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REACH Action Plan for Review/Improvement of Registration Dossiers

1. Introduction

The EU chemical industry acknowledges the importance of accurate, complete and clear information on the hazards, exposures, risks and conditions of safe use of chemicals. These elements are important to reach the overall REACH objectives, in particular a high level of protection of human health and the environment.

The second REACH Review[1] published in March 2018 by the European Commission highlights specific actions related to REACH registration dossiers, namely:

1. *"Action 1: Encourage updating of registration dossiers;*
2. *Action 2: Improve evaluation procedures".*

The European Commission and ECHA joint REACH Evaluation Action Plan contains a series of remedy measures covering years 2019-2027 (corresponding to the next EU multi-annual financial framework period). It foresees, among others, that "*by end of 2019, ECHA will have established working arrangements with major industry associations, which will be transparent and inclusive, aiming at industry committing to develop action plans for proactive and continual improvement of their registration dossiers*".

Implementing REACH is a top priority for the chemical industry. We take seriously the recent findings that there are REACH dossiers with shortcomings and we are committed to help solving this issue.

The first registrations of substances were submitted about ten years ago and both the industry and competent authorities have learnt a great deal about registration and evaluation over this past decade. In addition, new methodologies, guidance documents, IT tools and approaches have been developed and tested. These have evolved considerably over time.

Due to this evolution, registration dossiers that were submitted by the 2010 and 2013 deadlines may be assessed as presenting deficiencies when ECHA evaluates them today or in the future. Standards

[1] https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:52018DC0116&from=EN: Commission General Report on the operation of REACH and review of certain elements - Conclusions and Actions

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may further evolve in the future (e.g. updates to REACH Annexes and IUCLID system). With this Action Plan, Cefic also aims to achieve better alignment on these issues.

As a result, issues remain, such as, on how to fulfil additional data requirements while taking into account animal welfare obligations.

Dossier registration is the registrant's responsibility. The chemical industry, as represented by Cefic, is committed to contribute to dossier review/improvement, and to provide further information, where appropriate, to better identify substances of potential concern and ensure the safety of chemicals. We share this goal with ECHA, which is why cooperation between Cefic, its members and ECHA, is crucial.

On 14th June 2018, Cefic and ECHA signed a Joint Statement whereby they agreed to cooperate, among others, to promote a gradual and planned review/improvement of the REACH registration dossiers and identify (groups of) substances expected to present particular scientific or technical challenges, which would benefit from expert discussion.

This REACH Action Plan for Review/Improvement of Registration Dossiers aims to implement these objectives. It is part of a Dossier Review/Improvement Package, which also includes:

1. a model declaration of intent, for signature by individual companies,
2. a reporting template, and
3. a Cefic-ECHA cooperation agreement.

The Dossier Review/Improvement Package is intended to support and streamline the efforts that companies deploy for the review/improvement of their registration dossiers.

Other technical documents will be developed to support the practical implementation of this Action Plan, e.g. workshop reports, etc. These technical documents are expected to be developed gradually and to evolve over time.

While reviewing, improving and/or updating REACH dossiers and ensuring they are compliant with the legal requirements is the responsibility of individual companies, in the context of the relevant consortia or SIEF leadership teams as applicable, Cefic believes that the development of this voluntary Action Plan is essential. This plan can help registrants to decide on the allocation of resources, re-evaluate the data in their dossiers and improve and/or update them, if needed.

On the one hand, the Action Plan provides advice and recommendations that companies can use for their internal prioritisation work and, on the other hand, it contributes to a better alignment between Cefic and ECHA experts on some scientific issues underpinning the registration dossiers.

It should be noted that this Action Plan might be reviewed and revised based on the feedback Cefic will receive from companies, ECHA, EU Commission, competent authorities and stakeholders (e.g. to include a refinement of the prioritisation criteria to be used for dossier review/improvement).

Close collaboration with ECHA, National Associations and other stakeholders will be essential to successfully achieve the goals of this Action Plan.

Cefic invites all its member companies and member companies of Cefic Member/Associate Federations to sign a Declaration of Intent to state their intention to take steps to review their respective REACH registration dossiers, provide further information where appropriate, and keep Cefic informed of dossier reviews, via a model declaration of intent. Cefic will collate the feedback and make progress reports publicly available on an annual basis.

2. Timeline

The Action Plan development and implementation covers the period 2019-2026, as follows:

- **2019**: Preparatory phase corresponding to the development and initial implementation of this Action Plan, as well as the set-up of individual companies' activities: prioritisation and review/improvement system, preparing companies' own implementation plans.
- **2020-2026:** Second phase during which dossiers will be re-evaluated and, depending on the outcome, new information needs will have been identified and testing proposals will have been submitted[2], if needed. This will be done in line with the REACH requirements and data will be generated and submitted, if needed, in a stepwise and prioritised manner.

We recommend all companies taking part in this initiative reflect their REACH dossier quality maintenance activities in their company programmes.

3. Goals

The European chemical industry, as represented by Cefic, aims to achieve a significant contribution to the quality of REACH registration dossiers, in cooperation with ECHA.

Cefic endeavours to encourage as many companies as possible to sign up to this initiative. The liaison with consortia will be important for the success of this Action Plan. Cefic encourages companies to promote this Action Plan in the consortia – and relevant SIEF/communication platforms – in which they participate.

KPIs from ECHA and companies will be needed to track progress on the Action Plan implementation. These KPIs will also be used for regular, external reporting on the initiative to ensure transparency vis-à-vis stakeholders.

ECHA reports annual statistics on dossier and substance evaluations. These statistics - such as the number of Compliance Checks ('CCH', according to Article 41 of REACH) concluded with no action - constitute key measures of progress.

Company KPIs to track developments on the Action Plan implementation are identified, as follows:

- Number of companies committing to the initiative, including Cefic Members (ACOM or ABM) and Partners (e.g. Associate Companies) or Cefic Member Federations' and Associate Federations' company members;
- Percentage of companies having signed up to this initiative in the Cefic membership and the Member/Associate Federations membership;
- Number of individual dossiers re-evaluated[3] by each company
  - As individual submitter or as lead registrant;
  - As co-registrant (in a joint submission)
- Optionally: number of consortia supporting the initiative and re-evaluating a REACH registration dossier.

[2] In case a test proposal has been submitted, the new data may not be reflected in the registration dossier within this foreseen timeline.

[3] In this context, a dossier is re-evaluated when the reporting company has, following a review of the information in the REACH dossier, either re-submitted the dossier to the European Chemicals, or concluded that the dossier does not need to be resubmitted.

4. Scope and Prioritisation

By the end of 2019, companies are expected to develop a Company Implementation Plan and to start activities towards dossier review/improvement.

In doing so, companies are recommended to take into account the following guiding principles to prioritise their work in the context of this Action Plan (no priority order in this list):

- Substances for which the company acts as a lead registrant or as an individual registrant;
- Registration dossiers from the 2010 and 2013 registrations deadlines (i.e. more than 100 and 1000 tonnes/year, respectively, and self-classified CMRs[4]);
- Registration dossiers from 2018 deadline (i.e. more than 1 and 10 t/a) which may be grouped with higher volume substances;
- Substances that are (potentially) hazardous to human health or the environment, particularly potential CMRs or PBTs/vPvBs;
- Substances with (potential for) wide dispersive uses; particularly consumer and professional uses;
- Full registrations (non-intermediates);
- Dossiers in which read-across or categories are used;
- Substances where adaptations to standard testing requirements have been applied for higher tier human health and environmental endpoints e.g. read-across, exposure-based waiving, 'column 2' waiving arguments etc.

ECHA is currently mapping the "chemical universe" with a view to identify the substances that are potential candidates for further compliance check and/or substance evaluation (around 2,700 substances in the "uncertain" zone). More information on the "chemical universe" of registered substances can be found in ECHA's Integrated Regulatory Strategy report released on 17 April 2019[5]. It is expected that, by end 2019, ECHA will communicate this list of substances or groups of substances. This list is essential to help companies prioritise their work on dossiers.

ECHA is encouraged to inform registrants, ideally six months in advance, of the list of (groups of) substances it intends to work on, which includes potential candidates for Compliance Check (see the Cefic-ECHA cooperation agreement).

It should be noted that the 2019 list of substances subject to dossier evaluations will be gradually published in the PACT, albeit not in advance of ECHA's initiating the dossier evaluation activities. This means that, in 2019, it is up to each company to develop its own priority list of dossiers based on the indicative guiding principles provided above.

Companies are advised to pay particular attention to the information / data related to the eight "super endpoints"[6] in the registration dossiers.

[4] Currently-known CMRs subject to harmonised classification have already been scrutinised so new data generation would in principle not be a priority.

[5] https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2018_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425

[6] Higher tier (REACH Annexes IX and X) human health and environment endpoints – genotoxicity; repeated-dose toxicity; pre-natal developmental toxicity; reproduction toxicity; carcinogenicity; long-term aquatic toxicity; biodegradation and bioaccumulation.

5. Roles and responsibilities

- Companies are responsible for the review/improvement of the quality of their registration dossiers. In 2019, they are expected to set up an internal prioritisation and review/improvement system. Companies, in the context of the existing consortia or SIEF leadership teams, are encouraged to start their assessment and resubmission activities in this first year, where deemed necessary.
- In the period 2020-2026, companies proceed with their assessments and resubmission of registration dossiers, where deemed necessary and in cooperation with consortia or SIEFs as applicable, based on their internal prioritisation system and taking into account refined priority-setting criteria or lists of substances provided by ECHA in those years.
- Cefic facilitates the support and development of tools and solutions for cross-cutting, unresolved key issues related to registration dossiers.
- Cefic will look for collaboration with other trade associations (e.g. Eurometaux and Concawe) and scientific organisations.
- Cefic Member / Associate Federations are expected to contribute to the dissemination of information for engaging their company members to take part in the Action Plan.
- Cefic will maintain close collaboration with ECHA to facilitate the implementation of all activities related to this Action Plan, ensuring regular expert discussions on scientific and technical challenges, e.g. in the form of workshops (see Cefic-ECHA cooperation agreement).

6. Cooperation with ECHA

Within the framework of the June 2018 Joint Statement, close cooperation with ECHA will be pursued.

A separate Cefic-ECHA Cooperation Agreement has been developed to outline specific activities that will be pursued to support implementation of this Action Plan, including identification of and communication of priority substances, organisation of a pilot project to develop case studies for the benefit of the broader industry community, development of material illustrating case studies and common learnings, workshops and meetings to address technical and scientific challenges, dissemination of material and establishment of peer-to-peer cooperation in the form of a Steering Committee and of a Joint Expert Group.

7. Identification of critical issues

Further to a Cefic - ECHA workshop held on 30 January 2019, followed by a survey of Cefic PCPS members, the following, non-exhaustive list of topics and issues was identified as requiring particular attention:

- Substance identity issues (for complex substances);
- Approaches to address data gaps (such as missing data), if any:
    - Testing strategy in line with the REACH objective to use animal testing as a last resort;
    - Read-across justification for human health and for environmental data;
    - Category approach (domain, limits, structural similarity, adequate scientific justification, etc.) and QSAR;
    - Justification of waivers for human health or for environment, e.g. REACH Annex VII-X ‘column 2’ waiving arguments;
    - Application and justification of weight-of-evidence;

- Description of uses and exposure sufficiently clear and detailed.

The above list of critical issues will be reviewed regularly, as appropriate, and be subject to further expert discussion with ECHA, under the umbrella of the joint expert group.

8. Assessment of resourcing and costs

The implementation of this Action Plan at Cefic and at company level will entail new or additional cost and resource allocation, covering among others internal assessment within companies, consensus building in consortia / SIEFs, improvement of the content of dossiers, potentially running additional testing or experimental studies, IUCLID updates, measuring and reporting progress, etc.

Further testing may be performed as part of the re-evaluation of dossiers. Depending on the assessment this may result in shortage of laboratory capacity which may impact the timelines for updating actions.

It is not possible for Cefic to provide an indication of costs at this stage, as each case is unique.

9. Reporting

- Companies are expected to submit to Cefic, by 31 January of each year, starting in 2020, reports on their dossier review/improvement activities, as provided in the reporting template annexed to the model declaration of intent. The reports will cover activities from 1 January to 31 December of the preceding year.
- Cefic will aggregate the data from the annual company reports by 28 February of each year and publish aggregated, anonymised, progress reports on behalf of the sector by 31 March of each year, starting in 2020.
- Cefic will create a webpage on its website where it will publish relevant information related to the Action Plan. Cefic will publish a factsheet and a Q&A explaining the actions companies and Cefic are intending to take in the context of the Plan, KPIs, timeline and reporting.
- Additional supporting guidance and tools to help companies in the review/improvement of dossiers will also be made available.
- Annual status reports on the implementation of this Action Plan will be published on the Cefic website.

10. Governance

In Q1 2020, the current document will likely be reviewed and possibly revised following Cefic's operating rules, to take into account the expected developments taking place in 2019.

Disclaimer*: This Action Plan is of voluntary nature. It is not a substitute for legal advice and compliance with REACH legal obligations. It is for each individual company to ensure compliance with the duties and obligations arising from the REACH regulation. No liability will be accepted by Cefic for damages of any nature resulting from the use of or reliance on the information contained in the Dossier Review/Improvement Action Plan and Package. Commitment to this Action Plan does not suspend implementation and enforcement of REACH: ECHA and Member States may continue to or initiate*

regulatory actions when necessary. Neither does it affect the procedural or any other rights of companies under REACH and the Treaty on the Functioning of the EU.