6th Progress Report for Improvement of REACH Registration Dossiers

June 2025

cefic

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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

- 196 signatory companies, covering 1,125 legal entities ("registration holders"), actively participated in the 2024 reporting, reflecting the continued commitment to improving REACH dossier quality despite challenging regulatory and market pressures.

- In 2024, signatory companies voluntarily re-evaluated 2,514 full registration dossiers, including 949 by lead registrants/individual submitters and 1,565 by co-registrants. For lead registrants and individual submitters, this represents a cumulative total of 5,833 substances[1] updated with full registration requirements[2] since 2019.

- Approximately 73% of the lead/individual dossiers re-evaluated in 2024 (nearly 700 substances) are either updated or will be updated with new data or information[3]. Most updates include new hazard data, improved substance identity, and revised hazard and exposure assessments. These updates help ensure that dossiers remain scientifically sound and compliant with evolving regulatory requirements.

- 202 substances will be updated with higher-tier data according to Annexes IX and X[4]. These updates include studies on long-term toxicity, reproductive effects, environmental fate, and the use of adaptations and waivers. Companies have submitted testing proposals and are awaiting approval from ECHA to run the proposed tests.

- The voluntary pilot project and cooperation with ECHA provide valuable insights on grouping, read-across, and testing strategies. Lessons learned are shared across the broader industry to support alignment with regulatory expectations and facilitate scientifically justified approaches. Continued collaboration with ECHA is important for advancing the objectives of the Action Plan, driving improvement in chemical dossiers, and reducing animal testing through optimised data generation.

- The 2024 KPI report maintained high transparency, with companies providing detailed breakdowns of update types. Cefic is committed to engaging with signatory companies and supporting the success of the Action Plan, while adapting to developments in REACH regulations and scientific understanding.

[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

Since its launch in 2019, the REACH Dossier Improvement Action Plan has provided a voluntary platform to encourage companies to reassess and improve their REACH registration dossiers. The initiative, developed by Cefic in cooperation with its member companies and national associations, supports proactive updates to ensure that dossiers align with evolving regulatory expectations and scientific standards.

This report highlights the results from 2024, indicating that this initiative continues to play a key role in promoting responsible chemical management by encouraging companies to review their registration data and update relevant IUCLID endpoints. These updates include new scientific data, adaptations such as read-across justifications, bridging studies, and, where necessary, new testing proposals (TPs), ensuring dossiers reflect the most current understanding of substance safety while limiting the need for animal testing.

The REACH Regulation requires that chemical dossiers demonstrate the safe use of substances placed on the EU market. Companies must submit robust, complete data packages using the IUCLID system, covering identity, hazards, uses, exposure and risk assessment. In parallel, ECHA continues to evaluate registration dossiers through compliance checks (CCH)[5] and other mechanisms to verify conformity with the legal requirements under REACH and CLP.

ECHA and national authorities reinforced the need for the Action Plan, observing significant shortcomings in many dossiers submitted before or after the 2018 deadline[6]. While Cefic does not assess individual dossiers, it facilitates industry-wide improvements by encouraging voluntary updates and dialogue with ECHA, particularly on complex topics such as grouping and testing strategies.

Cefic collects yearly Key Performance Indicator (KPI) reports from all signatory companies. These reports are aggregated to track progress, identify trends, and monitor how companies improve their dossier quality. The present report marks the sixth year of implementation and summarises the re-evaluation activities in 2024. It also highlights broader trends, such as the increased CCH activity and the prioritisation of industry resources in response to evolving regulatory requirements and authorities' requests.

[5] More information on Compliance Check: What is Compliance Check-ECHA.
[6] More information on BRF report: Report publicly available.

Methodology

Since implementing the REACH Dossier Improvement Action Plan, Cefic has collected annual KPI reports from all signatory companies to monitor progress and support the voluntary re-evaluation of REACH registration dossiers.

The KPI report is structured into two main spreadsheets:

A. The reporting requirements for KPIs and
B. An additional information request targeting lead registrants and individual submitters who re-evaluated dossiers during the previous year.

In 2024, all signatory companies submitted their KPI reports, documenting their re-evaluation activities during the reporting period. This sixth annual report not only tracks the overall number of dossiers reviewed but also emphasises the updates made by lead registrants, particularly providing more detailed insights into the submission of TPs and the assessment from authorities.

By capturing this level of information, the report aims to shed light on how companies are proactively generating new data, supporting read-across justifications, and aligning with regulatory expectations for higher-tier endpoints.

The KPI reporting covers:

- The total number of legal entities covered by the signatory companies' commitment to the Action Plan.
- The number of lead dossiers, individual submissions, and co-registrations re-evaluated in 2024 for full registration dossiers.
- The number of dossiers prioritised for voluntary re-evaluation by signatory companies as lead registrants or individual submitters over the entire duration of the Action Plan (2019–2026). This helps estimate the scope and impact of the Action Plan over time.

Cefic also requests more detailed information from companies that have re-evaluated individual submissions (for stand-alone dossiers) and lead registrants (for joint submissions) during 2024 to complement the KPIs. This voluntary submission helps clarify the nature of updates made and reinforces transparency regarding the information being included in registration dossiers.

The additional information is categorised as follows:

A. No substantial update is needed: Expert confirmation that dossiers meet REACH requirements or minor updates are made to align with IT system changes or technical completeness checks.
B. Improvement of substance identity and chemical composition: New analytical data were generated to support the substance description and improve read-across justifications.
C. New data generation for Annex VII/VIII studies: Including studies to support read-across.
D. New data generation for higher-tier (Annex IX/X) studies: Including studies that required TPs, whether ongoing, completed or commissioned.
E. Updates to Chemical Safety Reports (CSR) based on new uses or exposure information.
F. CSR updates due to reinterpretation of existing data, such as revised hazard classification, updated PBT/vPvB assessments, or improved study summaries.

By collecting this additional information, Cefic and its signatory companies can better monitor progress, identify recurring challenges, and continuously improve the quality of REACH registration dossiers. This programme reflects the industry's commitment to regulatory compliance and the safe management of chemicals in Europe.

1. 2024 PROGRESS

Now in its sixth year, the Cefic REACH Dossier Improvement Action Plan remains focused on tracking data from signatory companies that voluntarily align their registration dossiers with REACH requirements while continuously improving the quality and robustness of the submitted data. The list of these signatory companies is in the annex and publicly accessible on a dedicated page on Cefic's website, updated monthly for transparency purposes.

Throughout early 2025, Cefic gathered updated KPI reports from all participating companies, providing detailed information on the re-evaluation activities carried out during 2024. These reports serve as an important monitoring tool to assess progress on the Action Plan's objectives and capture the evolving progress of signatory companies in meeting regulatory expectations.

In 2024, 196 companies reaffirmed their engagement with the REACH Dossier Improvement Action Plan, covering 1,125 legal entities. Despite market pressures and organisational changes within some companies, participation remained strong, demonstrating the continued commitment of both Cefic member companies and members of national associations to improving dossier quality and chemical safety transparency. For the 2024 reporting, special focus was placed on the nature and status of the submitted TPs, supporting the voluntary generation of higher-tier data under REACH.

All signatory companies submitted their 2024 KPI reports, along with the requested additional information from lead registrants and individual submitters involved in dossier re-evaluations. This continued engagement reflects the industry's sustained efforts to align with REACH requirements and to contribute to the safe and responsible management of chemicals in the EU.

2. DOSSIER STATISTICS

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

By the end of 2024, signatory companies to the Cefic Action Plan reported that approximately 5,220 substances remain in scope for voluntary re-evaluation[7] by the end of 2026. These include substances covered by individual submitters (stand-alone dossiers) and lead registrants (joint submissions), representing roughly 40% of the ~13,000 substances currently registered with full dossiers under REACH in ECHA's database[8].

In 2020, the initial estimate was 7,188 substances, but this figure was later revised after discussions with signatory companies revealed that the original number had included intermediates and, for some companies, co-registrations[9], which are categories excluded from the Action Plan's primary focus. 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.

Since 2021, the number of in-scope substances has steadily declined—from 6,108 in 2021 to 5,512 in 2022, 5,280 in 2023, and 5,220 in 2024. This represents an overall reduction of approximately 15%, or about 880 substances, over the four-year period.

One key reason for this decline is the need to redirect resources in response to the two amendments[10] to REACH Annexes VI–XI, which entered into force in 2022. These regulatory changes required companies to update dossiers submitted before 2022 to ensure compliance with the revised annex requirements. As a result, resources had to be diverted from other dossiers that were originally prioritised for re-evaluation by 2026. This reallocation has also led to several substances being re-evaluated more than once, with some already having undergone two rounds of updates.

Nevertheless, the number of substances identified for voluntary re-evaluation remained stable between 2023 and 2024. However, companies continued to face increasing regulatory obligations. In 2024 alone, ECHA carried out 251 CCHs, covering 234 individual substances[11],

[7] 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.

[8] More information on REACH registrations statistics: Information updated in ECHA's page on 30.04.2025

[9] Many companies reported re-evaluating dossiers on 'intermediates' as individual submitters, lead registrants, and co-registrants, primarily updating analytical information for substance identification.

[10] 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.

[11] Progress in Evaluation 2024

further drawing on company resources that might otherwise have been allocated to voluntary updates[12].

Additional external pressures, such as rising energy costs, regulatory context outside the EU, shifting EU market demand, and the closure of manufacturing sites, have contributed to the voluntary programme's narrowing scope. To expand on this, the decreasing competitiveness of European assets has led to changes in supply chain, triggering mergers and acquisitions, increased reliance on imports and the closure of production assets, all of which require significant regulatory attention and resources. Between 2022 and 2024, this resulted in a net decrease of 292 substances from the Action Plan's scope.

In addition to external market pressures, signatory companies have also had to respond to an evolving regulatory landscape. Since 2021, clear deadlines have been introduced through the clarification of Article 22, and new data requirements related to nanomaterials. At the same time, the emergence of REACH-like frameworks globally has increased the demand for compliance. These developments, while important for improving regulatory clarity and global alignment, have placed additional pressure on internal resources. As a result, it has become more challenging for signatory companies to balance mandatory regulatory obligations with voluntary efforts under the Action Plan, despite strong engagement.

Figure 1 below illustrates the year-on-year evolution of the number of substances covered under the Cefic Action Plan, from 2020 to 2024.

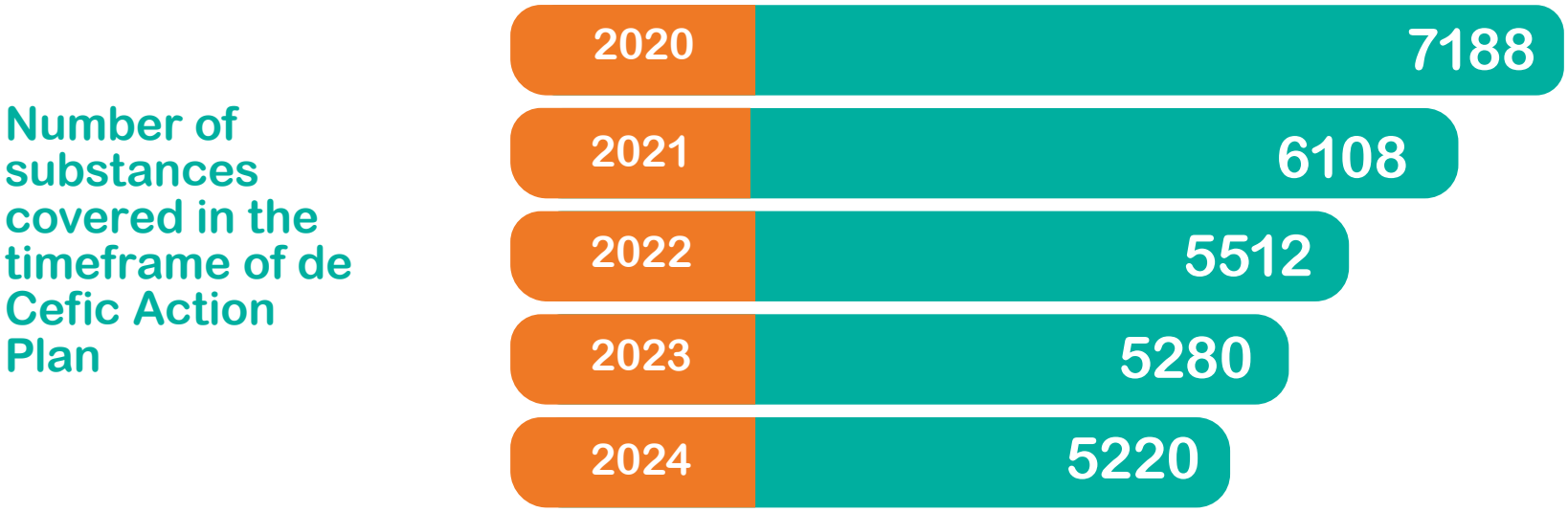


Figure 1: Number of substances covered in the timeframe of the Cefic Action plan (2019-2026)

[12] 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

As part of their annual commitment to the Cefic REACH Dossier Improvement Action Plan, all signatory companies submitted KPI data for 2024, including detailed information on the registration dossiers they re-evaluated during the reporting year. These updates cover dossiers submitted as lead registrants or individual submitters and as co-registrants within joint submissions[13].

In total, 2,500 full REACH registration dossiers were voluntarily re-evaluated by companies in 2024. This includes:

- 949 dossiers re-evaluated by lead registrants and individual submitters. These dossiers have a significant impact, as lead registrants are responsible for submitting the lead dossier on behalf of the joint submission. Updates at this level may trigger changes for multiple co-registrants.
- 1,565 dossiers re-evaluated by co-registrants, who typically rely on the information submitted in the lead dossier but may also update their own parts of the registration (e.g., use and exposure information or CSR elements, in the case it is not a joint CSR).

The number of lead/individual dossiers re-evaluated in 2024 is in line with previous years, indicating continued engagement despite competing priorities, such as resource constraints and growing global regulatory obligations. As shown in Figure 2, the number of updates in this category remained relatively stable compared to 2023.

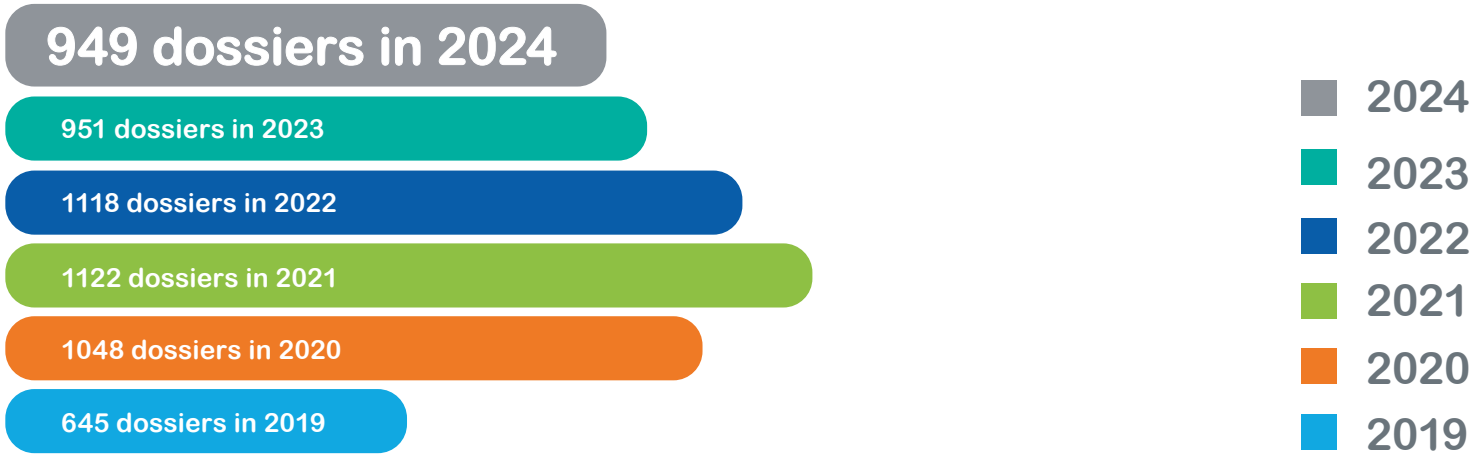
Since the start of the Action Plan in 2019, the cumulative total of lead registrant and individual submissions re-evaluated has reached 5833 dossiers, which serves as a meaningful proxy for the number of substances actively addressed under the programme. This number reflects ongoing efforts to ensure that dossiers remain scientifically robust and aligned with evolving REACH and CLP requirements.

It's important to note that dossier re-evaluation is not a one-off process. REACH is a dynamic regulatory system that continues to evolve through annex amendments, updates to ECHA guidance, and CCH decisions. As a result, some dossiers that were updated in previous years may require further revisions to meet new requirements, such as those introduced by the amendments to Annexes VI–XI in 2022, or following Board of Appeal decision (ex Chronic Fish) or follow new regulatory implementation, for example, to comply with the data information on new hazard classes.

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

Number of dossiers re-evaluated 2019 - 2024

Individual Submitter + Lead registrants



Co - registrant

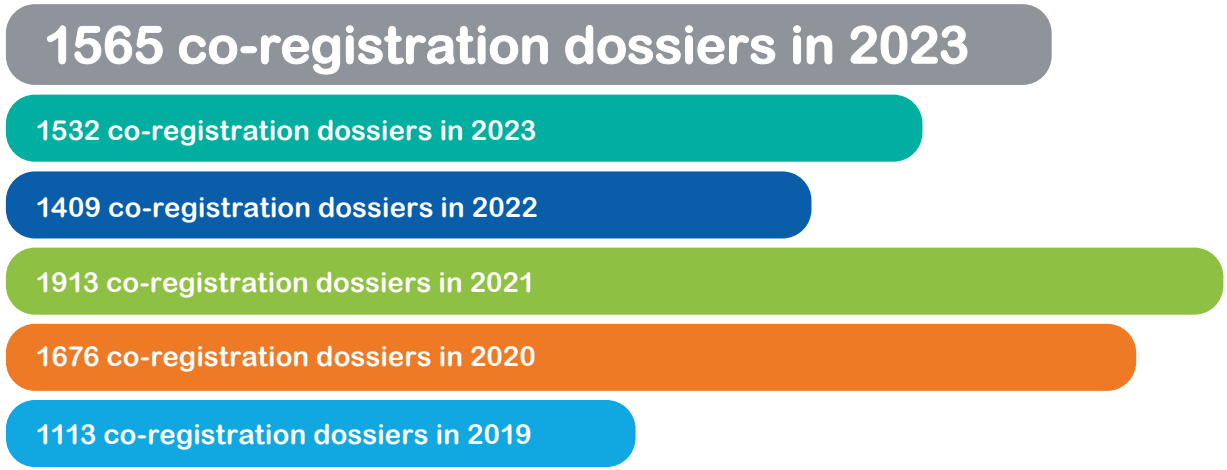


Figure 2: Comparison of dossiers re-evaluated in 2024 with previous years

c) Additional information about the type of updates

As part of the 2024 KPI reporting process, signatory companies to the Cefic REACH Dossier Improvement Action Plan were asked to provide additional information regarding the updates made to their lead and individual registration dossiers. This voluntary transparency effort improves the understanding of how companies maintain and improve dossier quality in response to scientific developments and regulatory expectations.

Of all the reassessed dossiers in 2024, approximately 27% (393 dossiers) required no substantial updates. After expert re-evaluation, these dossiers were concluded to be either already in line with current REACH requirements or only required minor administrative or IT-related adjustments to comply with format changes coming by updated IUCLID or TCC rules. No new data were added in these cases, and no scientific reinterpretations were necessary.

For the remaining 73% of dossiers, companies reported making updates, involving new data generation, refined substance identity information, revised use and exposure scenarios, or hazard and risk assessment updates. These updates were broken down into the following categories:

1. Improvement of Substance Identity / Chemical Composition

99 substances were updated to improve the characterisation of the registered substance.

These updates included the generation of new analytical data containing:

- Spectral information (*e.g.* NMR, IR, MS)
- Purity profiles and impurity characterisation
- Clarification of concentration ranges or structural identifier. Those refinements are especially important when using read-across strategies or justifying the boundaries of a substance category. They help ensure the registrant's dossier accurately reflects the substance's identity and composition as defined under REACH Annex VI.

2. Generation of New Data Under REACH Annex VII or VIII

292 substances were updated with new or ongoing studies required at the lower-tonnage band levels. This included:

- Physico-chemical testing (e.g. water solubility, vapour pressure)
- Toxicological endpoints (e.g. skin irritation, sensitisation, genetic toxicity, short-term repeated-dose toxicity or fertility and developemental screening)
- Ecotoxicological endpoints (e.g. algae, daphnia, short term fish toxicity)
- Studies supporting read-across hypotheses, including toxicokinetic (TK) or metabolic data.

3. Higher-Tier Testing Under Annex IX or X

202 substances included updates involving higher-tier data requirements. These updates generally involved:

- Long-term repeated dose toxicity (e.g. 90-day studies, chronic toxicity)
- Reproductive and developmental toxicity studies
- Environmental fate and behaviour testing (e.g. biodegradation, bioaccumulation)
- Long term Fish toxicity studies
- In some cases, these studies were commissioned following ECHA-approved TPs submitted in previous years. For ongoing cases, companies indicated this in the annual KPI report once a contract was signed with a CRO, even if the study had not been completed[14].

4. Updates Triggered by New Uses and Exposure Scenarios

198 substances were updated to reflect new uses or revised exposure information, prompting changes to the CSR. These updates included:

- Changes to operational conditions or risk management measures.
- Revised exposure estimates for workers, consumers, or the environment

Those updates are important to ensure that the safe use of substances is still demonstrated under realistic market conditions.

5. Other CSR Updates Based on Reinterpretation of Existing Data

275 substances were updated based on new scientific assessments or regulatory needs, even if no new test data were generated. These updates involved:

- Revised classification and labelling based on reanalysis of existing studies
- New or updated Derived No-Effect Levels (DNELs) or Predicted No-Effect Concentrations (PNECs)
- Updated PBT/vPvB assessments
- Improved summary and evaluation of key studies or endpoints.

It's important to note that not all re-evaluated dossiers have been fully resubmitted to ECHA yet. In some cases, updates are still in progress, particularly for studies involving CROs where testing is delayed due to capacity constraints. However, companies were asked to report these cases as "in scope" for 2024 if:

- A testing contract had been signed in 2024, and
- For higher-tier tests, a TP had been approved or was under review by ECHA during the same period.

This reporting highlights the Action Plan's emphasis on continuous improvement, capturing not only completed updates but also those actively progressing through regulatory or scientific review. It underscores the signatory companies' ongoing commitment to maintaining transparent, scientifically grounded dossiers that fulfil legal obligations and contribute to the safe and responsible management of chemicals in the EU.

[14] 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.

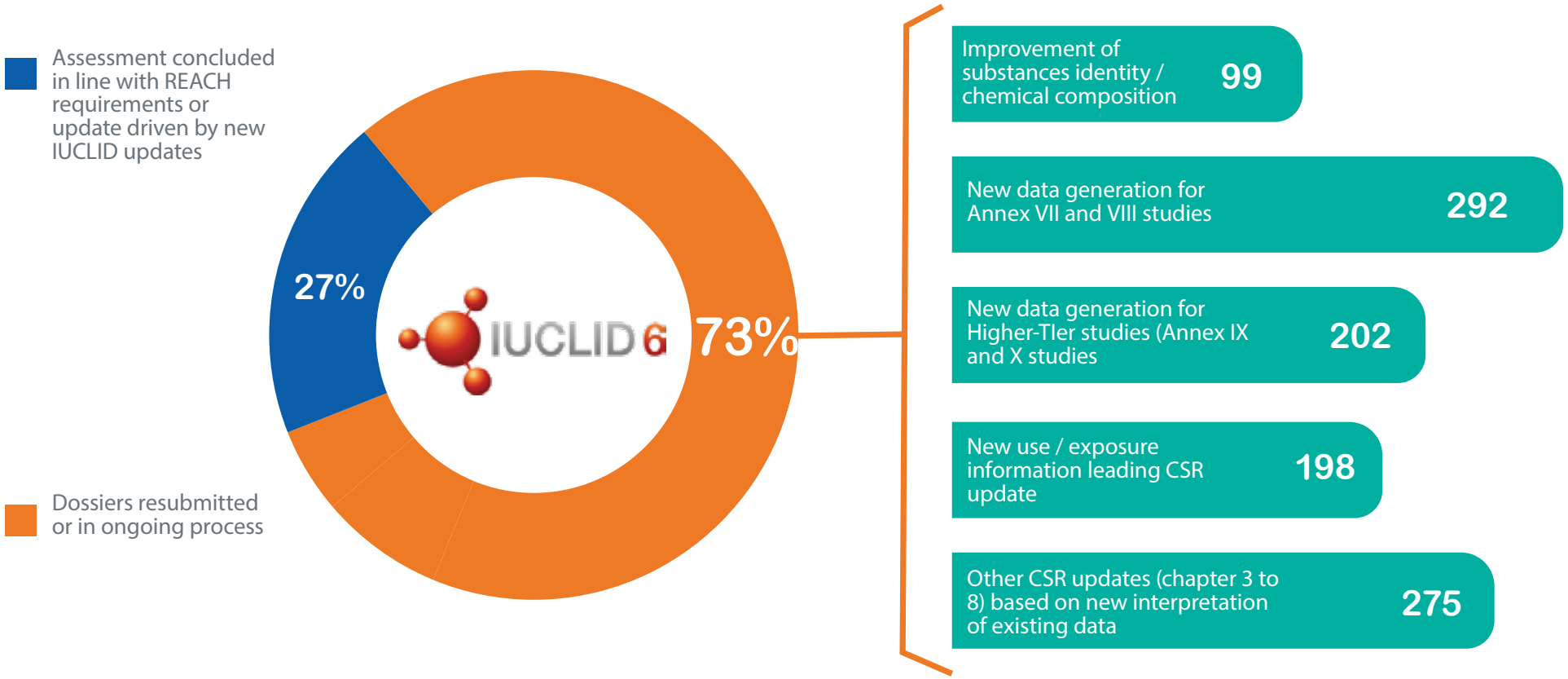


Figure 3: In 2024, 27% of re-evaluated dossiers required no substantial updates beyond minor administrative or IUCLID adjustments, while 73% underwent changes, e.g, new data generation, new information with substance identity, updated uses, or revised hazard assessment. This figure illustrates the types of updates reported

3. ANALYSIS OF THE 2021-2024 TESTING PROPOSALS (TPS)

The following sections provide more details on the status of the submitted testing proposals and the types of endpoint categories for which signatory companies will submit updated information. The analysis is based on publicly available information extracted from the Progress in Evaluation, ECHA CHEM, PACT and the KPI report from signatory companies.

Status and Outcomes of TP Evaluations

From 2021 to 2024, ECHA evaluated 705 TPs, and the TP issues by ECHA are 577 TPs; the majority of TPs are still in the follow-up stage.

- The status "*Wait for follow-up : Perform test with the substance*": A large number of those TPs (i.e. around 40%) the deadline has not expired yet and are still under "Wait for follow-up" status.
- In 40 cases, ECHA authorised testing to proceed with an analogous substance.
- 24 TPs were rejected, including tests proposed on the registered substance and those using analogs.

The full overview of the evolution of REACH TP Action can be seen in Figure 4.

Endpoint Categories in Testing Proposals

According to PACT and ECHA CHEM, an average of 65% of all "*wait for follow-up*" (see footnote 15) or "*follow-up*" TPs belong to companies participating in the Cefic Action Plan. These TPs are linked to 675 higher-tier endpoints to be addressed through new studies performed by contract research organisations (CROs).

The full list of tests that will be performed by signatory companies of the Cefic REACH Dossier Improvement Action Plan is indicated in Table 2; some highlights:

- Pre-natal Developmental Toxicity: 137 planned studies with the registered substance
- Mutagenicity / Genotoxicity: 121 planned studies with the registered substance
- Repeated-Dose Toxicity: 84 planned studies with the registered substance
- Long-Term Aquatic Toxicity: 149 planned studies with the registered substance.

These categories correspond directly with Annex IX and X data requirements. The demand for long-term aquatic and reproductive/developmental toxicity studies reflects the continued focus of ECHA and the authorities on the data available to assess chronic exposure and generational impacts.

Finally, these numbers confirm that Action Plan signatory companies are addressing the many higher-tier testing needs under REACH. This data reinforces the strategic role of the Cefic Action Plan in supporting compliant dossier updates while aligning with regulatory requirements.

[15] Wait for follow-up: this status refers to the cases for which the deadline set in the final decision has not yet expired. Follow-up to dossier evaluation starts when the deadline in the dossier evaluation decisions has passed. Once this deadline has passed, ECHA assess the information submitted in the dossier

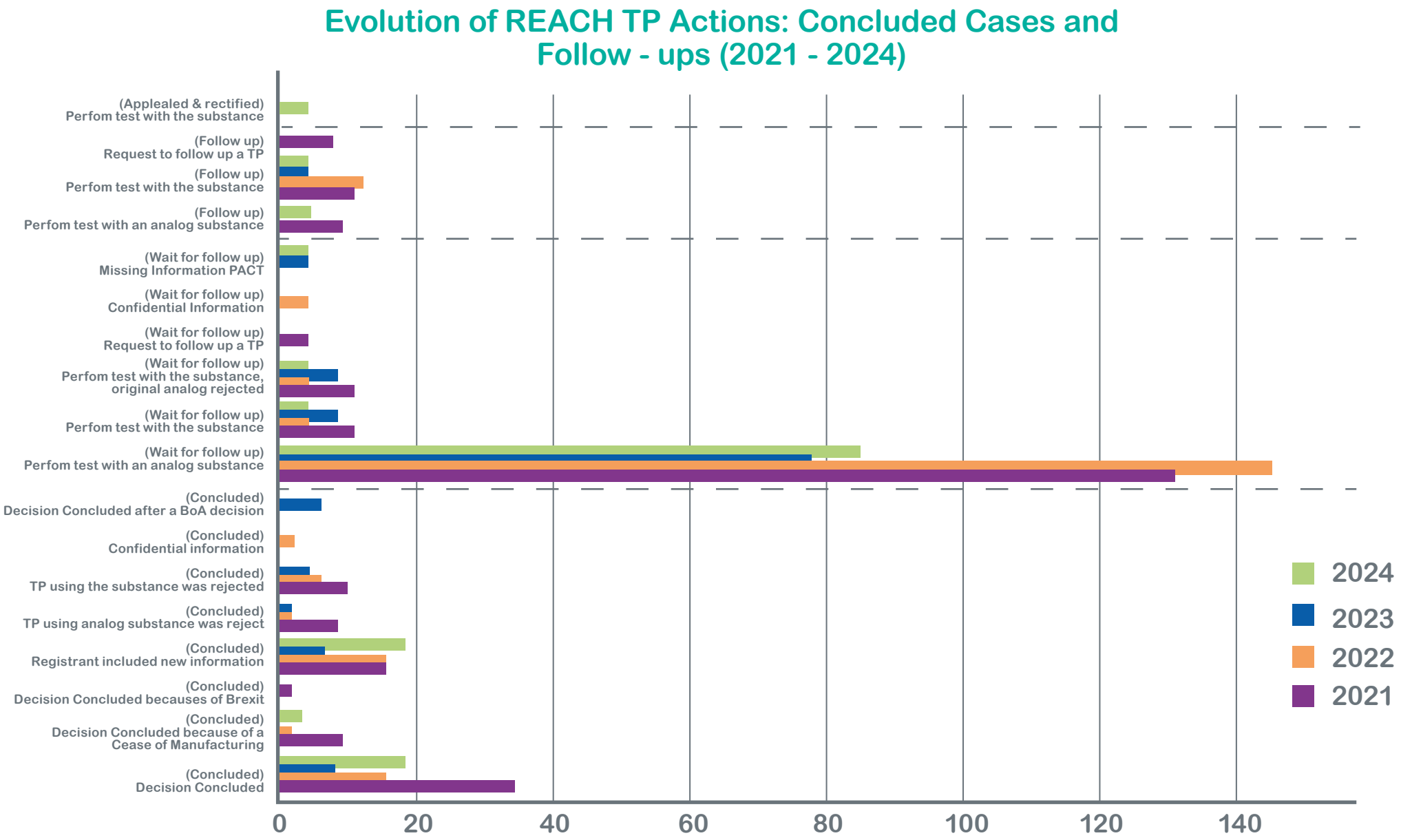


Figure 4: Status of REACH TPs – Follow-up and Concluded Actions (2021–2024) *Distribution of TP outcomes, including follow-ups, wait for follow-ups, and concluded decisions by year.*

	2021	2022	2023	2024
% of TP that will provide data and belong to the sinatory companies of the REACH Dossier Improvement Action Plan	60 %	66%	71%	61%
Carcinogenicity	0	0	0	0
Mutagenicity / Genotoxicity	47	35	34	5
Pre - natal developmental toxicity	34	45	40	18
Reproduction toxicity	12	18	15	9
Repeated - dose toxicity	27	23	26	8
Biodegradation	14	14	5	5
Bioaccumulation	1	0	0	1
Long - term aquatic toxicity	22	34	46	47
Physico - chemical properties	3	3	4	3
Other environment	17	37	16	7
Total	177	209	186	103

Table 2: Higher-Tier Endpoints Covered by TPs from Cefic Action Plan Signatories (2021–2024)

4. INTERACTION WITH ECHA

As part of the REACH Dossier Improvement Action Plan, a voluntary Cooperation Agreement was established in 2019 between Cefic and ECHA. This agreement launched a pilot project involving a few volunteer signatory companies to improve the quality and compliance of REACH registration dossiers.

The project focused on selecting case study substances to explore different read-across approaches and corresponding testing strategies. The goal was to generate data to improve dossier compliance and help the industry understand ECHA's expectations. While the agreement is not legally binding, it promotes best practices, transparency, and trust through open dialogue between regulators and industry.

The pilot project initially included four groups covering 34 substances. Findings were presented at a 2020 workshop and shared with all signatory companies. Building on these learnings, ECHA continued its engagement with the industry in 2021, prioritising four substance groups aligned with its regulatory objectives. Participating companies submitted initial testing strategies, which received informal feedback from ECHA.

In 2022, ECHA selected one group of 17 substances for further review and received the corresponding testing strategy. The project covers 84 substances, supporting updates across multiple active REACH registrations. Despite delays in generating data, primarily due to laboratory capacity constraints, ECHA has acknowledged these external challenges.

In 2025, ECHA began processing the TPs submitted for all selected groups. Key learnings from this collaborative effort have been shared in earlier workshops and, most recently, at the EFSA workshop on read-across[16].

Building on the experience gained from the pilot project, several key lessons have been identified to strengthen the use of read-across and category approaches. These insights reflect the challenges and successes encountered during the practical application of grouping and testing strategies across multiple substances.

The recommendations below represent the ECHA's findings from the pilot and Cefic's reflections on their practical implications for the industry. They aim to promote best practices and provide actionable steps to strengthen the scientific justification and regulatory acceptance of read-across. Companies are encouraged to focus on the following five key areas:

1. Realistic planning
2. Substance and category definition
3. Justify your read-across: Mechanisms, bridging data, and strategy
4. Align TPs with a strategic category approach
5. Consortia / Sector Coordination

These points are important to designing and implementing a successful category-based testing strategy that meets ECHA's expectations. Below is a detailed overview of these elements.

[16] Workshop on read-across: role and guidance in chemical risk assessment

Concerning read-across and category approaches, the five main points to consider:

1. Realistic planning

Companies should perform a careful data gap analysis when they group similar chemicals. They should build a clear data matrix that maps all substances and endpoints across the group or category.
Annex VII/VIII information requirements should generally be generated upfront without needing a TP, while fulfilment of Annex IX/X information requirements must be planned strategically. For a category of mainly Annex IX/X substances, experience from the pilot project shows that a proportion of 30-50 % higher tier studies with data from the registered substances is needed to support the read-across hypothesis
Initiating lower-tier testing or supporting data early is important to strengthen the testing strategy. For example, OECD 422 studies provide screening-level information on both reproductive and repeated dose toxicity and may provide useful supporting ('bridging') information. This is also a recommendation from Roe et al. (2024) study; it offers a robust statistical and qualitative analysis of over 1,500 ECHA TP [17].

2. Substance and category definition

To support a robust read-across and category approach under REACH, companies must begin with a clear understanding of the identity and composition of each substance, including relevant details on impurities and the manufacturing process. Defining the boundaries of the category is equally important. This includes setting parameters such as chain length, branching patterns, functional groups, and clear inclusion and exclusion criteria. Based on experience from pilot projects, the optimal size for a substance category is typically between 5 and 15 substances. Larger groups may introduce too much structural diversity, making it difficult to justify read-across, while overly narrow groups may not have enough data points to support strong conclusions.

3. Justify your read-across: Mechanisms, bridging data, and strategy

A robust and evidence-based read-across hypothesis is a cornerstone of any successful category approach under REACH. It must go beyond basic structural similarity by including, where relevant, mechanistic support — for example, toxicokinetic (TK) and toxicodynamic (TD) data. The testing strategy should be justified upfront and designed to withstand regulatory scrutiny, as revisions or negotiations during the dossier evaluation process are not permitted. To improve confidence in the read-across justification, bridging data, such as for key endpoints like reproductive toxicity, repeated dose toxicity, or to support mechanistic information (e.g. TK/TD), should be included where appropriate. This can strengthen the overall rationale and reduce the need for additional experimental studies.

[17] A systematic analysis of read-across adaptations in TP evaluations by the European Chemicals Agency. DOI: https://doi.org/10.14573/altex.2408292

4. Align TPs with a strategic category approach

TPs must be aligned with the overall category-based testing strategy and indicate which substances will be tested and for which endpoints. For higher-tier studies, Testing Proposals should be well-integrated into the broader strategy, and while some flexibility, for example, changing the test substance based on bridging study results, is possible, but it must be justified in advance.

Effective time management is important; companies should plan early, considering the availability of testing facilities and the time required to generate and evaluate results to avoid unnecessary delays.

5. Consortia / Sector Coordination

Efficient consortia management is vital to the success of sector-wide testing strategies under REACH. Companies should align early on testing, data needs, data-sharing arrangements, and strategic decisions to avoid internal disagreements that can delay progress. Given the complexity of collaboration, logistical challenges must be anticipated and addressed proactively, including the availability of scientific expertise (e.g. consultants, CROs), financial planning, and clarity on data ownership.

Looking ahead

Cefic remains committed to continuing collaboration with ECHA and the participating signatory companies. The goal is to build on the pilot project's outcomes and interaction process and share key learnings with the broader chemical industry.
Through this collaboration, industry and regulators deepen their understanding of the complexities of substance grouping and category approaches. By working together to develop and agree on testing strategies that optimise data, information generation at both the category and individual substance levels, the initiative aims to support regulatory compliance, strengthen the scientific basis for read-across, and ultimately contribute to reducing animal testing.

Next Steps

- With the Action Plan entering its final two years, Cefic will continue to emphasise the quality and transparency of these reports and will continue to provide granularity to authorities regarding the type of updates conducted by lead registrants.
- The active participation of all signatory companies and continued support from Cefic and national member associations have been key to the sustained commitment and engagement shown under the REACH Dossier Improvement Action Plan. Cefic remains dedicated to keeping this momentum and assisting signatory companies to ensure the initiative's continued success.
- As the REACH legal framework follows a revision and the Testing Guideline Regulations are updated, Cefic will ensure that signatory companies stay aligned with the latest regulatory and scientific developments.
- Building on the lessons learned from the pilot project and interaction process with ECHA, Cefic remains committed to sharing knowledge and updates to disseminate practical recommendations on grouping, testing strategies, and dossier updates. This will help all signatory companies apply the lessons learned from the pilot project and improve the scientific and regulatory robustness of their dossiers.

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List of companies that have signed the Declaration of Intent

3M
Adeka
Adisseo
AGC Chemicals
Agfa-Gevaert
Air Liquide
Ajay
Albemarle
Alkeemia
Allnex
Altair Chemica
Altana
AlzChem
Archroma
Arkema
Ashland
Aspen Oss
Atlantic Copper
Axplora
Baerlocher
Baikowski
BASF SE
Bayer AG
Bernardy
BioMCN
Boehringer Ingelheim
Bondalti Chemicals
Borax
Borealis
Borregaard
BorsodChem
Bruno Bock Thiochemicals
Budenheim
Butachimie
Calyxia
Celanese
Cepsa Quimica
Chemours
Chemox
Chevron Oronite
Chevron Phillips
Chimcomplex SA Borzesti
Clariant
Corbion
Corteva
Covestro
CTF 2000
Daikin
Dehon
Deretil
DHW Deutsche Hydrierwerke
Donau Chemie
Dow
DRT
dsm-firmenich
DuPont
Dynea
E&S Chimie
Eastman Chemical
Ecogreen Oleochemicals
Ecolab
Electroquímica de Hernani
Elix Polymers
Elkem Silicones
Endura
Ercros
Estener
Eurenco
Eurolysine
Evergreen Garden Care
Evonik Industries
ExxonMobil Chemical
F.Hoffmann-La Roche
Fertiberia
Fluorsid
Fuchs Lubricants
Giovanni Bozzetto
Givaudan Lavirotte
Henkel
Heubach
Honeywell
Huntsman
ICL
IFF
INEOS Group
Innospec
Interor
IOI Oleo
ITW Reagents
Janssen Phamaceutica
Johnson Matthey
Kao
KEM ONE
Kemira Oyj
Kraton
Kurita
Labema
Laboratorios Miret - LAMIRSA
Lamberti
Lanxess

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Lawter
Linde
Livbag
Lluch Essence
Lubrizol
LyondellBasell Industries
Mane
Manuel Vilaseca
MAPEI
Martinswerk
Maschem
Matrica
Merck
Metaux Speciaux
Michelin
Micro-Bio
Microtek
MINAFIN
Mitsubishi Chemical
Mitsui Chemicals
Miwon
MOL Group
Momentive Performance Materials
Nabaltec
Nexe
Neste
Niacet
Nitrochemie Aschau
Nouryon
Novabion
Novacarb
Novacid
Novacyl
Novapex
Noveal
OCI Nitrogen
Oleon
Olin
Orbia
OXEA
PCAS
Perstorp
PMC Isochem
Prayon
Procter & Gamble
Promox
Proviron Functional Chemicals
PVS Chemicals
Quaker Houghton
Quimica del Cinca
Radici Chimica
Rain Carbon
REPSOL QUIMICA
Robama
Röhm
Roquette Frères
SABIC
Sanofi
Sasol
Schill + Seilacher "Struktol"
SEPPIC
SEPR
Shepherd
Shell Chemicals
Shin-Etsu
SI Group
Sika
Silab
Società Chimica Bussi (SCB)
Solenis
Solvay
Sonneborn Refined Products
SOPHIM
Spolchemie
Stahl
Stepan
Syensqo
Synthos Dwory
Takeda
Tessenderlo
Thor
Total Energies
Tronox
UBE Chemicals
Uetikon
UPL
Uquifa
Urquima
Venator Corporation
Vencorex
Versalis
Vynova Group
Wacker Chemie
Westlake
WeylChem Lamotte
Yara

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