MARCH 2022

Cefic REACH Action Plan

3rd Progress Report for Improvement of REACH Registration Dossiers

2021 results

Key highlights

- **As of 31 December 2021, 198 companies** joined the Action Plan.
- **These 198 companies represent 1436 legal entities (registration holders)** covered by the Action Plan.
- **Participants of the Action Plan re-evaluated 3036 REACH dossiers in 2021.** This represents an increase of 7.1% compared to reported re-evaluated lead dossiers/individual submissions in 2020 and an increase of 14.2 % of co-registration dossiers re-evaluated in 2020. The numbers cover registration dossiers in all tonnage bands.
- **More than 6100 REACH lead registrants' dossiers (substances)** are expected to be reviewed by 2026, according to the participants' estimates.
- **2815 REACH lead registration dossiers/individual submissions (substances) have been re-evaluated** since June 2019.
- **Half of the lead/individual dossiers re-evaluated in 2021 (more than 500 substances) involve new data or new information[1]. Of these,**
    - **254 substances involve higher tier testing according to Annexes IX and X.**
    - **Another 336 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, the European chemical industry launched an unprecedented Action Plan to help its members proactively and systematically review and update data in previously submitted REACH registration dossiers. This initiative came in response to the European Chemicals Agency (ECHA) conclusion that many REACH registration dossiers require additional information. Cefic facilitates the implementation of the Action Plan but does not engage in consortia discussions nor in reviewing the content of individual registration dossiers.

One of the commitments of signatory companies is to annually report on KPIs that, once aggregated, are used by Cefic to track and report on progress.

This is the third annual progress report for this initiative. Previous reports can be found on the Cefic website.

Methodology

This year the KPI report was divided into **KPI reporting requirements** and **additional information** on the nature of updates.

In the KPI reporting requirements, 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 2021.
- The number of dossiers they have prioritised for voluntary re-evaluation in their role as lead registrants/individual submitters throughout the entire duration of the Action Plan (until 2026), as a proxy for the number of substances in the scope of the Action Plan.

The collection of more detailed information in addition to the KPIs as initially set is new in 2022. It is intended to understand better the type of new information or new data included in voluntarily updated dossiers (or information/data in the process of being generated). Cefic asked participating companies to provide additional information about the nature of the dossier updates made by individual submitters ('stand-alone' dossier) and lead registrants (joint submissions) in 2021. The purpose of this new request is to complement the KPI reporting exercise to increase transparency on the type of information registrants add or modify in their dossiers.

Additional information has been collected according to 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 IUCLID 6.8 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.

1. 2021 progress

198 companies have joined the Action Plan as of 31 December 2021, representing an increase of 33 companies since 2019.
The list of signatory companies is publicly available on a dedicated page on Cefic's website and is updated every month.

Three signatory companies, members of national federations, decided not to continue with the Action Plan in 2021. Two because they only hold co-registrations that are part of a consortium already participating in the Action Plan, and one because they do not hold full registration dossiers.
All 198 signatory companies submitted their 2021 KPIs.

The 198 companies that joined the Action Plan cover dossier improvement activities of **1436 legal entities**.

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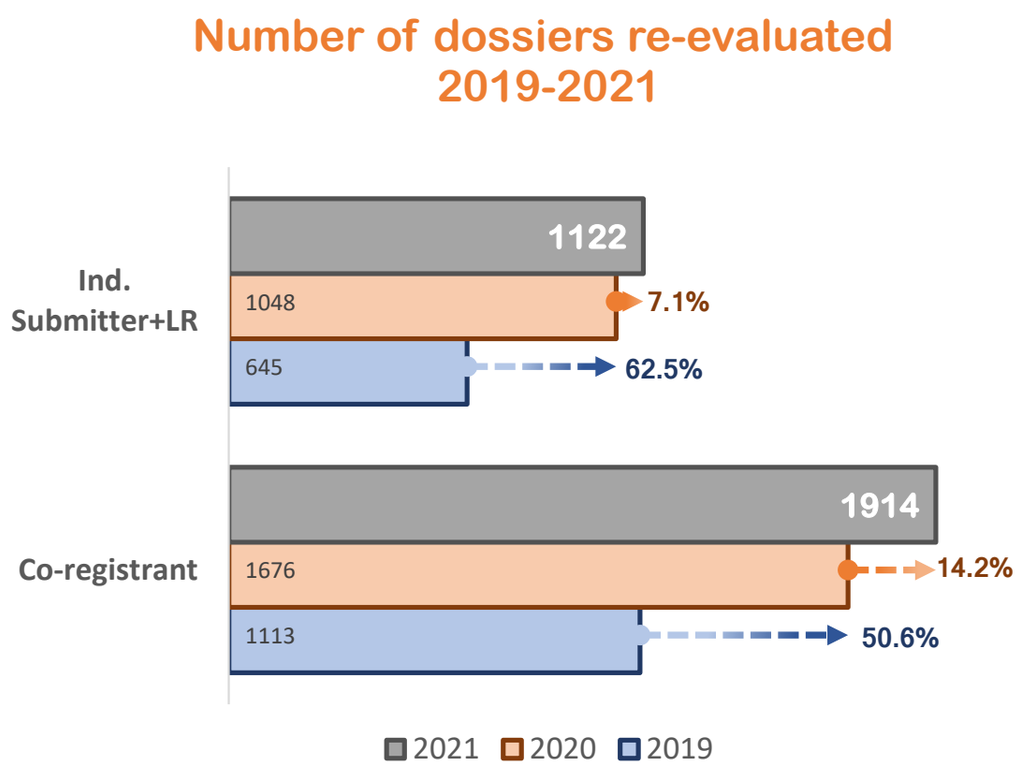
92.1% of the legal entities are Cefic member companies; the remaining 7.9% are legal entities from member companies of a National Association. Both Cefic and its national member associations have actively promoted the Action Plan with their members. French national associations (France Chimie) organised e-learnings and a workshop with their members on implementing the voluntary improvement of dossiers. Meetings between Cefic and members of the Spanish national association (FEIQUE) and Belgium national association (Essenscia) were also arranged.

2. Dossier statistics

Companies that signed the Cefic-Declaration of Intent are requested to provide the KPI data on the numbers of registration dossiers re-evaluated in 2021 as the lead registrant/individual submitters and as a coregistrant[2].

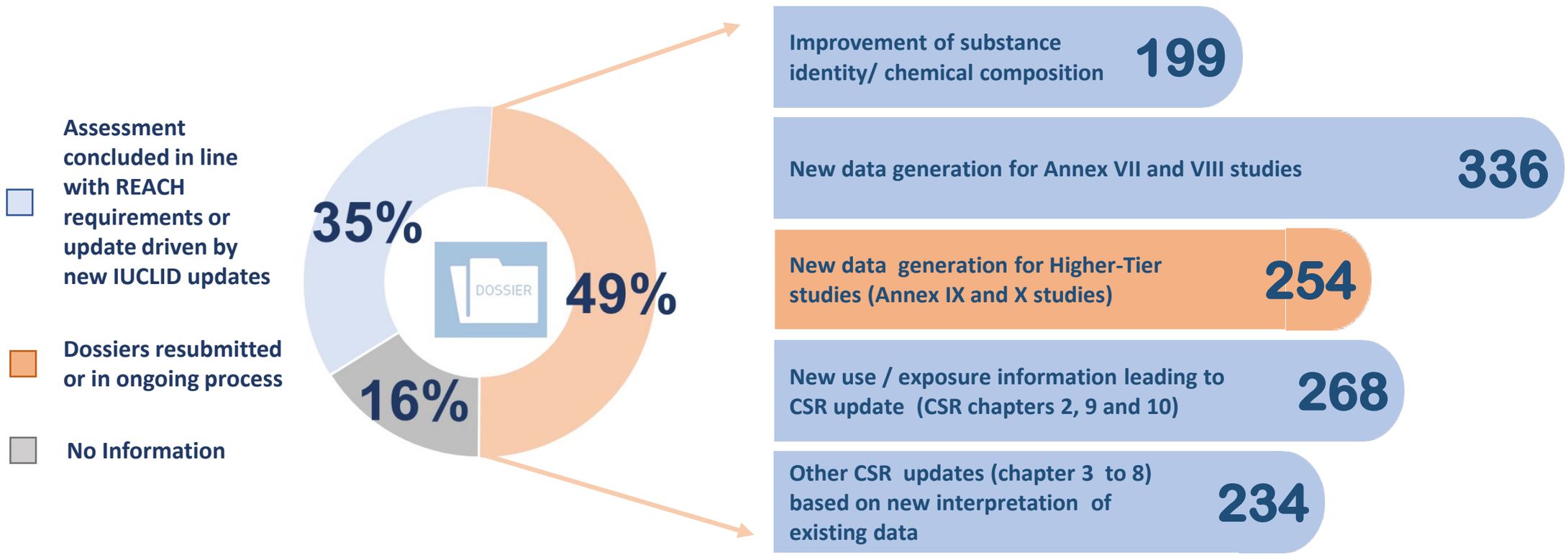
3036 dossier registrations were re-evaluated[3] in 2021: 1122 registration dossiers have been re-evaluated by individual submitters ('stand-alone' dossier) and lead registrants (joint submissions), and 1914 registration dossiers have been re-evaluated by co-registrants (joint submissions). **This represents an increase of 7.1% compared to reported re-evaluated lead dossiers/individual submissions in 2020 and an increase of 14.2 % of co-registration dossiers re-evaluated in 2020**. The numbers cover registration dossiers in all tonnage bands.

In 2019, companies reported **645** re-evaluated registration dossiers by individual submitters ('stand-alone' dossier) and lead registrants (joint submissions). In total, over 2019-2020-2021, **2815** lead dossiers/individual submissions (a proxy for the number of substances) have been re-evaluated since the beginning of the Action Plan (June 2019).



Altogether, approximately 6100 substances in the scope of the Action Plan are expected to be re-evaluated by both individual submitters ('stand-alone' dossier) and lead registrants (joint submission) during the entire duration of the programme (until 12/2026), representing about 50 % of substances with full registrations[4] from the database of substances registered at ECHA[5] (ca. 12 800 substances registered as full registration). This is a small decrease compared to last year due to three factors: consolidation of UK-based registrations after Brexit; changes to ECHA's chemical universe in the "not yet assigned" category (which is the basis for prioritising dossiers to be updated), with a significant reduction in the number of substances assigned to that category; and minor reporting errors by some signatories last year.

3. Additional information about the type of updates (new in the 2022 report)



Additional information on the nature of the updates was provided for 938 (84%) out of 1122 lead dossiers/individual submissions re-evaluated in 2021.

It was found that 49% of the dossiers re-submitted to ECHA or in the process of being updated contain new data split as follows:

- 199 substances were improved with new analytical data to support chemical composition, concentration ranges, and structural information of the substance.
- 336 substances re-evaluated in 2021 were updated or are in the process to be updated with studies from Annex VII or VIII or other types of studies/data to support read-across (toxicokinetic data, metabolism studies).
- 254 substances involve higher tier testing according to Annexes IX and X. Some companies included TPs submitted in 2020 as the TP examination process is still ongoing in 2021, and the TP needs to be approved before CROs can initiate the study[6].
- 268 substances included new uses in the dossiers that could trigger the update of exposure information containing in the CSR of the substance.
- 234 substances were improved with a new interpretation of the existing data in the IUCLID dossier that may lead to a change in C&L, PBT/vPvB assessment, new DNEL or 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 insufficient capacity of the CRO. However, individual submitters ('stand-alone' dossier) and lead registrants (joint submissions) were requested to include the additional information even if the process is in progress. 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 2021 and for higher tier test if a submitted Testing Proposal (TP) has been approved by ECHA or the approval was ongoing in 2021).

35% of the lead or individual submission dossiers re-assessed in 2021 were found either to be 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.

4. Interaction with ECHA

ECHA continued to cooperate with companies/consortia able to proactively submit testing strategies covering groups of substances within the limits of its resources. The experience gained with the 2020-2021 pilot project was used to propose a process outlining the interaction of ECHA with companies within the Action Plan framework. Thus, the learnings from this pilot are intended to inform the broad community of companies having committed to the Cefic Action Plan about steps to consider when reviewing and improving the content of their dossiers.

In respect of the pilot cases, the supporting data generation is substantially complete, and ECHA will be able to start processing the Testing Proposals in 2022.

Following the pilot, Cefic requested signatory companies to nominate groups of substances from the "not yet assigned" category of ECHA's Chemical Universe, for which registrants have a testing strategy to propose: 22 groups of substances were proposed in 2021. From that list, ECHA selected 5 groups of substances in accordance with its priorities (*e.g.* not subject to any ongoing regulatory process and not subject to group management teams (GMT) work yet). For the selected groups of substances, companies participating in the interaction process submitted an initial testing strategy to ECHA, which was reviewed, and an informal feedback was provided by ECHA on 4 groups of substances. After review, the initial testing strategy was refined, and Testing Proposals were submitted, as applicable, in line with ECHA's feedback.

Regarding the interaction process in 2021, volunteer companies are now working on refining their testing strategies, submitting the TP and generating the necessary Annex VII/VIII data to further substantiate the category justification.

The benefit of this programme for companies is that registrants acting voluntarily can develop and agree on testing strategies with a higher chance of data acceptance once testing strategies have been reviewed and finalised. Agreeing on potentially missing studies for individual substances out of a group or category may ultimately contribute to minimising animal testing. In addition, an interaction on smaller groups of substances could also be beneficial for difficult cases.

Furthermore, ECHA benefits also from this interaction as data gaps are filled without the need to open formal compliance checks, and the data generation facilitates further regulatory work. This was highlighted by ECHA at the Safer Chemical Conference 2021 under the topic of "*zero-tolerance approach to non-compliance*".

What has been found in general is that grouping approaches developed by ECHA (based on structural similarity) do not always match with the industry's grouping proposals. This is a point worth keeping in mind for future interactions.

ECHA will continue the interaction process with new group categories in 2022, taking account of its resources and priorities.

Next Steps

Cefic and ECHA will organise a workshop with signatory companies to review the progress of the Action Plan and, based on the learnings from the pilot project and the interaction process, provide support on how to improve dossiers' content, particularly when it comes to improving testing strategies, with animal testing as a last resort and filling data gaps.

The 2022 plan includes:

- Cefic will continue working with **all corporate members** to join the Action Plan.
- Cefic will continue the engagement and cooperation with partner associations, national associations and national federations to **expand participation and provide further information to their members on dossier improvement.**
- Based on the experience in 2021, **ECHA will continue the interaction process with signatory companies in 2022**, cooperating with companies and consortia proactively submitting testing strategies covering groups of substances. Thus, the learnings are shared with other signatory companies to help understand how to improve their dossiers to increase the success rate on ECHA's compliance check.

[1] Includes studies commissioned, on-going or completed.

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

[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. **Dossiers are considered re-evaluated only on a voluntary basis, and not as a result of an obligation imposed by a ECHA's decision.**

[4] 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.

[5] ECHA REACH registration statistics. Data as of: 28/02/2022

[6] 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.

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