Guidance on Substance evaluation

What is substance evaluation?

Evaluation has a role to play in all parts of the REACH Regulation. Not only is it the process by which dossiers are checked to ensure compliance with registration requirements, but it is also one of the processes by which substances may be identified as candidates for Restriction or Authorisation.

Substances are evaluated by Member States to establish whether their use poses a risk to human health or the environment, and whether these risks are sufficiently controlled by the measures identified in registration dossiers.

Selection of substances for evaluation

The general criteria which leads to a substance being selected for evaluation are listed in Article 44 of REACH, however the criteria were refined in 2011. As the process of substance evaluation is looking at risk, both hazard-related and exposure-related criteria are considered. These are shown in the table below:

Hazard-related selection criteria	Exposure-related selection criteria
- Suspected or known PBTs or vPvBs	- Wide dispersive use
- Suspected endocrine disruptors	- Number of using sites
- Suspected or known CMRs	- Consumer use and exposure of sensitive subpopulations
- Suspected or known sensitisers	- Aggregated tonnage

Identification of a substance meeting any of the above criteria does not automatically mean the substance will be subject to evaluation. Those substances recommended are ranked in order of priority with some being discounted due to the fact they are already subject to regulatory measures. Those that are going to be evaluated will be included in the Community Rolling Action Plan (CoRAP).

CoRAP

The first CoRAP was published on 29th February 2012 and, at that time, it contained 90 substances, 36 of which were to be evaluated in 2012 with the rest designated for evaluation in 2013 and 2014. The CoRAP list is updated on an annual (Q1) basis. Each substance on CoRAP is assigned to an evaluating Member State Competent Authority (MSCA) who is responsible for the evaluation process.

A list of substances included on the CoRAP can be found at Substance evaluation - CoRAP - ECHA (europa.eu) where there are details of not only the substance but the year in which it is to be evaluated and, importantly, the MSCA responsible for the evaluation.

Actions following evaluation

The evaluating MSCA has a period of 12 months, following publication of the CoRAP list, to evaluate the available information on the substance. Following this, they will either: produce a draft decision stating the need for further information; or notify ECHA that no further information is needed as the risks are considered to be sufficiently under control. Draft decisions will be sent to the registrants of the substance concerned for comment, before a final decision on information requirement is made. This final decision will state a deadline by which further information must be submitted by the registrants, which then be used by the MSCA to complete the evaluation. In concluding the MSCA may again confirm the risks associated with the substance are sufficiently controlled; or may suggest any of the below follow-up actions:

- Identification of the substance as a substance of very high concern (SVHC), potentially leading to an authorisation proposal.
- A proposal for a restriction to be placed on use of the substance in certain applications.
- A proposal for harmonised classification and labelling
- Need for other EU-wide measures (e.g. Occupational Exposure Limits)
- Need for action at national level, or voluntary action by industry.

What should registrants do?

If a substance is on the CoRAP list for this year

Keep an eye on your REACH-IT inbox! The evaluating MSCA will make contact using this tool and it is important to be able to act upon any information requests as quickly as possible. Where there have been a number of registrants for a substance, contact will usually be made through the Lead Registrant so it is also a good idea to contact the other companies to coordinate involvement in substance evaluation. When a draft decision is made, it would be best to comment with 'one voice'. If any testing is proposed it should be decided who will perform the studies and how costs and data will be shared. Ensure there is regular communication with the MSCA and that dossiers remain up-to-date.

If a substance is on the CoRAP list for one of the next two years

Get started early! The CoRAP list will inform not only of the year a substance will be evaluated but also the evaluating MSCA. Contact the MSCA and ensure your dossier remains up-to-date. Co-ordination with other registrants is key and contact should be made with downstream users to ensure all exposure information is included in the registration dossier. The CoRAP is updated annually, with a draft of the following year's update available from October; monitor the CoRAP to ensure a substance hasn't been removed or that no new substances of interest have been added.

Need further help?

If a substance you have registered is included in the CoRAP, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.