REACHReady guidance: Article 26 Inquiry

Introduction

The aim of REACH is to improve the protection of human health and the environment. In order to understand the risks of chemicals and know how to use them safely, the intrinsic hazardous properties of those substances must first be identified. Key to the philosophy of REACH is the importance of reducing both costs and testing on vertebrate animals. Furthermore, avoiding duplicate vertebrate animal studies and preventing unnecessary testing where other methods could be used to generate the information required are paramount.

What is Inquiry?

Inquiry is a notice of intention to register a non-phase-in substance (i.e. a substance was not eligible for the phased-in registration deadlines) or a phase-in substance that was not pre-registered. The potential registrant provides ECHA with details of the substance they intend to register. ECHA uses this information to determine whether the substance has already been registered, if data have already been submitted as part of a notification under Directive 67/548/EEC (also known as NONS), or if there are other potential registrants of the same substance. ECHA puts such companies in touch with each other; when existing data are available, both parties are expected come to an agreement on sharing to allow the potential registrant to register the substance without duplication of vertebrate animal testing.

Data requirements

An Inquiry dossier is prepared either directly in REACH-IT or in IUCLID 6. The data requirements of an inquiry include the need to provide analytical reports and spectral data to confirm the substance's identity. The dossier must also indicate the data the potential registrant will need in order to complete their registration dossier. The analytical data is then used by ECHA to check whether that substance has already been identified by other registrants and whether others may be in possession of animal test data. If the substance, or a similar substance, has already been registered (including former NONS submissions), the potential registrant will be invited to contact the Lead Registrant to negotiate data access; if there is a SIEF working towards registration, the potential registrant will be put in touch with them.

The key requirement is to provide sufficient analytical information to identify the substance and to allow ECHA to compare the substance with other Inquiries or Registrations. There is also some "intelligent" assessment of the data needed to see if there are opportunities for "read-across" with other substances, which is one of the methods available to registrants to avoid vertebrate animal testing.

The principals of Good Laboratory Practice (GLP) should be observed where possible, although not explicitly required under REACH. For all analytical reports, it is strongly advised to include details of the sample used (source, batch number, certificate of analysis etc), details of the testing laboratory and date, the methods followed, types of equipment used etc. The analytical report must be added to the IUCLID 6 dossier file in Section 1.4 and must provide sufficient evidence to justify details on the identity and purity in Section 1.2.

Spectral evaluation

The purpose of spectral evaluation is to provide evidence for the identity of the substance by spectral analysis, typically IR, UV-Vis, NMR or MS. Even in cases where it is not possible to interpret the results fully, the spectra will at least provide a "fingerprint" for future reference. Although not essential in all cases, it is recommended that if checking the UV-Vis spectra of a water-soluble material, evaluation should be at three pH levels.

If any specific method is not possible to perform, it is important to give reasons in the submission. However, in some cases, performing tests which seemingly give no meaningful results may be more time efficient than arguing the case later when asked why the method was not performed. Remember, for example, that if a spectrum shows no absorption it may help to confirm the purity of the substance.

Chromatography and other analyses

A number of qualitative and quantitative methods can be used to confirm identity and purity, including (HP)LC, GC, MS, X-Ray diffraction etc. The analysis must be sufficient to demonstrate that the substance under Inquiry, and later to be registered, is equivalent to any same material previously tested and registered.

Assessment of Inquiries

Industry's experience has shown that many Inquiries are initially rejected by ECHA; other than procedural issues, the typical reason for rejection is a failure for the analysis data to meet the stringent demands set by ECHA.

It is important to ensure good quality analysis is performed and reported in a way that helps ECHA to compare the substance with any past registrations. For example, if a potential registrant is aware that the substance was notified under NONS (i.e. has an ELINCS number, and is considered registered by the notifier) or earlier registration exists under REACH, then providing analytical data obtained using the same methods and conditions used to support those submission (if known) could be advantageous in regards to substance comparison. Guidance on substance analysis is available in ECHA's official guidance documents.

Some notable rejections have included some of the following points:

- UV-Vis spectral wavelength range too narrow
- Chromatography terminated too soon after main constituent is detected, not allowing confirmation of the presence of other, minor constituents or impurities
- HPLC conditions inappropriate for substance (e.g. pH of buffer does not match known dissociation properties, solvent peak not identified, retention times too short or long etc.)
- Wrong type of NMR used (e.g. carbon or hydrogen) and no integration curves
- Poorly defined methods or experimental conditions, including for inorganic analyses, preventing test repeatability
- Substance name did not conform to IUPAC standards, or did not correspond to details given in analyses
- Quality of the work failed to confirm substance identity.

Thus, it is important to not only get the science correct to confirm identity (structure, isomers, molecular weight etc), but to follow standardised methods where possible to allow repeatability. The analytical report should be prepared to a standard which would allow another trained scientist to

repeat the test. It is also important to complete the forms correctly and ensure that the submission passes the technical completeness check.

After acceptance

If successful, the inquirer will receive details of previous registrants of the substance (if indeed it has been previously registered (or notified under NONS)), or a statement confirming that there has been no known submission of animal data for this substance. ECHA will provide an Inquiry number which must be included in the registration dossier prepared in IUCLID 6.

If notified under NONS, the previous Notifier ("first registrant" hereafter) will not have the full REACH registration for a new potential registrant to access. National Competent Authorities can convert the old NONS submission to IUCLID 6, but it may be easier to enter the data manually into IUCLID 6 in order to produce a good quality registration dossier which passes completeness checking.

If the first registrant only provides access to the minimum vertebrate animal data, the other non-vertebrate data gaps will need to be completed through testing, read-across, modelling or other methods. Once all the required data endpoints are completed, it is necessary to complete the IUCLID 6 dossier and any other documentation required for the registration, such as a Chemical Safety Report (CSR) and Exposure Scenarios.

In many cases it is worth attempting to obtain as much data as possible from the first registrant as possible (a robust summary, if available, is the minimum required); even if this costs more to purchase access, sharing non-vertebrate animal data as well as the mandatory data to be shared may save time and money in the long term. Agreement on the value of data is a commercial process.

12-Year rule

If the data was submitted under the framework of a registration, including a NONS notification, more than 12 years before the Inquiry, there is no need to obtain permission to use the data from the first registrant, and no need to pay compensation for access.

ECHA will provide the new registrant with the robust summary to allow the new registrant to prepare the dossier with CSR and correct classification and labelling. Unfortunately, old NONS submissions did not include a robust summary and ECHA have to provide simple summaries of key data endpoints, which may not prove sufficient. It is also worth noting that notifications made more than 10 years ago may have certain key data endpoints missing such that the data set may not be complete. In these cases, new testing may be necessary.

Conclusions

The Inquiry process is an essential step in the process to register a non-phase-in substance or a phase-in substance without a valid pre-registration. However, it is not easy and many have failed at the first attempt, often meaning a delay to registration and manufacture or import of the substance. It can take a considerable amount of time to complete the Inquiry dossier, collate the data and prepare the registration dossier (some have been several months). Even when all the existing data has been provided and no further information is needed, there is still much work involved in preparing the necessary registration documents.

Further help

Need guidance in understanding your position? Realise you need to submit an Inquiry dossier but don't know where to start? As a Gold subscriber you can speak to one of our technical team by contacting the REACHReady Helpdesk at enquiries@reachready.co.uk or on +44 (0)207 901 1444.

We also offer training and consultancy to help you get to grips with your obligations. If Inquiry leaves you baffled, to find out how we can help you please see consultancy webpages.