

REACHReady Guidance: Examination of testing proposals

Testing proposals

As part of a registration under the REACH Regulation, a registrant is required to submit a dossier containing information about the substance to ECHA. What information needs to be submitted and what tests should be conducted to obtain this information are listed in Annexes VII-X of the Regulation, with the information requirement dependent upon the tonnage band of the registration. This information will include the results of various physicochemical and toxicological tests, which can be obtained either through a review of existing data, or the commissioning of the approved test method stated in the Annex. If the registrant is required to submit the information stated in Annex IX or X (registration of 100 tonnes or greater) however, they may not undertake or commission any of the tests stated without approval from ECHA. The main reason for the need to submit testing proposals is because many of these tests involve the use of vertebrate animals, and one of the fundamental aims of REACH is to reduce animal testing.

Examination of proposals

In examining a testing proposal, ECHA aim to establish: firstly, if the testing proposal is justified for the compliance of the dossier; and secondly, if the testing proposal is adequate. Testing on vertebrate animals should be the last resort in obtaining missing information on a substance, so ECHA will ensure that reliable and adequate data will be produced from the tests proposed. In assessing whether the testing proposal is justified, ECHA will look to establish: whether an endpoint has already been established; whether there are alternative test methods that could be used; whether the proposed testing is technically impossible; and whether an adequate justification based on an exposure assessment is available. This last point particularly displays that in examining the proposal ECHA not only assesses the proposal itself and the hazard of the substance, but also the likely risk to the community and environment. Substances whose use results in widespread and diffuse exposure will be prioritised for testing and so examination of chemical safety reports (CSR) forms a key part of the evaluation.

Results of an evaluation

Every testing proposal involving vertebrate animals is published by ECHA to allow for comment by third parties before a draft decision is made. Options for this draft decision are:

Acceptance of the testing proposal

Where a testing proposal is justified and adequate, it should be accepted by ECHA. ECHA will notify the registrant concerned to carry out the proposed test and the date by which it must be conducted.

Acceptance of the testing proposal with modifications to the test conditions

A testing proposal may be justified, but the proposal itself not deemed adequate by ECHA. Where modifications are requested the decision will state why and what modifications are expected.



Acceptance or rejection of the testing proposal but requiring one or more additional tests

In order to fulfil the REACH requirements, ECHA may feel it necessary for another test to be undertaken before examining further the need for the proposed test; or alternatively the result of the proposed test may dictate a requirement for additional tests. Where one or more additional tests are requested, ECHA will notify the applicant stating the nature of the tests.

Rejection of the testing proposal

If the justification made by the registrant is deemed not to be acceptable, or the information is already available, the testing proposal should be rejected by ECHA. The registrant will be notified of the rejection and the reason for it, but the registrant may appeal the decision.

Multiple proposals for the same substance

Where multiple registrants manufacture or import the same substance, they should create a joint submission to limit the costs and reduce testing. There are reasons however, why separate submissions may be made for the same substance, and testing proposals may also be made by downstream users. Where this has occurred ECHA will examine all testing proposals at the same time and establish whether all proposed tests must be undertaken or whether a single test may suffice. ECHA will enter into an informal discussion with the registrants and downstream users concerned in order to reach an agreement on who will perform the tests and how costs will be shared. If agreement is not reached, ECHA shall designate one of the parties to perform the test on behalf of all registrants or downstream users.

Need further help?

If you are unsure how to submit a testing proposal to ECHA, or need assistance in finding a company to perform the required testing, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.