

14 October 2021

UK REACH Questions and Answers

This document collects several UK REACH questions raised by industry associations with the HSE REACH helpdesk. The answers from the HSE helpdesk are provided in blue.

- 1. Once a company generates a DUIN number and submits their DUIN, can they update and re-submit the excel spreadsheet more than once? For example, if they have access to information missing from their first submission?**

We would prefer that all substances eligible for the DUIN provision for the same legal entity are submitted in one spreadsheet (remembering that they can be submitted until 27 October 2021). However, where this is not possible, submitting multiple spreadsheets is acceptable. All submissions must be done within the permitted timeframe i.e. within 300 days of the end of the transition period which ended at 11pm on 31 December 2020.

Please use the DUIN number you already have and email a new spreadsheet to the Agency. When you send your DUIN excel spreadsheet to ukreach.dunotification@hse.gov.uk, it would be helpful if you include in the cover email that you have previously submitted a DUIN spreadsheet covering a proportion of the substances for that same legal entity. This will help to ensure that each spreadsheet is grouped and filed accordingly.

There is no requirement to update a DUIN submission with any additional information that you may receive for substances that you have already notified to the Agency, as long as the mandatory information and chemical identifiers were included in the original submission.

- 2. We have a couple of questions in relation to the 2-year period prior to exit day for fulfilling the DUIN requirement.**

Can a company submit a DUIN in the scenario when...

- A company's last import was prior to this 2-year period (2018 for example) due to COVID-19 causing a business slowdown?**
- The last import was prior to this 2-year period and they have been using the substance during the 2-year period prior to exit?**

In order to be eligible for the Downstream User Import Notification (DUIN) the import must be a 'protected transitional import'. This means the import must be from the EU and covered by an existing EU REACH registration or it was previously imported from outside the EU and covered by an Only Representative (OR) in the EU. Additionally, the GB-based importer must have been an existing downstream user under EU REACH and imported or used the substance in the two years leading up to the end of the transition period (i.e., from 1 January 2019 to 31 December 2020 inclusive). Note that to be a downstream user requires you to have used the substance but not necessarily have imported it.

Applying this to your scenarios:

- A company's last import was prior to this 2-year period (2018 for example) due to COVID-19 causing a business slowdown?**

This company would appear to be neither an importer nor a (former) downstream user and so would appear not to qualify for a DUIN. Note that there is no lower tonnage threshold for being a downstream user and any use however small would count.

- **The last import was prior to this 2-year period and they have been using the substance during the 2-year period prior to exit?** *This company do appear to have been a user and so would seem to qualify for a DUIN.*

3. Can a DUIN be submitted for a substance that has been “used” during the DUIN window (1st Jan – 31st Dec 2020), even if it hasn’t been ‘imported’ during that time?

The Downstream User Import Notification (DUIN) is for GB-based companies who have become importers, but who were previously downstream users under EU REACH. Under EU REACH import from within the EU wasn’t classed as import and import from outside the EU under an OR arrangement was treated in the same way. The notifier must be a GB-based downstream user or distributor and the import should be a ‘protected transitional import,’ which means it should be imported from the EU and be covered by an existing EU REACH registration by the EU manufacturer or if the import was from outside the EU it was being covered by an EU-based OR (i.e., within the same supply chain).

*It is only possible for companies that were downstream users or distributors in the 2 years before the end of the Transition Period (1st January 2019 - 31st December 2020) to take advantage of the DUIN process. **The definitions in Article 127E don’t seem to require that the (former) downstream user actually imported the material in the 2 years before exit.** If the importer is a new user that wasn’t using the substance prior to the end of the TP, then a DUIN will not be possible. In this case, to import the substance, a full new registration will now be required by the GB importer once import into the UK reaches 1 tonne per year or more.*

Further clarification later received:

To be eligible to submit a DUIN, the company must have been an existing downstream user under EU REACH. In accordance with Article 127E(12) “existing GB downstream user under EU REACH” means a person who was, at any time in the 2 year period before IP completion day, a downstream user under EU REACH established in Great Britain in relation to a substance on its own, in a mixture or in an article. Therefore, as long as the company were using the substance they were a downstream user; the article does not explicitly state that the physical import into GB had to have occurred in the 2 year period. Article 3(13) states that downstream user: means any natural or legal person established within Great Britain, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user. Again the definition does not make reference to the physical import of the substance.

4. If we import polymers, do we have to include these or try to find out the monomers that they are made from, and include those on the DUIN?

Under UK REACH, the requirements for polymers remain the same as under EU REACH but in GB-only context. As such, polymers are exempt from registration (Article 2(9)) but the monomers and other relevant substances will require registration (Article 6(3)). As the submission of a DUIN extends the deadline to submit a new registration under UK REACH existing downstream users/distributors under EU REACH, for polymers, it is the identity of the monomers and other relevant substances that need to be reported. Much of the information in a DUIN is provided ‘to the extent it is available’ (to the DUIN submitter). This is in recognition of the paucity of information currently available to many (former) downstream users. For some polymers the identity of the monomers can be discerned from the name (e.g., polystyrene is clearly made from styrene) and this could help for some.

5. Request for advice regarding DUINs for polymers and mixtures where monomers/ components unknown.

For polymers on DUIN sheets, our advice is that where you know or can work out what the monomers and other reactants are, these should be included. It is then a choice about whether to include the polymer name. It isn’t the substance for which the registration duty is being suspended, but sometimes the name can give clues to the monomers. This could be because of our own prior knowledge, because a different company happened to give

us information on the same polymer or just because we have access to a wider range of information than a SME might have. It would also show that the company was being transparent, making their best effort to

comply and would put on record the polymers they import as part of an audit trail to show the monomers (whatever they turn out to be) were covered by the DUIN submission.

Yes we don't want the names of formulated mixtures to be submitted. The registration obligations in REACH apply to substances and not formulations/mixtures so it is not a requirement to submit these names. Unlike polymer names it is difficult to discern the ingredients in a mixture solely from the name.

Similarly, the SDS for mixtures are not really very useful in the context of a DUIN. The DUIN covers substances and a SDS for a formulated product covers the whole product, not the individual components. Again it is not usually possible to discern the components of a mixture just from the SDS and those in the sector are more likely to know about the components than us.

6. Will any sort of DUIN confirmation be supplied to companies that submit DUINs?

The generation of the DUIN number in Comply with UK REACH is only the first step in the DUIN process. Hence the DUIN number alone is not 'proof' that you have submitted the DUIN correctly. To complete the DUIN process, the additional information spreadsheet must be submitted to the Agency at ukreach.dunotification@hse.gov.uk. A form of acknowledgement of the submission of this spreadsheet should be received by the Agency. We advise that you document and retain relevant information, including copies of the emails containing the DUIN spreadsheet that you send to the Agency and any subsequent acknowledgement. This will form part of the evidence to support your compliance should you ever be challenged by enforcement authorities.

7. If we import biocides to use as in can preservatives, do we have to include them on our DUIN or do we need to do something under the BPR?

Active substances manufactured or imported for use in biocidal products only** and included either in the GB List or the Simplified Active Substance List defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products or Annex II of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, subject to the transitional measures detailed in Article 89 of Regulation (EU) No 528/2012, **shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

8. Apparently some DUIN submission emails are too large to go through. We have been advised that there is a large file upload facility but don't have any details. Please could you clarify?

The only way to supply the data is via email to ukreach.dunotification@hse.gov.uk. Our email facility will allow attachments of up to 20MB. In most cases the size limit is breached due to the inclusion of safety data sheets (often as PDF files which can be large). If the submission is limited to the spreadsheet only it should be possible to stay within the size limit. However, we are looking at implementing a Share File facility as an alternate method for supplying this information, but this is not yet available.

Note. More recently DEFRA has advised that if a submission fails due to email size, companies should reply to the HSE email that acknowledges the failure. It has been confirmed that the HSE can provide support on a case-by-case basis, including making a drop box facility available to provide the information separately if needed.

9. Some members have concerns about the security of submitting potentially confidential business information via email. Please could you comment on the risk assessment carried out/ security in place around the emails?

As previously stated, currently, the only method to supply the data is via email. However, the only mandatory information that is required as part of the DUIN submission is the DUIN number and the legal entity name within the additional information spreadsheet. Then, where a substance is included in the spreadsheet, it must contain one of the following identifiers: substance name, CAS number or EC Number. All the other information listed can be submitted to the extent that is available to you. So if your members did not feel comfortable submitting further details via the email method, they wouldn't be obliged to. The HSE emails

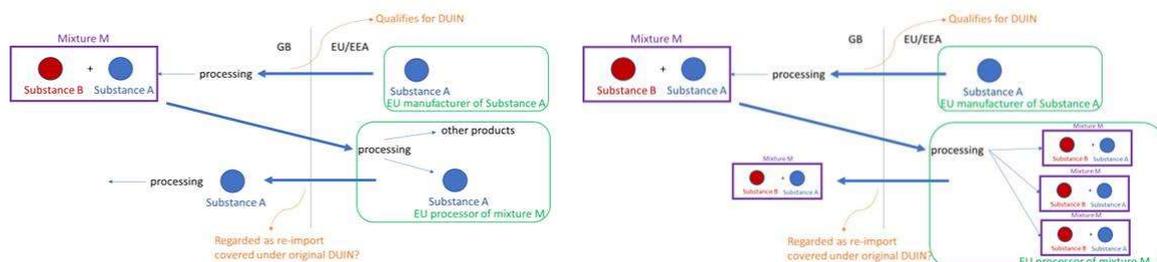
system operates on what was previously termed the Government Secure Intranet and strict firewalls etc are in place.

10. I understand that where information is not available to you, it need not be submitted (this is often the case for former DUs). However, could you comment on whether it is required to be submitted if you do have access to it?

Registrants are required to provide information on the substances to the extent that it is available to them; thus, if they have, it is available and should be submitted. Whilst the data is not needed initially for the DUIN submission it will eventually be needed. The registrant will need to find out the full information required for registration before the relevant deadline in order to complete a full registration. So, we see it as advantageous for registrants to submit as much information as they can in the DUIN.

11. May I please ask your advice in relation to the re-import exemption under UK REACH.

A substance A is sourced from an EU based supplier and imported to Great Britain. The substance is registered in the EU and the transaction qualifies for a DUIN for substance A. Substance A is then used in Great Britain and exported again in form of a mixture back to the EU to another party. This party then processes the mixture, which is then shipped again back to the GB to be further re-used. Can the 2nd movement be regarded as re-import and be covered by the initial DUIN done for substance A, i.e. does the re-import exemption applies to DUINs? The question is of particular interest as to whether the companies re-importing into GB (or the EU based suppliers via a GB OR) would otherwise have to pursue a UK REACH registration before the upstream registrants needed to pursue theirs, which would relieve the GB re-importers of their obligation to register. We have pulled together a drawing to be able to better represent the circumstances around the question for two cases: (1) left: re-isolation of substance A by EU processor and re-import of it to GB; (2) right: re-filling activities of mixture containing substance A by EU processor and re-import of the mixture to GB.



The submission of the Downstream User Import Notification (DUIN) suspends the registration duty by 2, 4 or 6 years plus 300 days since the end of the transition period. Which deadline depends on the tonnage band and/or hazard profile of the substances imported. As a result, the Great Britain (GB) importer does not have to comply with the registration duty under Title II of UK REACH until the deadline relevant to them.

Article 2(7)(c) of the UK REACH legislation states the following:

“7. The following shall be exempted from Titles II, V and VI:

(c) substances on their own or in mixtures, registered in accordance with Title II, exported from Great Britain by an actor in the supply chain and re-imported into Great Britain by the same or another actor in the same supply chain who shows that:

(i) the substance being re-imported is the same as the exported substance;

(ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;”

Where Title II is the registration of substances, Title V is downstream users and Title VI is evaluation.

Our interpretation of this is that the re-import exemption could apply to substances where a DUIN has been submitted. Although the substance has not yet been fully registered under UK REACH, the registration duty has been deferred by the submission of a DUIN. Therefore, the Title II duties have been fulfilled by the submission of a DUIN until the relevant deadline. As a result, provided a DUIN has been submitted for the original import into GB, the GB based importer can benefit from the re-import exemption. Note that the other conditions of the exemption must be fulfilled i.e., the substance imported must be the same as the exported substance and the information in accordance with Article 31 or 32 must be provided. Additionally, as long as these conditions are met, it does not matter how the substance is processed when it leaves GB before it is re-imported.

Also, Article 3(13) states that a re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user. Therefore, we would consider that as long as the first importer into GB has fulfilled their current obligations under UK REACH through the submission of a DUIN, then the re-importer has no registration obligation as they regarded as a downstream user.

If a GB importer believes an exemption applies, we recommend that they document their decision with any supporting evidence, should they ever be challenged by enforcement authorities.

12. A UK OR has created set up our parent account in “Comply with REACH IT” and created child accounts for each of the non-UK-GB companies they are representing. Under the child account it shows the business address separately from the parent organisation. For the child account should the OR

- **under “Address” should this be the address of the child or can it be of the parent?**
- **Under “Telephone” can this be the phone number of the parent or is it mandatory to use the number of the child?**
- **Under “Email” can this be an email address from within the parent organisation?**

The points mentioned in the REACH IT guidance (on page 3) makes the following points: you will be asked whether the organisation has the same address as the parent organisation. If it does not have the same address, press no. If you have chosen no, you will be asked for the address of the Child organisation. If no address returned enter post code in the look up table. You will be asked whether the contact details the same as for the parent organisation If they are different select the no radio button. If you have chosen no you will be asked for the contact details for this organisation. You will need to add a contact number and email address.

So in this case the details of the child account business would need to be provided (address, email of non-UK supplier)? However this then raises confidentiality issues and whether the above information will be made public or available to other potential registrants.

- **Under “Address” should this be the address of the child or can it be of the parent?** *This will depend on how the OR is set up. The address should be in GB and should be that of the OR. If the OR has multiple offices/sites in GB and for a particular sponsor company a certain office/site is relevant then that address can be used.*
- **Under “Telephone” can this be the phone number of the parent or is it mandatory to use the number of the child?** *Again, this will depend on how the OR is operating. The number should preferably be in the UK but should be for a relevant contact for that account.*
- **Under “Email” can this be an email address from within the parent organisation?** *As for the telephone number, this should be for the relevant contact for the registrations/DUINs being submitted from this child account.*

It is my understanding that for DUIN submissions the contact information will only be visible to the Agency (HSE) and therefore the information will be kept confidential. However, for Article 26 Inquiries and registrations the contact details will be visible to others in the Substance Group to facilitate contact so that data sharing can be agreed.

For naming the accounts, you can take an approach that suits you. 'Your Company OR account 001' or similar would be a useful approach if the sponsor or OR didn't want the link to be public or visible to others in the Substance Group, although you may have done this already.

13. When submitting an Inquiry for a new substance not already on the market in UK/EU, will a reference number be assigned along the lines of an EC number?

When submitting to GB REACH and there is no EU REACH IT account, is there a need for an 'official' UUID to be in the IUCLID dossiers? (IUCLID assigns 'unofficial' random UUID)

In response to your questions:

- 1. The only reference number that will be assigned in UK REACH will be the UK REACH registration number. We will not assign an EC number or equivalent UK reference number in UK REACH.*
- 2. In the UK REACH IT system we do not actively use the UUID in the same way that ECHA do. Therefore, it does not matter what UUID is included in the IUCLID dossier submitted for UK REACH.*

14. Please could you clarify the process that will be in place for NRES (I believe it's known as newly registered existing substances)?

In the case of a new registration of an existing substance (NRES – i.e., a substance that was registered under EU REACH before exit), the registration process is slightly different as there are currently no lead registrants with whom to negotiate access to the required data. As a result, to provide parity with grandfathered registrants and the former GB-based downstream users, although a new registrant must submit a registration dossier, the provision of the full information requirements for registration within the dossier can be deferred either 2, 4, or 6 years plus 300 days from the end of the transition period (i.e. 31 December 2020). The deadline will depend on the tonnage band and/or hazard profile of the substance, as seen in the table here.

We understand that in this situation the new registrants might not be in a position to include all the test summaries. Consequently, the dossier that is submitted for registration should include a waiver request that explains why the registrant is not currently able to obtain the information; that they will make every effort to negotiate with the other members of the Substance Group and will either provide the data themselves as lead registrant or will become a member of the joint registration.

We ask that the waiver request is included in Section 13.2 of the IUCLID dossier and is clearly labelled via its title. This is where general assessment reports and other non-specific attachments are added. The document should be a PDF file.

Therefore, in order to be compliant with UK REACH and begin importing the substance in GB at or above 1 tonne per year, the GB-based importer will be required to submit an Article 26 Inquiry, submit the registration dossier with the waiver request and pay the registration fee.

We aim to process Article 26 Inquiries within 10-15 working days of their submission, although if there are no problems with the inquiry they tend to be processed quicker than this. Once a registrant has received a successful outcome from their inquiry they can then submit a registration dossier that includes the waiver request. Once the fee is paid, HSE will undertake a completeness check of the dossier within three weeks. If the registrant does not hear anything to the contrary within this three-week period, then they can assume that the substance is registered and import at or above 1 tonne per year can begin

In summary, the mechanism for NRES process is as follows: Submit an Article 26 Inquiry → Submit the registration dossier with waiver statement & pay the registration fee → Submission of the full information requirements within the registration dossier or as part of the joint registration (by either 2, 4, or 6 years plus 300 days from the end of the transition period).