



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 → 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 not run consortia and does not 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 (syl@cefic.be), copying Danielle Deneef (DDE@cefic.be).

- 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 (mfb@cefic.be).



member companies



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!

Thank you!



For more info: syl@cefic.be / mfb@cefic.be

