

## COOPERATION AGREEMENT ON THE REVIEW/IMPROVEMENT OF REACH REGISTRATION DOSSIERS

25 June 2019

On 14<sup>th</sup> June 2018, Cefic and ECHA signed a Joint Statement<sup>1</sup> whereby they agreed to cooperate, among others, to promote a gradual and planned review/improvement of the REACH registration dossiers and identify (groups of) specific substances, or scientific and technical challenges, which require expert discussion.

On 26 June 2019, Cefic launched a voluntary initiative - the *Action Plan for Review and Improvement of REACH Registration Dossiers* - that is intended to support and streamline the efforts that companies deploy for a voluntary and proactive review and, if needed, improvement of their dossiers.

The Cefic Action Plan foresees a two-staged process:

- **2019:** development and initial implementation of the Cefic Action Plan and individual companies' preparatory activities: company prioritisation of substances/dossiers;
- **2020-2026:** re-evaluation of selected/prioritised registration dossiers by companies, in a stepwise manner, and resubmission where deemed necessary.

The re-evaluation and potential re-submission of REACH registration dossiers may require further action in the context of existing Substance Information Exchange Fora and REACH consortia. Cefic is not directly involved in these, but its Member Companies are, as are the member companies of the affiliated national chemical federations. The liaison with the consortia will be important for the success of the Cefic Action Plan and Cefic encourages companies to promote this Action Plan in the consortia – and relevant SIEF/communication platforms – in which they participate.

Cefic member companies and Cefic Member/Associate Federations' member companies will be invited to state their intention to take steps to review their respective REACH registration dossiers and provide further information where appropriate, via a model declaration of intent.

The Cefic Action Plan endeavours to support companies in their internal prioritisation work, facilitate the development of tools, activities and solutions for cross-cutting, unresolved key issues of technical and scientific nature related to registration dossiers; and foster a better understanding between Cefic, including its members and partners, and ECHA experts on some scientific issues underpinning the registration dossiers.

<sup>1</sup> [https://www.echa.europa.eu/documents/10162/23821863/jointstatement\\_cefic\\_signed\\_pdf/396578c6-e651-e023-0d3a-b7224e42d21f](https://www.echa.europa.eu/documents/10162/23821863/jointstatement_cefic_signed_pdf/396578c6-e651-e023-0d3a-b7224e42d21f)

ECHA and the Commission have adopted a Joint Action Plan<sup>2</sup> on 24 June 2019 which foresees 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".

We, the undersigned, acknowledge 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<sup>3</sup>.

Within this framework, Cefic and ECHA agree on the following:

- By end 2019, ECHA will communicate the list of substances or groups of substances, within the chemical universe<sup>4</sup>, that are potential candidates for further compliance check and/or substance evaluation.
- ECHA will consider practical mechanisms for timely notification of registrants, where possible six months in advance, of the list of (groups of) substances it intends to work on which includes potential candidates for Compliance Check<sup>5</sup>.
- In 2019, Cefic and ECHA will run a pilot project with a small set of volunteering companies to work with ECHA on the improvement needs of prioritised (groups of) substances within the company's portfolio. The objective of such pilot is to improve the registration dossiers and thereby serve as case studies to generate common learnings to be shared with the broader industry community (e.g. case studies on read-across that worked or failed, and what testing strategies could be proposed to resolve issues).
- Based among others on the outcome of the pilot project, Cefic, supported by ECHA, will develop material to provide a clearer understanding of the technical requirements set out in Article 41 of REACH<sup>6</sup>. This includes, among others:
  - Case studies to illustrate practical application of the Read Across Assessment Framework<sup>7</sup>
  - Examples of testing strategies or waiving justifications that have helped registrants successfully pass a Compliance Check, both for human health and the environment, while ensuring new vertebrate animal studies are performed only as a last resort<sup>8</sup>
- To support this work, ECHA and Cefic will organise expert discussions on scientific and technical challenges, e.g. in the form of 1-2 workshops or meetings per year, as appropriate. Cefic will make summaries publicly available.

<sup>2</sup> [REACH Evaluation Joint Action Plan - Ensuring compliance of REACH registrations](#)

<sup>3</sup> Article 1 of the REACH Regulation

<sup>4</sup>

[https://echa.europa.eu/documents/10162/27467748/irs\\_annual\\_report\\_2018\\_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425](https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2018_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425)

<sup>5</sup> According to the administrative procedure provided under Article 41 of the REACH Regulation

<sup>6</sup> According to the administrative procedure provided under Article 41 of the REACH Regulation

<sup>7</sup> [https://echa.europa.eu/documents/10162/13628/raaf\\_en.pdf](https://echa.europa.eu/documents/10162/13628/raaf_en.pdf)

<sup>8</sup> Art 25(1) of the REACH Regulation

- ECHA will consider providing feedback to registrants on dossiers that have been concluded with "no further action needed" after a Compliance Check.
- ECHA will consider mechanisms, possibly in REACH-IT, for registrants to flag on-going dossier reviews and, if needed, improvement. The development of such a mechanism should preferably be developed in close cooperation with industry.
- Cefic will draft annual progress reports on the implementation of its Action Plan and on progress achieved under this Cooperation Agreement.
- Cefic and ECHA will work further on transparently tracking progress, in particular to reflect proactive industry actions to improve the REACH registration dossiers and the provision of further information, if needed.
- Cefic will transfer all relevant information in relation to the implementation of its Action Plan for Review/Improvement of REACH Registration Dossiers to Cefic Member and Associate Federations, in order for the latter to support their member companies.

From an organisational perspective, the following levels of peer-to-peer cooperation will be developed:

1. Establishment of a **Steering Committee** to support and guide the implementation of this cooperation agreement and look for solutions when hurdles are encountered;
2. Establishment of a **Joint Expert Group between ECHA, Cefic and Cefic members**, which would have two main tasks:
  - Act as a platform for expert discussion on specific issues and case studies;
  - Disseminate learnings derived from individual cases for the benefit of the broader community (i.e. share lessons learnt).

*The agreement stipulates the intentions of best effort of both parties involved. It supports the voluntary initiative of Cefic and does not affect the procedural or any other rights of companies under REACH and the TFEU.*

Signed



Daniele Ferrari  
Cefic President

Signed



Bjorn Hansen  
Executive Director of ECHA