

# Cefic REACH Action Plan

## 1<sup>st</sup> Progress Report for Improvement of REACH Registration Dossiers 2019 results

### Key highlights

- On 26 June 2019, Cefic launched its **multi-annual voluntary Action Plan** to proactively and systematically review and, if needed, update data in REACH registration dossiers.
- 165 companies** joined the Action Plan between June and end of December 2019.
- 64%** of those joined represent Cefic members and **36%** are members of national chemical industry federations based in EU member states.
- 1758 REACH registration dossiers had already been re-evaluated** in 2019. The numbers cover registration dossiers in all tonnage bands.

### 1. Introduction

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. The aim of this initiative is to achieve a significant contribution to the quality of REACH registration dossiers, in cooperation with the European Chemicals Agency (ECHA).

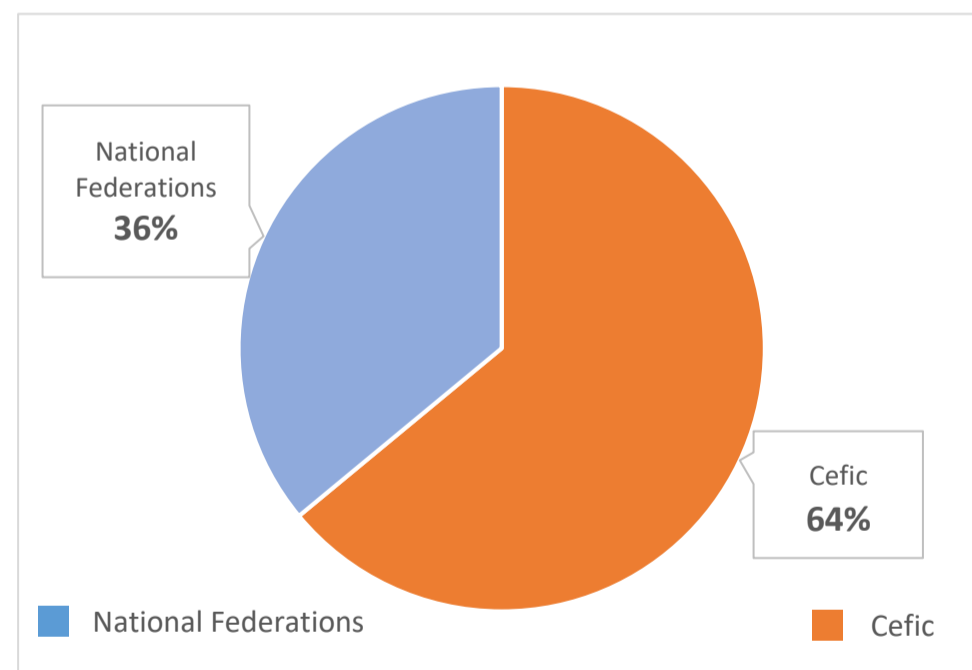
To track progress of the initiative, key performance indicators (KPIs) have been defined. These KPIs are also to be used for regular, external reporting to ensure transparency vis-à-vis stakeholders.

This is the first reporting on the KPIs defined within the Action Plan and the numbers presented reflect the efforts made by companies during the timeframe of this initiative, i.e. to re-evaluate registration dossiers since they joined the Action Plan. Some companies joined the Action Plan at its launch in June 2019 and many others joined in the second half of the year.

### 2. Companies that have joined the Action Plan

[165 companies](#) joined the Action Plan between June and end of December 2019. The names of those companies are publicly available on Cefic's website and the list is updated on a monthly basis<sup>1</sup>. To become a signatory of the Action Plan, companies need to have the status of a registrant, either as lead registrant or as co-registrant, and to be either a Cefic member, partners or a member of Cefic Member Federations & Associated Federations.

#### Percentage of signatory companies' members of Cefic and members of National Federations

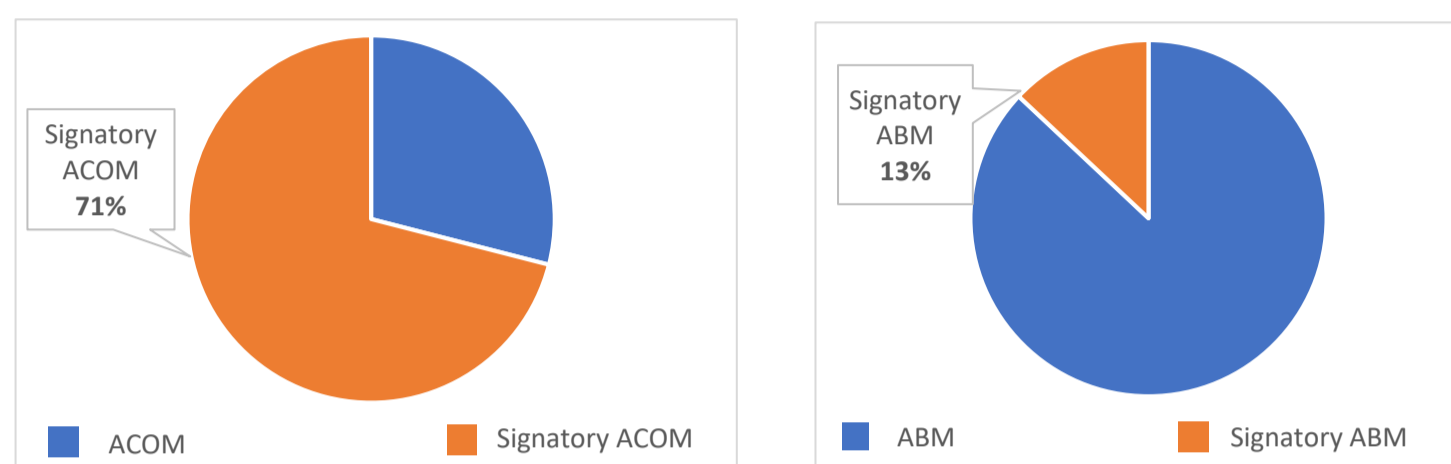


Of the 165 companies that joined the Action Plan in 2019, 64% are Cefic members and the remaining 36% are members of a National Federation. This demonstrates the complementary role of national associations in reaching out to as many registrants as possible.

<sup>1</sup> The published name of the company covers all of its legal entities and subsidiaries, which implies that one company can cover multiple registering legal entities. This, in turn, entails that the universe of participating registering legal entities is larger than the reported number of companies

Of the total number of [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, **71%** have already joined the Action Plan. Of the total number of [Cefic Business members](#) ('ABM'), i.e. sectoral businesses with a production base in Europe and a worldwide turnover in chemicals of less than 1 billion euros, **13%** have so far joined the Action Plan.

#### Percentage of signatory companies' in the Cefic's total Corporate (ACOM) and Business (ABM) membership, respectively

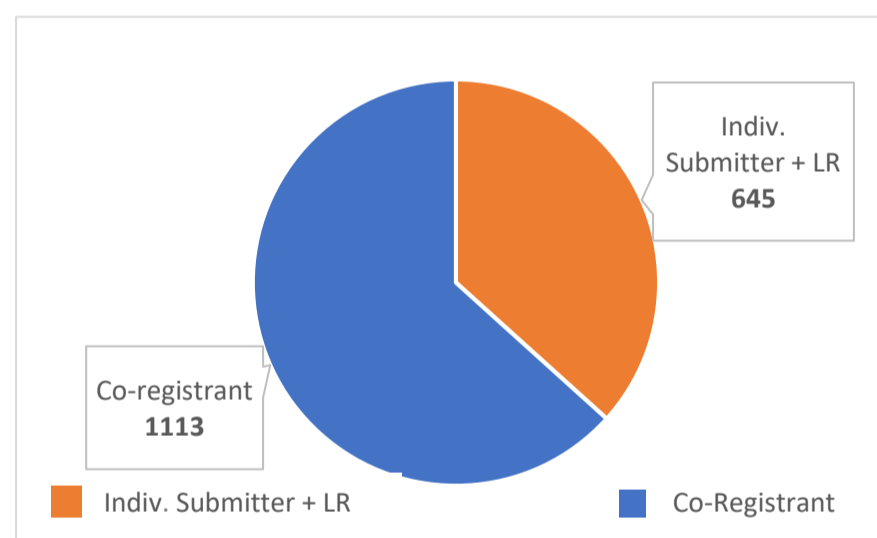


### 3. Action Plan Implementation's Progress Tracking

In line with the obligations set in the Declaration of Intent, companies were invited to submit data on the numbers of registration dossiers that they have re-evaluated as an individual submitter, as lead registrant and also as co-registrant<sup>2</sup>.

In total, **1758** registration dossiers were re-evaluated<sup>3</sup> in 2019 within the framework of the Action Plan.

#### Number of dossiers re-evaluated in 2019 within the Cefic's Action Plan framework.



**645** registration dossiers have been re-evaluated by individual submitters ('stand-alone' dossier) and lead registrants (joint submissions), and **1113** registration dossiers have been re-evaluated by co-registrants (joint submissions). The numbers cover registration dossiers in all tonnage bands.

In practice, the companies worked on internal planning and on prioritising the dossiers that need to be re-evaluated according to the criteria proposed in the Action Plan in 2019. Resources and budgets have been allocated to these activities. Major efforts have been spent on seeking alignment within the consortia.

Companies reported that, when re-evaluating the full content (i.e. all IUCLID sections) of the dossiers they processed in 2019, special attention was given to read-across, waivers, substance identity entries, and entries related to long-term study endpoints (repeated dose toxicity / reproductive toxicity).

<sup>2</sup> A reporting template was made available to the signatory companies.

<sup>3</sup> 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 the current knowledge, the dossier should then contain all the information needed to pass a compliance check by ECHA, should ECHA decide to run it.

### Next Steps.

Within only 6 months, 165 participants joined the Action Plan resulting in a total of **1758** re-evaluated registration dossiers. While the first results are promising, Cefic will continue to encourage companies to join the Action Plan in 2020.

#### The 2020 plan includes:

- Have all ACOM members of Cefic (i.e. corporations with a production base in Europe and a worldwide turnover in chemicals of more than 1 billion euros) **join the Action Plan**.
- Work with partner associations, national associations and ABM members to **further spread the initiative**.
- Continue close **cooperation with National Federations**.
- Continue **close cooperation with ECHA** to help companies understand how they can improve the content of their dossiers **to increase the success rate on ECHA's compliance checks**. A pilot project is ongoing with three volunteering companies and a selected set of (groups of) substances. The main objective of this pilot project is to identify successful testing strategies by working on concrete cases.

Companies' efforts in the continuous improvement of the quality of the data of their dossiers will be maintained throughout the year.