

# Cefic REACH Action Plan

## 4<sup>th</sup> Progress Report for Improvement of REACH Registration Dossiers

### 2022 results

#### Key highlights

- **The number of signatory companies has remained stable over the past year (199 participants).**
- **These 199 companies represent 1156 legal entities (registration holders)** covered by the Action Plan.
- **3934 REACH lead registration dossiers/individual submissions (substances) have been re-evaluated** since June 2019.
- **Participants of the Action Plan re-evaluated 1119 lead REACH dossiers in 2022.** The numbers cover registration dossiers in all tonnage bands.
- **More than 5500 REACH lead registrants' dossiers (substances)** are expected to be reviewed between 2019 to 2026, according to the participants' estimates, representing nearly 40% of the ECHA database for full registration dossiers<sup>1</sup>. The estimated number of substances to be reviewed in the timeframe of the Action Plan (2019-2026) decreased by 10% compared to 2021, which can be explained by two reasons:
  - i. ECHA's work on compliance checks which leaves fewer dossiers for voluntary re-evaluation, and
  - ii. companies ceasing the manufacturing of some substances due to high energy costs in 2022 which led to a decrease in the number of lead dossiers in scope for the voluntary programme.
- **Near 60% of the lead/individual dossiers re-evaluated in 2022 (more than 690 substances) are submitted or will be submitted with new data or new information<sup>2</sup>. Of these,**
  - **289 substances involve higher-tier testing according to Annexes IX and X.**
  - **Another 404 substances involve Annexes VII and VIII studies.**
- **The interaction process with ECHA** is of added value, particularly for complex categories of substances involving waivers and/or read-across.

#### Background

In June 2019, Cefic launched the REACH Dossier Improvement Action Plan to help its members proactively and systematically review and update data in previously submitted REACH registration dossiers. The aim of the Action Plan is to enhance the safety of chemicals for human health and the environment.

The REACH regulation is a crucial EU legislation that gives companies that manufacture or import chemicals into the EU the mandate to register them with the European Chemicals Agency (ECHA). The registration process includes submitting a dossier that outlines the chemical's properties, hazards, and risks associated with its use. Under the Dossier Evaluation process, ECHA evaluates these dossiers to determine whether the standard information requirements have been fulfilled. Further REACH processes may be initiated for substances where risks have been identified.

The REACH Dossier Improvement Action Plan was launched in June 2019 following ECHA's findings that many REACH registration dossiers lacked the necessary information. Cefic neither participates in consortium discussions, nor reviews individual registration dossiers but facilitates the implementation of the Action Plan. To ensure the effectiveness of the Action Plan, Cefic requires its member companies to provide an annual Key Performance Indicator (KPI) report, which Cefic aggregates to track and report on progress. This report details the fourth annual progress report. Previous reports are available on the [Cefic website](#).

#### Methodology

The KPI report for the Cefic REACH Dossier Improvement Action Plan was divided into two parts: **KPI reporting requirements** and **additional information** on the nature of updates.

The KPI reporting requirements included the following information that signatory companies were asked to provide:

- The total number of legal entities covered by the signatory's commitment to the Action Plan.
- The number of lead dossiers/individual submissions and co-registrations re-evaluated in 2022.
- The number of dossiers that signatory companies prioritised for voluntary re-evaluation as lead registrants/individual submitters throughout the entire duration of the Action Plan (until 2026). This indicates the number of substances in the scope of the Action Plan.

To better understand the type of new information or data included in voluntarily updated dossiers or in the process of being generated, Cefic also asked participating companies to provide additional information about the nature of the dossier updates made by individual submitters (for stand-alone dossiers) and lead registrants (for joint submissions) in 2022. The purpose of this request is to complement the KPI reporting exercise and increase transparency on the type of information registrants add or modify in their dossiers.

The additional information collected was aggregated into the following categories: that can trigger a change in the Chemical Safety Report (CSR) or overall regulatory status of the dossier.

The additional information collected was aggregated into the following categories:

- A. No major update on dossier content: the re-evaluation concluded the dossier is in line with REACH requirements, or the dossier was updated due to new regulatory IT requirements (adjustments and improvements had to be made to meet the newest International Uniform Chemical Information Database (IUCLID) format, completeness rules or quality expectations), but the dossier does not include new analytical data, physico-chemical, toxicological or ecotoxicity data, new uses or new interpretation that can trigger a change in the CSR or overall regulatory status of the dossier.
- B. Improvement of substance identity/ chemical composition: analytical information was generated to support read-across (chemical composition, concentration ranges, and structural information of the substance).
- C. New data generation according to Annexes VII and VIII of REACH or other types of studies/data to support read-across (toxicokinetic data, metabolism studies, also known as 'bridging studies'). This includes studies commissioned, ongoing or completed.
- D. New data generation involving higher-tier studies according to Annexes IX and X of REACH, for which a Testing Proposal (TP) is required. This includes studies commissioned, ongoing or completed.
- E. New uses/exposure information leading to CSR update.
- F. CSR updates other than those covered above, e.g. new interpretation of the data leading to classification changes, new PBT/vPvB assessment, new DNEL or PNEC derivation, study summary improvement, etc.

This additional information will help Cefic and its members track progress and identify any common issues or areas for improvement in REACH dossier submissions.

## 1. 2022 progress

As of 31 December 2022, the REACH Dossier Improvement Action Plan has gained the support of **199 companies** (one more than in 2021), all of which have committed to improving their dossiers in line with the REACH regulation requirements. The list of these signatory companies is publicly available on a [dedicated page](#) on Cefic's website and is updated monthly for transparency.

In total, 199 companies have engaged in dossier improvement activities for 1,156 legal entities (LEs). This marks a 19% decrease compared to the number of LEs reported in [last year's report](#). Some companies have attributed this decrease to divestments and carve-outs, while others have cited ceases of manufacture, changes in the lead registrant status, or changes in the 'chemical universe' of ECHA as reasons why certain substances were not within the scope of the Action Plan, resulting in the LEs not being counted in 2022.

Of these 199 companies, 90% are Cefic member companies, with the remaining 10% comprising legal entities from member companies of national associations. Both Cefic and its national member associations have played an active role in promoting the Action Plan to their members, encouraging widespread participation in this important initiative.

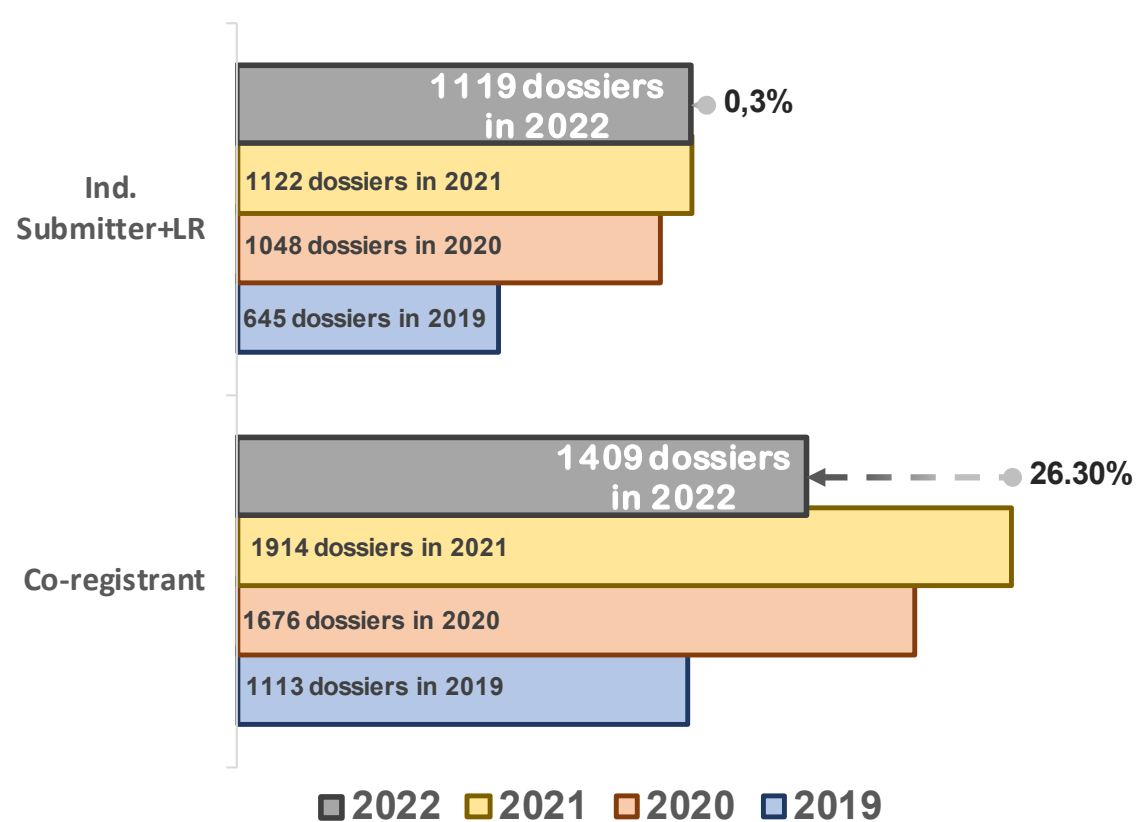
**All signatory companies have submitted their 2022 KPI report and additional information in cases where lead dossiers were re-evaluated during the year.** This ongoing commitment to compliance and improvement reflects the dedication of these companies to meeting REACH regulations and ensuring the safety of chemical products across Europe.

## 2. Dossier statistics

Companies that have signed the Cefic-Declaration of Intent are required to provide the KPI data on the numbers of registration dossiers that have been re-evaluated in 2022, both as lead registrant/individual submitters and as a coregistrant<sup>3</sup>.

In 2022, a total of 2528 dossier registrations were re-evaluated<sup>4</sup>. Of these, 1119 registration dossiers were re-evaluated by individual submitters (i.e. 'stand-alone' dossier) and lead registrants (joint submissions), and 1409 registration dossiers have been re-evaluated by co-registrants (joint submissions). This represents a similar number of re-evaluated **lead dossier/individual submissions compared to 2021, but there was a decrease of 26.3% in the number of co-registration dossiers re-evaluated**. These numbers cover registration dossiers in all tonnage bands. The data indicates that the level of engagement is stable for lead registrants and individual submitters, but the reason for the decrease in the level of activity of co-registrants is unknown.

Number of dossiers re-evaluated 2019-2022



In 2019, companies reported **645** re-evaluated registration dossiers by individual submitters ('stand-alone' dossiers) and lead registrants (joint submissions). Since the start of the Action Plan in June 2019, a total of **3934** lead dossiers/individual submissions have been re-evaluated; which serves as a proxy for the number of substances.

It is anticipated that approximately 5500 substances within the scope of the Action Plan will be re-evaluated by both individual submitters ('stand-alone' dossier) and lead registrants (joint submission) throughout the entire duration of the program (until December 2026) representing approximately 40% of substances with full registrations<sup>1</sup> in the database of substances registered at ECHA<sup>5</sup> (ca. 13000 substances registered as full registration). This number has decreased compared to previous years mainly due to changes in the ECHA's chemical universe, with a significant reduction in the number of substances assigned to the "not yet assigned" category, as well as the overlapping of compliance checks and voluntary improvement. Additionally, some companies/sites had to cease the manufacturing of some substances due to high energy costs in 2022, resulting in a decrease in the number of lead dossiers in scope for the voluntary programme.

### 3. Additional information about the type of updates

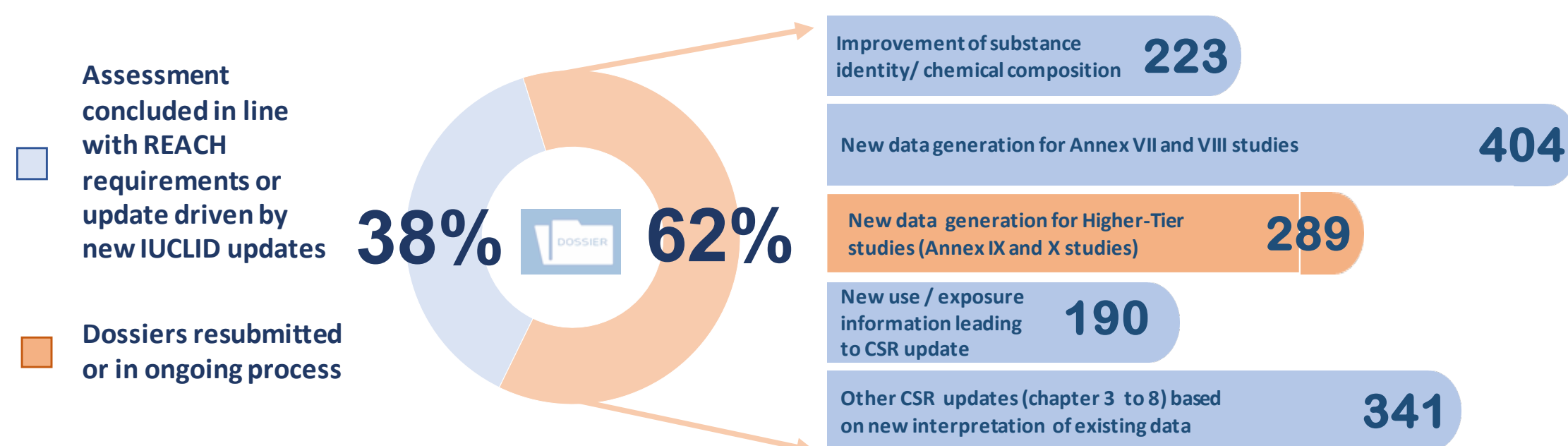
Additional information on the nature of the updates **was provided by all signatory companies that re-assessed lead dossiers/individual submissions in 2022.**

The picture is similar to the findings from 2021:

It was found that 62% of the dossiers (representing 697 substances) re-submitted to ECHA in 2022 or in the process of being updated contain new data. The information can be categorised as follows:

- 223 (n= 199 in 2021) substances were improved with new analytical data to support chemical composition, concentration ranges, and structural information of the substance.
- 404 (n=336 in 2021) substances re-evaluated in 2022 were updated or are in the process of being updated with studies from Annex VII or VIII or other types of studies/data to support read-across (toxicokinetic data, metabolism studies).
- 289 (n=254 in 2021) substances involve higher-tier testing according to Annexes IX and X. Some companies included TPs already submitted in 2021 as the TP examination process is still ongoing in 2022, and the TP needs to be approved before contract research organisations (CROs) can initiate the study<sup>6</sup>.
- 190 (n=268 in 2021) substances included new uses in the dossiers that could trigger the update of exposure information contained in the substance's CSR.
- 341 (n=234 in 2021) substances were improved with a new interpretation of the existing data in the IUCLID dossier that may lead to a change in classification and labelling (C&L); persistent, bioaccumulative and toxic or very persistent and very bio-accumulative (PBT/vPvB) assessment; new derived no-effect level (DNEL) derivation; predicted no-effect concentration (PNEC) derivation or study/endpoint summary improvement.

Some re-evaluated dossiers have not been re-submitted to ECHA yet because companies agreed on a testing plan with a contract research organisation (CRO), and testing is still ongoing or delayed due to the insufficient capacity of the CRO. However, individual submitters ('stand-alone' dossier) and lead registrants (joint submissions) were requested to include the additional KPI information even if the process is in progress (*i.e.* not information in the dossier). Pending studies were taken into account only if they were initiated *i.e.* after a contract agreement to conduct the study/studies had been signed with a CRO in 2022 and for higher-tier test if a submitted TP has been approved by ECHA or the approval was ongoing in 2022.





The remaining 38% of the lead or individual submission dossiers re-assessed by experts in 2022 were found to be either in line with the latest REACH requirements (thus not requiring an update) or to require only minor updates to meet new IUCLID requirements without new data being added.

In addition, many companies reported having also re-evaluated dossiers on 'intermediates' as an individual submitter, as the lead registrant, and as a co-registrant, mainly updating the analytical information of substance identification.

## 4. Interaction with ECHA

As part of the REACH Dossier Improvement Action Plan, a Cooperation Agreement was established with ECHA to run a pilot project, which was initiated in 2020. Learnings were disseminated with all signatory companies. The pilot led to more higher-tier data being proposed or generated. Although the supporting data generation experienced delays in 2022, mainly due to lab capacity issues, ECHA understands external factors causing delays and plans to start processing the TPs in 2023.

Building on the success of this pilot project, ECHA continued to collaborate with signatory companies to proactively encourage them to submit testing strategies covering groups of substances within the limits of its resources. A process for managing interactions with ECHA was developed, and the focus was placed on categories of more than five substances (due to limited ECHA resources).

In 2021, ECHA selected five groups of substances in accordance with its priorities. Companies participating in the interaction process submitted initial testing strategies to ECHA, which were reviewed, and informal feedback was provided by ECHA on four groups covering 33 substances.

One group of substances was selected in 2022, and ECHA has already received the initial testing strategy, with feedback to be provided in the first quarter of 2023.

Moving forward, Cefic aims to continue collaborating with ECHA and signatory companies to understand the complexity of grouping from the industry's perspective and to develop testing strategies that optimise data generation and agree on data generation on individual substances to support the category approach. This will ultimately contribute to minimising animal testing. ECHA will continue the interaction process with new categories in 2023 if industry still has large groups of substances to re-evaluate, where none of the substances is subject to compliance check, while also taking into account its resources and priorities.

## 5. Next Steps

Cefic remains committed to helping its members further improve their REACH registration dossiers. The expected revision of REACH is likely to bring about new data requirements and new challenges. Cefic will explore ways to ensure the Action Plan is adapted to the needs under the new REACH.

As a general observation: ECHA is progressing well in its Joint Evaluation Action Plan. It had indicated that all high-volumes (> 100 T/y) substance dossiers would be screened by the end of 2023, and a conclusion for potential regulatory management, or request for more data, or low priority for further actions would be reached. This concerns substances with the highest data requirements.

A meeting will be organised with ECHA in the course of 2023 to agree on the future of the Cefic-ECHA cooperation agreement.

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<sup>1</sup> Substances are registered either as “full registrations” or as “intermediates” under REACH. Intermediates are chemicals (substances) produced or used 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.

<sup>2</sup> Includes studies commissioned, on-going or completed. Dossiers re-evaluated are submitted or in the process of submission with experimental studies on the substance, new or improved adaptations, data waivers. For dossier in Annex IX or X, they were updated following a voluntary TP or read-across TP and not due to a CCH.

<sup>3</sup> A reporting template was made available to the signatory companies.

<sup>4</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 current knowledge, the dossier should then contain all the information needed to pass a compliance check by ECHA, should ECHA decide to perform one. **Dossiers are considered re-evaluated only on a voluntary basis, and not as a result of an obligation imposed by a ECHA’s decision (CCH). Annex IX and Annex X dossiers follow the TP procedure.**

<sup>5</sup> [ECHA REACH registration statistics. Data as of: 28/02/2023](#)

<sup>6</sup> Notes: the split between substance-TP and TPs supporting read-across for groups/categories of substances is not available, and one TP can cover one or more studies.