ECHA
EUROPEAN CHEMICALS AGENCY

FACTS & FIGURES

ECHA-14-A-02-EN

Key recommendations for industry

Evaluation report 2013: knowing more, getting safer

EVALUATION OF REACH REGISTRATION DOSSIERS -
MAIN OUTCOMES AND KEY RECOMMENDATIONS FOR INDUSTRY

The annual report explains ECHA's evaluation activities in 2013, highlighting the most common shortcomings in registration dossiers and providing recommendations to registrants. To further improve the quality of registration dossiers, registrants are requested to proactively update their dossiers.

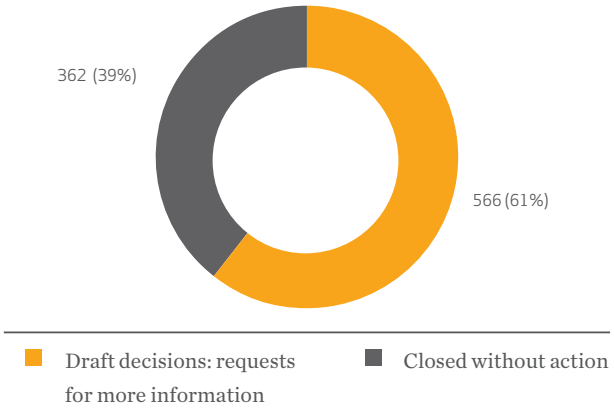
OUTCOME OF DOSSIER EVALUATION

ECHA examines all proposals to test substances in order to provide the data required by REACH. It also checks at least 5 % of all registration dossiers for compliance with the law.

In 2013, the focus of evaluation activities was on compliance checking. ECHA checked a total of 1 130 dossiers for compliance which were submitted for the 2010 registration deadline. Over a third of the substances registered for that deadline were covered by these checks.

The quality in registration dossiers still needs to be improved: in 61 % of the concluded compliance checks in 2013, ECHA requested more information from the registrants in draft decisions. The remaining 39 % of cases were concluded without the need for action.

Concluded compliance checks in 2013

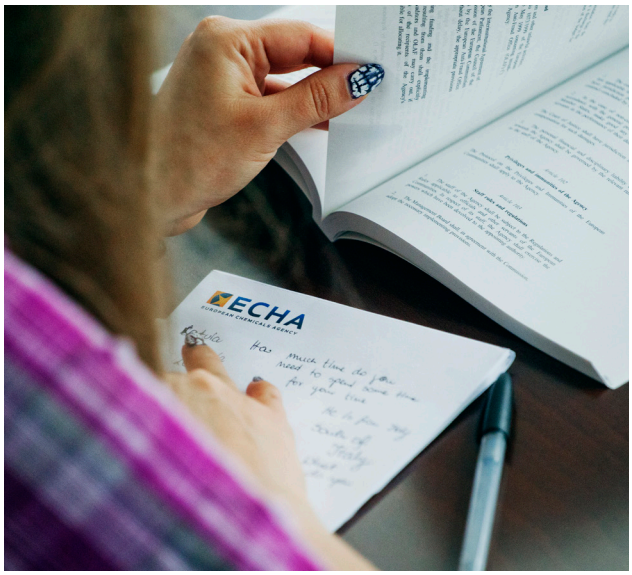


TESTING PROPOSALS

Regarding testing proposals, ECHA's focus was on examining dossiers which rely on read-across and category approaches. The Agency concluded 157 examinations and took 111 decisions. In 71 cases, ECHA accepted the tests proposed by the registrants and in 37 cases, it modified at least one of the proposed tests.

KEY RECOMMENDATIONS TO REGISTRANTS

ECHA's recommendations to registrants shift the focus somewhat from previous years. Whilst reminding registrants to keep registrations consistent and up-to-date, ECHA urges them to substantiate robustly any adaptation of the standard testing requirements. This time, specific attention is paid to the chemical safety reports. As more cases go through evaluation in 2014, there is also advice about how to react when receiving a (draft) decision, requesting for more information.



These recommendations are **relevant both to future registrants** preparing their registration dossiers **and to existing registrants** who need to update.

☐ Low-tonnage registrants (one to 10 tonnes/year) – pay attention to the following recommendations on yellow background.

1. Keep your dossier up-to-date

Relevant for low-tonnage registrants

It is your duty to submit and maintain a compliant registration, so be proactive: Integrate REACH compliance into your quality management system.

Your registration dossier must be consistent and reflect the reality of your business.

Keep talking in the SIEF (substance information exchange forum) and in your supply chain, even after receiving your registration number.

Check REACH-IT regularly: This is ECHA's way of contacting you about issues found in your dossier. If you receive a message, you need to respond promptly.

When you prepare your dossier, use all available support material from ECHA, including guidance, IUCLID plug-ins (particularly the Validation Assistant) and Chesar.

ECHA's webinars are an easy and interactive way to learn about common pitfalls and how to avoid them.

2. Know how to react if you get a (draft) decision

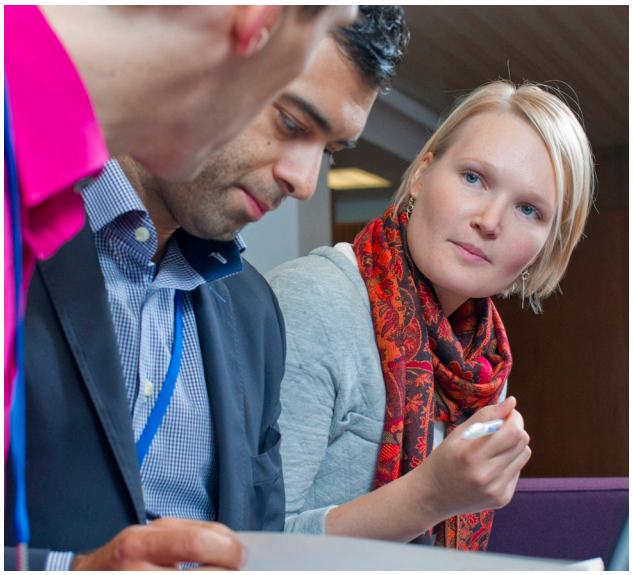
Relevant for low-tonnage registrants

Start to think carefully about how you will respond immediately after receiving a draft decision. The 30-day commenting period is your chance to give your views and bring your dossier into compliance.

It is even more important to keep talking in the SIEF if you receive a (draft) decision because it may impact on many registrants with the same substance: Endeavour to coordinate and respond to ECHA with one voice.

Understand the REACH decision-making procedure: The room for manoeuvre and the strict timing gets tighter as the process rolls on.

Remember ECHA and the Member States take regulatory action to help you and your customers to use the substance safely.



MOST FREQUENT SHORTCOMINGS

If ECHA finds information gaps when checking a dossier for compliance with the law, a decision is taken under REACH to request the missing information from the registrant. Most of these information requests in 2013 related to substance identity, physicochemical properties, sub-chronic toxicity studies, pre-natal developmental toxicity studies and exposure assessment.

3. Substantiate your reasoning if you adapt the standard testing regime

Relevant for low-tonnage registrants

Be specific on the legal basis for any adaptations you make and state it clearly at each endpoint; then justify and document how you have fulfilled the conditions that allow such an adaptation.

The adaptation needs to be adequate for the risk assessment, with a comparable level of confidence as the test it aims to replace.

For QSAR (quantitative structure–activity relationship), this means attaching the documentation in the right format in the right place, justifying fully why the model is valid and how it was applied to the substance. Just providing a number from an unspecified model will not do.

For read-across and category approaches, this means showing that the substances are very likely to be similar (eco-)toxicologically, preferably with a data matrix. A read-across hypothesis without a proper justification and supporting data will not be accepted.

If you need to propose a new test after all, do so explicitly by selecting "experimental study planned" at the endpoint in your IUCLID file.

4. The chemical safety report should reflect the actual uses and risks

If your substance is PBT (persistent, bioaccumulative and toxic) after careful assessment and checking the Candidate List, show clearly in the chemical safety report how you are minimising its release.

When you derive the DNEL (derived no-effect level), justify and document any deviation from the default assessment factors presented in REACH Guidance R.8 with scientific arguments that are specific to your substance.

When assessing the exposure, consider the scope of exposure assessment based on the hazards identified for the substance.

When using a model for estimating exposure, consider the domain of applicability of the model, use appropriate modelling parameters and justify their selection.

The exposure scenarios in the report must be transparent, have exhaustive coverage and each must be specific. The operational conditions and the risk management measures have to be provided in sufficient detail and should ensure safe use.

REGISTERING A SUBSTANCE: A LONG-TERM COMMITMENT

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

ECHA's evaluation reports serve as **a yearly reminder** on how to improve the quality of your registrations. Every year, the Agency provides recommendations based on the most common shortcomings in the dossiers evaluated. ECHA then also updates and improves its support for new and existing registrants.

USEFUL WEB PAGES

ECHA support web pages – links to:

- Guidance on REACH, CLP and Biocides implementation
- Practical guides and examples
- Webinars
- Contacts of ECHA and national helpdesks

echa.europa.eu/support

Evaluation under REACH – Progress Report 2013 and previous reports:
echa.europa.eu/evaluation