REACH: Hints and Tips for an Efficient Registration

Introduction

The final REACH registration deadline for phase-in substances was reached on 31 May 2018. However, if you are manufacturing of import a substance for the first time you will need to register it with ECHA before you manufacture or import more than 1 tonne per year. We have compiled some helpful hints and tips covering each stage of the process from substance identity through to dossier submission. We have also included a check list that highlights what ECHA are looking for during their post submission checks on your dossier do you don't get caught out!

Substance Identity

First you will need to conduct analytical tests on your substance to determine its identity profile.

- Spectral methods, such as UV Vis/NMR, to confirm the structure of the substance
- Chromatographic methods, such as GC/HPLC, to confirm the composition of the substance

The budget required for analytical testing can be estimated in the region of £2000 but if your substance is more complex, such as a substance of unknown or variable composition, complex reaction products and biological materials (UVCB substances), further detailed testing may be required. If you have good analytical facilities, you can do this yourself and not use an external facility. Once your substance identity profile has been determined you use it within your inquiry dossier.

Inquiry Process

Potential registrants have to submit an inquiry dossier to ECHA before they can begin the registration process. The dossier should clearly identify the substance that is being manufactured or imported. Companies must wait for ECHA to respond to their inquiry before they can submit the registration dossier. This is because ECHA checks to see if the substance the registrant is inquiring about has already been registered by other registrants. If this is the case ECHA will put you in contact with the lead registrant so you can join the already existing joint registration. If the substance hasn't been previously registered you will become the lead registrant and are able to undertake any necessary animal testing required to complete the registration dossier.

Working with Other Registrants Considerations

Registration is based on the principle of "one substance one registration" therefore, if the outcome of the inquiry is that the substance has already been registered you must join the existing registration. However, under certain conditions you may be able to submit part of the information separately for example if you do not agree with the joint classification you can opt out and include your own data in this section. You must gain access to the submitted data you require for your tonnage band via a letter of access (LoA) which can be purchased from the lead registrant. The cost of a LoA can vary from substance to substance and also depends on how many companies may be involved in the process.

The cost of the registration must be shared in a fair, transparent and non-discriminatory way and if the figures seem excessive, talk to REACHReady; most are fair, but if there is a dispute over costs, then this can be highlighted to ECHA when submitting the dossier.

Prepare your Dossier in IUCLID 6

If you are registering in the 1-10 tonnes per year tonnage band you could benefit from reduced data requirements by only having to submit physicochemical data if **neither** of the Annex III criteria listed below apply to your substance

- CMRs or PBT/vPvB substances are not eligible for reduced registration requirements;
- Substances having 'dispersive or diffuse use' **and** predicted to be classified for human health or environmental hazards are not eligible for reduced data requirements.

All member registrant dossiers, including the lead, must include their own company specific information

- Section 1.1 + 1.2 Identity and composition of substance
- Section 1.4 Analytical information of substance
- Section 3 Manufacture and uses
- Sections 11 + 13 Guidance on safe use and chemical safety report (upon agreement with the lead)

The lead registrant dossier must also include all information that the co-registrants submit jointly

- Section 2 Classification and labelling
- Sections 4-8 Scientific studies for Annex VII-X
- Sections 11 + 13 Guidance on safe use and chemical safety report (upon agreement with other participants)

The information requirements for intermediates tends to be reduced and there is no requirement to complete a chemical safety assessment

- Sections 1 and 3 need completing as normal, with special care in Section 3.5 (uses)
- Section 13 should be used for documenting information on risk management measures

Once completed the dossier must be uploaded to REACH IT where it can then be submitted to ECHA. It is important to remember that the dossier is a live document and must be updated when new information become available on the composition of your substances, its properties, how it's used by your customers or the specific risk management measures. The dossier should also be updated if there are significant changes in the production/import volumes or changes to company information.

How to Avoid Failing the Post Submission Checks

To pass the Business Rule Check

- Your dossier must be in IUCLID /REACH IT format
- Your admin information must be consistent

To pass the technical completeness check

The following four main areas are focussed on

- Correct substance identification – analytical information must be provided
- Data waivers – a valid justification must be provided
- Testing proposals on vertebrate animals – alternatives must have been considered and justifications provided
- Chemical Safety report- if one isn't attached to the dossier a justification must be provided

Before submitting use the validation assistant plug-in in IUCLID 6 which will highlight any sections that require further information

Once ECHA has carried out these checks on your submitted dossier you may be required to perform additional tasks which could include

- Updating your dossier if your initial dossier fails
- Paying the registration fee to ECHA

Therefore ensure that you check your task page in REACH IT regularly.

Further Information and Guidance

The ECHA website has dedicated pages for the REACH registration process which can be found at the following link https://echa.europa.eu/support/registration. These pages provide in depth information and guidance on each step of the registration process.

REACHReady Gold subscribers can speak to one of our technical advisors via the Helpdesk. Just call **+44 (0)207 901 1444** or email enquiries@reachready.co.uk