Newsletter
helpdesk luxembourg
REACH & CLP
Un service du Centre de Recherche Public Henri Tudor
En partenariat avec le Ministère du Développement durable et des Infrastructures, et le Ministère de l'Economie et du Commerce extérieur

Dossier and Substance Evaluation

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Title VI REACH* defines two evaluation procedures: dossier evaluation (Art. 40-43) including the examination of testing proposals and compliance check of registrations, and substance evaluation (Art. 44-48). The evaluation procedures differ in their aim, target and possible outcome. In all procedures, registrants** can be obliged to provide additional data but also have the possibility to participate in the different steps.

Aim, basis and outcome

	Dossier evaluation[1]		Substance evaluation
	Evaluation of testing proposals	Compliance check	
Aim	Produce reliable and adequate data in compliance with REACH and avoid unnecessary animal testing	Assure compliance of registration dossiers with the REACH requirements[3]	Clarify a concern that a substance constitutes a risk to human health or the environment
Target[2]	All testing proposals submitted as part of a registration dossier	At least 5% of the registration dossiers for each tonnage band	Registered substances selected and listed in the CoRAP (see box)
Check	Registration dossier and testing proposals of the registrant and Outcome of public consultation for vertebrate tests versus the data requirements and waiving options in Annex IX and X REACH	Registration dossier of the registrant: • Data requirements of Articles 10-13, Annexes III and VI-X REACH • Adaptations of the standard information requirements • Chemical safety assessments/reports • Risk management measures • Justifications for separate submission	All available information on the substance (if reasonable also on related substances), in particular those relevant for the identified concern
Possible outcome	ECHA Decision: Registrant to do • the proposed test • the proposed test with modifications • one or more additional tests • no test	• ECHA Decision: Registrant to submit any missing information required according to the REACH Annexes • Quality Observation Letter: Registrant to increase quality of the dossier • No further action (dossier is already in compliance)	• ECHA Decision: Registrant(s) to submit any needed information • Further actions by authorities within REACH&CLP (authorisation, restriction, classification and labelling) • Further actions by authorities outside REACH&CLP • Voluntary actions by registrant(s) • No further action (no risk identified)

[1] Before the actual evaluation, an automatic completeness check is undertaken as part of the registration process. However, it is purely technical without assessing the quality or adequacy of any data or justification submitted.

[2] On-site isolated intermediates that are used under strictly controlled conditions are exempted from evaluation.

[3] The compliance check can evaluate the whole dossier or can be targeted to a specific area of concern (e.g. substance identification). For more details, see ECHA's Q&A on targeted compliance checks.

CoRAP

The CoRAP (Community Rolling Action Plan) lists all substances selected by ECHA and Member States for substance evaluation in the three upcoming years. It is updated once a year. An inclusion of a substance in the CoRAP does not cause additional obligations.

Substances are selected based on information on hazards, exposure, tonnage (aggregated for all registrants), concerns identified in dossier evaluation, and concerns identified by Member States.

See also ECHA's Q&A on CoRAP and substance evaluation.

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** Regulation (EC) 1907/2006 for Registration, Evaluation, Authorization and Restriction of Chemicals*

*** Downstream users may under certain conditions also submit a Chemical Safety Report and testing proposals (see Article 37(4) REACH). When reference is made to the registrant in this newsletter, it applies in the same way to such a downstream user.*

Steps and possibilities for interaction

Step	Actor	Company action
1. Dossier evaluation		
Evaluation of the testing proposal (deadlines see Article 43 REACH), or Compliance check of the registration dossier (within 12 months after start)	ECHA	• No specific actions; follow your REACH IT account closely • Update dossier before the target date stated in a quality observation letter (QOBL) received from ECHA (only for compliance check)[1]
Adoption of the ECHA Decision	ECHA, MS, optionally also MSC and COM	• Comment on ECHA's draft decision within 30 days (testing proposal: 90 days if more than one registrant); use also the ECHA offer to have an informal exchange on the draft decision, update dossier if needed • Comment on proposals for amendment by Member States (MS), if any • Participate in meeting discussion of proposals for amendment in the Member States Committee (MSC), if any • Agree with other registrants of the substance, if any, on who generates the requested information (incl. cost and data sharing) • Prepare and submit the requested data to ECHA within the deadline fixed in the final decision and update dossier[2]
Evaluation of submitted information	ECHA	No specific action; if further data is needed, ECHA will restart the process; if request is not fulfilled, ECHA informs MS of non-compliance (enforcement)
2. Substance evaluation		
Selection of substances (CoRAP)	ECHA, MS	Follow the annual update of the CoRAP
Evaluation of the substance (within 12 months after start)	eMSCA	• Contact the evaluating Member States Competent Authority (eMSCA) for that substance early in the process to clarify the initial concern and to see if additional data can be provided (if so, update dossier) • Communicate with other registrants of the substance
Adoption of the ECHA Decision (on request of further data from the registrant, if any)	ECHA, MS, optionally also MSC and COM	• Comment on ECHA's draft decision within 30 days (ideally one joint comment for all registrants of the substance), update dossier if needed • Comment on proposals for amendment by MS, if any • Participate in meeting discussion of proposals for amendment in the MSC, if any • Agree with other registrants of the substance, if any, on who generates the requested information (incl. cost and data sharing) • Prepare and submit the requested data to ECHA within the deadline fixed in the final decision, and update dossier[2]
Evaluation of submitted information and finalisation of substance evaluation	eMSCA	Follow the finalisation of the substance evaluation and the identification of possible follow-up actions

[1] The QOBL is a communication by ECHA identifying shortcomings in a dossier that may be relevant for the safe use of the substance. It is an independent outcome of a compliance check although it is often sent at the same time as the ECHA draft decision.

[2] Instead, a registrant can decide to cease the manufacture or import, and inform the Agency accordingly (for details see Art. 50 REACH). Besides this, the addressee of an ECHA Decision has also the right to appeal before the ECHA Board of Appeal.

General information and guidance for companies

- Practical guide 12: How to communicate with ECHA in dossier evaluation
- Substance evaluation under REACH: Tips for registrants and downstream users and webinar.
- REACH&CLP Helpdesk Luxembourg – Webesection Evaluation
- ECHA – Webesection on Evaluation with ECHA annual Evaluation progress report with valuable tips, ECHA Guidance on dossier and substance evaluation, ECHA Guidance on priority setting for evaluation, ECHA Factsheet on substance evaluation, and ECHA Procedures on dossier and substance evaluation.

Some final remarks

- For some, but not all steps of the three evaluation procedures, deadlines are defined (some mentioned above), namely in Articles 40(2-3), 41(3), 43(1-2), 46(1+3), 50(1) and 51 REACH.
- In dossier evaluation, only data required in Annexes VII to X REACH will be requested from the registrant. In contrast, any information identified as needed, can be requested in the substance evaluation process.