Cefic Action Plan for Review/Improvement of Registration Dossiers

Mariana Barros, REACH Manager,
Product Stewardship – Cefic

ECHA Webinar
26 November 2019

2 parts presentation:

Part 1 – ***Context setting: why do we need to proactively review/improve registration dossiers?***

Part 2 - ***Cefic Action Plan for Review / Improvement of Registration Dossiers***

Part 1 – *Context setting: why do we need to proactively review/improve registration dossiers?*

We want REACH to work

We want people and the environment to be safe when handling and using chemicals.

⇨ Confidence in EU chemical legislation framework

⇨ Confidence in chemicals

How?

- Demonstrate safe use with data on hazards and exposure.
- Identify substances that cannot be used safely and uses that are not appropriate; and determine the most appropriate RMM.

We are proud of what has been achieved 2008-2018

- > 22.000 substances registered;
- > 95.000 registrations.

The EU is a trail blazer

REACH:

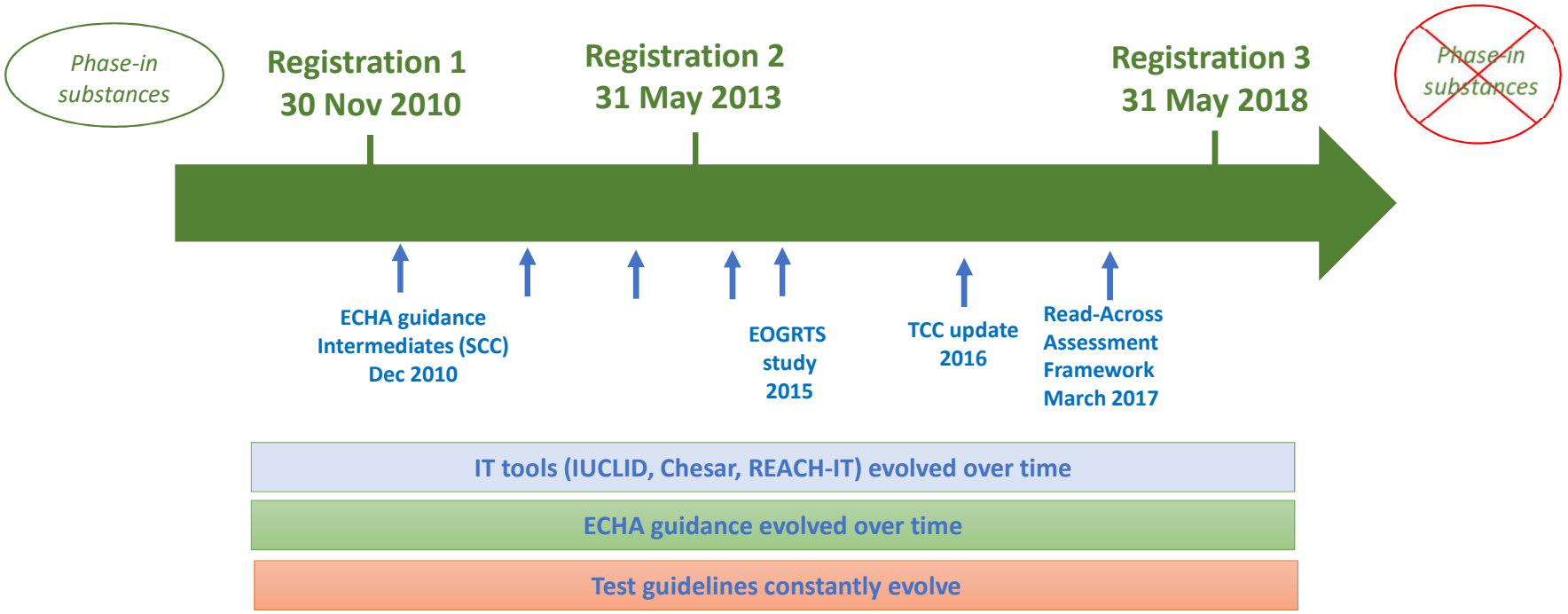
- is the most ambitious, most extensive chemical legislation in the world;
- introduced novel and unique features, e.g. SIEFs, burden of proof on industry, exposure scenarios, authorisation;
- extensively covers substance hazards and uses;
- is complex, subject to interpretation, both legally and scientifically;
- There is no one-size-fits-all model.

With sophistication comes complexity

One (full) registration is:

- ✓ > 2.000 data fields in IUCLID;
- ✓ Up to 70 phys-chem, tox and ecotox studies/tests;
- ✓ 100-150 hours of work (when all studies/info has been gathered);
- ✓ Complex consortia/SIEF dynamics;
- ✓ Some studies take 1-2 years to run;
- ✓ Complex use and exposure assessment;
- ✓ A lot of maintenance: requires update when new information is available.

REACH is an on-going learning process



We all learnt a lot in the last 10 years
Guidance and tools evolved

A difficult balance

particularly for long-term endpoints

Generate new data

Standard requirements:
One registration for > 1000T substance requires about 6000 rats and rabbits and 100 fish.

Animal testing as a last resort

Adaptation of standard requirements:

- predictive methods;
- "sufficient" weight-of-evidence;
- waiving based on "negligible exposure".

Read-across/grouping and waiving are essential but complex.
Common understanding needs to be further developed.

Part 2 - *Cefic Action Plan for Review / Improvement of Registration Dossiers*

Cefic developed an Action Plan for Review/Improvement of Registration Dossiers

Objectives

Proactive re-assessment of registration dossiers content, and effectively and efficiently identify/address data or information gaps (staged priority setting), if needed.

The commitment is open to all Cefic member companies, including national Association members.

Action Plan initiative launched on 26 June 2019

Key elements of the initiative?

Action Plan

- Timeline: 2019-2026;
- KPIs (on the Action Plan implementation);
- Roles and responsibilities: Cefic / companies;
- Criteria to prioritise substances for re-evaluation;
- Annual Reporting (template).

Declaration of Intent, *signed by individual companies*

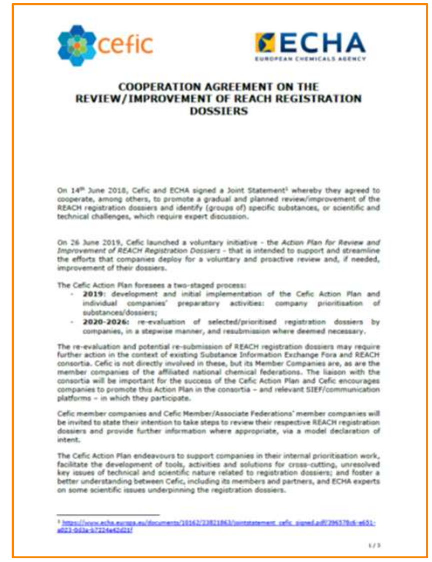
- Re-evaluate dossiers and provide further information, where appropriate;
- Report to Cefic on KPIs → Cefic annual reports.

Cooperation framework with ECHA

- Further cooperation with ECHA, under the umbrella of the June 2018 Cefic-ECHA Joint Statement.

Cooperation framework with ECHA: activities

- **Development of material to guide registrants** towards a clearer understanding of what is expected under Article 41 of REACH (CCH procedure)
  - Case studies to illustrate practical application of the Read Across Assessment Framework
  - Examples of testing strategies or waiving justifications that have helped registrants successfully pass a compliance check, both for human health and the environment, <u>while ensuring new vertebrate animal studies are performed only as a last resort</u>
- Identification and notification of **priority substances**
- Progress tracking
- Dissemination



COOPERATION AGREEMENT ON THE REVIEW/IMPROVEMENT OF REACH REGISTRATION DOSSIERS

On 14th June 2018, Cefic and ECHA signed a Joint Statement[1] 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.

[1] https://www.echa.europa.eu/documents/10162/23821863/jointstatement_cefic_signed.pdf/...

1 / 3

Transparent communication and progress reporting

Via Cefic's website

- Action Plan and related material;
- Guidance/tools produced during implementation;
- Workshop summaries;
- Annual progress reports.

https://cefic.org/our-industry/reach-dossier-improvement-action-plan

Information to stakeholders

Role of Cefic

- Act as a platform to support, coordinate and streamline companies' efforts for the review/improvement of dossiers.
  - Cefic does not run consortia and does not work on specific substances or dossiers;
  - Help generate common learning;
  - Develop and publish material, including progress reports;
  - Facilitate interaction with ECHA (technical and scientific challenges).
- Promote the initiative and engage as many companies as possible.
- Work together with National Associations.
- Dialogue with other registrants' associations.

What does it entail for companies?

- Prioritisation process;
- Resources and costs (more testing is expected);
- Company implementation plan;
- Further work with consortia / SIEFs.

Cefic is not and will not be involved in individual dossier assessment.
It is for each individual company to proactively review/ improve their dossiers, and to coordinate with consortia/SIEFs as applicable.

cefic

member companies

Invited to:

- Commit to the Cefic Action Plan initiative.
- Sign the Declaration of Intent:
  - Proactively re-evaluate your registration dossiers content and, if needed, review/ improve them.
  - Internal company dossier improvement plan.
  - Report to Cefic – help demonstrate progress (anonymised).

Help us to become proactive!

Thank you!

For more info: mfb@cefic.be