

***Inquiry your substance as soon as possible and get more.....***

## Inquiry under UK REACH



- “Downstream User Import Notification (DUIN) is completed but it is impossible for us to know who the co-registrants are. How can we start the data sharing process for the registration?”
- “Our substance cannot be notified, since one of the prerequisites for DUIN eligibility is not met. Any alternative to DUIN? Shall we submit a full registration to HSE before the substance is imported into GB?”

The answer: **First step of any new registration is to submit an Article 26 inquiry according to UK REACH.**

To be part of a substance group - a group of potential co-registrants of the same substance (formerly known as SIEF under EU REACH) -, you shall submit HSE an inquiry according to Article 26 of UK REACH. The process for compiling an inquiry dossier is analogous to the process under EU REACH and the requirements are the same.

Once you have successfully inquired about a substance and received your inquiry number, your contact details or the contact details of your appointed representative will be shared with existing registrants, grandfathered registrants and other successful inquirers regarding that substance. This will enable you to engage in the data sharing process.

Registrants of the same substance are automatically matched and put in a substance group. This is done after either:

- submitting the initial substance identification information - in the case of grandfathered registrations;
- submitting a substance inquiry if you are a new registrant, including those who wish to register, having submitted a Downstream User Import Notification

Once a substance group is formed, members of the group can access each other's contact details to organize a registration strategy, a cost-sharing model and group data sharing. A lead registrant should be appointed by the group to submit the joint registration dossier for that substance on behalf of all group members.

**In short, the inquiry process aims to put potential registrants and previous registrants in contact with each other to share data so that the joint submission obligations can be met. Studies involving vertebrate animals should not be repeated and available studies need to be shared. By doing so, it reduces registration costs and avoids unnecessary testing, especially on vertebrate animals.**

### **What should be included in an inquiry?**

An inquiry dossier should contain:

- Information about the potential registrant;
- Information about the identity of the inquired substance. The analytical data (qualitative and quantitative data) provided in the inquiry dossier should be sufficient to verify the identity and composition of the substance;
- Information requirements where the potential registrant would need to carry out new studies, including those involving vertebrate animals.

### **Does the analytical data included in an inquiry dossier have to be generated on the manufactured or imported substance?**

In principle, the analytical data included in an inquiry or a registration dossier must reflect the substance as manufactured or imported. Hence,

- If you are non-GB based manufacturer, your Only Representative (OR) must submit analytical data generated from a sample that you have manufactured.
- If you are non-GB based formulator, your OR must submit analytical data generated from a sample manufactured by your supplier, namely the non-GB based manufacturer.

Note: Only **substances** should be inquired; **not mixtures** (formulations). If you are non-GB based formulator, you only need to inquiry the individual substances within those mixtures if any will be imported into GB at or above one tonne per year.

### **Does HSE charge fees for inquiry?**

For inquiry no fee is charged by HSE.

### **Is there any alternative to DUIN? Yes, New Registrants of an Existing Substance (NRES)**

A NRES is a new registrant of a substance what was previously registered under EU REACH before 1 January 2021 by any legal entity. If the substance was registered under EU REACH on or after 1 January 2021 then the substance would be considered novel and a full registration containing all the information would be required straight away.

For NRES it is possible that the registrant can receive a registration number after submitting a "no data or limited data" registration with a waiver statement and paying the UK HSE fees. The submission of the full information requirements for the registration can be deferred either 2, 4 or 6 years plus 300 days from the end of the transition period (i.e. from 31 December 2020). The deadline will depend on the tonnage band and/or hazard profile of the substance.

Whether a registrant is a NRES will be confirmed to them after the successful submission of their Article 26 inquiry.

### **Our UK REACH Services**

If you are non-GB based manufacturer or formulator, we will gladly provide you with advice and support for gathering all relevant data for a quickest and effective inquiry.

OR and testing service on substance identification, providing by our partner:

GB based OR service: Takeover an OR-function under UK REACH

Upon request substance identification testing for mono/multi-constituent substance/UVCB (organic or inorganic)

Analytical data can cover:

- UV/VIS at 3 pH-values
  - FTIR with ATR
  - <sup>1</sup>H-NMR
  - <sup>13</sup>C-NMR
  - GC or HPLC Chromatogram
  - Mass spectrum
  - Water content
  - Solid NMR
  - XRF or ICP-OES / ICP-MS
  - XRD incl. Rietveld analysis for the quantitative determination of main phases and amorphous amount
  - BET
  - Zeta Potential
  - Dynamic light scattering (DLS)
  - Particle size distribution (PSD)
  - SEM/TEM and EDX
  - Moisture and water: gravimetric or with Karl-Fischer
  - Elemental analysis on C, H and N (necessary for surface treated samples) and more.....
- as well as evaluation of data incl. REACH Report in PDF format and disposal of the test item.

GEELIO's inquiry service:

- Consulting on inquiry strategy especially in case of substance involved in indirect import into GB
- Inquiry dossier preparation and submission to HSE
- Communication with HSE
- UK REACH registration strategy consultation, based on HSE inquiry result.

We are looking forward to answering your questions and ensure that we are helpful in every possible way.

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