5th Progress Report for Improvement of REACH Registration Dossiers

May 2024

Cefic REACH Action Plan

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the forum of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 14% of world chemicals production. Cefic members form one of the most active networks of the business community, complemented by partnerships with industry associations representing various sectors in the value chain. A full list of our members is available on the Cefic website.

Cefic is an active member of the International Council of Chemical Associations (ICCA), which represents chemical manufacturers and producers all over the world and seeks to strengthen existing cooperation with global organisations such as UNEP and the OECD to improve chemicals management worldwide.

KEY HIGHLIGHTS

- By December 31, 2023, the REACH Dossier Improvement Action Plan received support from 200 companies committed to enhancing their dossiers in line with the latest REACH regulation requirements. **These companies cover 1172 legal entities ("registration holders"), demonstrating a significant effort across the industry to re-evaluate and improve REACH registration dossiers.**

- **Since June 2019, a total of 4885 substances[1] registered as full registration have undergone thorough re-evaluation**, reflecting a commitment to continuous improvement and ensuring that dossiers are in line with current REACH regulations.

- In 2023, **participants of the Action Plan re-evaluated 951 substances registered as full registration**, covering registrations across all tonnage bands.

- The estimates indicate that **over 5200 substances registered as full registration will undergo re-evaluation between 2019 and 2026**. These registrations represent nearly 40% of the ECHA database or substances registered with full registration requirements[2] . Compared to 2021, the estimates for substances to be re-evaluated in the scope of the Cefic Action Plan decreased by nearly 14% to the 2023 estimates. This is attributed to the re-prioritisation of companies' resources addressing ECHA's compliance checks and the re-evaluation of dossiers to be in line with the amendments in annexes VI-XI that came into force in 2022, handling non-EU registrations and industry adjustments amidst EU economic uncertainty.

- **Approximately 74% of the lead/individual dossiers re-evaluated in 2023 (more than 700 substances) are either submitted or will be submitted with new data or information[3]** . Among these dossiers, 180 substances involve higher-tier testing according to Annexes IX and X[4], while another 234 substances involve Annexes VII and VIII studies, showing a commitment to robust data generation and compliance with REACH requirements.

- The interaction process with ECHA continues to provide value, particularly for **addressing complex categories of substances involving waivers and/or read-across**, facilitating informed decision-making and alignment with regulatory standards.

- Cefic is committed to engaging with signatory companies and supporting the Action Plan's success while **adapting to the developments in REACH regulations and scientific understanding**.

- Continued collaboration with ECHA is essential for advancing the objectives of the Action Plan, driving improvement in chemical dossiers, **and reducing animal testing through optimised data generation**.

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[1] The number of substances referred to in this report is based on the dossiers submitted by lead registrants and individual submitters participating in the Cefic Action Plan. The number of lead registrants and individual dossiers serves as a proxy to estimate the coverage of substances within the Action Plan's scope. Further information is also included on page 5, Methodology.

[2] 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.

[3] 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.

[4]Information included both: experimental studies on the substance via testing proposal (TP) or read across-TP and data adaptations like waivers and read-across.

BACKGROUND

In June 2019, Cefic introduced the REACH Dossier Improvement Action Plan to support and encourage its members and members of national associations to re-evaluate existing REACH registration dossiers and to improve existing data. After expert re-assessment and when information is needed, the signatory companies update their IUCLID endpoints with supporting data like read-across, quantitative structure-activity relationship models (QSARs models), new scientific information, updating waivers, bridging studies, and as a last resort, update IUCLID endpoints[5] with new animal studies. This update aims to ensure that current chemicals in the market have sufficient data to prove their safety for both people and the environment and comply with the latest REACH requirements.

The REACH Regulation aims to ensure a high level of protection of human health and the environment against harmful substances. As a complex and evolving chemical regulation, it makes sure that companies manufacturing or bringing chemicals into the EU must register them with the European Chemicals Agency (ECHA). This process involves providing a detailed dossier in IUCLID format, describing the uses, the chemical's characteristics, hazards, risks and exposure information. ECHA reviews the registration dossiers to ensure they meet the necessary information standards according to the REACH and CLP regulations. If the dossiers fail to provide the necessary information, additional steps may be taken to assess the risks or request additional information, such as a compliance check (CCH)[6].

The REACH Dossier Improvement Action Plan started in response to ECHA's assessment that many registration dossiers after the 2018 registration deadline lacked information to comply with minimum requirements. The German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA) came up with similar findings in other reports[7]. Thus, while Cefic does not directly participate in consortium or company discussions regarding dossiers, nor does it individually re-assess them, it assists its members in implementing the Action Plan to re-evaluate substances in their chemical portfolio voluntarily.

Cefic requests all signatory companies to submit an annual Key Performance Indicator (KPI) report to assess the effectiveness of the Action Plan and monitor the activities of signatory companies. These reports are aggregated anonymously and serve to track progress and qualitatively measure the type of information submitted by lead registrants in their registration dossiers. The current report marks the fifth annual update, reporting all the activities from signatory companies during 2023, with past reports publicly available on **Cefic's website**.

[5] More information on IUCLID: **ECHA's website what is IUCLID**.
[6] More information on Compliance Check: What is **Compliance Check-ECHA**.
[7] More information on BRF report: **Report publicly available**.

METHODOLOGY

Every year, Cefic collects the Key Performance Indicator (KPI) report from all signatory companies for the Cefic REACH Dossier Improvement Action Plan. The KPI report is structured into two main sections: **reporting requirements for KPIs and additional information requests**. This additional information request is reserved only for lead registrants and individual submitters who re-evaluated dossiers during the previous year. This year, all signatory companies provided the KPI report that reflects the work in re-evaluating dossiers during 2023.

The KPI reporting includes the following information requested from signatory companies:

- The total count of legal entities by the signatory companies' commitment to the Action Plan.
- The number of lead dossiers/individual submissions and co-registrations re-evaluated in 2023 for full registration dossiers.
- The number of dossiers prioritised by signatory companies for voluntary re-evaluation as lead registrants/individual submitters over the entire duration of the Action Plan (2019-2026). **This information serves as an indicator of the number of substances within the Action Plan's scope.**

In addition to KPIs, Cefic sought further information on the nature of the "re-evaluated" dossiers within this voluntary programme. Participating companies were asked to provide additional information detailing the types of re-evaluation carried out by individual submitters (for stand-alone dossiers) and lead registrants (for joint submissions) during 2023. This request aims to complement the KPI reporting process and enhance transparency regarding the types of information registrants submit in their registration dossiers.

The additional information collected was grouped into the following categories:

A. No substantial updates to dossier content: re-evaluation affirmed that dossiers are in line with REACH requirements; thus, there was no need to update the registration dossier or adjustments were made to align with new regulatory IT standards or administrative-technical completeness check (TCC) information without incorporating new analytical data, physico-chemical, toxicological, or ecotoxicity data, new uses, or revised interpretations impacting the CSR or regulatory status of the dossier.
B. Improvement of substance identity/chemical composition: analytical data generated to support read-across, including details on chemical composition, concentration ranges, and structural information of the substance.
C. Generation of new data as per Annexes VII and VIII of REACH or other studies/data to support read-across (such as toxicokinetic data, metabolism studies, 'bridging studies'). This data encompasses ongoing, completed, or commissioned studies.
D. Generation of new data involving higher-tier studies as per Annexes IX and X of REACH, for which a Testing Proposal (TP) is needed. This data includes ongoing, completed, or commissioned studies.
E. Incorporation of new uses/exposure information prompting Chemical Safety Report (CSR) updates.
F. CSR updates unrelated to the abovementioned categories, such as revised data interpretations leading to classification changes, new assessments for PBT/vPvB, derivation of DNEL or PNEC, Improvement in study summaries, etc.

This additional information aids Cefic and its signatory companies in monitoring progress and identifying any recurring issues or areas for enhancement in REACH dossier submissions.

1. 2023 PROGRESS

By December 31, 2023, 200 companies committed to improving their registration dossiers to comply with the latest REACH regulation requirements. The list of these signatory companies is publicly accessible on a dedicated page on **Cefic's website**, updated monthly for transparency purposes.

In February 2024, Cefic collected the KPI reports from signatory companies and assessed the information provided in the KPI report. Four companies will stop their participation in the Cefic Action Plan:

- Two companies deal mainly with intermediate manufacturing, and their full lead dossiers were already re-evaluated in prior years; for the next two years, they will focus on addressing the CCHs received in 2023.
- One company ceased manufacturing operations in October 2023.
- The remaining company merged with another signatory company, resulting in an agreement to provide one combined KPI report for the following years. These updates are reflected in the public list of signatory companies.

Until the end of 2023, 200 companies have actively engaged in dossier improvement activities covering 1,172 legal entities (LEs). This figure remains consistent with the reported number in 2022 despite divestments and carve-outs by several small companies being members of a National Association during 2023. Some manufacturing sites were acquired by other signatory companies, contributing to the steady LE count.

Among these 200 companies, 91% of the legal entities come from Cefic member companies, while the remaining 9% consist of legal entities from companies being members of a National Association. Both Cefic and national member associations have been influential in promoting the Action Plan to their members, encouraging widespread participation in this initiative.

All signatory companies have submitted their 2023 KPI report and the additional information requested to all lead registrants/individual submitters that re-evaluated registration dossiers during 2023. This ongoing commitment to compliance and re-evaluation underscores these companies' dedication to meeting REACH regulations and upholding European chemical product safety standards.

2. DOSSIER STATISTICS

a) Overview of dossiers undergoing re-evaluation in the Cefic Action Plan (2019-2026)

Cefic expects that around 5200 substances covered by the Action Plan will undergo re-evaluation[8] by both individual submitters (stand-alone dossier) and lead registrants (joint submission) by December 2026. These substances represent approximately 40% of substances with full registrations in ECHA's database[9], which is around 13,000 substances.

This number has decreased over time. In 2020, it was reported to be around 7100 substances. However, after clarification with signatory companies, it was noted that this number included some intermediates and co-registrations[10]. While the Cefic Action Plan encourages all types of updates, it's important to note that this program does not measure the re-evaluation of intermediate dossiers. Intermediates are produced for further chemical processing and are registered with minimum data requirements, whereas the focus here is on re-evaluating full IUCLID endpoints.

The figures for 2021 present a more realistic view of the substances to be re-evaluated in the program, with a significant decrease of nearly 14% (around 800 substances) compared to the estimates in 2023 (Figure 1). This decline is partly due to the two amendments[11] to the REACH Annexes VI-XI that came into force in 2022. Part of the resources allocated to substances originally planned for re-evaluation until 2026 were moved to substances already re-evaluated before 2022 so that those dossiers would be in line with the new amendments in the annexes.

Another factor is the changes in ECHA's chemical universe and the prioritisation of substances for CCHs. Many signatory companies allocated fewer resources to re-evaluate dossiers voluntarily in 2023, prioritising resources for CCHs. ECHA conducted 301 CCHs in 2023, addressing 274 individual substances[12]. The agency has met its legal target for dossier evaluation, which was increased from 5 % to 20 % in 2019[13]. Meanwhile, for substances registered at quantities of 100 tonnes or more per year, ECHA has checked compliance for around 30% of the total amount.

With the Cefic Action Plan's scope, there was a decrease of 233 substances from 2022 to 2023. Internal resources were redirected to handle an increased number of CCHs[14] and non-EU registrations. Additionally, due to the energy crisis and a lower EU market demand, some companies/sites had to cease manufacturing resulting in another factor for the decrease in the number of substances in scope for the voluntary programme.

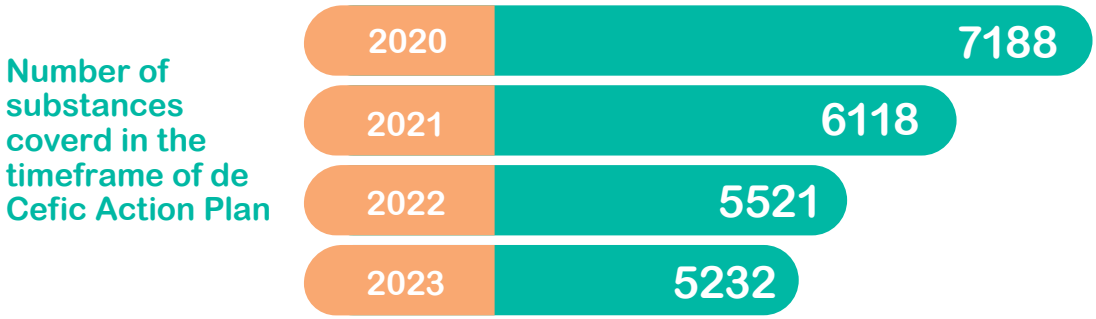

Figure 1: Number of substances covered in the timeframe of the Cefic Action plan (2019-2026)

[8] 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**.
[9] More information on REACH registrations statistics: **Information updated in ECHA's page on 30.04.2024**.
[10] Many companies reported re-evaluating dossiers on 'intermediates' as individual submitters, lead registrants, and co-registrants, primarily updating analytical information for substance identification.
[11] Two amendments came into force in 2022. **Commission Regulation (EU) 2021/979** was implemented on 17th June 2021 and applied from 8th January 2022. **Commission Regulation (EU) 2022/477** was implemented on 24th March 2022 and applied from 14th October 2022.
[12] ECHA all news February 2024: **ECHA checked over 20% of REACH registration dossiers for compliance**.
[13] More information on REACH Evaluation Joint Action Plan: **Ensuring compliance of REACH registrations**.
[14] Although CCHs are not in the scope of the Cefic Action Plan, some signatory companies re-evaluated additional IUCLID endpoints from dossiers subject to a CCH. These additional endpoints re-evaluated are not resulting from an obligation due to a decision from ECHA.

b) Updates from Lead registrants and co-registrants

The companies that have signed the Cefic-Declaration of Intent (DoI) are committed to provide the KPI data on the number of registration dossiers re-evaluated in 2023, both as lead registrants/individual submitters and as co-registrants[15].

In 2023, a total amount of 2483 registration dossiers underwent re-evaluation[6], encompassing full registration dossiers across all tonnage bands. 951 registration dossiers were re-evaluated by individual submitters and lead registrants, accounting for a more extensive impact since lead dossiers encompass information from joint submissions, potentially affecting updates in multiple co-registrations. This aggregated KPI from 2023 indicates a slight decrease of 15% in re-evaluated **lead dossier/individual submissions compared to 2022 (Figure 2). As explained above, companies had to prioritise resources for addressing CCHs, resulting in a slight lower number of voluntary re-evaluations.**

1532 registration dossiers were re-evaluated by co-registrants (joint submissions).

Since the start of the Action Plan in June 2019, a cumulative total of **4885 lead dossiers/individual submissions** have undergone re-evaluation, serving as a proxy for the number of substances.

It is worth noting that as REACH regulations and scientific understanding evolve, some dossiers re-evaluated in 2019 may require another re-evaluation in the coming years.

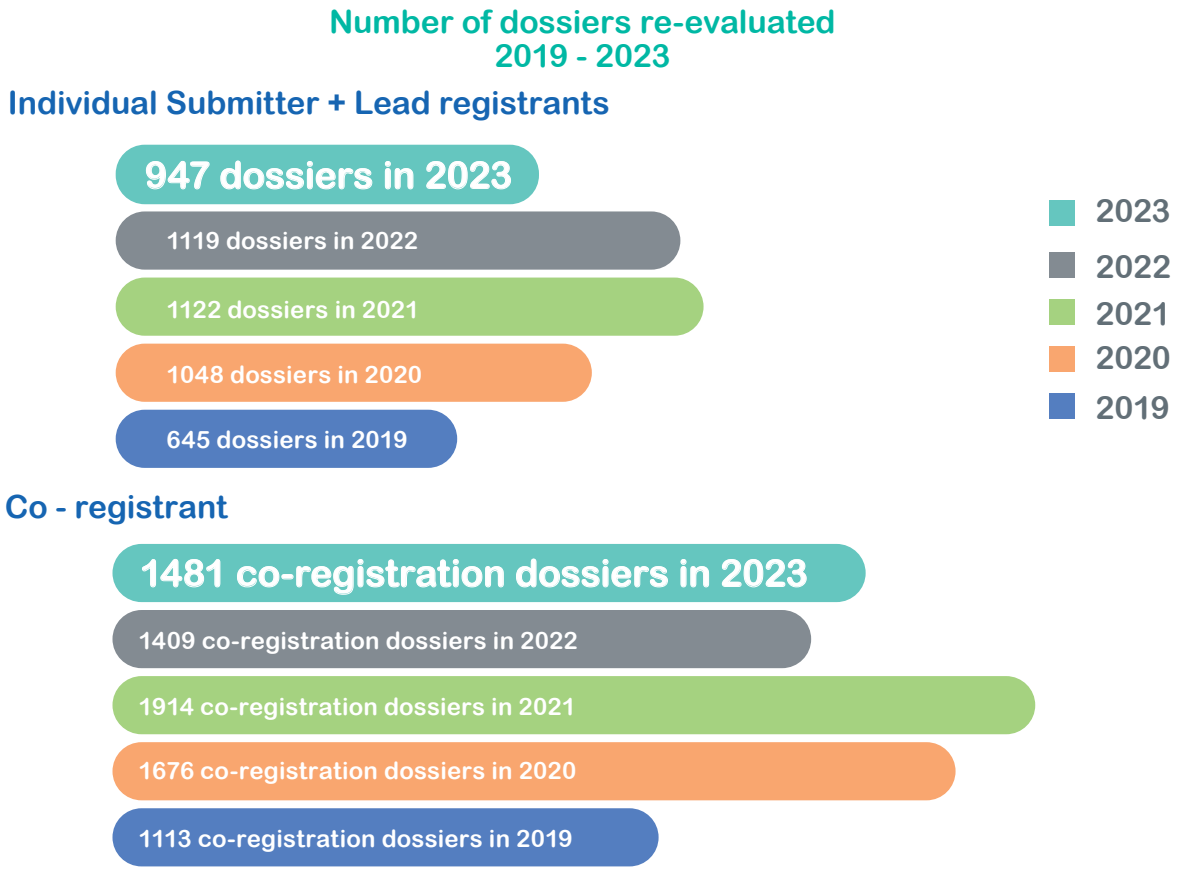

Figure 2: Comparison of dossiers re-evaluated in 2023 with previous years

[15] A reporting template was made available to the signatory companies: Template is public available from the **Cefic Action Plan Page**.

c) Additional information about the type of updates

Almost 1 out of 3 (26%) of the reassessed lead/individual submission dossiers were found to be in line with the latest REACH requirements, necessitating no updates or requiring only minor updates to meet new IUCLID requirements without the addition of new data.

In the other cases (74% - equivalent to around 700 substances), the re-evaluation triggered dossier's updates containing new or additional data; further insights into the nature of updates were provided by all signatory companies **that re-assessed lead dossiers and individual submissions in 2023 (Figure 3).**

These updates can be classified as follows:

- For 113 substances *(compared to 223 in 2022)*, improvements were made with new analytical data supporting chemical composition, concentration ranges, and structural information.
- 234 substances *(compared to 404 in 2022)* re-evaluated in 2023 were updated or are in the process of being updated with studies from Annex VII or VIII, or other relevant data supporting read-across (such as toxicokinetic data, metabolism studies).
- 80 substances *(compared to 289 in 2022)* involved higher-tier testing as per Annexes IX and X. Some companies included TPs submitted in previous years. The examination process is still ongoing in 2023, awaiting approval before contract research organisations (CROs) can initiate the study[16].
- 177 substances *(compared to 190 in 2022)* incorporated new uses triggering updates in exposure information within the substance's Chemical Safety Report (CSR).
- 262 substances (compared to 341 in 2022) had improvements with a new interpretation of existing data in the registration dossier, potentially leading to changes in classification and labelling, PBT/vPvB assessment, new DNEL or PNEC derivation, or enhancement of study/endpoint summaries.

Some reassessed dossiers have not yet been resubmitted to ECHA as companies agreed on a testing plan with a CRO, and testing is still ongoing or delayed due to CRO capacity constraints. However, additional KPI information was requested from individual submitters and lead registrants, even for ongoing processes. 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 2023 and for higher-tier test if a submitted TP has been approved by ECHA or the approval was ongoing in 2023).

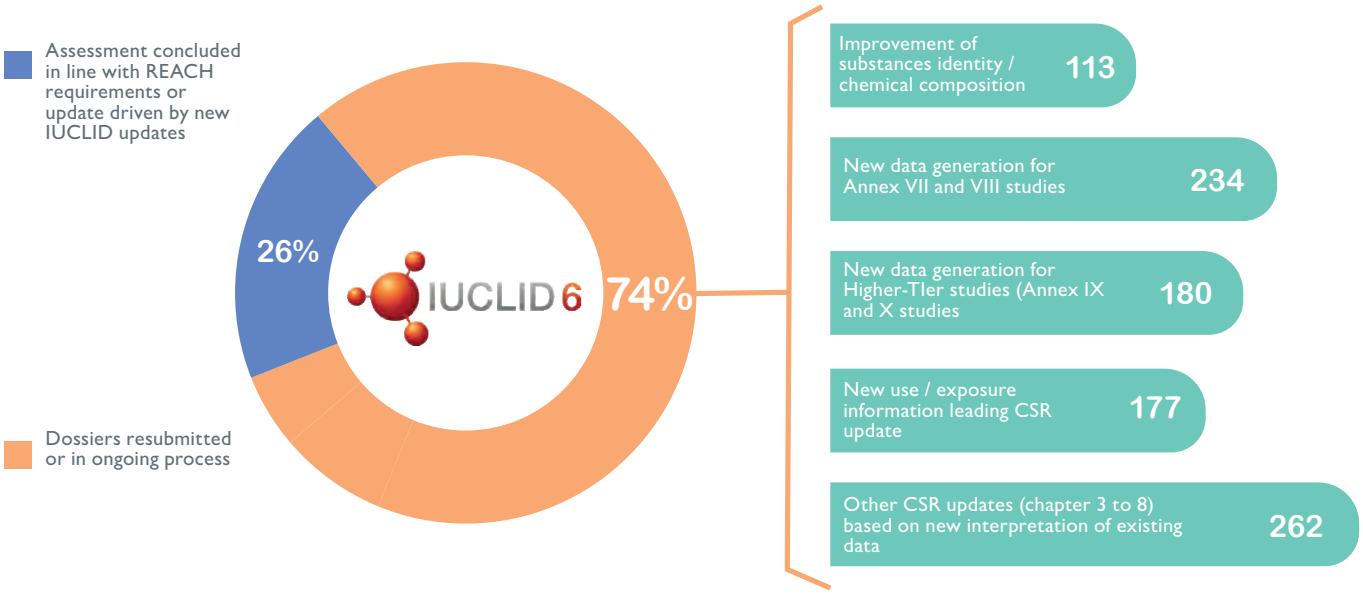

Figure 3: Dossiers re-evaluated in 2023 and additional information on the nature of updates.

[16] 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.

3. INTERACTION WITH ECHA

As part of the REACH Dossier Improvement Action Plan, a Cooperation Agreement was established between Cefic and ECHA to work on a pilot project with the active participation of a small set of volunteer signatory companies. The objective of the pilot project was to select substance case studies and to explore different read-across approaches and respective testing strategies, with a view to generating data to improve compliance of registrations under REACH and for the industry to better understand ECHA's expectations.

The pilot project's findings were presented in a workshop in 2020 and learnings and summaries from the workshop were shared with all signatory companies. Despite encountering delays in generating supporting data, primarily due to laboratory capacity constraints, ECHA has acknowledged the external factors contributing to these delays. In 2024 ECHA will start processing TPs for groups where further clarification are not needed.

The experience gained with the pilot projects has been used to propose a process outlining future interaction of ECHA with companies within the framework of this Action Plan. Thus, ECHA continued collaborating with signatory companies, proactively encouraging them to submit testing strategies for substance groups within resource constraints.

In 2021, ECHA prioritised five groups of substances which aligned with its objectives. The participating companies in the interaction process submitted initial testing strategies to ECHA for review. Subsequently, ECHA provided informal feedback on four groups covering 33 substances.

In 2022, ECHA selected one group of substances and has already received the initial testing strategy.

Looking ahead, Cefic aims to continue collaborating with ECHA and signatory companies to provide results and share the learning with the chemical industry. The interaction process helps to comprehend the intricacies of substance grouping from the industry's perspective. This collaboration seeks to develop and agree testing strategies that optimise data generation on the category and individual substance level, supporting the category approach and ultimately reducing animal testing.

NEXT STEPS

- With the participation of all signatory companies and ongoing support from Cefic and national member associations, the Action Plan has demonstrated ongoing engagement and commitment. **Cefic remains committed to maintaining this level of engagement and supporting signatory companies for the initiative's continued success**.

- The Action Plan started in response to the identified data gaps in registration dossiers after the 2018 registration deadline. As the REACH regulations and scientific understanding evolve, **the Action Plan will adapt accordingly and stay abreast of regulatory and administrative updates, ensuring that signatory companies remain aligned with the latest requirements to address emerging challenges effectively**.

- The annual Key Performance Indicator (KPI) reports serve as valuable tools for monitoring progress and identifying areas of improvement. **Cefic will continue to emphasise the quality and transparency of these reports and provide more granularity to authorities regarding the type of information re-evaluated for lead registrants.**

- The pilot project and ongoing collaboration with ECHA highlight the importance of cooperation and knowledge-sharing between ECHA and signatory companies. Cefic believes that fostering cooperation to understand more about grouping, testing strategies, and optimising data generation is critical to advancing the objectives of the Action Plan and driving continuous improvement in chemical dossiers. **The next step is to inform all signatory companies about what members of the pilot project and interaction process have learnt and allow signatory companies to share and apply the learnings with the chemical industry.**

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