# Guidance on dossier updates

## Introduction

Many of the registrations already submitted under REACH need to be updated to include more information. Two means exist by which an update may be triggered: spontaneous (i.e. at the initiative of the registrant), and when requested by ECHA or Member State Competent Authorities.

In some cases, for example changes to classification and labelling, only the Lead Registrant will need to submit additional information. In other situations, for example changes to substance identification or perhaps the addition of new uses, all affected registrants may need to update their dossiers.

This short guide identifies when updates are needed and who needs to submit the additional information.

## When are updates needed?

Updates may be requested by ECHA of Member State Competent Authorities in response to dossier or substance evaluation. These updates may be needed by only the Lead Registrant if relating to test data as a result of the review of testing proposals, or questions over data interpretation. Joint Registrants will need to be involved if the questions relate to issues specific to each registrant, such as substance identity or analytical information. Where there have been requirements for new data, the joint registrants may need to pay for new testing or administration costs. If the updates follow a request from ECHA, it is important that the dossier is updated within the timeline provided in the decision received from the agency.

In general, spontaneous updates by the Lead Registrant are needed when new information is available, when classification has been changed, when DNELs or PNECs are revised, or when any other changes are needed to the dossier that is relevant to all registrants and was part of the joint dossier.

Joint registrants need to consider spontaneous updates for example if they have new uses to add to those that were part of the initial registration or if any other changes to their specific part of the dossier (for example substance identity, guidance on safe use, tonnage). In some cases, all registrants may need to make an update if uses on the joint CSR have been changed or if there are new uses advised against.

REACH Article 22 lists all the scenarios which trigger the need for a proactive update of the dossier without undue delay. The timelines to update the dossiers have been clarified by the COMMISSION IMPLEMENTING REGULATION (EU) 2020/1435. These are generally set at three months for updates of administrative nature, while deadlines of six or twelve months are envisaged for more

complex updates, such as those requiring the generation of data or changes to the safety assessment. Please check the relevant scenario in the regulation.

## How to make updates

Whether updating a lead or a member dossier, the easiest approach is to take the original IUCLID substance dataset and make the required changes. If you wish to claim confidentiality in your dossier don't forget to flag these items in the dataset. In the dossier creation wizard tick the box 'update' and indicate if spontaneous or on request.

The new dossier is then submitted with REACH-IT as before, waiting for responses from ECHA to show completion in 'pipeline'. As with a new registration, an updated dossier needs to pass Business Rules and the technical completeness checks. Some updates may attract a fee from ECHA; these are set out in the Fee Regulation, a copy of which you can find on our REACH Legislation page of the REACHReady website. You may also wish to use the IUCLID Fee Calculator plug-in to work out what fee your dossier will attract before you submit the update.

## Dossier errors resulting in updates: some examples

Most updates, whether spontaneous or request, fall into a small number of categories:

- Simple errors, for example typing errors, decimal points in the wrong place, missed end-points.
- Significant errors in data, for example incorrect interpretation of data, or incorrect classification. One example found included a substance classified as STOT RE and Repro 2 on the basis of adaptive changes in a toxicity study.
- Calculation errors in DNELs / PNECs: as well as simple errors (missing zeros or decimal points), some gross errors have resulted in inappropriate DNELs. These often only come to light when preparing Exposure Scenarios for the extended SDS.
- Substance identity: new analysis may result in changes in purity or in the case of UVCBs, identity of components. If significantly different, it may be necessary to discuss with ECHA.

Note that most cases so far have been 'spontaneous' where the registrant or customers have found the errors. Dossier evaluation resulting in requested updates has often come from the checking of substance identity and analytical information. As more dossiers are evaluated, other sources of errors are expected to be found. We think it is better for registrants to correct any errors before they are discovered by the regulators!

Perhaps with the exception of substance identity, most of these examples are common to the whole registrants' group and an update of the lead dossier may suffice. Note that if changing the classification or CSR, all suppliers may need to update their own SDS, labelling and notification to the C&L Inventory etc.

## Planned updates

By “planned updates” we refer to spontaneous updates where a change of circumstance is anticipated, even if the update is applied in retrospect of that change. Such updates will usually be specific to the individual registrant:

- Change in tonnage: some registrants entered precise figures in their initial submission, for example 278 tonnes per annum. If manufacture/import exceeds 278 tpa, then an update is needed. We suggest that tonnages are rounded up, but not too far, as the CSR and Exposure Scenarios (as appropriate) must reflect the registered tonnage.

- Change in tonnage band: if an increase in tonnage results in crossing a tonnage band boundary for the highest registrant, the lead dossier needs to be updated with the additional information requirements assessed. The updated dossier may need testing proposals and/or new data, and there may be consequences on the CSR. For member registrants moving up to the next tonnage band within a joint submission where higher registrations exist a new Letter of Access will be needed and the member registrant’s dossier must be updated.

- New uses: may be collective (i.e. all registrants and the shared CSR updated) or it could be limited to single registrants. Either way, the CSR (if applicable) needs to be updated to reflect the new uses as appropriate.

- Change in purity: if deciding to import or manufacture lower grade material with different impurity profiles, individual registrants may need to change their dossier to reflect this (assuming the hazard profiles still apply). It is recommended that a broad purity range is entered where possible, to allow for future fluctuations.

- Change in purity and classification: if impurities impact on the classification, more significant changes to the registration may be needed. The lead dossier may need to be amended as well as that of the registrant(s) responsible.

## Need further help?

If you need help understanding the dossier update process and what you need to do, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.