Feedback from evaluation

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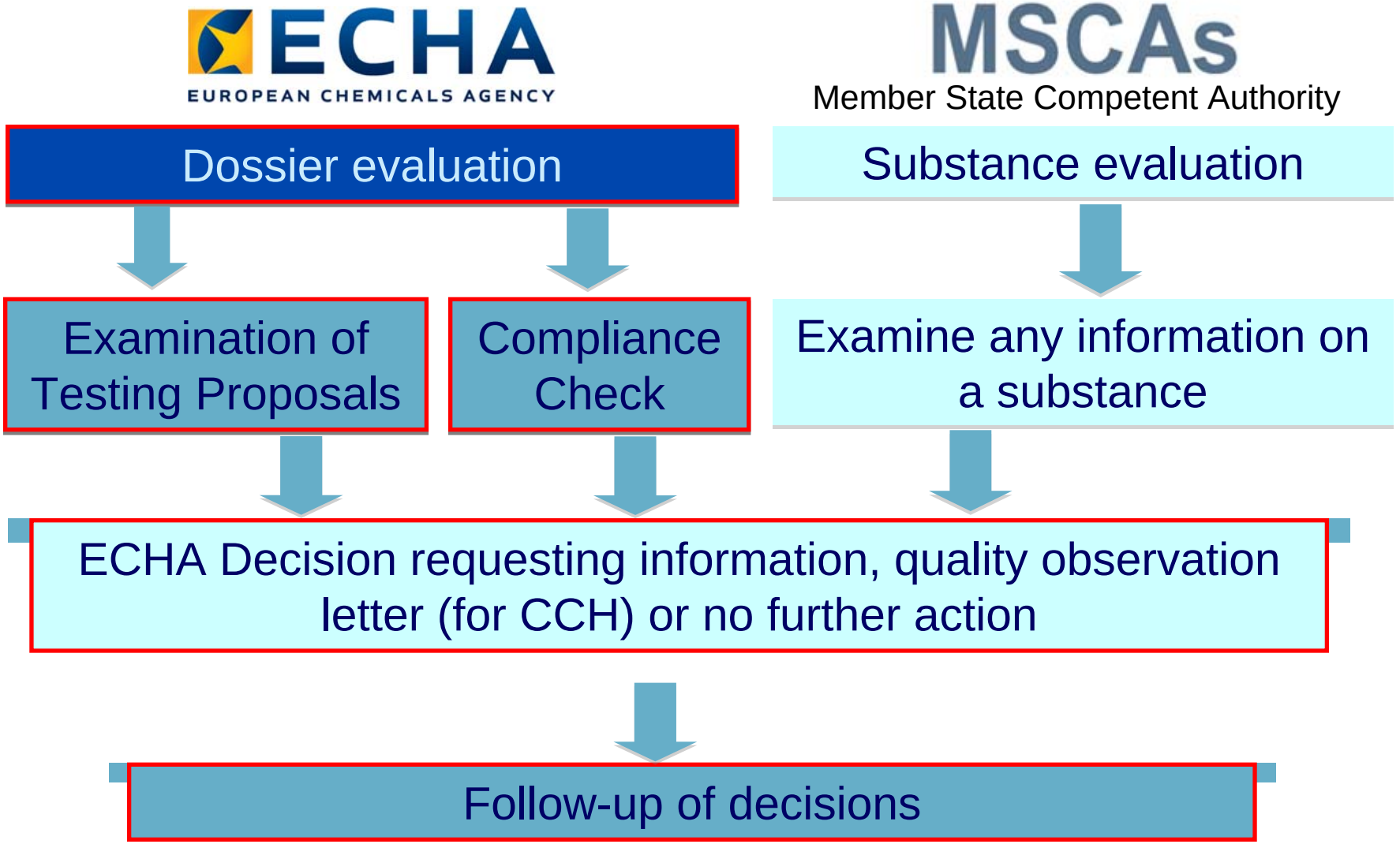
Dossier Quality

- Good quality information in registration dossiers is needed to ensure the safe use of chemicals
- REACH places the responsibility on companies to ensure safe use of their substances and compliance
- Evaluation (the “E” in REACH) is there to support registrants in their obligation to provide adequate information on registered substances
- The main findings of the evaluation processes are reported each year in Evaluation reports (since 2008)

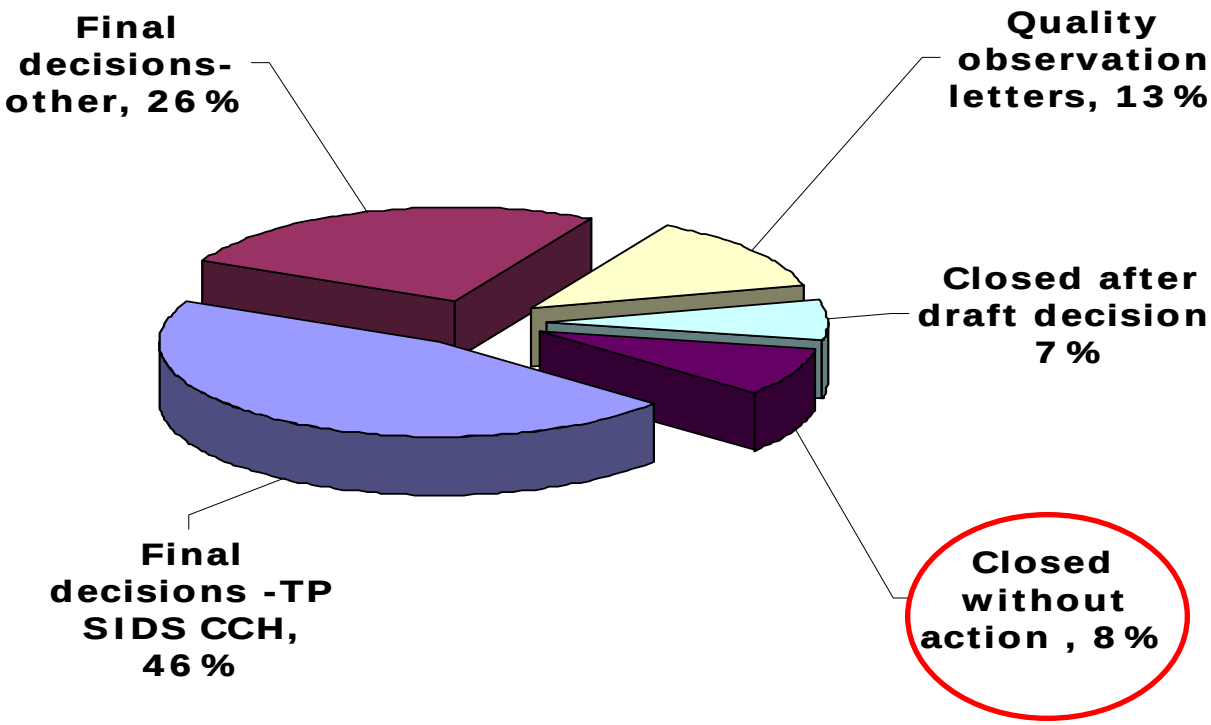
Evaluation Progress Report 2011

- Annual Report
- On ECHA website, now available in 22 languages
- Progress in our activities
- Information on common pitfalls
- Recommendations
- All (existing and future) registrants are strongly advised to read this report

Evaluation - Overview



Dossier quality - Compliance checks 2011



Example scientific issue – Need for clear Substance Identity (SID)

- Defines the scope of your registration
- Is a pre-requisite for a sound hazard and safety assessment
- Is needed to conclude on testing proposals and dossier compliance

- Therefore:
  - Deliver appropriate analytical information on the substance as manufactured
  - Make sure that the substance identity and the test material used in studies are representative for the registered substance.

Example administrative issue - Testing proposals not made correctly

- Higher tier information gaps (Annexes IX and X) require the submission of a TP
  - Under the relevant IUCLID endpoint in the section “study result type” select “experimental study planned” from the drop-down menu
- TPs have not been submitted correctly
  - TP provided only in the Chemical Safety Report
- TPs have been omitted
  - TP omitted awaiting the outcome of planned/ongoing lower tier test

Therefore,

- Learn from the Evaluation Progress reports
- Urgently update your dossier with testing proposals where necessary.

Improving dossier quality

Compliance check

- ECHA uses compliance checks to see if information from registrants fulfills the legal requirements.
- At least 5% of all registration dossiers received within each tonnage band to be checked.
- ECHA can decide which dossiers to check
- Dossier selection is either random or based on concern-driven criteria
- Mix of approaches allows different aspects of poor quality to be addressed (e.g. all or specific aspects of a selected dossier)

Improving dossier quality by targeted Compliance Checks

- Complements current compliance check activities
- Aimed at having maximum impact on safe use of chemicals
- More efficient use of limited ECHA Evaluation resources
- ECHA will target compliance checks to specific dossier issues (e.g. endpoints) that have immediate impact on safety
- Poor information on these endpoints affects safety and reliability of the chemical safety assessment

And how will it work?

- ECHA and Member State Competent Authorities identify dossier issues (e.g. endpoints) where safety matters
- IT tools screen **all** submitted registration dossiers to identify suspicious dossiers with respect to the specific concern
- The specific endpoints in selected dossiers are then evaluated manually under a REACH compliance check
- Criteria for automatic selection for checking will include, *inter alia*:
  i) Individual registrations outside of a joint registration;
  ii) Dossiers where the Chemical Safety Report is missing
- If incompliant, the registrant receives a compliance check decision from ECHA

Effects of the new CCH strategy 1(2)

- REACH does not limit the number of compliance checks so registrants with a number of incompliances in a dossier may get multiple decisions
- Registrant has an opportunity to make formal comments
- ECHA does not foresee an opportunity for informal communication with ECHA during the 30-day commenting period due to the high numbers of such targeted CCH draft decisions

Therefore:

- Registrants are encouraged to proactively update their dossiers to avoid multiple decisions
- Doing a good job from the start and is worth the effort and will help you avoid getting one or more draft decisions

Effects of the new CCH strategy 2(2)

- Rewards companies that do a good job by addressing poorly performing companies effectively
- The chances of poor quality dossiers being picked up for compliance check are much higher with the new approach
- Companies have the last chance to update their dossiers before they are picked up for evaluation – **improve your dossier quality now**!
- Monitoring and follow-up of compliance with the ECHA decisions is an integral part of Evaluation

Take-home messages

- Keep yourself up-to-date with Evaluation Progress Reports and act to avoid common pitfalls
- Keep your dossiers up-to-date
- Join or follow our events
- Joint registration is not an option, it is a legal obligation
- Do not wait for a draft decision – **improve your dossier quality now**!

Thank you.

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