

Manufacturing a new substance where there is no existing GB- Lead Registrant appointed and no data set submitted to the HSE

Challenge

A company is manufacturing a substance for the first time and a DUIN does not apply, but they know that there are existing EU Registrants. It is possible some UK importers from the EU have made a DUIN as part of their historical supply. There is no intent to export the substance to the EU and no EU Registration is needed.

Solution

The first step is to make an Inquiry to the HSE using IUCLID and the 'comply with REACH' Government Gateway. The HSE will consider the substance identity details (eg NMR, IR, UV-Vis, Chromatography etc) to confirm the substance identity. A link will be made with existing EU Registered substances with existing EC numbers (and it is recommended to point this out in the Inquiry submission if known).

After successful acceptance of the Inquiry, the HSE will expect a full Registration. Where there is an appointed UK Lead Registrant for GB REACH, they will be identified, and the new Registrant will be expected to join them and pay for data access as needed. However, in this transition period, it is possible that there is no Lead Registrant yet appointed in the UK and even if some importers have DUINs in place, there is no guarantee that they will convert to full registrations before the final Registration date. Conversely, it is illegal to repeat animal testing known to exist, so even if wanting to generate new data as a new UK Registrant, effort is needed to access data, but EU REACH (non-UK) data holders have no obligation to share for non-EU REACH.

The temporary fix is to complete a full dossier 'as well as possible' using waivers or public data where there is no formal access agreements. It is important to make it clear that the reason for no data in certain sections is due to unresolved data access, but also point out that it is expected that this will be resolved when GB Registrations are finally made by DUIN holders. Of course, if in due course no other data holders come forward and the new manufacturer finds itself the de-facto Lead Registrant, then the data will need accessing by some other way. As yet, there is no official guidance on what to do in the scenario where the non-UK data holders refuse to share animal data, but the HSE is reluctant to force new animal work.

Further information

Here at REACHReady our [Matchmaker](#) offers a fast and efficient means to help our customers find reliable organisations providing services to comply with UK REACH obligations. Whether it's an Only Representative you are seeking and someone to compile an IUCLID dossier for registration purposes, we have a line-up of the most appropriate suppliers to meet your every need.

Please do contact us on +44 (0) 20 7901 1444 or email enquiries@reachready.co.uk