



Quality information is required to comply with REACH

EVALUATION REPORT 2012 - MAIN OUTCOMES AND KEY RECOMMENDATIONS FOR INDUSTRY

If your company is preparing for the next registration deadline, you can use the analysis and recommendations from ECHA's Evaluation Reports to ensure that your dossier is compliant with REACH. If you have already registered and realise that your dossier can be improved, be proactive and update it in line with these recommendations before ECHA opens it for evaluation. As a downstream user, you may also find the recommendations useful because they may help you to communicate with your suppliers.

The most frequently found shortcomings in registration dossiers addressed by an ECHA decision in 2012 related to information on substance identity (66 %), exposure assessment and risk characterisation (23 %), prenatal developmental toxicity study (26 %) and sub-chronic toxicity study (18 %).

The recurrent nature of these shortcomings provides a good basis for the recommendations to new and existing registrants detailed in the 2012 Evaluation Report.

NEW WAYS OF WORKING

In 2012, ECHA introduced a new approach for selecting dossiers for compliance checks. An advanced data analysis tool identifies dossiers with typical shortcomings and thereby streamlines ECHA's evaluation activities. With this new approach ECHA targets information requirements where safety matters most. Used in combination with full or concern based compliance checks, it increases the chance of non-compliant dossiers being evaluated and consequently helps to improve the overall quality of information in the registration dossiers.

In a move towards greater transparency, ECHA also started to provide non-confidential versions of adopted evaluation decisions on its website. This means that evaluation decisions taken by ECHA addressed to you will be made public.

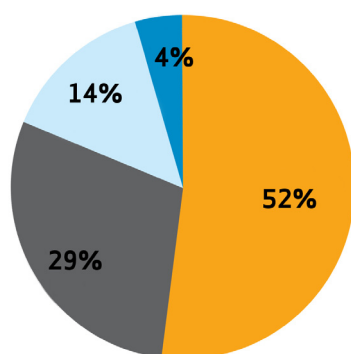
The Agency also developed, in cooperation with the Member States, a procedure to follow up on ECHA's evaluation decisions. Essentially, registrants who do not update their dossiers by the deadline given to them in the decision, will have their case referred to the enforcement authorities in the Member States.

OUTCOME OF DOSSIER EVALUATION

ECHA examined all proposals to test substances registered in 2010 by the legal deadline of 1 December 2012. This means 557 dossiers which contained adequate description of the substance identity were examined.

Where the identity of the substance was not clear, ECHA had to suspend the examination of testing proposals and seek clarification from the registrants. This was the case for 128 dossiers. In 59 cases, the registrants clarified the substance identity. In 55 cases resolving the substance identity issues had to be done in parallel with the examination of the testing proposal. In the remaining cases, ECHA has informed the Member States of the continuing incompliance.

Outcome of testing proposal examinations in 2012

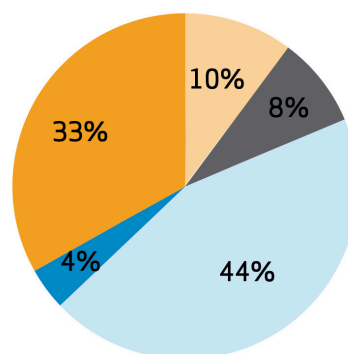


- Draft decisions
- Decisions taken
- Closed - testing proposals inadmissible or withdrawn
- Continue in 2013

In 2012, ECHA concluded 354 compliance checks. Using the new targeted compliance check approach, the Agency opened 295 dossiers and sent 183 draft decisions.

The outcome of the compliance checks suggests, as in previous years, that the quality of the information needs to be further improved to ensure the safe manufacture and use of chemicals. In 2012, only in a third of the cases could ECHA close the compliance check without action. In the remaining cases, ECHA had to take an action, urging registrants to improve their dossier.

Outcome of compliance checks in 2012



- Decisions taken on substance identity for a dossier prior to a testing proposal examination
- Decisions taken
- Draft decisions
- Closed - upon dossier update after draft decisions
- Closed without actions

EVALUATION - SCRUTINISING THE QUALITY OF YOUR REGISTRATION

Draft decision - As registrant, you can comment on it. Read the draft decision carefully and act upon it. If the dossier is updated as required before the draft decision is referred to the Member States, there may be no need for an ECHA decision to be taken.

Decision taken - Legally binding decision sent to you requiring you to submit information within a specified

deadline. Takes effect after the three months appeal period. ECHA informs the Member State competent authorities and publishes the non-confidential version on its website.

Follow-up - ECHA evaluates whether the new information you provided by the deadline set out in the decision requires further action. When the information requested was not provided, ECHA informs the Member States of the continuous incompliance. It is then for the national enforcement authorities to take action.

KEY RECOMMENDATIONS FOR REGISTRANTS

Identify clearly your substance

Whether you are a lead or a member registrant, you are responsible for providing the information that is specific to the substance which is manufactured or imported by you. When a substance concerned by the registration cannot be identified the registration may be considered invalid.

Actions to take

- Clearly and specifically identify the substance as marketed by you. This should be your first and most important step.
- Provide analytical data that comes directly from the substance you put into the supply chain.

ECHA support: Guidance on the identification and naming of substances under REACH and CLP and an updated Data Submission Manual – Part 18, on reporting substance identity in IUCLID 5.

For all uses, provide clear information on use and exposure

The uses of the substance covered by your registration should reflect the market reality. The description should cover all relevant uses, exposure scenarios, operational conditions and risk management measures.

Actions to take

- Describe the actual use of your substance, not hypothetical uses.
- Member registrants – you need to make sure that the use description in your technical dossier covers your actual use.
- Make sure that your use descriptions and exposure assessments are realistic and understandable for downstream users.
- Downstream users, ensure that your uses are covered by a registration dossier.

ECHA support: Updated IUCLID templates. Chesar software. The Exchange Network on Exposure Scenarios (ENES), which promotes good practice. Examples of chemical safety reports and exposure scenarios.

Demonstrate the relevance of the test material

Your test data is only useful if via the identity of the test material it can be linked to the registered substance and its uses.

Actions to take

- Identify the test material clearly and ensure that it is representative for the registered substance.
- Make sure that the test material is representative for all relevant forms from all registrants in joint registrations.

ECHA support: Identification of the test material should follow the same lines as identification of the substance registered - use Guidance for identification and naming of substances under REACH and CLP

Make good use of information and alternative approaches

Under REACH, the first step for addressing environmental and health hazards is to gather existing and relevant information and consider alternative approaches to fill any data gaps. Testing in vertebrate animals can only be used as a last resort.

Actions to take

- Conduct a search of the scientific literature for relevant information on your substance and make it available in your dossier.
- Use that information to classify your substance according to the CLP Regulation.
- If you build your dossier on read-across hypothesis, support it with scientifically credible information and factual data.
- Where necessary, propose the experimental studies required by REACH, but only start them after receiving ECHA's decision.

ECHA support: Guidance on information requirements and chemical safety assessment; Guidance on the application of the CLP Criteria; Practical guides; Information toolkit (for using existing information and non-test methods)

FIND OUT MORE IN THE ANNUAL EVALUATION REPORTS.

Evaluation under REACH - Progress Report 2012 and previous reports can be downloaded from ECHA's website at: echa.europa.eu/evaluation

Further information

- REACH 2013 web section: echa.europa.eu/2013
- ECHA support web pages, including links to guidance on REACH and CLP implementation, practical guides and examples, webinars and contacts of ECHA and national helpdesks: echa.europa.eu/support

REGISTERING A SUBSTANCE IS A LONG-TERM COMMITMENT

You need to set up a business routine to ensure your dossier is kept up to date.

Consider the publication of the annual evaluation reports in February each year as an important milestone for reviewing your business arrangements for complying with REACH. Every year, ECHA provides recommendations based on the most common shortcomings in the evaluated dossiers and builds up its support to new and existing registrants.

