1 What is the status of EU REACH registration and dossier evaluation?

Under EU REACH, the manufacturer or importer shall apply for registration for substances manufactured or imported in quantities more than one ton per year. The registration must be successfully completed and a registration number assigned to the registrant before a substance can be manufactured, imported or placed on the EU market. From 1st June 2008 until 28th February 2025, 109 251 valid registrations has been granted by ECHA with 22 948 substances and 18 239 companies involved.

Following registration, ECHA will evaluate the dossiers, which includes conducting compliance checks and examining testing proposals to ensure the quality and adequacy of the submitted data. Between 2009 and 2024, ECHA have checked the compliance of 15 500 registrations, representing 23 % of all submitted registration dossiers and covering 3 200 substances. Regarding high-volume chemicals registered at quantities of 100 tons or more per year, 34 % have been checked.

2 Why does authority evaluate dossiers?

Once registrants have submitted registration dossiers and passed the completeness check, ECHA will assign the substances with registration numbers. However, the completeness check of the registration dossier does not include an examination of the quality or adequacy of the data submitted. ECHA evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals to check whether registrations are in compliance with the requirements of REACH Regulation and to clarify if a given substance constitutes a risk to human health or the environment.

3 What are evaluated under dossier evaluation?

Dossier evaluation consists of examination on testing proposals (TP) and compliance checking (CCH).

After registrants submit testing proposal (TP) for data endpoints in Annexes IX and X to REACH for high tonnage substance registration, ECHA has the duty to examine all testing proposals in the registration dossiers, they will always evaluate the justification for conducting the proposed test, as well as the test design registrants have submitted. The registrants are not allowed to undertake new studies listed under Annex IX or Annex X to REACH before ECHA has taken a decision on the proposed tests.

For compliance checking, ECHA shall check that the substance has been identified appropriately. ECHA verifies whether the information submitted fulfils the requirements in Annexes I, III, VI and VII to X, or the general rules for adaptation as described in Annex XI. ECHA checks that the classification and labelling of the substance reported in the registration dossier is consistent with the information provided in the dossier and in line with the legal classification and labelling rules defined in the CLP Regulation10. ECHA may also check whether the information provided in the chemical safety report (CSR) is consistent with the information in the registration dossier and in compliance with Annex I to REACH.

4. What is the procedure under dossier evaluation?

Step 1 Before Draft Decision

- ECHA Selects the substances and dossiers which are meeting the priority criteria.
- ECHA assesses the information provided in the dossiers and lists in the draft decision the tests requested (under compliance check or testing proposal examination)

Step 3 After Final Decision

- The registrants need to inform ECHA on who will conduct the tests.
- The registrants must submit the requested information by the deadline indicated in the decision

Step 2 Decision Making

- ECHA sends the draft decisions to the registrants concerned by the non-compliances and the decision-making process is initiated
- At the end of the process ECHA adopts the decision

Step 4 After the deadline

- ECHA assesses whether the information submitted fulfils the requests in the decision and the corresponding information requirement.
- If the information requested is not submitted or not fulfilling the requests, another decision may be prepared and national enforcement actions will be launched.

5. What shall applicants act properly to reach compliance under dossier evaluation?

✓ **Before receiving the Draft Decision**

- Keep eyes on REACH-IT and ECHA website, check the evaluation status
- Ensure that the information and data in the dossier are up to date (new hazardous information and uses)

✓ **After receiving the Draft Decision**

- Consider whether to stop production or import. Cease of manufacture and/or import upon receipt of the draft decision, then you don't have to fulfill further obligations.
- Reduce your registration tonnage band, and you have to provide relevant documents to proof that actual export tonnage in preceding years is lower than tonnage bands after downgrading, then you are only obliged to fulfill the obligations under lower tonnage bands.

✓ **After receiving the Final Decision**

- All registrants collectively identify who shall perform the additional tests;
- The designated registrant (usually the LR) to conduct the testing;
- LR submits the requested information in an updated registration dossier and CSR by the set deadline;
- Co-registrants share the costs of the tests and update the individual part of joint registration dossier