ECHA
EUROPEAN CHEMICALS AGENCY

EVALUATION REPORT 2011

ECHA-FS-12-05-EN

Summary of Evaluation Report 2011

EVALUATION OF REACH REGISTRATION DOSSIERS

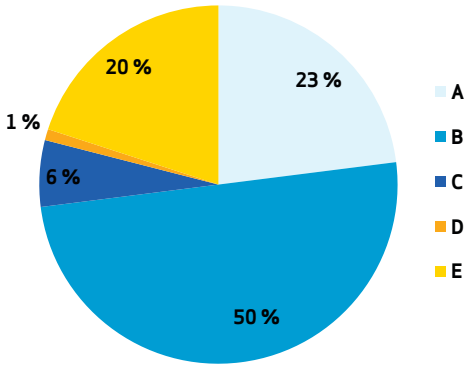
Companies, which have to register substances by the next REACH deadline of 31 May 2013, are strongly advised to use the recommendations from the 2011 Evaluation report to ensure that their dossiers are compliant. Existing registrants are urged to update the dossiers they have already submitted in line with the recommendations before ECHA opens them for evaluation.

This document presents the main findings and highlights the key messages to companies from the 2011 evaluation progress report.

OUTCOME OF DOSSIER EVALUATION

As part of dossier evaluation, ECHA examines all proposals to test substances as specified in REACH. It also checks at least 5% of all registration dossiers for compliance with the legislation. In 2011, the Agency gave priority to testing proposals. ECHA needs to examine all proposals for experimental studies submitted by the 2010 registration deadline by 1 December 2012. The Agency has made significant progress towards meeting this target.

ECHA had to open more dossiers for compliance checks than initially planned because in about a quarter of the dossiers containing testing proposals, the substance identity was ambiguous and needed to be clarified by the registrant before the proposals could be examined. Consequently, the Agency checked the compliance of 239 dossiers and examined 216 testing proposals.



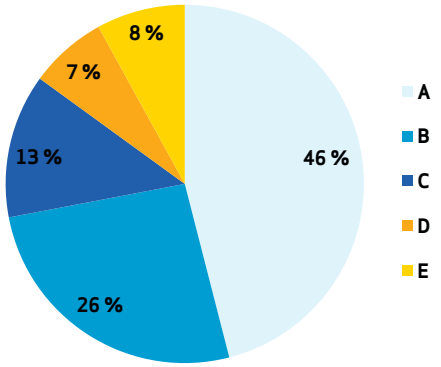
TESTING PROPOSALS:

A	Ongoing - in compliance check due to ambiguous substance identity;
B	Draft decision;
C	Final decision - testing proposal accepted;
D	Final decision - testing proposal modified;
E	Closed - testing proposal inadmissible (e.g. test already requested under other legislation)

Draft decisions –Registrants and Member States can comment before it becomes final.
Final decisions – Legally binding decision sent to registrants requiring them to submit information within a specified deadline.
Quality observation letter – A letter sent to registrants indicating shortcomings in the dossier.
Closed – evaluations, which did not result in final decisions.

A large part of the testing proposals had been adequately prepared and ECHA was able to accept them upon examination. In some cases however, ECHA needed to refine the approach; modify the studies proposed or clarify the identity of the substance registered by opening a targeted compliance check before the proposed test could be examined.

In the compliance checks, only a small proportion of the dossiers were closed without further action. The most frequent shortcomings addressed through final decisions refer to substance identity (72%); in vitro mutagenicity studies (16%); exposure assessment and risk characterisation (9%) as well as robust study summaries (8%). The 2011 evaluation report provides recommendations to registrants on how to address these issues.



COMPLIANCE CHECKS

A	Final decision - substance identity checked for a dossier with a testing proposal;
B	Final decision - a dossier without testing proposal;
C	Quality observation letter;
D	Closed - upon dossier update after draft decision;
E	Closed - no regulatory action

KEY MESSAGES TO REGISTRANTS

Substance Identity

When a substance is not well defined, this may not only signal that the dossier contains more than one substance, but also undermines the pertinence of the hazard data, the risk assessment and consequently the risk management measures on how to use the substance safely.

Recommendations:

- Define your substance precisely and unambiguously. The identity and composition specified in the registration dossier needs to be supported by appropriate analytical information on the substance manufactured.
- Make sure that the substance identity and the test materials used in studies are representative for the registered substance.

ECHA Support: Guidance on the identification and naming of substances under REACH, updated in 2011 to align it with the CLP Regulation

Use of Read Across

Read across makes best use of existing data and can avoid unnecessary testing on vertebrate animals. However, this only holds true when the read across is scientifically justified and well documented. The registrant must ensure that the information needs are covered for all properties as they would be with the standard test data on the substance.

Recommendations:

- Justify your read across approaches with sound reasoning, scientific evidence and available experimental data.

ECHA Support: Practical Guide 6 – How to report read across and categories

Chemical Safety Assessment

The Chemical Safety Assessment is crucial for the safe use of chemicals. If the assessment does not cover all the relevant hazards, uses and exposures, then the risks are not properly identified and remain uncontrolled. Consequently, the main aim of REACH, i.e. the safe use of chemicals, cannot be achieved.

Recommendations:

- Be thorough in completing the chemical safety assessment.
- Classify the substance according to the CLP Regulation.
- Cover all identified hazards and uses in the exposure scenarios.
- Demonstrate the safe use of your substances in the chemical safety report.
- Provide advice on the safe use of your substances and communicate it to your customers in complete safety data sheets.

ECHA support: Special tool for preparing the chemical safety assessment and report (Chesar) and examples of exposure scenarios

FURTHER INFORMATION

Evaluation under REACH - Progress Report 2011 and previous reports can be downloaded from ECHA's website at: echa.europa.eu/evaluation
REACH 2013 web section: echa.europa.eu/2013
ECHA support: echa.europa.eu/support