Chemical Industry Conference

on Environment Protection & Industrial Safety

REACH dossier quality – an overview of recent developments. What can the industry expect?

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Product Stewardship – Cefic

MAVESZ, Eger
06 November 2019

3 parts presentation:

Part 1 - ***Context setting: why do we need to work on and review/improve registration dossiers?***

Part 2 - ***The Commission-ECHA "REACH Evaluation Joint Action Plan"***

Part 3 - ***Cefic Action Plan for Review / Improvement of Registration Dossiers***

Part 1 – *Context setting: why do we need to work on and 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;
- 80% of lead registrants have already made an update (high-volume substances).

32 Cefic Board members cover
~ 11.000 registrations (excl intermediates)

The EU is a trail blazer

REACH:

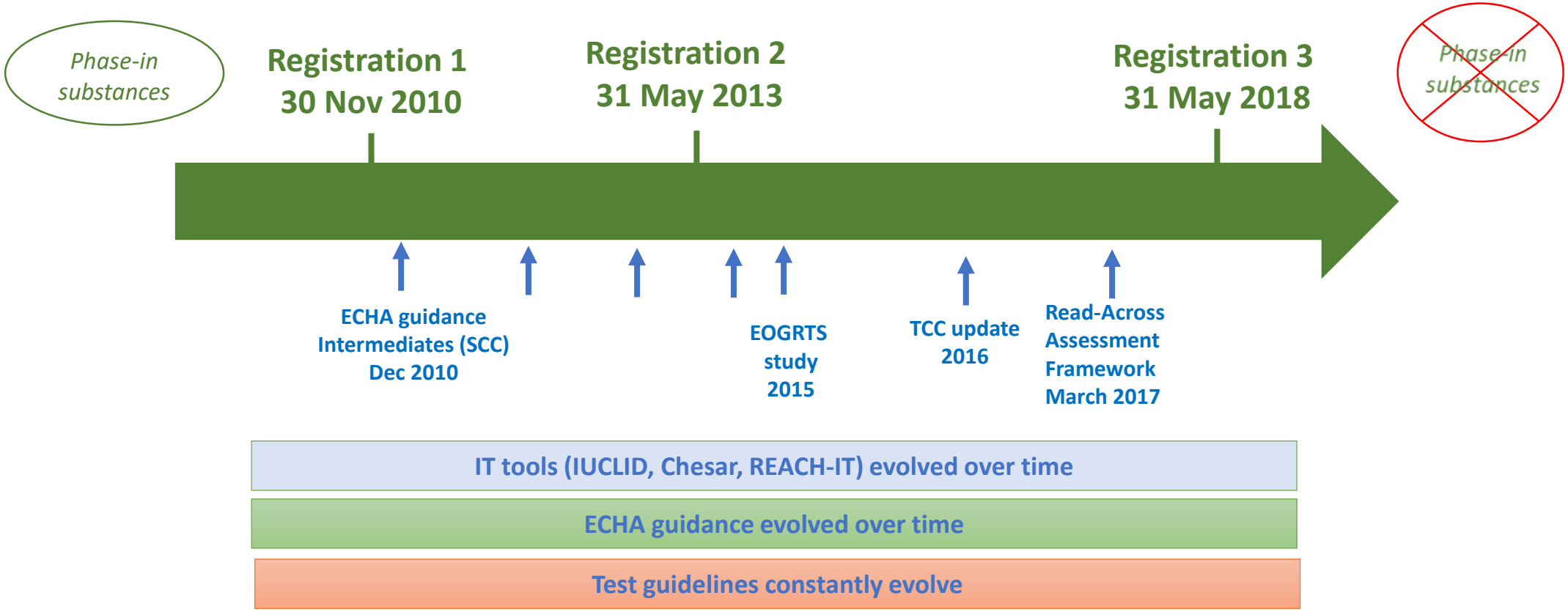
- is the most ambitious, most extensive chemical legislation in the world;
- introduced novel and unique features, e.g. SIEFs, burden of proof on industry, exposure scenarios, authorisation;
- extensively covers substance hazards and uses;
- is complex, subject to interpretation, both legally and scientifically;
- 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:

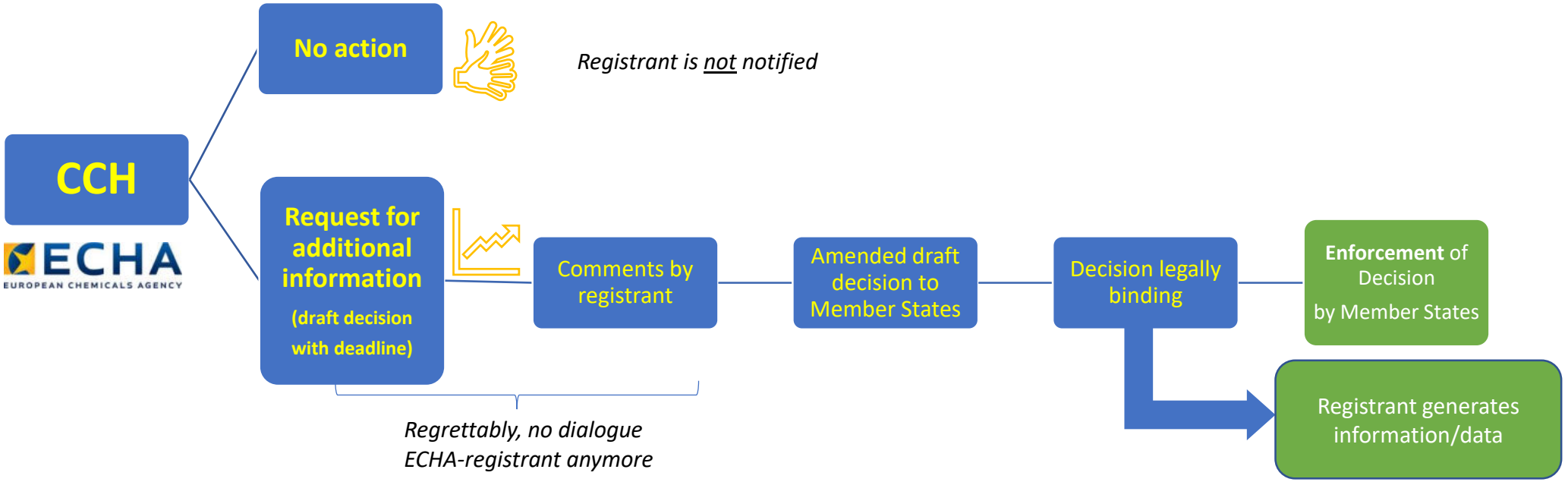
- predictive methods;
- “sufficient” weight-of-evidence;
- waiving based on “negligible exposure”.

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

Compliance Check (CCH) process

- Many different situations / chemistries.
- Difficult role for the Lead Registrant.
- There is no model/benchmark for what constitutes a 'perfect' dossier:

  → *positive and timely feedback would be helpful.*
- Partial updates <u>not</u> possible → can we find a remedy as an incentive to update?

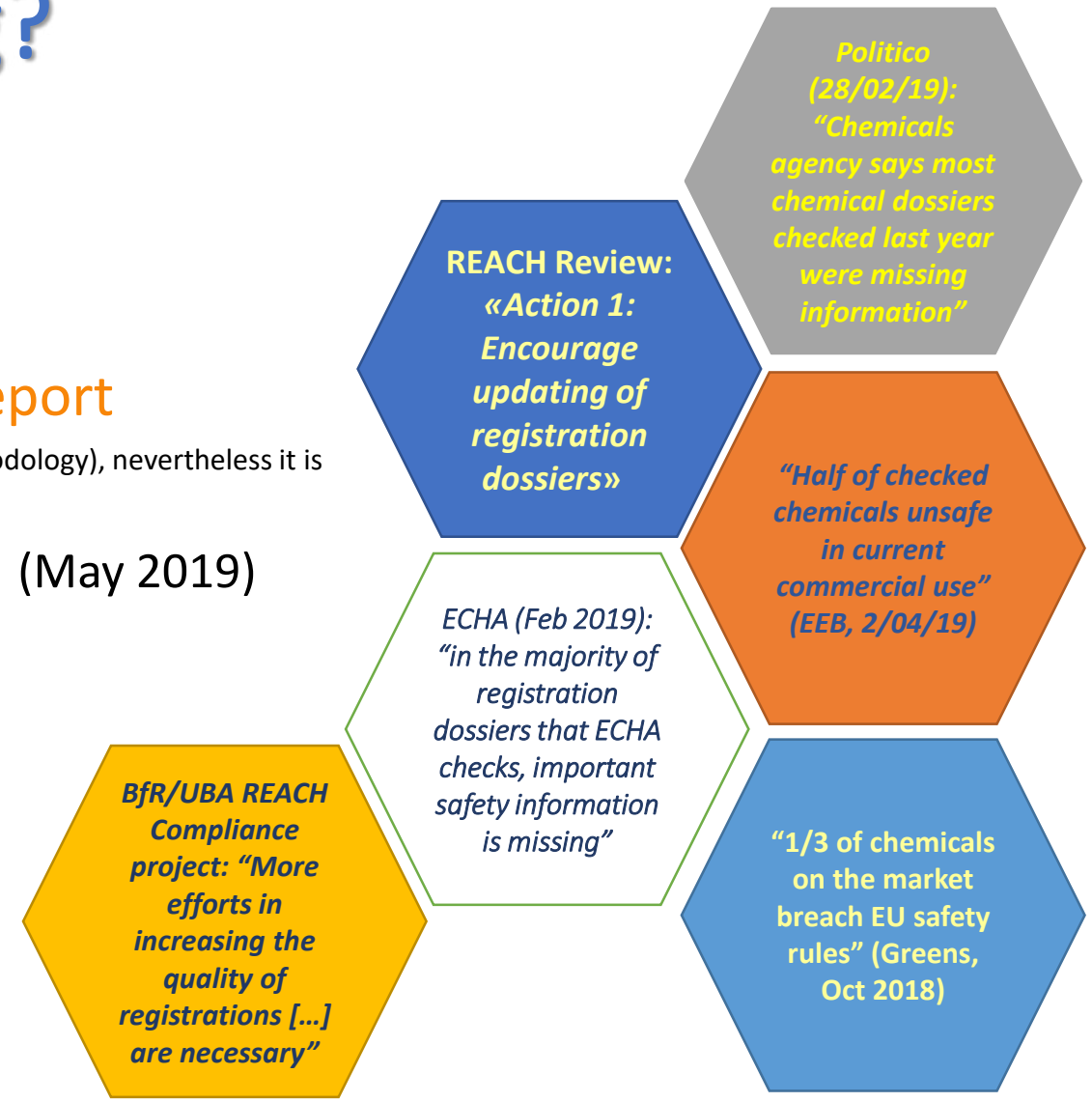


What are we hearing?

- 2nd REACH Review (March 2018)
- ECHA annual evaluation reports
- BfR/UBA screening - awaiting 3rd report

  N.B. BfR/UBA's assessment is not a formal CCH (e.g. different methodology), nevertheless it is useful to understand potential shortcomings
- NGO and media 'name and shame' (May 2019)

We take these findings very seriously



Part 2 - *The Commission-ECHA "REACH Evaluation Joint Action Plan"*

2nd REACH Review

EUROPEAN
COMMISSION

Brussels, 5.3.2018
COM(2018) 116 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Commission General Report on the operation of REACH and review of certain elements

Conclusions and Actions

{SWD(2018) 58 final}

EU Commission concluded that even though **REACH is fully operational and delivering results towards its objectives**, the **non-compliance of registration dossiers is hampering progress**.

2nd REACH Review

Action 1: *Encourage updating of registration dossiers*

The Commission in collaboration with ECHA, Member States and industry will identify why registrants are not updating their dossiers and make proposals for improvements by first quarter 2019, as appropriate.

Action 2: *Improve evaluation procedures*

ECHA is requested to significantly increase the efficiency of the evaluation procedures by 2019 by:

(1) identifying the main reasons for non-compliance of registration dossier and developing remedies;

(2) where appropriate, applying the various evaluation procedures in parallel;

(3) systematically implementing a grouping approach[25], where this is possible;

(4) improving work-sharing across evaluation activities with Member States; and

(5) improving decision-making procedures.


EUROPEAN
COMMISSION

Brussels, 25.6.2019
COM(2019) 264 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses

{SWD(2019) 199 final}

Commission Fitness Check of the most relevant chemicals legislation (excluding REACH)

- EU Commission concluded that, overall, the **EU chemicals legislation delivered results as intended and is fit-for-purpose**. However, it also found a **number of areas where there is scope for further improvement, simplification and burden reduction or that warrant attention**.
- The Fitness Check has **assessed over 40 pieces of legislation** that cover a great part of the EU chemicals *acquis*.

Commission Fitness Check of the most relevant chemicals legislation (excluding REACH)

In page 6 of the report:

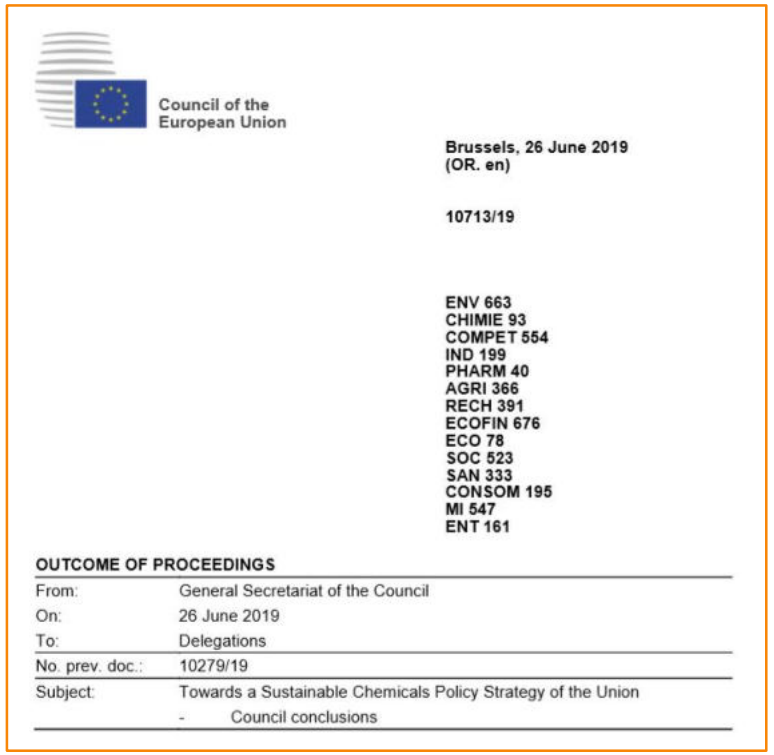
> of environmental/eco-system services). The quality and the availability of data needed to perform robust risk assessments and to make sound risk management decisions has improved considerably in recent years. Also, the EU's knowledge base on chemical hazards and risks has become a world-class asset and continues to grow and improve. Much of this reflects the shift of responsibility from EU and Member State authorities to industry for generating the necessary data for hazard and risk assessments and the significant investment of resources in the establishment of recognised and independent EU agencies.

In page 10 of the report:

> The proper functioning of the EU chemicals legislation and its capacity to respond to future challenges depends, amongst other things, on the ability of the EU and Member States to make their decisions based on robust and relevant up-to-date data. Enormous efforts have been made at the EU and Member State level to ensure that the necessary data to take effective chemical risk management decisions is available, comparable and of good quality.

Importance of good quality data for chemicals legislation.

Council conclusions on chemicals



Council of the
European Union

Brussels, 26 June 2019
(OR. en)

10713/19

ENV 663
CHIMIE 93
COMPET 554
IND 199
PHARM 40
AGRI 366
RECH 391
ECOFIN 676
ECO 78
SOC 523
SAN 333
CONSOM 195
MI 547
ENT 161

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
On:	26 June 2019
To:	Delegations
No. prev. doc.:	10279/19
Subject:	Towards a Sustainable Chemicals Policy Strategy of the Union - Council conclusions

- The adopted Council conclusions on chemicals intend to offer political guidance on the development of a **sustainable EU chemicals policy strategy**.
- Those conclusions specifically address, among others, topics of REACH, namely on Registration.

Council conclusions on chemicals

18. REITERATES the importance of concrete actions by the Commission to ensure the compliance and improve the quality of REACH registration dossiers, as this data is the basis on which all necessary measures will be taken to protect human health and the environment; TAKES NOTE of ECHA's Integrated Regulatory Strategy and CALLS UPON the Commission to monitor its timely implementation; EMPHASISES that all relevant registration dossiers, e.g. those that have been identified in this process as of priority for data generation, should be checked by ECHA for their compliance with the REACH standard data requirements by 2028; UNDERLINES the need for an effective mechanism for the updating of registration dossiers including, for instance, update queries by ECHA where registrations have not been updated for a long time, as well as a measure for accelerating and streamlining the REACH evaluation procedures; CALLS upon the Commission and ECHA, in close cooperation with all stakeholders, to develop by December 2019 an action plan on dossier compliance;

Clear link to the Commission-ECHA 'REACH Evaluation Joint Action Plan'.

ECHA – Mapping the chemical universe to address substances of concern

- First report of the **Integrated Regulatory Strategy**.
- Aims to ensure the coherent implementation of the REACH and CLP processes and supports authorities in addressing substances of concern as soon as possible.
- Presents a **mapping of the universe of registered substances** that are on the EU market ('chemical universe').

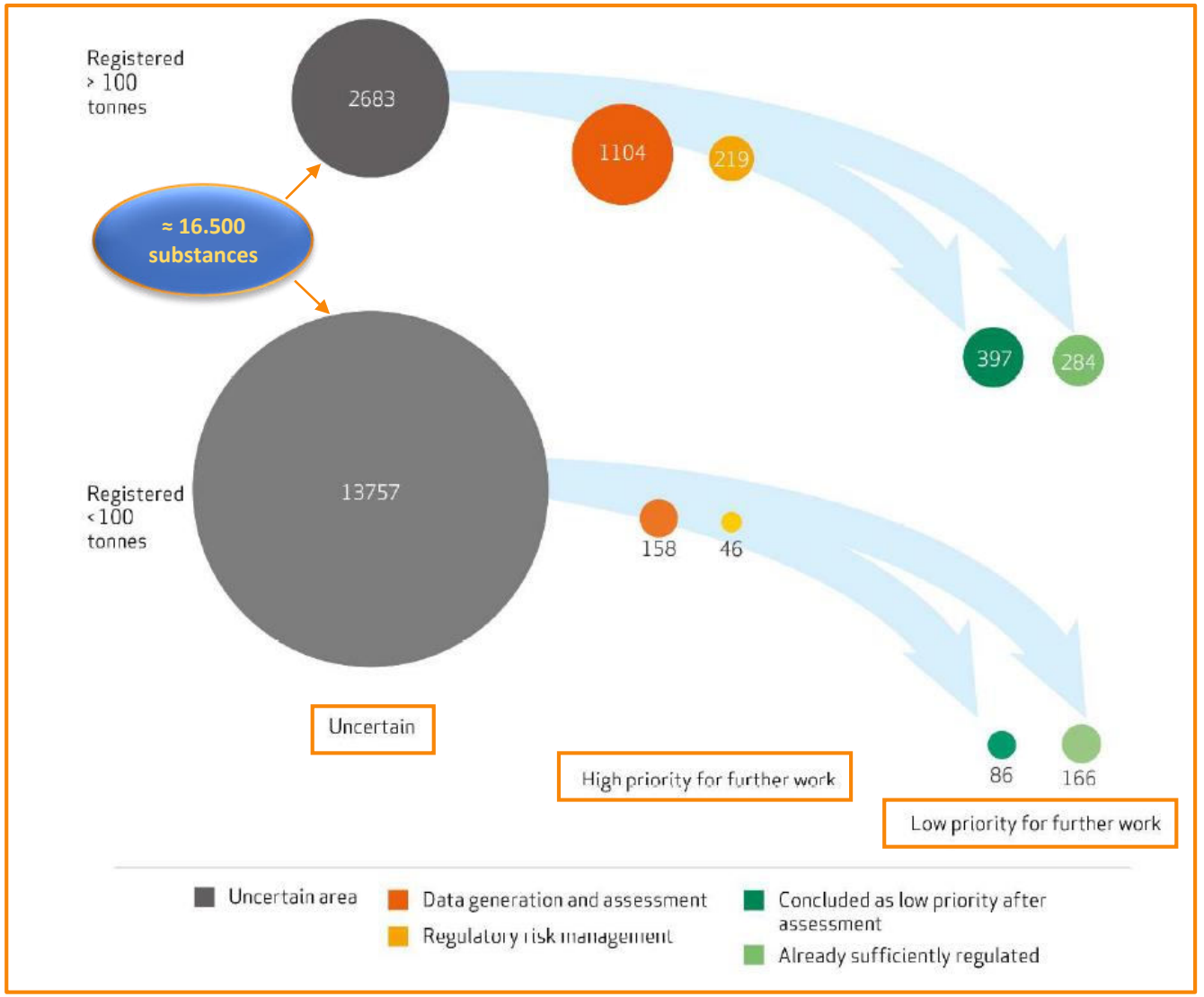
ECHA – Mapping the chemical universe to address substances of concern

Substances of the **chemical universe** in their pools of different priority for further work (data from May 2018).

- different pools of substances.

One of the main recommendations:

- **Quality** of registration information needs to be **improved**, in particular for substances with a high potential for exposure and currently lacking hazard data.



Commission-ECHA 'REACH Evaluation Joint Action Plan'

- The **Joint Action Plan** is ECHA's and the Commission's **answer to address the lack of compliance** of the information in the registration dossiers.
- It also requires:
  - commitment from authorities to make the process more efficient;
  - **industry to review their dossiers** and **generate further information** as needed.
- The substances concerned are the **16.500 substances** registered in full in 66.000 dossiers as of end 2018.

Commission-ECHA 'REACH Evaluation Joint Action Plan'

1. Address all substances

Action 1: By mid-2019, the Commission will propose an amendment of Article 41(5) of REACH to raise the 5% minimum target in Article 41(5) to 20% of dossiers selected for compliance checking.

Action 2: By end of 2020, ECHA will have concluded for all substances registered above 100 tonnes/y if they are i) of priority for regulatory risk management, ii) currently of low priority for further regulatory action, or iii) need more data for a judgement to be made. Substances under iii) are candidates for further compliance check and/or substance evaluation. These conclusions will be made publicly available and will be accompanied by clear communication to all stakeholders involved.

Action 3: By end of 2021, ECHA will have developed an approach that will allow drawing similar conclusions for substances registered in lower tonnage bands.

Action 4: By 2023 for all registrations in the tonnage bands over 100 tonnes/year and by 2027 also for the tonnage bands 1-100 tonnes/year, ECHA will have concluded for each of the registered substances submitted by the 2018 deadline if it is a priority for regulatory risk management, of low priority for further regulatory action, or have requested information under compliance check where needed.

35-40% of substances registered above 100 t & 20% of substances registered in the 10-100 and 1-10 t bands are expected to be priority for data generation. Corresponds to the 20% to be checked for compliance (in each tonnage band) by 2027.

By 2020, allocation in the right pool within the chemical universe of substances registered above 100 t .

By 2023, compliance check decisions will have been taken for substances above 100 t & by 2027 for substances in the below tonnage bands.

Commission-ECHA 'REACH Evaluation Joint Action Plan'

2. Improve clarity of certain legal provisions

Action 5: By end of 2019, the Commission will assess the need, and if necessary make a proposal, to amend the Annexes VI to X of REACH to provide greater clarity to the information requirements set out therein.

Action 6: By end of 2019, on the basis of the experience gained by ECHA, the Commission will assess the need, and if necessary make a proposal, to amend Annex XI to ensure that adaptations to standard information requirements are properly justified.

Action 7: By end of 2019, the Commission will assess the need of a possible implementing regulation that would efficiently put into effect the REACH evaluation decision making process.

Commission-ECHA 'REACH Evaluation Joint Action Plan'

3. Accelerate the compliance check decision making

Action 8: By end of 2019, ECHA will simplify the compliance check decisions and improve the statement of reasons, to be clearer and more focused.

Action 9: By end of 2019, ECHA will organise workshops with Member States, also on bilateral basis, with the aim of resolving underlying differences of view. The result will be presented to ECHA's Member State Committee for endorsement. In addition, ECHA will continue, as far as possible, identify and plan discussions on more generic issues that may arise in upcoming compliance checks.

Action 10: By end of 2019, ECHA will make a refined proposal to CARACAL how to better integrate substance evaluation and compliance check.

- Simplification of compliance check process.
- Better integration of compliance check and substance evaluation processes.

Commission-ECHA 'REACH Evaluation Joint Action Plan'

4. Keeping dossiers compliant, improving follow-up and enforcement of ECHA evaluation decisions

Action 11: By end of 2019, ECHA will ensure that any company submitting relevant new information during a restriction, an identification of substance of very high concern, an authorisation or a harmonised classification process and that has not preceded such submission with the corresponding update of the registration dossier, will be informed of its updating obligations according to Article 22 of REACH. Moreover, in such cases ECHA will inform the responsible MS(s), so enforcement action is pursued as appropriate.

Action 12: By end of 2019, ECHA will prepare a compilation of enforcement measures in place in each Member State to address the breach of dossier evaluation decisions and an assessment to what extent enforcement authorities in different Member States address non-compliance with ECHA's decisions through prohibition of marketing of the substance.

Action 13: By end of 2020, the Commission will assess the effectiveness of the enforcement measures above, including the information submitted by Member States in their Article 127 report by 1st June 2020.

Action 14: By mid-2020, ECHA's Forum will have established the template to test annual reporting to the ECHA's Secretariat including a summary of all enforcement actions taken by each Member State in the area of dossier compliance. The first such report should be made available by mid-2021. ECHA's Secretariat will propose to ECHA's Forum that such annual reporting is permanent and becomes integrated in the Article 127 report.

As of 2019, ECHA's decisions sent to all member registrants.

Ensure consistence between data provided in different REACH processes.

Importance of enforcement enhanced.

Commission-ECHA 'REACH Evaluation Joint Action Plan'

5. Industry takes on the compliance challenge

Action 15: 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.

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ECHA
EUROPEAN CHEMICALS AGENCY

COOPERATION AGREEMENT ON THE REVIEW/IMPROVEMENT OF REACH REGISTRATION DOSSIERS

In practice, this means….

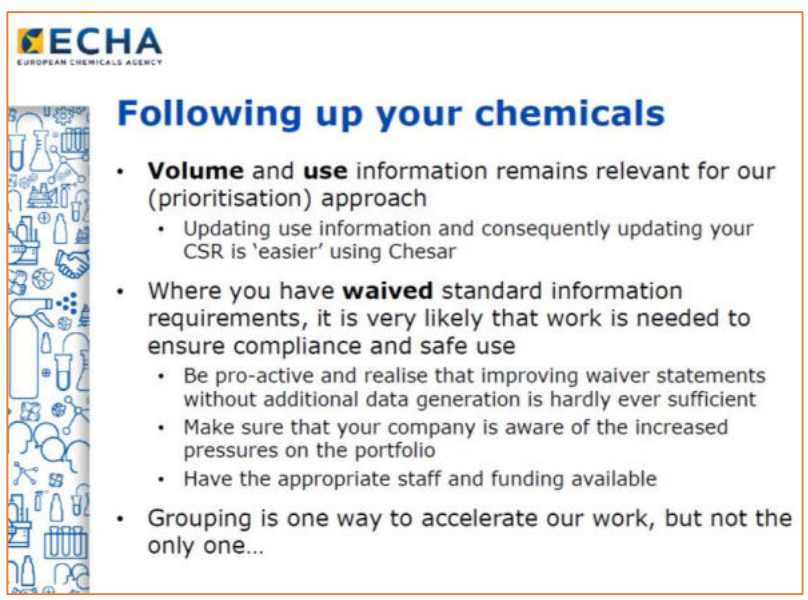
ECHA
EUROPEAN CHEMICALS AGENCY

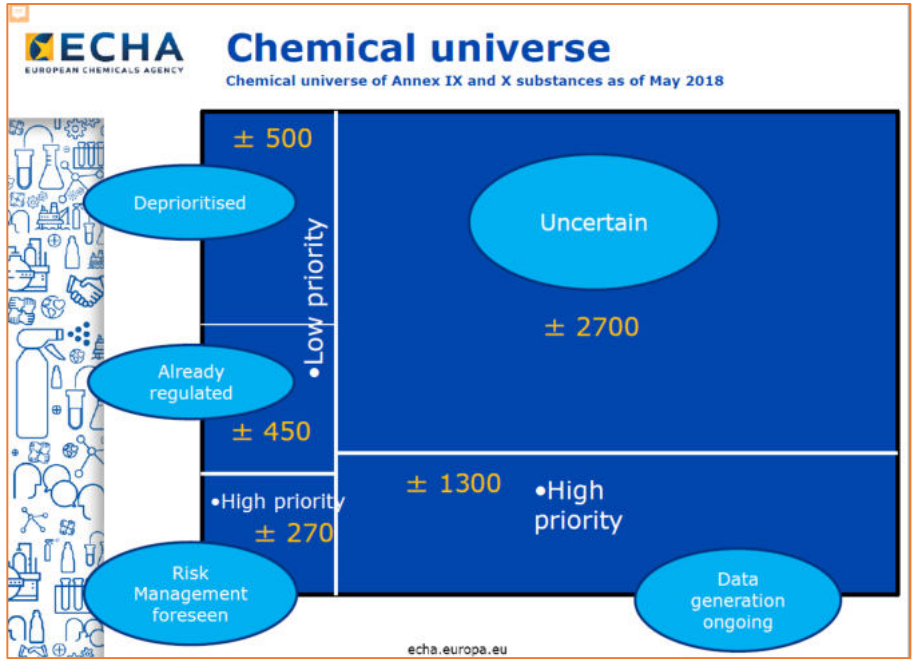
Focussing on substances that matter

- Higher-tonnage registration dossiers with
- Important data gaps and with
- High exposure potential for:
  - Workers or
  - Consumers or
  - Environment

☑ NOW
☐ LATER

echa.europa.eu 5





Part 3 - *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*

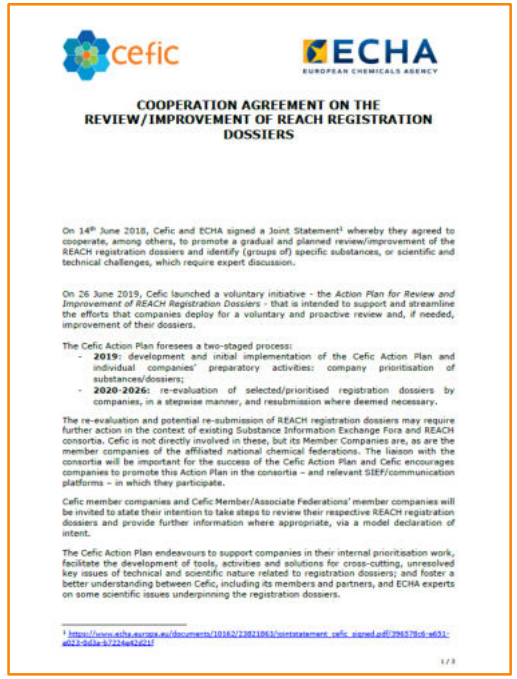
- Re-evaluate dossiers and provide further information, where appropriate;
- Report to Cefic on KPIs → Cefic annual reports.

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, while ensuring new vertebrate animal studies are performed only as a last resort
- Identification and notification of **priority substances**
- Progress tracking
- Dissemination



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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.

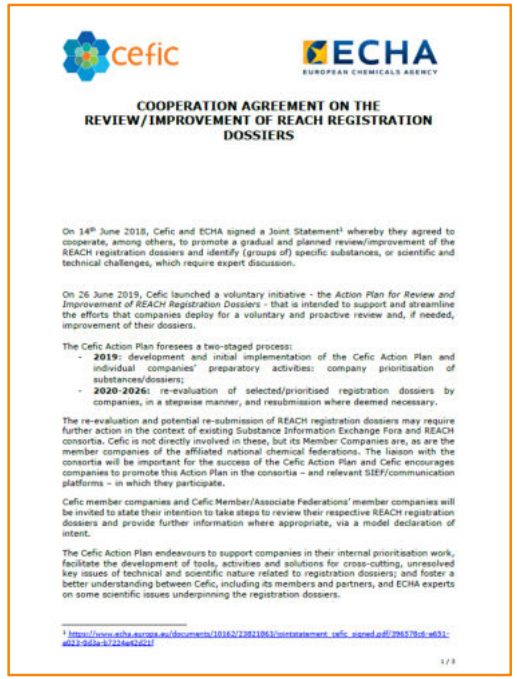
The Cefic Action Plan endeavours to support companies in their internal prioritisation work, facilitate the development of tools, activities and solutions for cross-cutting, unresolved key issues of technical and scientific nature related to registration dossiers; and foster a better understanding between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

[1] https://www.echa.europa.eu/documents/10162/23821063/jointstatement_cefic_signed.pdf/2965578d-a651-a021-0d3a-b7224e42d21f

Cooperation framework with ECHA: governance

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

- a **Steering Committee** to support and guide the implementation of the collaboration agreement and look for solutions when hurdles are encountered.
- a **Joint Expert Group between ECHA 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).



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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.

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!

Conclusions - *To take home!*

To conclude

- We are determined to make REACH work; the journey is not over.
  - With sophistication comes complexity;
  - No one-size-fits-all.
- REACH is an on-going learning process: need to clarify the complexities and review need for additional information based on most recent guidelines.
- We all need to work together to make it work: better alignment between ECHA's expectations and registrants' understanding of those expectations.
- The Cefic Action Plan is a big response to a big issue.
  - More data will need to be generated
- We need dialogue with ECHA: it takes time but it saves resources, animals and costs to everyone.
- More enforcement is needed: we need a level-playing field.

All together, we can make a difference!

Thank you!

For more info: mfb@cefic.be