

Implementation of the REACH Action Plan for Review/Improvement of Registration Dossiers

Summary report from the Kick-off Workshop on Cefic's Action Plan for REACH registration dossiers

(29 November 2019, Brussels)

On 26 June 2019, Cefic launched an unprecedented action aimed at proactively and systematically reviewing and improving, if needed, the data previously submitted in REACH registration dossiers. The Cefic multi-annual Action Plan provides a framework for REACH registrants to evaluate the safety data in a stepwise manner. Within that framework, a Cooperation Agreement has been established with ECHA. More information is available on Cefic's website¹.

The 'Kick-off Workshop' on Cefic's Action Plan for REACH registration dossiers was the first workshop organised by Cefic in collaboration with ECHA, as foreseen in the Cooperation Agreement.

The workshop was attended by close to 100 representatives from Cefic, from ECHA and from companies who have joined the Cefic Action Plan. The workshop agenda was prepared based on input from the companies. The main purpose of the workshop was to contribute to exchanging expert advice on scientific and technical challenges related to registration dossiers, in particular on read-across and categories, building on concrete examples as much as possible. The outcomes of such discussions aim at generating knowledge to further support companies in the review/improvement of their registration dossiers.

Intense, lively and well-informed discussions took place. The agenda included four sessions:

- The first session dealt with 'grouping and prioritisation of substances' with a presentation by ECHA, in two folds, followed by a Q&A session.
- The second session dealt with issues related to Consortia and SIEF interactions with two presentations by industry and a panel discussion.
- Session 3 focused on the Evaluation process with two presentations by ECHA, covering the evaluation procedure principles, most frequent deficiencies and some learnings from Board of Appeal decisions.
- Finally, Session 4 focused on 'Read-Across' with four presentations by industry, presenting successful and unsuccessful case studies, followed by a panel discussion.

The workshop was closed with an overview of concluding remarks highlighting key messages and learnings.

¹ <https://cefic.org/our-industry/reach-dossier-improvement-action-plan/>

Key messages and main learnings from the workshop:

- The ECHA chemical universe was published on 4 December 2019.
- ECHA will screen all substances by 2027 and run compliance checks for 20% of the dossiers. The screening will always lead to one of three outcomes: (1) high priority substance for regulatory risk management, (2) need for more data to enable decision, and (3) low priority for further work.
- A mindset change is needed: REACH is about generating all the necessary information to ensure safe use.
- If companies are proactive, as foreseen for companies who joined the Action Plan, it opens a (limited) route for interaction and feedback from ECHA, but in the end the formal processes apply.
- If companies provide an adequate testing plan and the data support the read-across/category, they have a chance to reduce costs (and use of animals). In the end, it relies on having reliable source studies. If read-across is formally rejected under Compliance Check, testing will be requested on each individual substance and, ultimately, it will be more expensive and more animal testing will be needed.
- It is not ECHA's role to develop adaptations or read-across justifications on behalf of registrants.
- Board of Appeal decisions helped clarify certain responsibilities of registrants and ECHA in the dossier evaluation process.
- Dates of dossier updates will be published with the names of companies on the dissemination website.
- It is of critical importance that companies plan and forecast, and ensure the necessary resources are appointed.
- The time required to coordinate work within the consortia should not be underestimated; Larger consortia need an efficient structure and disciplined management.