

Cefic REACH Action Plan

2nd Progress Report for Improvement of REACH Registration Dossiers

2020 results

Key highlights

- On 26 June 2019, Cefic launched its **multi-annual voluntary Action Plan** to proactively review and, if needed, update data in REACH registration dossiers
- **As of 31 December 2020, 190 companies** joined the Action Plan
- **These 190 companies represent 1355 legal entities (registration holders)** covered by the Action plan.
- **Participants of the Action Plan evaluated 2731 REACH dossiers in 2020.** This represents an increase of 55% compared to reported re-evaluated dossiers in 2019. The numbers cover registration dossiers in all tonnage bands, both lead, and member registrations.
- **4489 REACH registration dossiers have been re-evaluated** (both lead and member registrations) since June 2019.
- Companies have also been asked to provide estimates about the number of lead registrants' dossiers (which is a proxy for the number of substances) they intend to review until the end of the Action Plan in 2026; more than 7,000 REACH lead registrants' dossiers (substances) are expected to be reviewed by 2026.
- The Action Plan is still in its early days and more work will need to be done to get a more in-depth assessment of potential data gaps and submit testing proposals, where needed. Cefic will continue working with **the European Chemicals Agency (ECHA)** to help companies understand how they can improve their dossiers' content **to increase the success rate** on ECHA's compliance checks.

1. Introduction

The Cefic multi-annual Action Plan was launched on 26 June 2019 and intended to support European companies' effort to review and improve REACH registration dossiers. The initiative aims to significantly contribute to REACH registration dossiers' quality in cooperation with the European Chemicals Agency (ECHA).

The progress is being tracked with key performance indicators (KPIs). **Based on the learnings from the 1st progress report¹, signatory companies were asked to provide two additional KPIs in 2020.** One was to include the total number of legal entities covered by the signatory's commitment to the Action Plan. The number of legal entities is a better indicator of the number of registration holders involved in the Action Plan. For practical reasons, the signatory companies' names as published on the Cefic website cover all the legal entities and subsidiaries but do not list them all.

Furthermore, companies were asked to include the number of dossiers they have prioritised for voluntary reassessment in their role as lead registrants throughout the entire duration of the Action Plan (until 2026). This provides an indication of the number of substances that are in the scope of the Action Plan (from start to end). The selection of these substances is largely based on ECHA's Chemical Universe and particularly on the "not yet assigned" category of the Chemical Universe.

This is the second report on the KPIs defined in the Action Plan, reflecting companies' efforts during 2020. The first report can be found [here](#).

It is important to note that these KPIs are meant to assess the size and scope of this programme but do not measure actual dossier improvement, nor whether more Compliance Checks are concluded without further data requests. Cefic does not have access to registration dossiers and leaves it to companies/consortia to re-evaluate dossiers' content.

2. Companies that have joined the Action Plan

190 companies have joined the Action Plan as of 31 December 2020. This represents a substantial increase of 25 companies during 2020.

The list of signatory companies is publicly available on Cefic's website¹ and is updated every month. Three signatory companies decided not to continue with the Action plan in 2020. One because of the economic situation and the other two because they do not hold registration dossiers.

The dossier improvement activities of **1355 legal entities** are covered by the 190 companies that joined the Action Plan. 93% of the legal entities are Cefic member companies; the remaining 7% are legal entities from member companies of a National Federation. Both Cefic and its national member associations have been actively promoting the Action Plan with their members.

Of the total number of 75 [Cefic Corporate members](#) ('ACOM'), i.e., corporations with a production base in Europe and a worldwide turnover in chemicals of more than 1 billion euros, **64 companies** have joined the Action Plan so far. With the active support of the President of its Board and its Board members, Cefic has been able to reach out to all ACOM members and expect the missing ACOM companies to join the Action Plan in the near future (some have joined after 31 December). Cefic 'ABM' members (smaller companies) and Associated and National Federations are also encouraged to join.

3. Action Plan Implementation's Progress Tracking

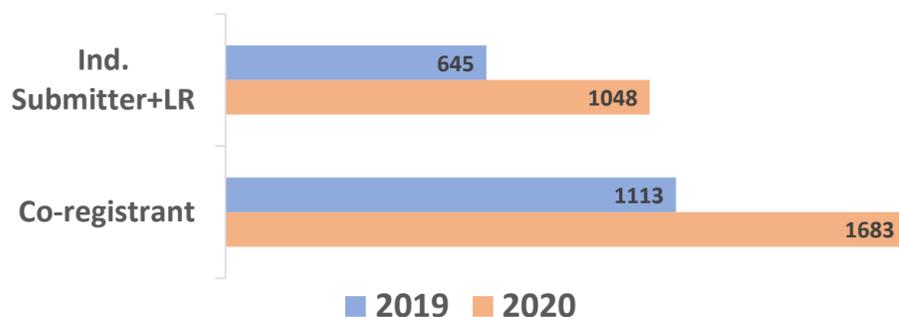
In line with the obligations agreed in the Declaration of Intent, companies were invited to submit data on the numbers of registration dossiers they have re-evaluated as an individual submitter, both as a lead registrant and as a co-registrant².

In total, **2731** individual registration dossiers were re-evaluated³ in 2020 within the framework of the Action Plan. **This represents an increase of 55% compared to reported re-evaluated dossiers in 2019**, which is a very encouraging trend.

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

² A reporting template was made available to the signatory companies.

Number of dossiers re-evaluated in 2019 and 2020



1048 registration dossiers have been re-evaluated by individual submitters ('stand-alone' dossier) and lead registrants (joint submissions), and 1683 registration dossiers have been re-evaluated by co-registrants (joint submissions). The numbers cover registration dossiers in all tonnage bands.

In 2019, companies reported 1758 re-evaluated registration dossiers. In total, 4489 dossiers have been re-evaluated since the beginning of the Action Plan.

Looking at companies' forecasts, around 7170 lead registrant dossiers are expected to be reviewed by 2026 (*i.e.*, dossiers in the lead registrant category). Since this KPI relates to lead registrants only, this KPI represents the **number of registered substances** in the Action Plan's scope, from start (mid-2019) to end (2026). This means the Action plan covers about one-third of the database of substances registered at ECHA (*ca.* 23.000 substances have been registered), or more than 50% of substances with full registrations⁴.

Lead registrants re-evaluating the content (*i.e.*, all IUCLID sections) of the dossiers have to pay particular attention to read-across, waivers, substance identity entries, and entries related to long-term study endpoints (*e.g.*, repeated dose toxicity/reproductive toxicity), as applicable.

In addition, some companies reported having also re-evaluated dossiers on 'intermediates' as an individual submitter, as the lead registrant, and as a co-registrant.

While the above numbers are encouraging, it is important to keep in mind that these KPIs reflect the size and scope of the project, not its achievements in terms of content of dossiers. The Action Plan is still in its early days and more work will need to be done to get a more in-depth assessment of potential data gaps and submit testing proposals, where needed.

4. Pilot Project

Within the Action Plan framework, a Cooperation Agreement has been established with ECHA to run a pilot project. The objective was to select and perform case studies on groups of substances, including different testing strategy challenges, aiming to identify successful testing strategies.

The pilot project consisted of four case studies involving groups of substances registered by three volunteer companies. The project started in December 2019, and testing is still ongoing. A workshop was organised in October 2020 to report on the learnings, providing guidance to the signatory companies on how to achieve dossier compliance. A summary of the Workshop was published on Cefic's website⁵.

Volunteer companies are now working on submitting test proposals to ECHA and updating their registration dossiers.

³ In the context of the Action Plan, a dossier is considered 're-evaluated' when the company has, following a review of the information in the registration dossiers, either re-submitted the dossier to ECHA or concluded that the dossier does not need to be re-submitted. The intention is that the re-evaluation of a dossier would lead to, if necessary, its improvement. Based on current knowledge, the dossier should then contain all the information needed to pass a compliance check by ECHA, should ECHA decide to perform one.

⁴ Substances are registered either as "full registrations" or as "intermediates" under REACH. Intermediates are chemicals (substances) that are produced or used in order to be transformed into other chemicals. They are used under strictly controlled conditions (and never in end products); they are subject to reduced registration requirements. Cefic's Action Plan instructs member companies to prioritise review of "non-intermediates" (full registrations), as these dossiers are more complex in content.

⁵ https://cefic.org/app/uploads/2021/01/Pilot-project-report_-Dec-2020_summary.pdf

Next Steps.

Cefic will continue to encourage its members to join the Action Plan in 2021 and interact with signatory companies to determine which support is needed to improve dossiers' content, particularly when it comes to improving testing strategies or filling data gaps.

The 2021 plan includes:

- Have **all corporate members** of Cefic join the Action Plan.
- Continue the work with partner associations, national associations and to further **expand the participation**.
- Close cooperation with **National Federations**.
- Continue **close cooperation with ECHA** to help companies understand how they can improve their dossiers' content **to increase the success rate** on ECHA's compliance checks.
- Building on the lessons learned from the pilot project, **ECHA intends to cooperate** with companies and consortia proactively submitting testing strategies covering groups of substances. ECHA foresees interaction with industry on at least six testing strategies for 2021.