlines for UK businesses to submit their preliminary information, and eventually their data dossiers.

146. **When will UK REACH be available/come into force/be operational?**

- UK REACH will come into force on 1 January 2021.

- The Comply with UK REACH IT system which is due to go live alongside UK REACH coming into force on 1 January 2021.

147. **You made reference to UK REACH on the final slide, does this mean GB REACH?**

- Under the Northern Ireland Protocol, UK REACH will regulate the GB market while EU REACH will continue to apply to Northern Ireland. The domestic REACH regime is still referred to as 'UK REACH' because Northern Irish actors will be able to participate directly in it for some purposes. It will also reduce the potential for confusion following the references to UK REACH over the last two years, and is consistent with the Government's aims in the United Kingdom Internal Market Bill.

- References to UK REACH are intended to reflect where the specific regulatory scenario relates only to England Scotland and Wales.

- More information on the actions you may need to take to comply with UK REACH and EU REACH rules is available at: https://www.hse.gov.uk/brexit/reach-guidance.htm.

148. **Are there any plans for DEFRA or HSE to publish a consolidated UK REACH text incorporating the original EU text and UK SI's?**

- There is currently no confirmed timing for publishing a consolidated version of the legislation underpinning UK REACH although the intention is to release consolidated text. More broadly we have released extensive guidance to support industry through the compliance process and will continue to do so moving forward.

149. **In order to clarify what legislations we need to refer to in our SDS and Labels, are we going to have a consolidated legislations for UK REACH/ GB CLP to be used in all communications?**

- There is currently no confirmed timing for publishing a consolidated version of the legislation underpinning UK REACH although the intention is to release consolidated text. More broadly we have released extensive guidance to support industry through the compliance process and will continue to do so moving forward.

150. **Apart from doubling the work load in preparing and managing two REACH Systems, what specific differences are they between UK REACH and EU REACH?**

- The EU Withdrawal Act converts EU legislation into GB law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the current obligations in EU REACH will therefore be carried into UK REACH.

151. **Is the grace period under REACh only applicable to chemical import from EU?**

- UK REACH transitional provisions provide a period of 120 days for existing GB based REACH registrants and 300 days from 1 January 2021 for downstream users of EU REACH registered

substances to provide initial information to the HSE (so we know who is using what chemicals in GB).

- Full data packages or complete new registrations will then be required for a two-year, four-year or six-year period after the initial 300 days (commencing from 1 January 2021), depending on tonnage and/or hazard profile of substances. This will allow companies to form joint registration groups for a chemical substance, negotiate access to the data packages and provide that to the HSE in order to complete the 'full registration'.

- UK REACH will continue with the OR system, allowing non-UK entities to appoint a GB-based OR. This means that non-EU/EEA suppliers can appoint a GB OR to submit DUINs under UK REACH if their chemical is covered by a registration held by an EU/EEA-based OR and then sold into GB. The import will require notification followed by complete UK REACH registration, as above.

152. **You may be independent but what about the lift and shift policy?**

- The EU Withdrawal Act converts EU legislation into GB law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the current obligations in EU REACH will therefore be carried into UK REACH.

- While both GB and the EU will operate REACH, the two systems will not be linked in any way. This means that there will be new processes that exporters and importers will have to comply with, whatever the outcome of negotiations with the EU. It also means that from 1 January 2021, UK REACH will operate independently of EU REACH and business seeking to manufacture using, or to bring into GB, a Substance of Very High Concern (SVHC) that is not already authorised, will need to make a new application to HSE. As two separate regulatory regimes, the decisions taken under GB and EU REACH may differ.

153. **REACH Art 26 is not suspended for the transitional substances - does that mean that next to nominating transitional substances also inquiries are required?**

- Yes, article 26 substance inquiries are required for new registrations, including those following the submission of DUINs. Potential registrants are then placed into substance groups with the UK REACH IT system, Comply with UK REACH, in order to begin the process of negotiating data access.

154. **Regarding fluorinated gases and ozone-depleting substances: If a UK company purchases from an EU supplier - does the UK company need to do anything other than CLP and REACH?**

- The UK will leave the EU F gas system and will manage its own F gas quota system.

- If you produce, import or export HFCs (the main class of F gases) or products containing HFCs you'll need to apply for a:
  - UK quota to place them on the UK market
  - EU quota to place them on the EU market

- Until exit day you should continue to use your EU quota to place HFCs on the UK market.

- After exit day you'll need a UK HFC quota if your business places on the UK market HFCs equivalent to 100 tonnes or more of carbon dioxide (CO2) per year. This total includes any imports to the UK from the EU.

- The Environment Agency will manage a new UK F gas system, including UK HFC quota allocation which you'll use to:
  - apply for a UK quota
  - report on your activities

- If you're registered as a UK-based organisation on the EU portal, you should have received an email about registering you on the new UK system. If you haven't been contacted, email f-gassupport@environment-agency.gov.uk.

- If you prefer, you can register on the new UK F gas system yourself.

- Please visit here for more information - https://www.gov.uk/government/publications/fluorinated-gases-and-ozone-depleting-substances-how-to-do-business-if-the-uk-leaves-the-eu-with-no-deal/using-and-trading-fluorinated-gas-and-ozone-depleting-substances-rules-and-processes-if-the-uk-leaves-the-eu-with-no-deal

155. **How will UK REACH align with other Chemicals regulation such as RoHS, POP etc?**

- Answer to follow.

156. **What is the situation with exempt materials - e.g. citing Annex V section 9? Is a similar set up going to be in UK Reach?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the Annexes of EU REACH will be carried into UK REACH as they exist at the end of the transition period.

157. **If a product manufactured in the UK contains at least 60% of ingredients that already adheres to EU REACH within the formulation then does it have to be registered again? Does the end product have to be registered separately?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the current requirements for formulations and mixtures in EU REACH will be carried into UK REACH.

- From 1 January 2021, UK REACH will operate independently of EU REACH and businesses will need to comply separately with both regimes. As such, after the transition period ends, Northern Ireland-based businesses will no longer be able to rely on EU REACH registrations held by Great Britain-based businesses.

158. **There is an extension decision already in place on certain chemicals such as chromium under EU REACH until 2024 or 2026? Would this remain the same under UK REACH?**

- Existing EU REACH Authorisations will be carried over into UK REACH. Full details can be found here.

- Ongoing GB applications awaiting a Commission decision will have to reapply for authorisations under UK REACH. However, if ECHA have already adopted its opinion, then it will move to the latter application stages of UK REACH for a final decision by the Defra Secretary of State. Further information can be found in our guidance.

- On the other hand, if the authorisation decision has already been taken and you are a UK downstream user of the 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, 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.

159. **We are currently an Importer of a HAZ Chemical Approx 12 tonne a year. We then redistribute this chemical to customers based within the UK. Do I need to Register this under REACH (UK)?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

160. **Is the organization which imports (or manufactures) a material or product in the EU or UK market the only organization in the supply chain who has REACH reporting / registration obligation if the material/products has an SVHC above the threshold level and the volume is over 1000 kg/year? What with the others in the supply chain (processors or users of the material)?**

- As with EU REACH, under UK REACH you can have specific obligations for each individual substance you manufacture, import or use. Your obligations depend on your role in the supply chain for the specific substance.

- If you produce or extract a chemical substance, you must comply directly with UK REACH obligations.

- If you buy a chemical product directly from a supplier based outside GB and bring it into GB territory you are an importer and must comply directly with UK REACH obligations, unless your non-GB supplier has appointed a GB-based "Only Representative" to register the substance, in which case you are regarded as a downstream user under UK REACH.

- You are not a manufacturer under UK REACH if you only blend substances into mixtures or use chemicals to produce articles. In that case you are a downstream user and you have to fulfil downstream user requirements.

- Downstream users have important responsibilities. For example, when downstream users receive a safety data sheet (SDS), they need to identify and apply appropriate measures to adequately control the risks. When it is an extended SDS, they must additionally check whether the exposure scenario covers their own use of the substance and their conditions of use or take alternative action.

161. **Am I right that if an UK based company imports materials from the EU or other areas of the world and those material don't contain EU REACH SVHCs above the threshold level of 0,1% w/w and the total volume of the SVHC is below 1000 kg/year, the organization does not have obligations under the UK REACH? What if the total volume is above the 1000kg/year?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

- In relation to SVHCs, suppliers of articles containing substances that appear on the Candidate List may need to submit a notification to the HSE.

- Notification by the producer or importer of the articles is required when the following conditions are met:
  i. The substance has been included on the candidate list
  ii. The substance is present in the articles above a concentration of above 0.1% weight by weight (w/w) and
  iii. The total amount of the substance in the articles exceeds one tonne per producer or importer per year and
  iv. The substance has not been registered for that specific use.

162. **The implementation of Article 25 (12 year rule) could have a profound effect on data sharing of information belonging to non-UK study owners for the first and second registration deadlines. How will HSE implement Article 25, especially since the information of interest was shared in the context of EU legislation which will not apply in UK?**

- UK REACH will implement the 12 year rule. The period starts from when the information was supplied either to HSE or to ECHA under EU REACH. We won't restart the clock on 1 January 2021, so if for example the information was provided in a registration to ECHA in 2010 the 12 year period comes round in 2022.

163. **Will initial tonnage bands be worked out from 1st Jan to 28th Oct 2020? or a three-year rolling average?**

- The 3-year rolling average policy was changed for EU REACH in October 2019. UK REACH will mirror the latest policy, in that the volume of the substance you manufacture or import needs to be determined in tonnes per calendar year. The calendar year is from 1 January to 31 December. You also need to aggregate the volume of your substance as a substance on its

own, in a mixture, and in an article intended to be released. Volumes manufactured or imported as isolated intermediates under strictly controlled conditions need to be counted separately.

164. **As a UK Manufacturer what tonnage bands can we produce from 1st Jan? we have EU Reach at 10-100T but are we able to produce any volume until the new deadline dates? Because there is no limit for UK reach until the new dates?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

165. **Is there a PPORD facility within REACH UK?**

- 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 takes place in Great Britain (England, Scotland and Wales), will be grandfathered into UK REACH.

166. **We currently manufacture electronics assemblies using COTS, solder wire, paste and glues (all REACH compliant) from a UK distributor. Do we need to register for anything or is having a REACH statement detailing that we do not use any haz chemicals and flowing this to our suppliers adequate?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

167. **As a user of chemicals in the uk for other manufacturing processes (non chemical products) how are we affected if all our chemicals are procured via a UK supplier (who in some cases imports elements of those chemicals from outside the UK)?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer not with the end-user. You will need to check there is an upstream UK REACH notification which is followed by a new registration in order to maintain your status in the supply chain as a downstream user.

- Downstream users have important responsibilities. For example, when downstream users receive a safety data sheet (SDS), they need to identify and apply appropriate measures to adequately control the risks. When it is an extended SDS, they must additionally check whether the exposure scenario covers their own use of the substance and their conditions of use or take alternative action.

168. **We import a microbiological surfactant blend and counteractant then we take those blends and mix and bottle into a final branded product. We import from Netherlands less than a tonne annually. Our end products are non clp. What do we need to do about registering our products and what is the contact details for this the website is not very clear? If we then sell into NI what other things do we need to do?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

169. **Would REACH Annex II update (2020) be adopted into UK REACH and when?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the Annexes of EU REACH will be carried into UK REACH as they exist at the end of the transition period.

- Annex II of the Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation (EC) No 1907/2006 was amended in July 2020. The amendment, known as Commission Regulation (EU) 2020/878, will come into force in the EU on 1 January 2021, i.e. after the end of the transition. UK REACH will therefore not automatically adopt this provision.

170. **Is the exemption from registration for reimported substances that applies under EU REACH (Article 2.7) expected to be applicable also under UK REACH?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. All of the current exemptions in EU REACH will be carried into UK REACH. They will also apply to the notification requirements.

- As such, substances which have been registered, exported and then re-imported are exempted from registration under certain conditions.

- To benefit from this exemption, the GB business will need to document that the following conditions are fulfilled:

    1. The substance must have been registered before it was exported from the EU.
    2. The substance already registered and exported must be the same, as the substance being re-imported.
    3. The substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered.
    4. The re-importer must have been provided with information on the exported substance as required by REACH (e.g. safety data sheet).

171. **I buy materials from an EU source for use in my own processes and not for resale. From Jan 2021 will I be classed as an importer with those obligations?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the

substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH. Details can be found here.

172. **We buy chemicals from distributors to produce cosmetics so we are an end user. Currently our suppliers have performed the REACH registrations. After Brexit, do we need to register the raw mats coming into the UK or will the distributor need to register with UK REACH?**

- UK REACH registration obligations apply to those companies manufacturing or importing substances in quantities of a tonne or more per year. Depending on the providence of the substances a business may be able to make use of the notification provisions developed to ease the transition to UK REACH.

- You are a distributor under REACH and CLP if you source a chemical substance or a mixture within GB, store it and then place it on the market for someone else (also under your own brand without changing its chemical composition in any way). For example, retailers and wholesalers are distributors under REACH and CLP.

- You are not a distributor if you buy chemicals from outside GB and place them straight on the market in GB - you are an importer.

- If you buy chemicals within GB and mix them with other chemicals, dilute them or (re)fill containers, before supplying them to others, you are a downstream user.

- If you are the importer, the import will require a notification to HSE within 300 days (by 27 October 2021 – please visit this page for more details – https://www.hse.gov.uk/brexit/scenario2.htm).

- A complete UK REACH registration will then be required within 2, 4 or 6 years after the initial 300 days, depending on tonnage and/or hazard profile of substances (visit this page for details – https://www.hse.gov.uk/brexit/scenario1.htm). These will be classed as new registrations and will be subject to fees payable to HSE.

173. **If I'm using a UK registered company who are importing chemicals from EU who are classed as distributor all the clearance and duties etc should be managed by the distributor? Should I be worried about anything from my side being the end user?**

- UK REACH will apply in the same way as EU REACH where registration obligations rest with the importer not with the end-user. You will need to check there is an upstream UK REACH notification which is followed by a new registration in order to maintain your status in the supply chain as a downstream user.

- Downstream users have important responsibilities. For example, when downstream users receive a safety data sheet (SDS), they need to identify and apply appropriate measures to adequately control the risks. When it is an extended SDS, they must additionally check whether the exposure scenario covers their own use of the substance and their conditions of use or take alternative action.

174. **Do I need to do anything with Exemptions that I hold?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over the same regulatory obligations under UK law after exit as current EU regulations. All of the current exemptions in EU REACH will be carried into UK REACH. You may need to submit some basic information to the HSE informing them of your ongoing use of a substance. Details can be found here.

UK handling of upcoming EU changes

175. **Will the UK implement the recent implementing regulation relating to article 22 of REACH – the timings for updates to REACH dossiers?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over retained EU law and regulatory obligations as they exist at the end of the transition period. If implementing regulation comes into force after this point it will not be retained under UK law.

176. **There is a lot of additional work on polymers requiring registration taking place in Europe at the moment. Does the UK have any intention of also working on this aspect or will the focus mainly be on setting up UK REACH for the next few years?**

- The EU Withdrawal Act converts EU legislation into UK law, carrying over retained EU law and regulatory obligations as they exist at the end of the transition period. If implementing regulation comes into force after this point it will not be retained under UK law.

CLP

Timing

177. **When will UK CLP be available/come into force?**

- GB CLP will come into force on 1 January 2021.

178. **When will GB CLP be enacted and what a likely grace period might be following enactment/implementation on GB side?**

- GB CLP will come into force on 1 January 2021.
- There will not be a transition period for enforcement of GB CLP.
- GB based CLP duty holders should already be fully compliant with the EU CLP Regulation and therefore should already be meeting many of their duties and obligations under the GB CLP Regulation in relation to classification, labelling and packaging.

- Where suppliers have new duties under the GB CLP Regulation, e.g. where they have become 'importers', it will be expected that duty holders will make arrangements to ensure compliance from 1 January 2021.

- HSE will continue to adopt a pragmatic approach to enforcement in accordance with the HSE Enforcement Policy Statement and Enforcement Management Model. HSE will also take account of circumstances such as that products may need extra time to make their way through the supply chain.

- In GB, the GB CLP Regulation is also enforced by local trading standards officers, the General Pharmaceutical Council (for pharmacies) and the Office for Road and Rail. These enforcing authorities should be approached for further information on their enforcement arrangements.

179. **Will C&L notifications be required for all relevant substances from 1 Jan 2021 or is this required only for NEW relevant substances placed on market in UK after 1 Jan 2021 (i.e. not for those already notified in EU pre 1 Jan 2021).**

- Where the GB based supplier is an established manufacturer or importer and has already notified the required substance information to ECHA for inclusion in the Classification and Labelling Inventory before the end of the Transition Period, no re-notification is needed to HSE.

- 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.

180. **If an EU-27 or NI supplier address is not allowed, when would the goods need to be relabelled? At customs or when on GB importer's site? [think this is a 'goods on the market' question] Our company imports products from the EU which are subject to CLP labelling. How long will this CLP labelling be valid on the UK market after the transition period has ended?**

- From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

- In terms of how long existing CLP labelling will be valid on the GB market after 31 December 2020, unlike for other goods, there is no transitional period after 1 January 2021 for businesses to update their labels for substances and mixtures to comply with GB CLP Regulation requirements.

- From 1 January 2021, GB-based businesses must classify (identify hazardous properties), label (communicate those hazards) and package the substances and/or mixtures according to the GB CLP Regulation before placing them on the GB market. Labels must be in English but other languages are also permitted.

- However, GB-based businesses will not have to recall substances or mixtures already placed legally on the GB market to update their labels provided that:

  - the substances or mixtures have already been placed on the GB market before 1 January 2021; and
  - the hazard labelling is in accordance with GB mandatory classification and labelling (MCL) in the GB MCL list published on the HSE website (the GB mandatory classification and labelling list carried over all EU harmonised classification and labelling, in force, on 31 December 2020. They have the same legal effect in GB).

- From 1 January 2021, GB based downstream users and distributors supplied by EU/EEA based businesses with substances and mixtures after 31 December 2020 will be importers for the purposes of GB CLP and have new obligations and duties, including classification (identifying hazardous properties), labelling and packaging the substances and/or mixtures according to GB CLP before placing them on the GB market.

- GB businesses will continue to have to update their labels for their substances and mixtures or make information available to their supply chains without undue delay where the hazard classification is more severe. This includes substances with harmonised classifications (GB MCLs) included in the 14th ATP, 15th ATP, and 17th[1] ATP to the CLP Regulation that appear in the GB MCL list.

181. **For CLP you mentioned that existing stock in the supply chain can be continued to be sold in GB for some time. What would be the end of the this transition period? / How far is there going to be an interim period during which the current labels are still ok to be used in the UK?**

- Please see response above.

182. **When do you have to make a notification under CLP? If you have previously bought materials from EU27 do you have to now make a notification to HSE for import into UK? How do you make these notifications?**

[1] If the 17th ATP does not take legal effect before 31 December 2020, its entries will not be retained in GB. The proposed changes (2019 RAC Opinions) will need to be considered separately by the GB CLP Agency (HSE) under the new GB mandatory classification and labelling system (see question above)].

- After 1 January 2021, there is now a requirement on GB based manufacturers and importers to notify the specified classification and labelling information of the substances they place on the GB market for the first time, whether on their own or in mixtures, where they meet the criteria for notification, irrespective of production or import volume/tonnage of the substance.

- Notifications will be made to the GB CLP Agency (HSE) using the new online GB notification web form. The information will be included in the new GB notification database. This database will be made publicly available in due course omitting the notifiers' details as is the case in the EU system.

- The HSE webpages will be updated regularly with any new information. You can also subscribe to e-bulletins to inform of any future updates. https://www.hse.gov.uk/brexit/clp-ni.htm

183. **Is there a date in which to complete GB CLP notifications? Or as an importer are we expected to complete hundreds of these on day 1?**

- There is no transitional period after 1 January 2021 for complying with GB CLP.

- GB CLP Regulation requires notification of substances placed on the GB market, either on their own or in a mixture, within one month after their placing on the GB market, provided they have not already been notified to ECHA's Classification and Labelling Inventory by 31 December 2020 or are exempt from the notification duty.

  - Where the GB based supplier is an established manufacturer or importer and has already notified the required substance information to ECHA for inclusion in the Classification and Labelling Inventory before the end of the Transition Period, no re-notification is needed to HSE.

  - 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.

Substances already notified / classified under EU CLP

184. **Will Manufacturers and importers have to notify C&L of substances to HSE if they have previously done so to ECHA under their obligations under EU CLP before the end of the transition period?**

- The GB CLP Agency (HSE) wants to make sure that GB notifications are only made where necessary and companies avoid unnecessary re-notifications. A general exemption from notification is described in the Chemicals Exit SI. It will operate as follows:
  - Where the GB based supplier is an established manufacturer or importer and has already notified the required substance information to ECHA for inclusion in the Classification and Labelling Inventory before the end of the Transition Period, no re-notification is needed to HSE.
  - 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.

185. **We have notified nearly 1000 chemicals to the EU CLP inventory notification, do we need to notify all of these to the UK system?**

- Please see answer above.

186. **If substances have been registered already in EU by our supplier, do we still need to re-register under GB CLP or older registration with ECHa will remain valid?**

- Please see answer above relating to notifications; there is no registration regime under GB CLP.

187. **Do you envisage that under GB CLP existing EU classifications will be changed at any time and if so for what value since for most chemicals they will also need to have the EU classification?**

- GB and the EU will operate separate CLP regimes and it is possible that decisions will diverge or be taken at different times.
- GB will not adopt any decisions on harmonised classification and labelling made by the Risk Assessment Committee, without scrutiny. GB has a new stand-alone GB mandatory classification and labelling system that follows procedures independently of the Commission, ECHA and the EU.

- GB will not automatically align with harmonised classification and labelling arising from ECHA Committee for Risk Assessment (RAC) Opinions without independent consideration by HSE, as the GB CLP Agency, with input from other experts such as the Environment Agency where environmental hazards are involved.

- After consideration of a published RAC Opinion, and, where necessary, consultation with relevant experts as well as other interested government departments, the Devolved Administrations and affected agencies, HSE as the GB CLP Agency will reach an opinion and will make a recommendation about whether or not to align with the RAC Opinion to the Secretary of State for a final decision to be made; the decision will only be made with the consent of the Devolved Administrations (Scotland and Wales). Where HSE does not recommend aligning with the RAC Opinion, it has the option of producing a new proposal for new or revised GB mandatory classification and labelling or, alternatively, decide not to propose any classification and labelling.

- The proposed GB mandatory classification and labelling of a substance will continue to be based on scientific justification of the hazard classification and evaluation of all available scientific information that is considered adequate, reliable and relevant.

- However, **how** the mandatory classification and labelling is implemented will be subject to consideration of the wider implications of the classification including the socio-economic impact on the sectors most likely to be affected especially downstream consequences. The final recommendation to ministers, with the consent of the Devolved Administrations (Scotland and Wales) will take into account a broader picture, although the hazard classification and the evaluation of scientific data will still take precedence over these other considerations.

Clarifying the regulation

188. **EU CLP consists of both the regulation and guidance. Is it planned to migrate all the guidance as well or will HSE being reviewing and/or revising this?**

- HSE has developed basic guidance on the GB CLP Regulation outlining the key changes and differences in the new GB processes and procedures covering alternative chemical names, the GB MCL system and GB notifications that are available on HSE's Chemical Classification website.

- In the short to medium term, as the majority of the EU CLP Regulation has been retained, publicly available ECHA technical guidance on the application of classification criteria and on labelling and packaging will continue to be helpful and relevant to GB-based companies.

- From 1 January 2021, further information will be available on the HSE's Chemical Classification web pages.

189. **With regards to the new CLP notification process, do you need to notify every substance you import? How do you notify?**

- The GB CLP Agency (HSE) wants to make sure that GB notifications are only made where necessary and companies avoid unnecessary re-notifications. A general exemption from notification is described in the Chemicals Exit SI. It will operate as follows:

  a) where the GB or NI based supplier (supplying qualifying Northern Ireland goods directly to the GB market) is an established manufacturer or importer, and has already notified the required substance information to ECHA for inclusion in the Classification and Labelling Inventory before 1 January 2021, no GB re-notification is needed;

  b) where a new GB based importer is part of an existing EU to GB/NI supply chain (as a downstream user or a distributor), in place on 31 December 2020, and the information already notified by the manufacturer or importer elsewhere in that supply chain can be relied on as accurate, no re-notification is needed. This avoids the problem of the inability of the GB based downstream user or distributor being able to access the original notifier's details which are not open to public view. The legal obligation to demonstrate that the information is correct will rest with the new GB based importer if challenged by a GB enforcing authority;

  c) where new supply chains are established from 1 January 2021, notification would be needed by the GB based manufacturers and importers, or by the NI based supplier who supplies qualifying Northern Ireland goods directly to the GB market;

  d) where the hazard information in an exempted notification changes, a new GB notification is needed;

  e) where a valid UK REACH registration is in place, a GB CLP notification is not required and the obligation to notify is deemed to be fulfilled.

190. **Some of the premises of EU CLP notification is that notification is required if the substance requires registration OR is classified. The GB CLP guidance does not have such a stipulation, stating that you need to notify, unless it's already been notified via EU REACH. So is my understanding correct that GB CLP notification does not have the tonnage / registration dependent requirement that EU CLP notification has?**

- After 1 January 2021, there is now a requirement on GB based manufacturers and importers to notify the specified classification and labelling information of the substances they place on the GB market for the first time, whether on their own or in mixtures, where they meet the criteria for notification, irrespective of production or import volume/tonnage of the substance. Notifications will be made to the GB CLP Agency (HSE) using the new online GB notification web form. The information will be included in the new GB notification database. This database will be made publicly available in due course omitting the notifiers' details as is the case in the EU system.

- Further guidance on submitting notifications to the GB notification database can be found on the 'Submitting a GB notification' webpage on the HSE Chemical classification webpages.

191. **Are CLP notifications required for materials which are not REACH registered?**

- The EU Withdrawal Act converts EU legislation into GB law, carrying over the same regulatory obligations under GB law after exit as current EU regulations. All of the current obligations in EU CLP will be carried into GB CLP.

- As such, whereas under GB REACH there is an exemption for substances manufactured or imported at less than 1 tonne per year, under GB CLP, after 1 January 2021, GB based manufacturers and importers will be required to notify the specified classification and labelling information of the substances they place on the GB market for the first time, whether on their own or in mixtures, where they meet the criteria for notification, irrespective of production or import volume/tonnage of the substance. Notifications will be made to the GB CLP Agency (HSE) using the new online GB notification web form. The information will be included in the new GB notification database. This database will be made publicly available in due course omitting the notifiers' details as is the case in the EU system.

- On the other hand, where a valid UK REACH registration is in place, GB notification will not be required under the GB CLP Regulation. This mirrors the arrangement in place under the EU CLP Regulation system.

192. **We have notified to clp some substances which we supply at <1 tonne/annum (exempt from REACH) do we need to notify to UK clp?**

- The GB CLP Agency (HSE) wants to make sure that GB notifications are only made where necessary and companies avoid unnecessary re-notifications. A general exemption from notification is described in the Chemicals Exit SI. It will operate as follows:

  a) where the GB or NI based supplier (supplying qualifying Northern Ireland goods directly to the GB market) is an established manufacturer or importer, and has already notified the required substance information to ECHA for inclusion in the Classification and Labelling Inventory before 1 January 2021, no GB re-notification is needed;

  b) where a new GB based importer is part of an existing EU to GB/NI supply chain (as a downstream user or a distributor), in place on 31 December 2020, and the information already notified by the manufacturer or importer elsewhere in that supply chain can be relied on as accurate, no re-notification is needed. This avoids the problem of the inability of the GB based downstream user or distributor being able to access the original notifier's details which are not open to public view. The legal obligation to demonstrate that the information is correct will rest with the new GB based importer if challenged by a GB enforcing authority;

  c) where new supply chains are established from 1 January 2021, notification would be needed by the GB based manufacturers and importers, or by the NI based supplier who supplies qualifying Northern Ireland goods directly to the GB market;

  d) where the hazard information in an exempted notification changes, a new GB notification is needed;

  e) where a valid UK REACH registration is in place, a GB CLP notification is not required and the obligation to notify is deemed to be fulfilled.

193. **When a UK company is purchasing raw materials from the EU, they are going to be the importer in UK. It was said the importer is then responsible for the labels meeting UK requirements - but also for materials which are consumed and not traded on?**

- GB companies will have importer obligations where they import substances or mixtures into GB from the EU/EEA or elsewhere. As importers, they will need to comply with the relevant GB CLP Regulation duties and obligations on importers.

- For some companies this could mean a significant change depending on what role they play in existing EU to GB supply chains. For instance, GB based distributors or downstream users who are currently supplied by the EU/EEA will now be importers if these supply arrangements continue. Such companies will have to ensure they have sufficient competence to carry out the obligations placed on importers by the GB CLP Regulation.

- Supply of qualifying Northern Ireland goods from Northern Ireland businesses to the Great Britain market will NOT be deemed import under the terms of the Northern Ireland Protocol and the GB CLP Regulation.

194. **What is meant by a UK REACH statement on the label?**

- From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

195. **Potential Conflict between CLP and CE mark IVDR compliant labelling requirements which continue to be accepted (according to the MHRA) until 30th June 2023, which has precedent, the GB medical device regulation or the CLP GB regulation specifically where there is a conflict in the labelling requirement? There will also be an ongoing conflict for NI EU CE marked compliant IVD product supplied to the GB market after 30th June 2023?**

- Response to follow.

196. **Will GB-CLP take information from the Comply with UK REACH IT systems?**

- No, there is no IT interface between the GB CLP Regulation notification system and GB REACH registration.

- However, where a valid UK REACH registration is in place, GB notification will not be required under the GB CLP Regulation. This mirrors the arrangement in place under the EU CLP Regulation system.

197. **So GB CLP will always follow after the EU, and there will be a period where Classifications in GB and EU may differ, and potentially, in GB substances may not be as well controlled!?**

- GB will not immediately adopt any decisions on harmonised classification and labelling made through the EU system without scrutiny.

- GB is free to decide on its own regulatory positions independently to ensure the continued protection of people, the environment, and the interests of UK business, but will consider EU decisions. Where GB does not align with the EU, we will present justification.

- From 1 January 2021, GB will have its own stand-alone GB mandatory classification and labelling (GB MCL) system that will follow its own procedures independently of the European Commission, ECHA and the EU. GB, in line with government policy on Global Britain, is looking beyond the EU to the rest of the world and will be looking at what happens in other countries and GHS jurisdictions.

- From 1 January 2021, the GB MCL system will no longer recognise new or revised EU harmonised classification and labelling entries adopted by Commission Delegated Regulations and listed in Table 3 of Part 3 of Annex VI of the EU CLP Regulation.

- Instead, GB's new procedures for mandatory classification and labelling will only consider proposed harmonised classifications published in ECHA Committee for Risk Assessment (RAC) Opinions. GB will not automatically align with proposed harmonised classification and labelling arising from published RAC Opinions without independent consideration by HSE, as the GB CLP Agency, with input from other experts such as the Environment Agency, Scottish Environment Protection Agency and Natural Resources Wales, where environmental hazards are involved.

- After consideration of a published RAC Opinion, and, where necessary, consultation with relevant experts as well as other interested government departments, the Devolved Administrations and affected agencies, HSE as the GB CLP Agency will reach and publish its own Agency opinion and will make a recommendation about whether or not to align with the RAC Opinion to ministers for a final decision to be made. The decision will only be made with the consent of the Devolved Administrations (Scotland and Wales).

- Where HSE does not recommend aligning with the RAC Opinion, it has the option of producing a new proposal for a new or revised GB mandatory classification and labelling or, alternatively, where the scientific evidence is insufficient or not persuasive may decide not to propose any mandatory classification and labelling.

- The overall timeframe for new or revised GB mandatory classification and labelling will be broadly comparable to the timeframe for the adoption of new/revised harmonised classification and labelling by the EU but will not align directly.

- Any proposed new or revised GB MCL that diverges from a published RAC Opinion, or as a result of an original GB-only MCL proposal, is subject to public consultation.

- All decisions on GB MCLs are made by ministers, with consent of the Devolved Administrations (Scotland and Wales), and where accepted, will be given legal effect in GB.

- Guidance on the GB MCL system will be available on HSE's Chemical Classification web pages after the end of the transition period.

198. **We currently export non haz chemicals from 3 EU Countries over 50 tonne in total. As an importer do I need to register these with CLP? as a notification. Where can I find this documentation and when can I start this process?**

- After 1 January 2021, there is now a requirement on GB based manufacturers and importers to notify the specified classification and labelling information of the substances they place on the GB market for the first time, whether on their own or in mixtures, where they meet the criteria for notification, irrespective of production or import volume/tonnage of the substance. Notifications will be made to the GB CLP Agency (HSE) using the new online GB notification web form. The information will be included in the new GB notification database. This database will be made publicly available in due course omitting the notifiers' details as is the case in the EU system.

- Further guidance on submitting notifications to the GB notification database can be found on the 'Submitting a GB notification' webpage on the HSE Chemical classification webpages.

199. **We've acquired a company in the EU which hasn't been fully integrated into the main company. The acquired company is supplying the UK through distributors. We want to continue this but with us as the main company taking on the obligations of placing the product on the market. Is that possible?**

- Manufacturers, importers, downstream users, distributors and producer of an article (within scope of CLP) must be natural or legal persons established within GB, if they want to place substances and mixtures on GB market.

- The requirement for a person or business to be based or established in GB is defined as that person or business having a physical presence, such as registered office, central headquarters or permanent business establishment, in GB.

- A physical presence is considered to be the permanent location where the necessary human and technical resources needed to carry out the business operations of the person or company (either in whole or in part) are based.

Address info

200. **If you are selling a product in GB and within the EU, will products need to contain a GB address and an EU address on the label and Safety data sheet?**

- Yes. From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

201. **Under CLP - does a label of a product from a non-EU27 manufacturing site need to contain an EU address? i.e. should the label contain a UK and EU address from a UK manufacturing site and should the UK address be changed to an EU address on a product from a manufacturing site in America/Asia for example?**

- Please see response above.

202. **How long after 31st Dec 2020 will GB businesses have to update their labels?**

- Unlike for other goods, there is no transitional period after 1 January 2021 for businesses to update their labels for substances and mixtures to comply with GB CLP Regulation requirements.

- From 1 January 2021, GB-based businesses must classify (identify hazardous properties), label (communicate those hazards) and package the substances and/or mixtures according to the GB CLP Regulation before placing them on the GB market. Labels must be in English but other languages are also permitted.

- However, GB-based businesses will not have to recall substances or mixtures already placed legally on the GB market to update their labels provided that:

  - the substances or mixtures have already been placed on the GB market before 1 January 2021; and
  - the hazard labelling is in accordance with GB mandatory classification and labelling (MCL) in the GB MCL list published on the HSE website (the GB mandatory classification and labelling list carried over all EU harmonised classification and labelling, in force, on 31 December 2020. They have the same legal effect in GB).

- From 1 January 2021, GB based downstream users and distributors supplied by EU/EEA based businesses with substances and mixtures after 31 December 2020 will be importers for the purposes of GB CLP and have new obligations and duties, including classification (identifying hazardous properties), labelling and packaging the substances and/or mixtures according to GB CLP before placing them on the GB market.

- GB businesses will continue to have to update their labels for their substances and mixtures or make information available to their supply chains without undue delay where the hazard classification is more severe. This includes substances with harmonised classifications (GB

MCLs) included in the 14th ATP, 15th ATP, and 17th ATP[2] to the CLP Regulation that appear in the GB MCL list.

203. **Can products which only carry an EU27 postal address on their pack labelling be placed on the GB market from Jan 1? If so, for how long will this be permitted and what are the conditions? Once, placed on the GB market, can such consignments continue to sell through until exhausted or will there be a deadline sell through date?**

- Please see the response above.

- Also, GB-based businesses will not have to recall substances or mixtures already placed legally on the GB market to update their labels provided that:
  - the substances or mixtures have already been placed on the GB market before 1 January 2021; and
  - the hazard labelling is in accordance with GB mandatory classification and labelling (MCL) in the GB MCL list published on the HSE website (the GB mandatory classification and labelling list carried over all EU harmonised classification and labelling, in force, on 31 December 2020. They have the same legal effect in GB).

- From 1 January 2021, GB based downstream users and distributors supplied by EU/EEA based businesses with substances and mixtures after 31 December 2020 will be importers for the purposes of GB CLP and have new obligations and duties, including classification (identifying hazardous properties), labelling and packaging the substances and/or mixtures according to GB CLP before placing them on the GB market.

- GB businesses will continue to have to update their labels for their substances and mixtures or make information available to their supply chains without undue delay where the hazard classification is more severe. This includes substances with harmonised classifications (GB MCLs) included in the 14th ATP, 15th ATP *[and 17th ATP – see question above on ATPs]* to the CLP Regulation that appear in the GB MCL list.

Exports to the EU/EEA

204. **If we supply into both U.K. & E.U. Markets, for the same products, will this mean we need 2 different labels, for each market? / On the CLP are you saying that we could have two labels, for the same product one for UK and one for the EU?**

- Yes. From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

[2] If the 17th ATP does not take legal effect before 31 December 2020, its entries will not be retained in GB. The proposed changes (2019 RAC Opinions) will need to be considered separately by the GB CLP Agency (HSE) under the new GB mandatory classification and labelling system (see question above)].

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

205. **When exporting from GB to EU from 2021, will my chemical goods need to have an EU registered address on the product label? These are supplied business to business.**

- This issue relates to EU CLP and as such is a matter for ECHA. However ECHA guidance, available here, https://echa.europa.eu/eu-based-company, may be helpful. It states that if an EU / EEA business purchases a mixture from a GB-based supplier to be placed on the EU market, the EU / EEA business will become an importer of that mixture into the EU. The EU / EEA business will have to fulfil all the CLP obligations for that mixture, including the requirement that the importer's address should appear on the EU CLP label as the supplier and not the address of the GB business. This applies even if you do not change the composition of the mixture.

- If an EU / EEA business plans to import substances from a GB-based company into the EU after the transition period ends, it is them, not the GB-based company, who will have to submit the C&L notifications to ECHA. A C&L notification must also be submitted for substances in mixtures, when the concentration of the substance triggers the classification of the mixture. A separate C&L notification is not needed when you have registered the substance. Any mixture that you import will need to comply with the CLP Regulation.

206. **To sell product into the EU do we need have an EU address on our labels & SDS or will a UK address suffice (we are currently based in UK only). If yes what is your advice?**

- Please see response above.

207. **If we export a chemical product to EU27 directly to a customer, (rather than a distributor or EU warehouse), then the customer is the importer under EU-CLP. Am I correct in assuming that we need to give contact details of an EU-agent on the supply label and SDS even if they are not involved in the supply chain?**

- This issue relates to EU CLP and as such is a matter for ECHA. However ECHA guidance, available here, https://echa.europa.eu/eu-based-company, may be helpful. It states, if an EU / EEA business purchases a mixture from a GB-based supplier to be placed on the EU market, the EU / EEA business will become an importer of that mixture into the EU. The EU / EEA business will have to fulfil all the CLP obligations for that mixture, including the requirement that the importer's address should appear on the EU CLP label as the supplier and not the address of the GB business. This applies even if you do not change the composition of the mixture.

- If an EU / EEA business plans to import substances from a GB-based company into the EU after the transition period ends, it is them, not the GB-based company, who will have to submit the C&L notifications to ECHA. A C&L notification must also be submitted for substances in mixtures, when the concentration of the substance triggers the classification of the mixture. A separate C&L notification is not needed when you have registered the substance. Any mixture that you import will need to comply with the CLP Regulation.

Northern Ireland

208. **Under CLP, we understand that there needs to be an EU address for products sold within EU. How does this impact NI? We are shipping product from England to NI - does this need an EU address also?**

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- Under the Protocol, the EU CLP Regulation will apply in Northern Ireland. This will mean that:
  - chemicals (substances or mixtures) placed on the market in Northern Ireland must comply with the EU CLP Regulation;
  - Northern Ireland- based businesses will be required to notify the European Chemicals Agency (ECHA) of the hazard classification and labelling of the substances they place on the NI market, for inclusion in the Classification and Labelling Inventory, whether on their own or in mixtures, where they meet the criteria for notification (notification is not required if the substance is subject to REACH registration);
  - Northern Ireland-based downstream users and distributors who are currently supplied by businesses in the EU/EEA will not face any new EU CLP Regulation requirements if these supply arrangements continue;
  - Responsibility for the classification, labelling and packaging of chemicals traded from Great Britain to Northern Ireland will rest with the Northern Ireland based business who places the chemical on the Northern Ireland market even if they are currently a downstream user or distributor.

- This means that, yes, from 1 January 2021 the NI importer's address should appear on the EU CLP label as the supplier and not the address of the GB business.

- In terms of EU CLP, that is a matter for ECHA to advise on. We understand that ECHA has advised the following, but this should be verified with ECHA:

  - Regarding the **obligations under the CLP Regulation**, the responsibility for fulfilling the requirements of CLP, such as labelling and packaging, lies with the **importers** established **in Northern Ireland or the EU/EEA**.

  - The **non-EU manufacturer** of a substance or a mixture should **cooperate with** their **importer** to ensure proper hazard classification, labelling and packaging of the product.

  - **Non-EU supplier information** may be considered as supplemental information in accordance with Article 25(3) and included along with the EU supplier(s) information on the CLP label so long as it does not contradict or cast doubt on the validity of the information required by CLP Article 17 (1) (a) to (g), nor makes it more difficult to identify such information. However, the 'non-EU supplier' would need to be part of the same supply chain. It would be expected that contacting that supplier would provide more detailed information on the chemical than contacting the EU-based importer/distributor. The compliance of the label information with CLP can only be determined on a 'case-by-case' basis by the national enforcement authorities, depending on the information being proposed by the importer.

  - Finally, it is the **national enforcement authorities** who can ultimately determine whether they consider the label compliant and clear enough.

209. **Referencing Northern Ireland and CLP, do you need to set up a legal entity in NI or EU country in order to continue supply of mixtures from GB based on EU Reach registered substances?**

- "Import" means the physical introduction into the customs territory of the Community.

- "Importer" means any natural or legal person established within the Community who is responsible for import.

- In order to export to the EU27/EEA, it is necessary to identify an importer on whom the legal obligations of EU CLP can fall. In order to determine who that import might be, it is necessary to keep in mind what this means for the purposes of CLP. The definitions in Article 2 make clear:
  - *16. 'import' means the physical introduction into the customs territory of the Community;*
  - *17. 'importer' means any natural or legal person established within the Community who is responsible for import;*

- It is also worth noting that the act of import itself is deemed to be placing on the market
  - *18. 'placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party.* ***Import shall be deemed to be placing on the market****;*

- If the substances or mixtures, in your case, are supplied directly to the customer in the EU, the customer themselves may be identified as the importer for the purposes of EU CLP compliance when looking at these definitions.

210. **GB based retailer with NI stores. Do the products need both GB address and EU address to comply with both EU CLP and GB CLP?**

- Manufacturers, importers, downstream users, distributors and producer of an article (within scope of CLP) must be natural or legal persons established within GB, if they want to place substances and mixtures on GB market.

- The requirement for a person or business to be based or established in GB is defined as that person or business having a physical presence, such as registered office, central headquarters or permanent business establishment, in GB. A physical presence is considered to be the permanent location where the necessary human and technical resources needed to carry out the business operations of the person or company (either in whole or in part) are based.

- Northern Ireland based manufacturers, importers, downstream users, distributors and producers of certain articles (currently within the scope of the EU CLP Regulation and in the EU Single Market regulatory regime) must continue to comply with the EU CLP Regulation where they supply within Northern Ireland or import substances and mixtures into Northern Ireland. This includes the presence of an EU address.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. Where supply chains from GB to Northern Ireland exist, the GB CLP Agency (HSE) would encourage GB based suppliers and NI businesses to work together to co-operate to meet classification and labelling requirements by sharing any necessary information, evidence or data.

211. **Can we reference a GB contact telephone number for products distributed for NI?**

- This relates to EU CLP and is therefore for ECHA to advise on, however you may find this link helpful - https://echa.europa.eu/regulations/clp/labelling. For GB, there should only be a single telephone number on the label.

212. **Can products which only carry a Northern Ireland (NI) postal address on their pack labelling be sold in GB from Jan 1? Or will GB authorities require an on-label GB postal address for products only being sold in GB? If so, when will this requirement come into force (Jan 2021 or perhaps 2022??)**

- From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

Only Representatives / legal entities

213. **Can an GB based Only Representative/OR submit CLP notification on behalf of GB Importers? under EU CLP OR concept is not there so they cannot notify.**

- There is no reference in GB CLP to Only Representative (OR) and therefore no option to use an OR to fulfil the obligations on importers under GB CLP.

214. **Can an Only Representative of an EU Company do the CLP notification on behalf of their UK importers?**

- There is no reference in GB CLP to Only Representative (OR) and therefore no option to use an OR to fulfil the obligations on importers under GB CLP.

Guidance

215. **When the relevant guidance on GB CLP and Compilation of GB SDSs will be available?**

- HSE has developed basic guidance on the GB CLP Regulation, including on labels and safety data sheets, outlining the key changes and differences in the new GB processes and procedures covering alternative chemical names, the GB MCL system and GB notifications that are available on HSE's Chemical Classification website.

- In the short to medium term, as the majority of the EU CLP Regulation has been retained, publicly available ECHA technical guidance on the application of classification criteria and on labelling and packaging will continue to be helpful and relevant to GB-based companies.

- From 1 January 2021, further information will be available on the HSE's Chemical Classification web pages.

Classification of substances under evaluation

216. **Will the GB CLP take on the classification of substances currently under evaluation for reclassification.**

- After 1 January 2021, applications in the system where the zonal Rapporteur Member State (zRMS) evaluation has not be completed and GB is a concerned Member State (cMS), may be considered by HSE as a standalone GB application, depending on the outcome of negotiations As a result of this you may be asked to submit additional supporting information in support of GB's evaluation.

Safety Data Sheets

217. **Will the new EU format SDS be brought into UK CLP?**

- The EU Commission has issued new legislation (Regulation 2020/878), requiring extensive updates to current safety data sheets (SDSs). The updates relate to:
  - addition of technical content on the acute toxicity estimates (ATEs), multiplying factors (M-factors), and specific concentration limits for substances and ingredients of mixtures
  - specific mention of new hazards, particularly nanomaterials and endocrine disruptors
  - more detailed requirements for physico-chemical properties
  - data from modelling required for environmental effects where no direct test data available
  - formatting changes

- While the EU Commission Regulation amends Annex II of the EU REACH Regulation, and while the EU Withdrawal Act converts EU legislation into UK law, it only carries over the same regulatory obligations into UK law which are in force at 31 December 2020. As the new Commission legislation applies from 1 January 2021 (current SDSs are allowed until 31 December 2022, giving suppliers time to adapt), it will not be carried over under UK REACH.

218. **Do you expect when all SDS need to change to a LE/GB address?**

- From 1 January 2021. Unlike for other goods, there is no transitional period after 1 January 2021 for businesses to update their labels for substances and mixtures to comply with GB CLP Regulation requirements.

219. **Is there a deadline for SDS to be in accordance with UK-REACH?**

- There are no transitional provisions relating to SDS. However, the format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried

across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

220. **Assuming that the UK does not adopt the changes to SDS from REACH Annex II – will UK companies need to have an EU and UK SDS or will the UK accept the updated format?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

221. **Which format SDS will be valid in GB from 1st of January 2021?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

222. **Will EU 2020/878 content of an SDS be applicable to the UK given it comes in to force effective 1st January 2020?**

- The EU Commission has issued new legislation (Regulation 2020/878), requiring extensive updates to current safety data sheets (SDSs). The updates relate to:
  - addition of technical content on the acute toxicity estimates (ATEs), multiplying factors (M-factors), and specific concentration limits for substances and ingredients of mixtures
  - specific mention of new hazards, particularly nanomaterials and endocrine disruptors
  - more detailed requirements for physico-chemical properties
  - data from modelling required for environmental effects where no direct test data available
  - formatting changes

- While the EU Commission Regulation amends Annex II of the EU REACH Regulation, and while the EU Withdrawal Act converts EU legislation into UK law, it only carries over the same regulatory obligations into UK law which are in force at 31 December 2020. As the new Commission legislation applies from 1 January 2021 (current SDSs are allowed until 31 December 2022, giving suppliers time to adapt), it will not be carried over under UK REACH.

223. **Will the UK expect REACH registration numbers to be listed next to each ingredient in section 3 of the SDS?**

- Answer to follow.

224. **We understand there are modifications to Annexe II (affecting SDS content) in January 2021 which are not being adopted by the UK. Will we need to have individual EU and UK REACH style SDS?**

- The EU Commission has issued new legislation (Regulation 2020/878), requiring extensive updates to current safety data sheets (SDSs). The updates relate to:
  - addition of technical content on the acute toxicity estimates (ATEs), multiplying factors (M-factors), and specific concentration limits for substances and ingredients of mixtures
  - specific mention of new hazards, particularly nanomaterials and endocrine disruptors

  - more detailed requirements for physico-chemical properties
  - data from modelling required for environmental effects where no direct test data available
  - formatting changes

- While the EU Commission Regulation amends Annex II of the EU REACH Regulation, and while the EU Withdrawal Act converts EU legislation into UK law, it only carries over the same regulatory obligations into UK law which are in force at 31 December 2020. As the new Commission legislation applies from 1 January 2021 (current SDSs are allowed until 31 December 2022, giving suppliers time to adapt), it will not be carried over under UK REACH.

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH as they exist at the end of the transition period. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

225. **What is the recommendation for preparing of SDS for placing of a new product on GB market, what SDS format to use?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

226. **Would REACH Annex II (2015 or 2020) formats be accepted?**

- While the EU Commission Regulation amends Annex II of the EU REACH Regulation, and while the EU Withdrawal Act converts EU legislation into UK law, it only carries over the same regulatory obligations into UK law which are in force at 31 December 2020. As the new Commission legislation applies from 1 January 2021 (current SDSs are allowed until 31 December 2022, giving suppliers time to adapt), it will not be carried over under UK REACH.

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH as they exist at the end of the transition period. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

227. **Will there be a new New GB Safety Data Sheet?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

228. **Are MSDS (Material Safety Data Sheets (MSDSs)) affected? What changes and what steps need taking to prepare re MSDS as per UK Reach?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

229. **Isn't there currently the EU Reach registration number on the MSDSes? How is this going to change then with regard to UK Reach?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

230. **As a UK manufacturer of mixtures sold to Europe, do we need to add an EU legal entity address to section 1 of our SDS as well as our UK address?**

- This relates to EU CLP and is therefore for ECHA to advise on, however you may find this link helpful - https://echa.europa.eu/-/guidance-on-the-compilation-of-safety-data-sheets.

- From 1 January 2021 the GB importer's address should appear on the GB CLP label as the supplier and not the address of an EU/EEA business.

- Where there has been a change in role owing to the UK leaving the EU (for example, where a GB-based business (i.e. a downstream user or a distributor) becomes the importer and takes on the role and duties required by the GB CLP Regulation, HSE would expect the label to be changed as soon as possible after 31 December 2020. It must be clear to the user where to go for additional advice about the substance or mixture concerned.

- The address of the EU/EEA business must not appear on the GB CLP label but may appear as supplemental information provided it does not create confusion for the user. But the responsibility for providing additional advice to the user if requested rests with the GB supplier.

231. **Will SDS's produced before 1/1/2021 and still referring to EU REACH in the various sections, still be compliant in the UK after 1/1/2021 until the moment the SDS will be updated.**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

232. **What address needs to be on EU safety Data sheets and labels? Can it be the OR? Or importer? What if the company names are different?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

233. **Do substances EU REACH registration numbers need to be removed from safety data sheets in section 1 and 3 for Great Britain? Shall we keep them for Northern Ireland? I expect we need to remove for GB as no longer valid.**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

234. **Shall we stop providing extended safety data sheets for customers based in Great Britain for substances registered under EU REACH in 10 MT or more? Again as not UK registered at >10 tpa I expect no eSDS is require any longer.**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH as they exist at the end of the transition period. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

235. **Shall we replace the statement According to Regulation (EC) No. 1907/2006 (REACH) Article 31, Annex II as amended for According to The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 No.1144 in safety data sheets? I expect yes as the SDS now has to comply with UKREACH.**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH as they exist at the end of the transition period. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

236. **Will SDS be a mandatory requirement in DUIN?**

- The information requirements for submission of a DUIN are available here. Safety Data Sheets are specifically required for notifications for imports of 10 tonnes or more. However, as the guidance notes, for volumes of 1 to 10 tonnes, you should provide any other available and relevant information necessary to enable appropriate risk management measures to be identified and applied.

237. **EC Number of chemicals still be valid in GB?**

- The format, content and the conditions under which SDSs are required are specified in EU REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

238. **Will UK REACH require substances to have eSDS? – will this requirement be extended to mixtures?**

- The format, content and the conditions under which SDSs are required are specified in REACH. These will be carried across into UK REACH. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

Mandatory Classification & Labelling list (MCL)

239. **Is there an ETA for the publishing of the GB MCL (Great Britain mandatory classification and labelling) list?**

- There is no date available yet, however HSE will continue to update its guidance pages with the most up-to-date information and inform stakeholders via the e-bulletin for the chemical regimes which you can sign up to via https://www.hse.gov.uk/brexit/clp-ni.htm.

240. **When will the Mandatory Classification List be published? when will the new GBCLP regulation be published? We will need time after their publication to review and implement the associated changes in order to be able to comply from 1 Jan 2021.**

- The GB CLP regulation has been published and is available here - https://www.legislation.gov.uk/en/ukdsi/2019/9780111181539 - as part of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.

- There is no date available yet, however HSE will continue to update its guidance pages with the most up-to-date information and inform stakeholders via the e-bulletin for the chemical regimes which you can sign up to via https://www.hse.gov.uk/brexit/clp-ni.htm.

UK Internal Market

241. **Will CLP be impacted by inter-GB movement of substances, for example will CLP be interpreted and applied differently by the devolved nations?**

- Competence under GB CLP is retained and the regime is therefore GB-wide. After consideration of a published RAC Opinion, and, where necessary, consultation with relevant experts as well as other interested government departments, the Devolved Administrations and affected agencies, HSE as the GB CLP Agency will reach an opinion and will make a recommendation about whether or not to align with the RAC Opinion to the Secretary of State for a final decision to be made; the decision will only be made with the consent of the Devolved Administrations (Scotland and Wales).

- Additionally, the United Kingdom Internal Market (UKIM) Bill puts the building blocks in place for this regime for the long term. It enshrines in primary legislation that qualifying NI goods will benefit from mutual recognition - enabling goods to continue to be placed on the whole UK market, even where the Protocol applies different rules in Northern Ireland - and prohibits checks and controls as goods move from Northern Ireland to the rest of the UK.

- The definition of qualifying NI goods will be set out in regulations made under the European Union (Withdrawal) Act (2018), which will outline that qualifying goods are:

  - any goods present in Northern Ireland (and not subject to any customs supervision, restriction or control which does not arise from the goods being taken out of the territory of Northern Ireland or the European Union);

  - any goods that have undergone processing operations in Northern Ireland incorporating either domestic goods or goods not under customs supervision, restriction or control at the time of processing.

UN GHS

242. **UN GHS and EU CLP have slightly different classification elements e.g. UN-GHS has Acute Toxicity 5 category, but this category is not covered by EU-CLP. Will the UK move from the lifted EU-CLP to UN-GHS? If so, when is this envisioned?**

- On 1 January 2021, GB will effectively adopt the GHS in the same way as the EU, adopting all the same GHS building blocks (hazard classes and categories) that the EU has adopted in the EU CLP Regulation.

- After 1 January 2021, GB will have more flexibility when deciding whether to continue to adopt GHS in the same way as the EU in relation to the 8th Edition of GHS and future criteria changes at UN level (new/revised hazard classes and categories) or changes to the GHS Annexes. The 9th Edition of GHS is expected to be agreed in December 2020. Any proposals to adopt GHS differently will be discussed with stakeholders as is the case now and will be given legal effect through domestic regulations set out in a statutory instrument.

- The UK continues to play an important role in the UN Sub-Committee of Experts for the Globally Harmonized System of the classification and labelling of chemicals (UNSCEGHS) and will continue to work to make improvements to the GHS to ensure high levels of protection for people and the environment.

- The UK leaving the EU should not lead to divergence from the EU CLP Regulation's adoption of GHS in the short term because the EU adopted the 6th and 7th edition of GHS, agreed by the UN in 2014 and 2016, respectively, through the 12th Adaptation to Technical Progress (ATP) to the CLP Regulation (Commission Regulation (EU) 2019/521), which was published on 27 March 2019. The 12th ATP has entered into force and is now fully implemented in EU law. Businesses in the EU including the UK had until 17 October 2020 to introduce and make all the necessary changes to their classification and, labelling as a consequence of the 6th and 7th Edition of GHS's changes to the classification criteria made to the EU CLP Regulation.

- However, the EU has not yet adopted the criteria changes in the 8th Edition of the GHS agreed by the UN in 2018 which means that GB will have flexibility when deciding whether to continue to adopt GHS in the same way as the EU.

243. **How often will HSE update the CLP regulation according to GHS? Will HSE follow EU implementations, or will HSE implement in their own speed?**

- See above

244. **The CLP slide says UN GHS is currently applied in EU but that's not the case E.g. H320 hazard statement.**

- See above

Mixtures

245. **Concerning the new CLP classification process, what about importers of mixtures that do not have access to their supplier's entire mixture breakdown of substances?**

- Answer to follow. Alternatively, please contact ukreachca@hse.gov.uk.

246. **For CLP, GB companies who want to access the EU market have been told to appoint an EU legal entity. I understand this would apply to substances but how does it apply to mixtures if the substances are already purchased from the EU?**

- This relates to EU CLP and is therefore for ECHA to advise on.

EUH and UK handling of upcoming EU changes

247. **How will HSE deal with decisions voted at Commission Standing Committee but not yet in force on 1st January 2021?**

What about harmonised classifications brought into effect under 14th or 15th ATP that come into force after the end of the transition period - will they brought in under the UK CLP?

- All existing EU harmonised classification and labelling entries agreed by the EU, listed in Table 3 of Part 3 of Annex VI of the EU CLP Regulation and which are in force on 31 December 2020, will continue to be recognised by the GB mandatory classification and labelling system and will apply to GB suppliers supplying within the GB market, and Northern Ireland suppliers when supplying qualifying Northern Ireland goods directly to the GB market. The GB mandatory classification and labelling list will be published electronically on the HSE website.

- The application dates for GB mandatory classification and labelling for substances in the so called' 14th ATP, 15th ATP [*and 17th ATP*] to the CLP Regulation are:
  - 14th ATP (2017 RAC Opinions – **1 October 2021** (not 9 September 2021);
  - 15th ATP (2018 RAC Opinions – **1 March 2022**;
  - [*17th ATP (2019 RAC Opinions) – **1 July 2022.** If the 17th ATP does not take legal effect before 31 December 2020, its entries will not be retained in GB. The proposed changes (2019 RAC Opinions) will need to be considered separately by the GB CLP Agency (HSE) under the new GB mandatory classification and labelling system (see question above)].*

- Where the hazard classification is more severe or where there are new supplemental labelling elements, for example, as a result of UK REACH restrictions, then the label must be updated 'without undue delay'.

248. **Regarding CLH -harmonised classifications that have been published but not yet in force. Will they be adopted by GB?**

What is going to happen in CLP to the EUH hazard statements?

Are EUH phrases being transferred into GB (CLP)

Will GB CLP adopt the titanium dioxide classification? And will it adopt EUH statements?

- The GB CLP system will continue to use European Hazard Statements (EUH Statements) as they form part of the retained GB CLP Regulation and so will remain part of the GB CLP system after 1 January 2021.

- Under the terms of the Withdrawal Agreement, GB is bound by EU decisions (e.g. new and revised harmonised classification and labelling) which were in force by and on 31 December 2020 but not after 1 January 2021. This includes decisions by the European courts.

- For the EU CLP Regulation, the harmonised classification and labelling for titanium dioxide in the 14th ATP to the CLP Regulation (Commission Delegated Regulation (EU) 2020/217 of 4 October 2019) has already been published and entered into force in the EU and will be included in the GB mandatory classification and labelling list from 1 January 2021. This is because it is currently an existing entry in Table 3 of Part 3 of Annex VI of the EU CLP Regulation. The GB mandatory classification for titanium dioxide will apply from 1 October 2021 (not 9 September 2021).

- As with any other existing GB mandatory classification and labelling, it is possible that a GB proposal to amend the mandatory classification for titanium dioxide could be submitted in the future where new scientific evidence is presented to justify a change. Such a proposal will then be subject to the GB MCL system.

Please note: The advice contained in this document should not be taken as a definitive statement of the law or its interpretation. Only the courts can decide on the definitive interpretation of the law.

POISON CENTRES

249. **Does NI have a solution for a poison centre yet?**
250. **Do products like alcohol-based hand sanitisers now require UK supplier details if we import them to the UK from the EU? Do they need to be registered to NPIS now?**
251. **Please confirm the options for PCN's for chemicals exported into the EEA/EU after 1 Jan 2021.**
252. **How should a company handle unique formula identifiers (UFIs) for Northern Ireland and exports to the EU?**
253. **As a UK company can we submit to EU poison centres, including ECHA for products which require a UFI?**
254. **In regards to CLP items been sold in Northern Ireland that require a UFI code. Is it possible to only suggest that the UFI code is only relevant to Ireland (Incl. R.O.I. and Northern Ireland) and that the UFI code is not relevant in GB to not confuse GB authorities. Noting that GB notifications are voluntary.**
255. **You said to contact HSE re UFI and EU Poison centres. Please can you supply a link?**
256. **How can a NI based company submit at poison centre notification?**
257. **Will a NI based legal entity be regarded as an EU based legal entity when it comes to REACH registrations and Poison Centre Notifications?**
258. **With NI being in EU REACH what is the situation regarding poisonous substances registration?**
259. **Do GB companies need to register UFI's with poison centres if they are supplying within GB?**
260. **Good Morning, can you please confirm that the UFI number system will not be implemented in the UK after 01/01/2021?**
261. **Does a Distributor of a UK manufactured product with mixtures than originated in EU, require a UFI if they then sell that product outside of UK? Or does it fall on the original manufacturer?**
262. **Is there a requirement to include UFI information on primary packaging into the UK retail marketplace as of January 2021 for fragrance type chemicals that have already been registered with the UK poisons centre (NPIS)?**
263. **Can you clarify if a business will have to meet Annex VIII to CLP obligations when placing mixtures hazardous for physical and health effects in the UK?**

- Guidance will be published in early December on gov.uk.

BIOCIDES

Clarifying the regulation

264. **When will UK BPR be available/come into force?**

- GB BPR will come into force on 1 January 2021.

- Any biocidal active substance approval in place before 1 January 2021 will remain valid in GB until its expiry date. Any biocidal product authorisation in place in GB before 1 January 2021 (including union authorisations and mutual recognitions) will remain valid until its expiry date, although the authorisation holder should ensure that they comply with requirements to submit data to HSE, be established in the UK and obtain active substances from suppliers on the GB Article 95 list.

265. **For Biocides, when will guidance be published for the Secretary of State (also for data sharing disputes)?**

- Guidance on GB BPR is available here - https://www.hse.gov.uk/brexit/biocides.htm.

- A scenario table is available here - GB BPR scenario table.

- On data sharing disputes – if you hold a biocidal product authorisation that is valid in Great Britain, it will remain valid from 1 January 2021 until its normal expiry date. However, the authorisation holder will need to be established in the UK (including Northern Ireland) by 1 January 2022. Any biocidal product authorisation in place in GB before 1 January 2021 (including union authorisations and mutual recognitions) will remain valid until its expiry date, although the authorisation holder should ensure that they comply with requirements to submit data to HSE (see scenario table), be established in the UK and obtain active substances from suppliers on the GB Article 95 list.

- Active substance approvals will remain valid in Great Britain until their normal expiry date. If your business is already on the EU list it will be included in the Great Britain list. To stay on the Great Britain list, you will need to submit supporting information to HSE. This is the same information you submitted to ECHA, for example, an active substance dossier or a letter of access to data held by HSE. You will also have to ensure that your business is established in the UK. You will have 2 years to meet these requirements; providing time to manage and mitigate any data disputes, should these arise.

266. **For the Republic of Ireland you can still put some products into this country without the requirement to have an EU legal entity e.g. locally notified biocides products. If these products are CLP classified do we need to have an EU legal entity?**

- Regarding the EU requirements for biocidal product labels we recommend applicants discuss these with the relevant EU Member State(s).

267. **Further clarity on the legal entity question - the supplier needs to be established in the EU, so would you not need to have a legal entity in the EU for this - CLP, but also for BPR dossier submissions? How is a legal entity set up?**

- Regarding the EU requirements for EU BPR and legal entities we recommend applicants discuss these with the relevant EU Member State(s).

- After the end of the Transition Period the authorisation holder of a product authorised by HSE will need to become established in the UK (if they have not already done so) or transfer the authorisation to a company which is established in the UK. There will be a one year 'period of grace' ending on 31 December 2021 for existing authorised products. Being 'established in the UK' is normally interpreted as a person, company or authorised representative having a physical presence, such as a registered office, central headquarters or permanent business establishment, in the UK. A 'physical presence' is considered to be the permanent location where the necessary human and technical resources needed to carry out business operations are based.

268. **For biocides dossiers submitted pre-IUCLID, will companies have to generate data in a new format?**

- After 1 January 2021 HSE will no longer have access to R4BP3 for processing GB applications. HSE has developed its own systems for receiving and processing applications.

- Submissions must be made using a secure file sharing service which HSE has introduced to receive biocides applications and other submissions. Further details of this service will be made available soon.

- For more detail or if you have further enquiries please contact the helpdesk at biocidesenquiries@hse.gov.uk

269. **There is too much conflicting information on the need to submit full dossiers for Biocidal Products and or Biocidal Substances within 90 to 180 days from the end of the TP. The HSE website says only ongoing biocidal products need to be submitted in the 90 to 180 window. What dossiers are needed to be submitted in 90 to 180 days? Ongoing Active substances? Ongoing Biocidal Products? Both?**

- If your biocidal product application is still being processed by another EU Member State on 1 January 2021 as part of an EU-wide authorisation process (e.g. a mutual recognition or union authorisation application), you will need to re-apply to GB for a national product authorisation, ensuring that all of the necessary data to support the application is submitted to the Health and Safety Executive within 180 days of 1 January 2021 (29 June 2021) (this includes any underlying data which may be relied upon via a letter of access).

- However, if HSE has previously been the evaluating competent authority for the application, resubmission to HSE should be within 90 days of the end of the Transition Period.

- Timelines in Articles 29 and 30 of the Biocidal Products Regulation will apply in GB in relation to the application for national product authorisation.

- HSE will not charge specifically for receiving a resubmission but does recover the costs of processing individual biocides applications from applicants.

270. **Will the waiving of ENS requirement apply to ALL imports, not just from EU 27?**

- Answer to follow.

271. **Distributors procuring finished product from the EU which contains Biocides, what obligations apply?**

- Before you distribute biocidal products, you should check that they are authorised under GB BPR before making them available.

- If the biocidal product is not yet authorised, check that the active substance in the product is in the Review Programme.

- Before distributing the product you must also check that there is a supplier included on the GB Article 95 list of active substances and suppliers.

272. **Will the UK BPR run in the same way as UK REACH?**

- No, GB BPR will mirror how EU BPR operates, i.e. a biocidal product/biocidal family must be authorised to be placed on the market.

How to apply

273. **We have read the HSE webpage "Biocides: What you'll need to do after the transition period ends" but many scenarios include the comment "HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks." In a number of instances, industry has actions it must complete in the early months of 2021, but lack of systems and defined processes makes it impossible to prepare or be compliant. How should industry act in such circumstances? Will the HSE accept that not having this information now may make it impossible for industry to meet the deadlines and so allow extensions if required?**

- Further information on this will be published on the guidance webpages and via the e-bulletin service; you can subscribe to e-bulletins at https://www.hse.gov.uk/brexit/clp-ni.htm

Northern Ireland

274. **Can you confirm if HSENI will be delivering Biocidal Product authorisation for Northern Ireland from the 1st Jan, so that MR/UA of pending BP or BA assessment will be applicable there. Can an English, Welsh or Scottish Legal entity be authorisation holders of these NI authorisations?**

- Under the Protocol, the EU Biocidal Products Regulation will apply in Northern Ireland. This means that:
  - a biocidal product made available on the market in Northern Ireland must comply with the EU Biocidal Products Regulation;

- EU establishment requirements are fulfilled by being established in Northern Ireland as well as within the EU itself.

- HSENI will be responsible for the enforcement of the EU Biocidal Product Regulation in Northern Ireland.

- English, Welsh or Scottish Legal entities cannot hold NI authorisations. Under the EU BPR, authorisation holders must be established in the EU (including Northern Ireland), the EEA or Switzerland.

- However, where a Northern Ireland-based business has obtained an authorisation or other permit for a biocidal product which is valid in Northern Ireland and wants to market the product in Great Britain, HSE will treat the product as authorised in the whole of the UK. To protect workers, consumers and the environment, the active substance must be on the GB approved list, and the NI business must notify HSE by submitting the same information that was submitted in support of the original authorisation or permit.

- Once this information has been submitted, the product may be made available on the market in Great Britain after 90 days, provided HSE does not raise any objections. If HSE identifies concerns over whether the product could pose unacceptable risks or is sufficiently effective, it may request additional information. In this case the 90-day period may be suspended for up to 90 days for the provision of such additional information and a further 90 days for the information to be considered by HSE.

- To protect workers, consumers and the environment, HSE has powers to amend the terms and conditions under which a notified product can be marketed in Great Britain, or prohibit it being made available on the market. However, these powers can only be used in specific and limited circumstances, including where HSE considers the product poses unacceptable risks or is insufficiently effective. HSE has similar powers to cancel or amend the authorisation of a biocidal product marketed by a company based in Great Britain.

275. **From Jan 1st 2021 NI will be under EU BPR but who grants the mutual recognition?**

- NI business will have the right to place a biocidal product on the market in Great Britain where they already have an authorisation to place this product on the market in Northern Ireland via EU BPR, providing that they notify HSE with information that they would submit to the EU. Companies with qualifying status face no further regulatory approvals if the product already has a valid approval in NI.

- If HSE have any serious concerns that a product poses a risk public health or the environment, they have the ability to take safeguarding measures.

276. **If a product is authorized under the BPR by the HSE but not from IE PRCD do we need to remove it off the NI market by Jan 1st?**

- If a product has an authorisation in place before 1 January 2021 under EU BPR it remains valid in both GB and NI until its expiry date, although the authorisation holder should ensure that they comply with GB requirements to submit data to HSE, be established in the UK and obtain active substances from suppliers on the GB Article 95 list.

277. **If a product is under UK notification, does the UK notification still enable the product to be sold in NI (even if no Irish notification and no EU address)?**

- Please see above.

278. **Can NI now be a member state for authorization of biocide dossiers?**

- EU countries will not mutually recognise products authorised in the UK and will require an independent application under the EU application system i.e. R4BP3. However for a number of countries outside the EU, a certificate of free sale or export statement based on a UK authorisation is accepted as the basis for a national biocide authorisation (further information is available at https://www.hse.gov.uk/biocides/certificates-of-freesale.htm).

UK handling of EU positive opinions

279. **Concerning the Biocide law, what will be the status of active substances with a positive opinion from the ECHA BPC but not yet officially approved. Will they need a complete re-evaluation?**

- In such situations, you will need to re-apply to GB for a national product authorisation, ensuring that all of the necessary data to support the application is submitted to the Health and Safety Executive within 180 days of 1 January 2021 (29 June 2021) (this includes any underlying data which may be relied upon via a letter of access.) Timelines in Articles 29 and 30 of the Biocidal Products Regulation will apply in GB in relation to the application for national product authorisation.

Fees

280. **On UK BPR, when can we expect fees and registration timelines to be communicated for Biocidal Product and actives that companies will have to re-submitted to HSE?**

- It is a long-standing government policy that HSE recovers its costs in processing biocides applications. This will remain the case after 1 January 2021 and fee levels will not change at the end of the Transition Period. Information on BPR fees is available here - https://www.hse.gov.uk/biocides/eu-bpr/fees.htm.

- There will also be some new activities that HSE will need to undertake for GB, that are currently done by ECHA, and for which we will need to recover our costs (e.g. a technical equivalence assessment). ECHA already charges for these activities for the EU.

- There will be no fees applied by HSE for the resubmission of data or applications due to loss of access to EU databases and IT systems.

- You should be aware that after 1 January 2021, if you want to have a biocidal product authorised in both the EU and GB, you will have to apply separately to HSE and ECHA. This means you would have to pay both sets of fees.

PIC

281. **When will UK PIC be available/come into force?**

- The GB PIC regime will come into force on 1 January 2021. The PIC regime will apply to listed chemicals that are exported from Great Britain, including to EU countries and to NI. Companies that currently only move listed chemicals within the EU single market and do not export them outside the EU or NI will have to start to notify these to HSE.

282. **When will UK PIC open for 2021 notifications? As explicit consent can take 60 days we are already in a position where 2021 exports are likely to be delayed due to not having the relevant consent from the importing country. When will forms be available to apply for Jan 2021 export?**

- Where the consent of the importing country is required before export can proceed, HSE, as the PIC Designated National Authority (DNA), will seek this on the exporter's behalf. Under the EU PIC Regulation, consents usually apply to all member states. Where there is an existing consent in place that is relevant to the UK, we are in the process of contacting the DNAs of those importing countries to ask that they recognise these as continuing to apply to GB exports after 31st December. We have already received a number of positive responses. When the transitional arrangements go live, the GB DNA team will prioritise exports where consent is required and there has been no confirmation from the importing country that existing consents are still valid. As with EU PIC, our new PIC regime will include a process whereby the DNA can grant a waiver to the explicit consent requirement if certain conditions are met.

283. **If I am a UK entity, but want to export from EU storage, will this be the ePIC system that must be used or is it UK system?**

- As an export from the EU, you will need to use the ePIC system.
- GB based companies will not have access to ePIC.
- ECHA guidance in ePIC is available here - https://echa.europa.eu/guidance-documents/guidance-on-PIC.

PESTICIDES & OTHER REGS

284. **Will the CRD Pesticide Database continue in same format?**

- Documentation supporting an application will as far as possible be the same as it is now. HSE will accept applications in the same way and will still require a registration/assessment report in the same format in support of an application for authorisation/approval.

- Any further questions can be directed to the PPP helpdesk CRDInformationManagement@hse.gov.uk

285. **What is happening about the detergent regulations?**

- The Detergents (Amendment) (EU Exit) Regulations 2019 and the Detergents (Safeguarding) (Amendment) (EU Exit) Regulations 2019 were laid last year. They will ensure continued operability of retained EU regulation on detergents in the UK after we leave the EU.

- These SIs are being amended by the Detergents (Amendment) (EU Exit) Regulations 2020 to cater for the Northern Ireland Protocol. The 2020 Detergents SI is proceeding through the parliamentary channels and should be made by the end of the year.

- Guidance on the EU-Exit SIs as well as the 2020 amendment Regulations will be made available on the HSE website.

COSMETIC REGULATIONS

286. **There is no guidance on the cosmetics regulations. Is responsible person in UK required on day one for imports, or is an EU RP OK (and for how long?) Will there be a difference in NI?**

- Guidance has now been published here. Yes, there must be a Responsible Person based in the UK from 1 January 2021, under the new regime [Articles 4, 5 and 5A]. There will however be a 2-year transition period from 1 January 2021 before businesses have to include the UK Responsible Person details on product labels, provided the EU responsible person details are included. This will enable existing stocks to make their way through the supply chain. UK Responsible Persons will need to notify existing products (previously available in the UK, EU or EEA and notified to CPNP) by 31 March 2021 to the Secretary of State via the UK SCPN service if they are placing them on the GB market after the end of the transition period. There is a reduced amount of information required where this is the case– and you can use the same information you have previously provided to the EU CPNP service. The rules for Northern Ireland are different and guidance specifically on those can be found here.

287. **Will PIFs prepared prior to UK leaving the EU still be valid?**

- An up-to-date Product Information File (PIF) must be maintained in English, and made available to market surveillance and enforcement authorities at the UK address provided when asked to do so [Article 11]. Guidance has been published here.

288. **What about the qualifications of safety assessors (i.e. for cosmetic products) - will the UK qualification be accepted in the EU or must something be done to get the UK degree recognised in EU?**

- Recognition of professional qualifications is a matter for negotiations. As a default, you will need to have your UK professional qualification officially recognised if you want to work in a profession that is regulated in the EEA or Switzerland. Confirmation of how this applies to cosmetics is available here. If you wish to continue providing this service in the EEA, you are recommended to approach the relevant national authorities in EU Member States.

WASTE FRAMEWORK

289. **Waste Framework Directive - If our product required a notification to ECHA under SCIP who would make such a notification for a UK manufacturer after 1st January?**

- The EU's revised Waste Framework Directive requirement to set up a database for articles containing substances of very high concern (SVHCs) does not apply to the UK. The obligation to report to the EU database begins after the end of the transition period and does not apply to UK based suppliers of articles. However, UK companies providing articles to companies in the EU should expect to be asked to supply the information as those EU companies will be required to report to the database.

- Defra is considering how best to address the identification and tracking of chemicals in products across supply chains to reduce barriers to reuse and recycling. We are committed to the safe and effective management of chemicals, including the use of SVHCs.

290. **Will the UK mirror the SCIP database requirements?**

- The EU's revised Waste Framework Directive requirement to set up a database for articles containing substances of very high concern (SVHCs) does not apply to the UK. The obligation to report to the EU database begins after the end of the transition period and does not apply to UK based suppliers of articles. However, UK companies providing articles to companies in the EU should expect to be asked to supply the information as those EU companies will be required to report to the database.

- Defra is considering how best to address the identification and tracking of chemicals in products across supply chains to reduce barriers to reuse and recycling. We are committed to the safe and effective management of chemicals, including the use of SVHCs.

291. **How does the transition to UK REACH affect the requirement for SCIP notifications to ECHA?**

- The EU's revised Waste Framework Directive requirement to set up a database for articles containing substances of very high concern (SVHCs) does not apply to the UK. The obligation to report to the EU database begins after the end of the transition period and does not apply to UK based suppliers of articles. However, UK companies providing articles to companies in the EU should expect to be asked to supply the information as those EU companies will be required to report to the database.

- Defra is considering how best to address the identification and tracking of chemicals in products across supply chains to reduce barriers to reuse and recycling. We are committed to the safe and effective management of chemicals, including the use of SVHCs.

292. **What is the impact on EWC codes and waste transfer?**

- Response to follow.

293. **How is SCIP database implementation affected for companies in the UK?**

- The EU's revised Waste Framework Directive requirement to set up a database for articles containing substances of very high concern (SVHCs) does not apply to the UK. The obligation to report to the EU database begins after the end of the transition period and does not apply to UK based suppliers of articles. However, UK companies providing articles to companies in the EU should expect to be asked to supply the information as those EU companies will be required to report to the database.

- Defra is considering how best to address the identification and tracking of chemicals in products across supply chains to reduce barriers to reuse and recycling. We are committed to the safe and effective management of chemicals, including the use of SVHCs.

FOOD CONTACT MATERIALS

294. **Which UK body is taking on the responsibilities of EFSA (European Food Safety Authority) for chemical materials with food? Eg 10/2011 (chemical materials used in plastics) and 450/2009 and management of the associated chemical lists?**

- These regulations come under the Materials and Articles in Contact with Food Regulations. After the end of the transition period responsibility will fall to the FSA, to take on the role of risk assessing substances that may be used in specific food contact materials for the UK market. This will also include recycled plastic processes. It will reflect the current EU requirements. Further information can be found at the following links:

  - https://www.food.gov.uk/business-guidance/requirements-for-regulated-product-applications-from-1-january-2021
  - https://www.food.gov.uk/business-guidance/submitting-a-regulated-product-authorisation-application-from-1-january-2021

TARIFFS, TRADE REMEDIES AND COMMODITY CODES

295. **Would it be possible to arrange a call or get an e-mail address for the group who manages / supports Chemicals classification (commodity coding / HS coding for duty determination) for the UK government when importing chemicals**

- tariff.classification@hmrc.gsi.gov.uk.

296. **What about providing a proper tariff search facility - by CAS number? This is as the EU offers. The Database I have seen is unwieldy and has no search facility. Will this be provided and how soon?**

- The UK also offers this service: https://www.trade-tariff.service.gov.uk/chemical_search.

297. **Will EU anti-dumping duties on chemicals automatically stop being taken on importation as of 1st Jan 2021?**

- The UK will continue to apply certain existing trade remedies from 1 January 2021 as part of its independent trade remedies regime. All anti-dumping, anti-subsidy and safeguard measures that the UK keeps will undergo a UK-wide transition review led by the Trade Remedies Investigations Directorate (TRID). Further details are available here: https://www.gov.uk/guidance/trade-remedies-transition-policy.

298. **Will there be any duty suspension for reworked products, so Enters the UK as Raw and leaves the UK as finished product?**

- The UK will continue to apply all current customs facilitations beyond 1 January 2021, including Inward Processing Relief: https://www.gov.uk/guidance/apply-to-delay-or-pay-less-duty-on-goods-you-import-to-process-or-repair.

CUSTOMS PROCEDURES

299. **If you cannot apply for a duty deferment account until after 1st January in order not to have to put up a financial guarantee will it be approved in enough time to be able to make supplementary declarations?**

- You can apply for a Duty Deferment Account (DDA) right now and you can also apply for a guarantee waiver. Further information is available here. If you do not have a DDA, you can still use the DDA of your freight forwarder or customs agent to delay customs declarations on imports from the EU of non-controlled goods between 1 January and the end of June 2021. Further detail on delaying declarations is available here.

300. **If an importer of formulated finished goods needs to return them to the manufacturer in Europe how can this be done? They may be returned as faulty, but this is not being an exporter.**

How can this be done? Also includes sending chemical samples being sent to a lab in Europe for analysis - is this exporting chemicals?

- Response to follow.

301. **Is it worth getting AEO certification? And what is involved?**

- Authorised Economic Operator (AEO) status is an internationally recognised quality mark that shows your business's role in the international supply chain is secure and has customs control procedures that meet UK and EU standards. Businesses who currently only trade with the EU can apply for AEO status in preparation for 1 January 2021. The authorisation will not become valid until 1 January 2021. Further information on how businesses could benefit from AEO status and how the application process works is available here.

- Please bear in mind that if you interact with EU customs authorities (e.g. by making declarations to them), UK-issued AEO status will no longer transfer to AEO status with EU Member States' customs authorities. However, Gov will automatically transfer your AEO authorisation (AEOC, AEOS or AEOF) to the new UK AEO scheme from 1 January 2021. This will be a new UK status and will replace your existing EU status. We will write to you before the end of this year with more details about this change.

302. **Any tips on the mentioned usage of ISPM15 pallets from EU to UK and vice versa, will it be mandatory?**

- Yes, all pallets moving between the UK and EU after the end of the Transition Period will need to be ISPM15 compliant. Further information is available here.

303. **The UK - EU export guidance speaks of the need to have a pre-lodged import declaration in the EU prior leaving UK. This is not a standard way of working and will need a declaration type D in EU, which is not always supported in every Member State. Can you confirm the pre-lodgement is only for the UK-FR shipments?**

- From 1 January 2021, hauliers travelling via the Port of Dover or Eurotunnel must use the 'Check an HGV is ready to cross the border' service to prove that an HGV has the right EU import and commodities documents for the goods it's carrying before it crosses the GB / EU border. It will be optional to use the service for all other GB ports. Beyond that, future use of the pre-lodgement model is a commercial decision for port operators. Annex B of the Border Operating Model has further details on how the main Ro-Ro freight destinations in the EU – France, Belgium, The Netherlands, Ireland and Spain – all have systems allowing advance completion of customs declarations and entry summary documentation for Ro-Ro freight.

304. **Where can I find a comprehensive list of products of animal origin as controlled goods? Does it include antibodies, blood based products, Bovine albumin etc. as used in the life science sector and specifically in IVD kits?**

- Further details on the rules for importing products of animal origin after 1 January 2021, including a link to check animal by-product lists in detail, are available here.

305. **What is the current situation with regards to CHIEF and the new Customs Declaration Service (CDS)? When will CDS be rolled out nationally to process imports/exports, and if delayed, is CHIEF suitably sized to handle all transactions currently handled by EMCS?**

- There will be a customs platform in place to handle the volume of declarations expected from the end of the transition period. CHIEF and CDS will dual run as HMRC continues to develop CDS. CHIEF hardware capacity has been increased and fully tested to handle 300 million declarations per annum, with a performance increase to 70 declarations per second. The CDS Minimum Viable Product (MVP) has been built to handle 60 million declarations per annum, 14 declarations per second – and we will have increased CDS peak average hour performance across all declaration types to 26 declarations per second by December. Combining a scaled CHIEF system and CDS means projected increases in declaration volumes after the Transition Period can be accommodated. HMRC is focused on ensuring traders use the right platform in time for December 2020. They are developing the following migration journeys to guide this work:
  - onboarding new GB traders to CHIEF
  - onboarding new NI traders onto CDS
  - migrating existing CHIEF traders to CDS for their NI Imports trade, and RoW Imports where they are ready to do so
  - NI to RoW Exports remains on CHIEF until the supply chain is ready.
  - GB to RoW Exports remains on CHIEF until the supply chain is ready.

306. **The grants via the link for export declarations are only available to direct exporters. If we use an agent - it appears that we are not eligible. Is that correct?**

- You can still apply for training through the grant link even if you do not intend to complete your own declarations but want to undertake basic customs training: https://www.gov.uk/guidance/grants-for-businesses-that-complete-customs-declarations.

307. **When importing excise product into UK, and moving under registered consignor license from a UK port, how will that process work? i.e. will the port notify the customer on arrival, and will we need to create the EMCS movement immediately to that the driver can be given a copy of the ARC?**

- From January 2021, businesses importing excise goods into Great Britain will need to complete a customs declaration. This can be a full or simplified declaration for imports (the Simplified Declaration procedure available to importers of excise goods from the EU is the same as is available to importers from RoW). Excise duty will be collected following the same rules that apply to goods from the RoW, and importers will be able to enter excise goods into duty suspension as they can do now for RoW imports. All excise duty will be collected via CHIEF/Customs Declaration Service.

- You can use Customs Freight Simplified Procedures (CFSP) to import some excise goods such as alcohol and tobacco. All other excise goods are excluded from using CFSP.

- The Excise Movement and Control System (EMCS) will continue to operate but solely for internal UK duty suspended movements, including movements from the port to the importer's warehouse.

- For goods entering Great Britain through a location with existing customs controls systems, the registered consignor must complete and submit an electronic administrative document (eAD) through EMCS before the movement takes place. This will generate a unique Administrative Reference Code (ARC) for that specific movement. The code must travel with the goods at all times. You'll need to supply the person accompanying the goods (for example, the driver of the vehicle transporting the goods) with a printed version of the eAD or any other commercial document which clearly states the ARC.

- Where goods are entering Great Britain through border locations that do not have existing customs control systems, you will have until the end of the next working day to notify HMRC that the goods have entered the country. In this scenario, the entry to EMCS may also be delayed until the end of the next working day. This is on the condition that you enter the excise movement guarantee reference on the customs import declaration. When you complete the eAD, you'll need to tick the 'deferred movement' box to indicate this is a retrospective declaration.

- A comprehensive guide on importing excise goods from1 January 2021 can be found here.

EXPORT CONTROLS

308. **We ship Category 2 drug precursor materials to the EU and ROW. I understand we will have to apply for an export licence in order to ship. So far I have not been able to establish if the EU countries will require an Import permit to ship these products from UK to EU after 1st Jan 2020**

- For category 2 chemicals, shipping from Great Britain to the EU will require the same licences as are currently required for category 2 chemicals being shipped to non-EU countries. That means that no import licence is required in the EU. For drug precursor chemicals, the burden is on the exporter – an Export licence would be required and possibly a PEN. Further details on trading in drug precursors from 1 January 2021 are available here.