

REACH Action Plan for Review/Improvement of Registration Dossiers

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Cefic developed an Action Plan for Review/Improvement of Registration Dossiers

Objectives

Proactive re-assessment of registration dossiers content, and effectively and efficiently identify/address data or information gaps (staged priority setting), if needed.

The commitment is open to all Cefic member companies, including national Association members.



Key elements of the initiative?

Action Plan

- Timeline: 2019-2026;
- KPIs (on Action Plan implementation, not on the improvement or quality);
- Roles and responsibilities: Cefic / companies;
- Criteria to prioritise substances for re-evaluation;
- Annual Reporting (template).

Declaration of Intent, signed by individual companies

- Re-evaluate dossiers and provide further information, where appropriate;
- Report to Cefic on KPIs \rightarrow Cefic annual reports (no 'quality KPI').

Cooperation framework with ECHA

• Further cooperation with ECHA, under the umbrella of the June 2018 Cefic-ECHA Joint Statement.

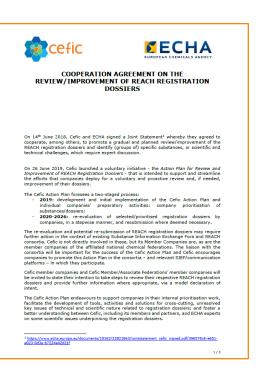






Cooperation framework with ECHA: activities

- **Development of material to guide registrants** towards a clearer understanding of what is expected under Article 41 of REACH (CCH procedure)
 - Case studies to illustrate practical application of the Read Across Assessment Framework
 - Examples of testing strategies or waiving justifications that have helped registrants successfully pass a compliance check, both for human health and the environment, while ensuring new vertebrate animal studies are performed only as a last resort
- Identification and notification of priority substances
- Progress tracking
- Dissemination

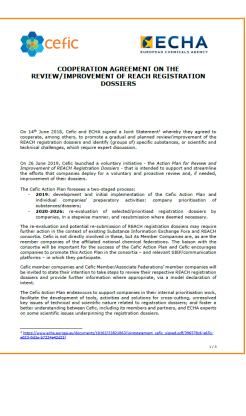




Cooperation framework with ECHA: governance

From an organisational perspective, the following levels of peer-to-peer cooperation will be developed:

- a Steering Committee to support and guide the implementation of the collaboration agreement and look for solutions when hurdles are encountered.
- a Joint Expert Group between ECHA and Cefic members, which would have two main tasks:
 - Act as a platform for expert discussion on specific issues and case studies;
 - Disseminate learnings derived from individual cases for the benefit of the broader community (i.e. share lessons learnt).





Transparent communication and progress reporting

Via Cefic's website

- Action Plan and related material;
- Guidance/tools produced during implementation;
- Workshop summaries;
- Annual progress reports.

https://cefic.org/our-industry/reach-dossier-improvement-action-plan

Information to stakeholders



Role of Cefic

- Act as a platform to support, coordinate and streamline companies' efforts for the review/improvement of dossiers.
 - Cefic does <u>not</u> run consortia and does <u>not</u> work on specific substances or dossiers;
 - Help generate common learning;
 - Develop and publish material, including progress reports;
 - Facilitate interaction with ECHA (technical and scientific challenges).
- Promote the initiative and engage as many companies as possible.



What does it entail for companies?

- Prioritisation process;
- Resources and costs (more testing is expected);
- Company implementation plan;
- Further work with consortia / SIEFs.

Cefic is not and will not be involved in individual dossier assessment. It is for each individual company to proactively review/ improve their dossiers, and to coordinate with consortia/SIEFs, as applicable.



What are the next steps? Come and join us !

- Action Plan initiative launched on 26 June 2019.
- Signatures *companies* commitment:
 - Cefic member companies;
 - National Associations member companies.
- National Associations engagement.
- Dialogue with other registrants' associations.

REACH Dossier Improvement Action Plan



Cefic launches Action Plan to help REACH registrants review chemical safety data

A critical mass from the start:

32 Cefic Board member companies committed to join, representing a large majority of the EU chemicals market.



Practicalities

• To whom should the Declaration of Intent be sent?

The signed Declaration of Intent should be sent to Sylvie Lemoine (<u>syl@cefic.be</u>), copying Danielle Deneef (<u>DDE@cefic.be</u>).

• Contact point

To facilitate future communication regarding the Action Plan, one person from the company should be nominate. That person will be the focal point for all e-mails related to this Action Plan (e.g. reporting request, progress reports, workshop reports) – you can provide such information in the email sending the Declaration of Intent.

• Who should I contact if I have any questions/doubts regarding the Action Plan?

If you have any questions/doubts regarding the Action Plan please contact Mariana Barros (<u>mfb@cefic.be</u>).



Invited to:

- Commit to the Cefic Action Plan initiative.
- Sign the Declaration of Intent:
 - **Proactively** re-evaluate your registration dossiers content and, if needed, review/ improve them.
 - Internal company dossier improvement plan.
 - Report to Cefic help demonstrate progress (anonymised).

Help us to become proactive!





For more info: <u>syl@cefic.be</u> / <u>mfb@cefic.be</u>

