

Overview of REACH Registration Opt-out process



Many of the actions involving opt-out due to disproportionate costs being levied by a Lead Registrant must be conducted by the opt-out registrant and cannot be performed directly by Stewardship Solutions. For this reason, it is essential that the client follows the correct procedures under the guidance of Stewardship Solutions consultants.

The workflow described below is subject to change in light of the dialogue between the client, lead registrant, ECHA and national REACH competent authorities.

Key steps towards a successful REACH opt-out registration may include:

1. Client to request a breakdown of Letter of Access (LOA) costs from the Lead Registrant.
2. If no response/ unsatisfactory response is obtained, client will make his own offer to obtain the LOA for a fair and equitable sum of money, previously established by Stewardship Solutions.
3. If the offer is not accepted, client will explain the circumstances leading to the rejection of the financial offer to his national REACH Competent Authority. ECHA may also be informed.
4. Stewardship Solutions will generate an individual REACH-compliant IUCLID dossier in the name of client. The dossier will include completion of all endpoints relevant to the registration tonnage, through measures including:
 - a. use of public information;
 - b. read-across to similar substances or in the form of justified waivers;
 - c. purchase of selected data if necessary;
 - d. commissioning of new non-vertebrate studies.
5. Client will make a fair and equitable offer to purchase any animal test data held by the Lead Registrant to include in the IUCLID dossier.
6. If offer is refused, Stewardship Solutions will advise on next-steps, including further engagement with the national REACH Competent Authority and ECHA. The aim will be to obtain the token necessary for a Joint Submission registration with opt-outs.
7. With the support of Stewardship Solutions, Joint or Individual submission will be made, and client will pay fees to ECHA.

For further information, please contact:

Dr Chris Eacott

Stewardship Solutions Ltd

e: chriseacott@stewardshipsolutions.co.uk

t: +44 (0)1706 220901

m: +44 (0)7834 676908

w: www.stewardshipsolutions.co.uk