

Guidance on Dossier evaluation

What is dossier evaluation?

Evaluation forms a key part of the REACH Regulation, it's what the 'E' stands for after all. It is a process that can be divided into three distinct parts: dossier evaluation; examination of testing proposals, and substance evaluation. Dossier evaluation is a process performed by ECHA to ensure the information submitted with a registration aligns with that required by the REACH regulations and allows accurate conclusions to be drawn as to the safe use of the substance.

REACH requires that a proportion of dossiers submitted for each tonnage band are evaluated and the dossiers to be evaluated are selected in one of two ways: random or concern-based.

Is the whole dossier evaluated?

Randomly selected dossiers will receive a full compliance check however ECHA can also concentrate on concern-based or targeted checks. Under the targeted approach, IT tools are used to screen all submitted dossiers and select those for a targeted check. Dossiers with incomplete chemical safety reports and those submitted outside of a joint submission are likely to be subject to a targeted check. These checks will then focus on specific endpoints relevant to the substance (such as CMR status) and the information provided therein.

Results of a dossier evaluation

No action

If the information checked is compliant with the requirements of the REACH Regulation, no administrative action will be taken. This does not necessarily confirm that the entire dossier is compliant, and it is still possible that further targeted checks on other parts of the dossier will result in action.

Quality observation letter

The QOBL is used where an issue is identified relating to a dossier, but it does not relate to a lack of information provision. It is used where, for example, the risk management measures or classification given is contradictory to the information obtained from studies. Following receipt of a letter, the registrant is invited to update the dossier.

Additional information request

Where it is felt information required by the legislation for the tonnage band in question is missing, ECHA will prepare a draft decision stating the information requirements. The registrant will be given a 30-day period to comment on this decision before it is sent to the individual Member States for approval. The draft decision may be amended based upon the comments, and if so another commenting period will follow. If there are no amendments, or following a second consultation, a



final decision will be taken by the European Commission and the registrant(s) will be given a deadline by which to submit the information requested.

Updating the dossier

The actions involved in updating the dossier will be dependent on the specific information requested by ECHA; however it is likely that some additional testing will be required to fill the data gaps. As the regulation requires that dossiers are updated without delay whenever relevant new information is available to a registrant, any new information which comes out of these tests must be submitted as soon as it is received, but at the latest by the deadline set. Once the deadline is reached, ECHA will notify the Member States and the Commission of whether the dossier has been updated to include the information requested. Any statement of non-compliance may trigger local enforcement action by the Member States.

Where the evaluated dossier was submitted as part of a joint registration, the registrants must agree who is going to carry out the testing, and costs must be shared equally. Registrants also have the right to appeal an ECHA decision where they feel they have given sufficient grounds to waive the requested information. The appeal must be received within three months of the date of the contested decision, accompanied by the required fee.

Need further help?

If you have received a request for further information from ECHA, or want to know anything else about dossier evaluation and updating your registration, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.