REACH registration dossiers
Challenges and solutions

ECHA Conference “Safer Chemicals”

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We want REACH to work

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

  ⇨ 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

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

Let's remember (1)

REACH :

- is the most ambitious 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 use
- is complex, subject to interpretation, both legally and scientifically

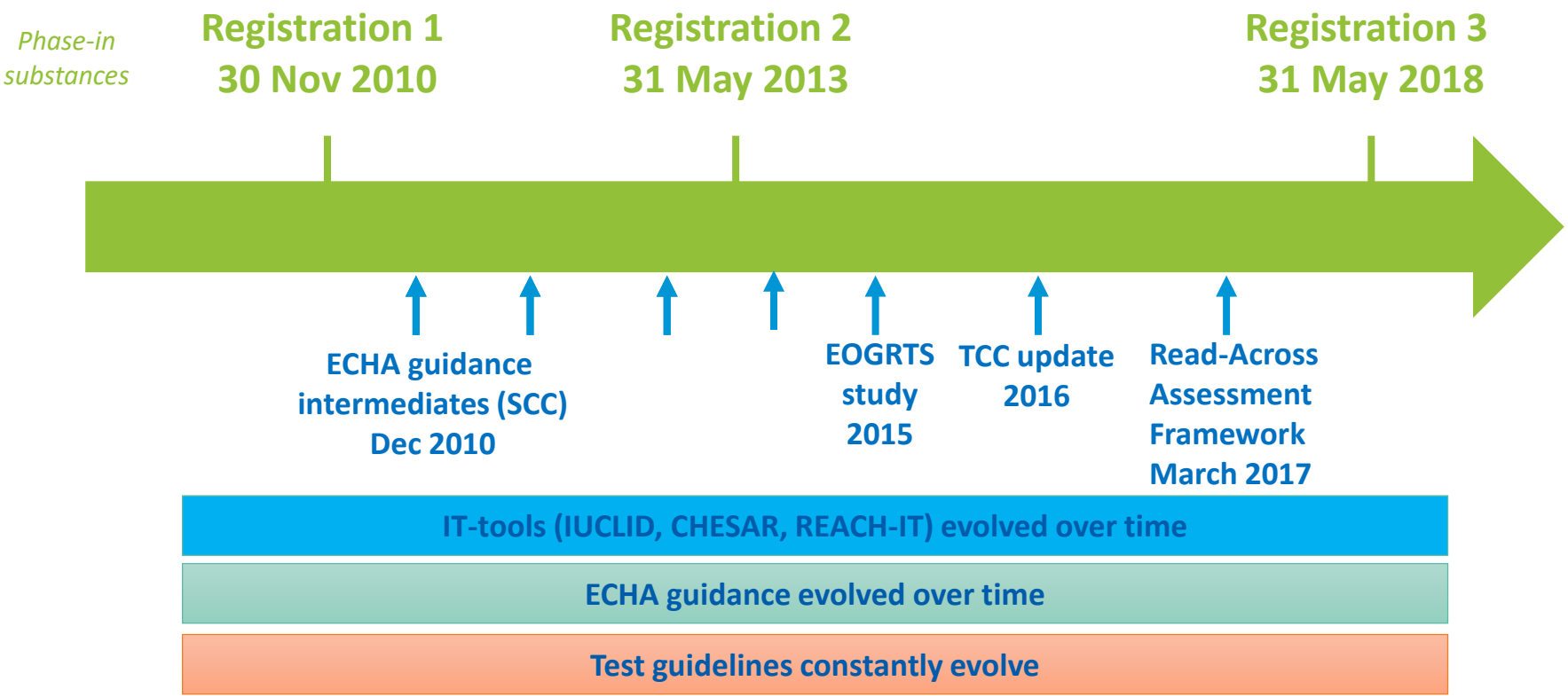
One (full) registration is:

- ✓ > 2000 data fields in IUCLID
- ✓ Up to 70 phys-chem, tox and ecotox studies/tests
- ✓ 100-150 hrs of work/dossier*
- ✓ 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

* when all studies/info has been gathered

It has been a tremendous effort to get this far

Let's remember (2)



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

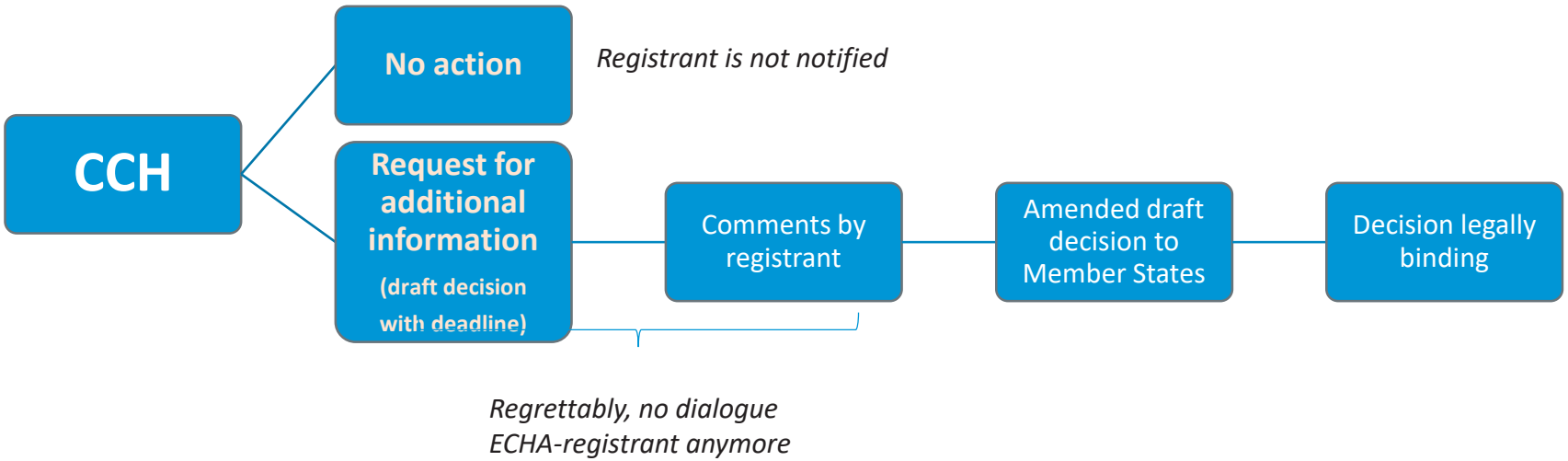
Minimise animal testing

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

Compliance Check - challenges

- 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 not possible → can we find a remedy to facilitate update ?

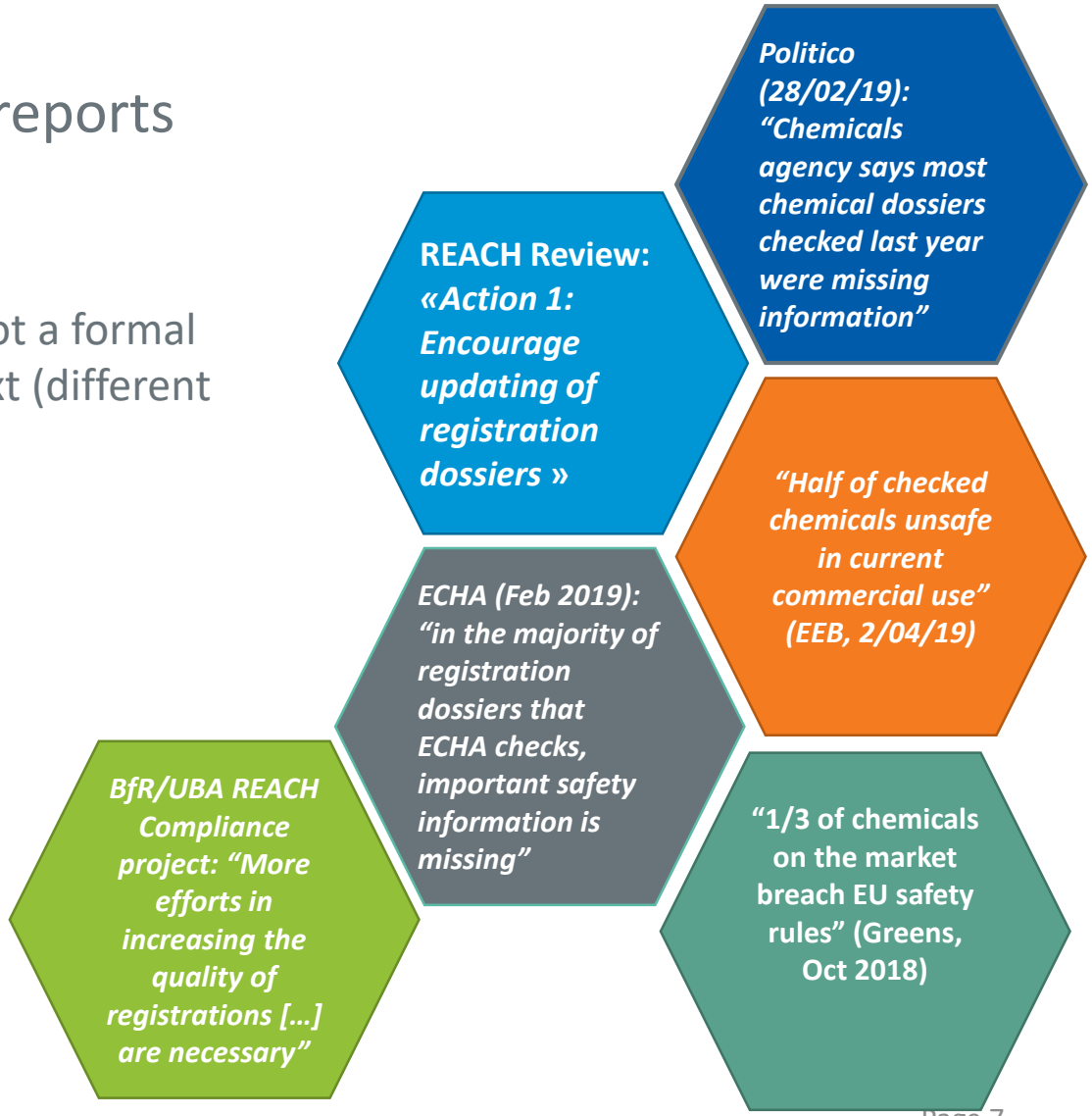


What are we hearing?

- ECHA annual evaluation reports
- BfR/UBA screening

  N.B. BfR/UBA's assessment is not a formal CCH as required by the legal text (different methodology)

We take these findings very seriously



Zooming into dossiers:
what is behind the numbers?

Case 1 – company A

- BfR/UBA provided details on their dossiers (100-1000 t/a) → which substances/endpoints are missing information?
  - BfR/UBA: 32% of Company A's dossiers contained one or more "non-compliant" endpoint(s)

- Company A's experts analysed BfR/UBA's assessment

Animal testing?

Technical feasibility

1. Administrative /formalities/mistakes
2. Waiver for chronic fish for substance with low (<1mg/L) water solubility not accepted, despite available chronic algae/ daphnia studies without adverse effects at concentrations below water solubility.
3. Hydrolysis main study was stated as missing. However, conduct of study was technically not feasible
4. Some of the „non-compliant" entries were already corrected through a dossier update

- <u>In summary</u>:
  - Majority of „non-compliances" were formalities or had already been updated
  - None of the shortcomings identified represents a safety issue
  - Only 6% of dossiers remain to be further improved (vs 30% stated)

Case 2 – Company B

- BfR/UBA findings for Company B dossiers
  - 57% of dossiers have at least 1 “non-compliant” endpoint (37% screening and 20% screening + refined checks)
  - No problem: 43 % of dossiers
- Looking at all endpoints (not dossiers) : < 10% are “non-compliant”
- The main reason for “non-compliances” across dossiers is one ecotox endpoint: long-term fish study not available
- In summary: by solving the ecotox issue (i.e. one endpoint), significant improvement can be achieved

Difficult to test: water solubility < 1 mg/L

Case 3 – Company C

- Product family X, 5 substances X1 to X5, structurally similar (used mainly as intermediates, but full registration)
- 2015: ECHA Compliance Check on X4 → request for more information (read-across). Company C proposed tiered testing strategy covering full family:
  - Test X1 and X5 (toxicokinetics + 90 d + repro + mutagenicity) , then R/A to others
  - No MSC objection, testing performed, dossiers updated
- 2018: read-across from X1 and X5 to X4 not accepted because of small explainable differences in toxicology for X1 and X5 (secondary effects)
- Company maintains R/A and proposed 90 d study on X4 to support R/A – awaiting feedback → could end up testing 5 substances if R/A rejected on full family
- In summary: Common understanding on interpreting toxicological study results is essential; dialogue needed

Case 4 – SME

- Company is LR for 20-25 substances (> 100 t/a)
- Potential rejection of waivers leads to testing up to $ 25M
- Business-critical for an SME (that has accepted to be LR)
- Support needed

So, what are the solutions?

Cefic is working on an Action Plan

- **Proactive** re-assessment of registration dossier content, and effectively and efficiently identify/address data or information gaps (staged priority setting), if needed
- Cefic members will dedicate human and financial **resources**
- **Transparent** communication and progress report
- Further **cooperation with ECHA**, under the umbrella of the June 2018 Cefic-ECHA Joint Agreement
- Information to **stakeholders**
- **More to come…**

Conclusion

- **We are determined to make REACH a success**
  - ✓ We are all still learning
  - ✓ We should be outcome-focused: safe use and handling of chemicals
- Registration dossiers are the **basis** for safety information
- **We all need to work together to make it happen**: achieve common understanding of 'good quality' dossier
- We need **dialogue with ECHA**: it takes time but it saves resources, animals and costs to everyone
- **We are actively working on a way forward**
- More enforcement is needed: we need a **level-playing field**
- We are liaising with other industry associations

ChemistryCAN !
https://chemistrycan.com/

Designing with energy efficiency in mind ("cool roofs")

Recycling food packaging into school desks

Preserving wild fish stocks

Advanced chemical additives boost the quality of recycled paper

Thank you

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