May 2022

Summary Report from the Workshop on Cefic' s Action Plan for REACH registration dossiers

1. Welcome and Opening of the Workshop

The workshop on Cefic's Action Plan for REACH registration dossiers is the third workshop jointly organised by Cefic and ECHA, as foreseen in the cooperation agreement.

The workshop was attended by close to 170 representatives from Cefic, ECHA and companies who signed up to Cefic's Action Plan. The primary purpose of the workshop was to exchange on how companies are using the learnings from the Action Plan and achieve a mutual understanding of technical challenges related to the voluntary dossier updates.

Interactive and informed discussions characterised the workshop.

2. Industry feedback for the Action Plan

2.1. Improving dossier compliance and quality

France Chimie mentioned that they have been actively involved in the Action Plan since 2019, encouraging their members to sign the Action Plan. In 2021, an e-learning tool was provided with essential information and tools to improve the quality of dossiers; this was followed by a workshop open to all members.

France Chimie offered a first-line diagnosis service to the member signatory companies with support from consultant Atout Chimie, aimed at identifying the first actions to take to improve a dossier.

A second expert workshop was organised to discuss read-across strategies and obstacles to the voluntary improvement of dossiers.

Based on this experience, France Chimie developed recommendations for their members.

2.2 Improving dossier compliance and quality

Stepan provided their perspective on the Action Plan as a signatory company that manufactures mainly surfactants and as a lead registrant for different substances.

The Action Plan is seen as a critical tool for planning the company's REACH activities and prioritising resources (time, cost, and competencies). In order to plan the REACH activities and manage resources, companies need to balance ECHA's evaluation work, the chemical universe and internal drivers.

Compliance is a complex task in view of changes to guidance, test guidelines, as well as changes to the business situation (volumes). In addition, finding an agreement in consortia is often cumbersome.

Stepan concluded that REACH is one of the most ambitious chemical regulations globally, and the work has been hectic for the past 14 years to submit compliance dossiers. Voluntary updates come in addition

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to new regulatory demands (*e.g.* UK REACH, Turkey REACH). Something crucial for the chemical industry and regulatory bodies is to support innovation.

3. Cefic reflections

3.1 KPI report

Cefic summarised the 2021 report released end of March 2022, highlighting that 198 companies joined since the initiative was launched in June 2019. This represents more than 1400 legal entities shared among Cefic member companies and companies from National associations.
In 2022, the report was divided into KPI reporting requirements and additional information requested from companies with lead registration dossiers or individual submissions with the intent to understand better the nature of updates being made to dossiers.

From the statistics, a steady increase in the number of re-evaluated dossiers was reported in 2021. From the start of the Action Plan to December 2021, more than 2800 substances have been re-evaluated.
From the additional information provided this year, nearly 50% of the substances re-evaluated in 2021 include new data or studies from Annexes VII, VIII, IX or X that will improve the quality of the dossiers. The full report is available on the Cefic Website.

3.2 Learnings from the Action Plan

Based on the experience since the launch of the Action Plan, the KPI reports have shown that there is activity and a serious will from the Industry to improve.
Signatory companies find the Chemical Universe helpful as it allows them to prioritise the voluntary work of their chemical portfolio. However, as shown from the pilot and voluntary work, it takes some time to get results, especially to fill data gaps with higher tier studies and when Testing Proposals (TPs) are involved, often 2 to 3 years. In this regard, Cefic was invited to provide ideas on how the TP process could be faster and more efficient and raise the proposals for the REACH revision.

Cefic reminded that ECHA's statistics on Compliance Checks (CCH) do not give the full picture of the quality of dossiers since there is a selection bias applied by ECHA: CCH focus on dossiers with data gaps. Based on learnings from the pilot project and interactions process, it is noted that every case is unique, especially for read-across and categories. There is no 'model' that can be applied to all dossiers.

It is clear to the signatory companies that the pilot project was helpful, and there were learnings for both sides. The pilot projects helped achieve a mutual understanding of the expectation to pass the CCH for complex categories.

Signatory companies that are involved in the interaction process do see the benefits of the voluntary dossier improvement as it is more cost-effective to be proactive with a good testing strategy that ideally is discussed and agreed upon with ECHA rather than receiving a CCH decision with the risk of providing many studies with a tight deadline and no time to prepare a testing plan. Being proactive should ultimately help save animals.

Cefic mentioned that companies should use as a reference the tips provided in the ECHA Safer Chemical Conference 2021,

Cefic ended the presentation with its general position on the REACH revision:

- Cefic supports revocation of registration numbers in case of persistent failure to comply and subject to a robust legal procedure, with a more substantial role for the Enforcement Forum to coordinate the enforcement of revocation with the Member States.
- The REACH revision is an opportunity to take a fresh look at how safety assessment is done and give broader space for the use and acceptance of NAMs. Cefic believes that based on scientific development, it is an opportunity to modernise the legal requirements in REACH with predictive and validated NAMs.
- There is a need for better use of exposure information in terms of NAMs and to avoid animal testing.

4. ECHA reflections

ECHA started by reminding that, in recent years, they increased the number of CCHs, which represents a considerable amount of additional effort for them. CCH is a tool to bring a dossier to compliance and to generate data on substances that may need regulatory risk management.

The grouping that ECHA uses is based mainly on structural similarity (including constituents of concern) and takes into account grouping approaches in the registrations or from external sources. The groupings may also take account of different chemistries and technical functions. This approach was used to be efficient and not to ask for data for every single individual substance.

ECHA indicated that the figures provided in the Cefic KPI report show that companies are working. They value the effort of signatory companies that are proactive in the voluntary REACH dossier improvement Programme.

4.1 Status of the ongoing pilot and 2021 groups

The voluntary action from the chemical industry in collaboration with ECHA was launched to have an improvement of registration dossiers. Companies have developed testing strategies and category justifications from the pilot project and interaction process.

Under the interaction process, companies propose groups on which they plan voluntary data generation, and ECHA screens the suitability of the proposed groups based on their criteria and work plan. ECHA reviews and informal feedback is provided on selected groups. Based on the feedback, the companies update the testing strategy and submits applicable TPs.

4.2 Learnings from the Action Plan

ECHA mentioned that the timeline from the start of the process to submitting the requested information could take up to several years. It requires sufficient resources and expertise to develop, assess and execute read across based testing strategies. ECHA therefore expects the submitted strategies to provide a timely and clear path to generating compliant data and adaptations.

5. Conclusions of the Workshop

- Cefic indicated that there were some valuable tools developed by France Chimie that could be extended to all signatory companies.
- It is clear that companies face different hurdles, whether linked to consortia or lab capacity. Cefic and Industry's key message is that it is worth being proactive as it allows to accommodate resources. It may be time to re-think the consortium agreement.
- Progress from the pilot run in 2020: in 2022, ECHA will proceed with the TP evaluations and in in 2024 dossiers should be submitted with the new data. This indicates that, in reality, data generation takes time.
- Cefic will organise the nomination of groups for the 2022 interaction process and will further discuss the process with ECHA.
- On Animal testing, NAMs were briefly discussed. NAM will not provide a 1-1 replacement of existing information requirements. Cefic will make a call to use the REACH revision opportunity to optimise NAMs use.
- Signatory companies need to be realistic with the data gaps and how they re-evaluate the dossier and look at the information requirements instead of trying to defend the current approach.