ECHA
EUROPEAN CHEMICALS AGENCY

ECHA's support for industry action

Session:
Zero tolerance approach to non-compliance

Safer Chemicals Conference 2021

Sampo Karkola

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Background and objectives

Background

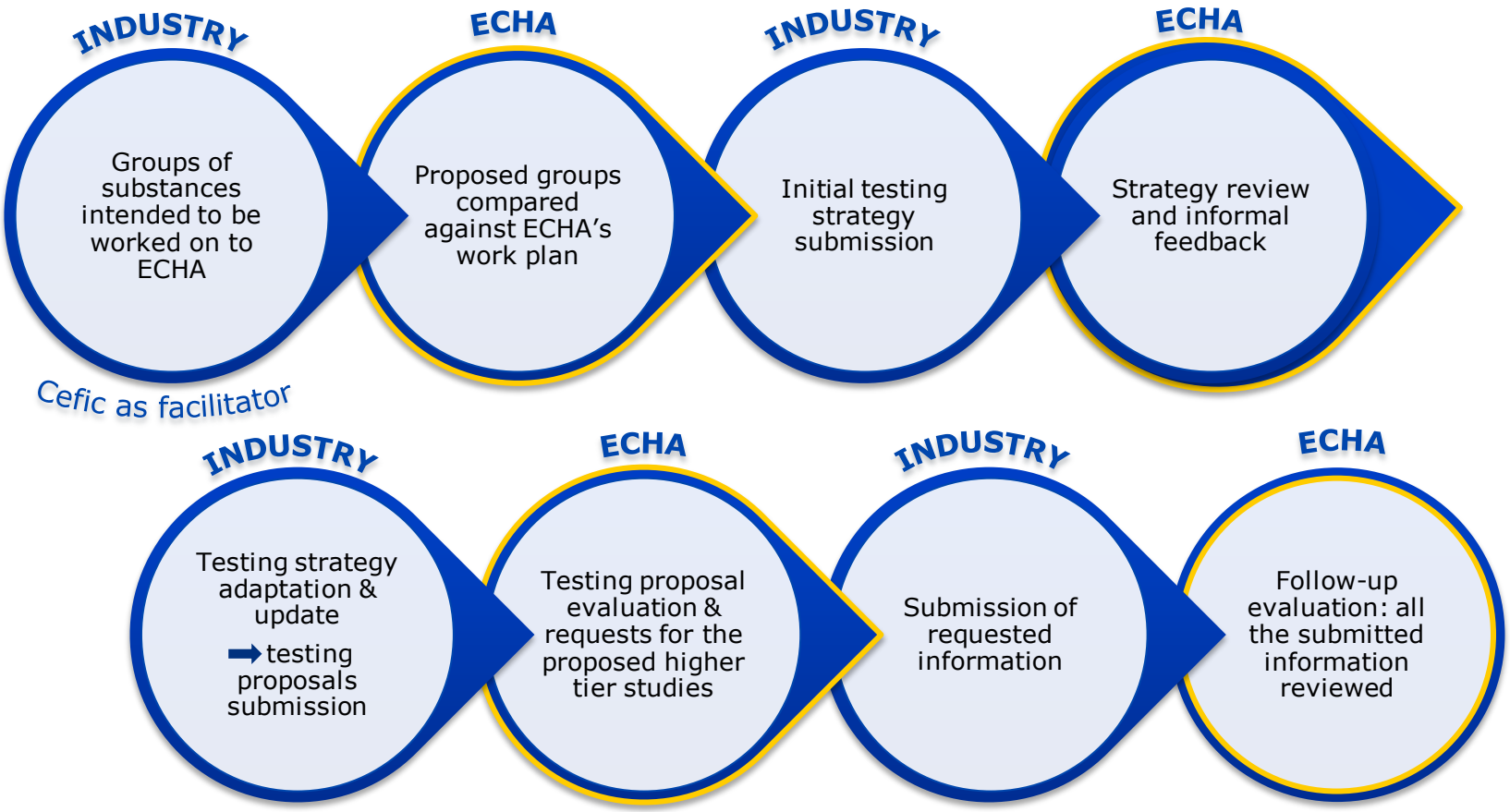
2018	2019	2019
Joint statement of ECHA and Cefic: Agreement to cooperate to improve registration dossiers	REACH Evaluation Joint Action Plan Industry to improve their registration dossiers proactively and continuously along the agreed working arrangements	Voluntary Action Plan launched by Cefic, in cooperation with ECHA • 190 companies, 1 355 legal entities (in Dec 2020)

Objectives of Voluntary Action Plan

- Voluntary review of registrations of groups of substances by Cefic member companies
- Development of testing strategies
  - Review groups and category justifications
  - Identify data gaps
  - Optimise data generation (in terms of costs and process efficiency)
  - Minimise the need for compliance checks
- Informal support from ECHA
- Improve the safe use of substances

Description of the support process and pilot

How does it work?



Pilot 2020

- Four groups of 2-15 substances selected together by ECHA and companies
- Initial category justifications and testing strategies reviewed by ECHA

  → Informal feedback provided to companies
- Category justifications and testing strategies refined by companies
- ECHA requested to see proof that companies had ordered lower-tier studies

  → Companies submitted testing proposals for long-term endpoints

Observations from the pilot

- Substance identity must be clear → pre-requisite for read-across
- Supporting studies are essential in deciding on substances to be tested for higher tier endpoints
  - Should be conducted before developing a testing strategy
- Category read-across justifications should follow ECHA's Read Across Assessment Framework (RAAF)
- Testing proposals should be submitted for the (most probable) test substances
- Consortium negotiations take time

Our requirements for groups of substances

- Coherent groups of substances with similar structure and hazard properties
- Clear substance identity
- No expected tonnage band changes
- Reasonable group size, preferably 5-15 substances
- No regulatory processes ongoing for any of the substances in the group
- Substances should be in the “not yet assigned” pool of ECHA’s chemical universe

Benefits and further considerations

Benefits to companies

- Systematic review of registration dossiers
  - Dossier up to date in terms of tonnage, use and hazard information
- Time to develop categories and testing strategies
- Informal interaction with ECHA to better understand regulatory requirements
- Higher chance of data compliance once testing strategy has been implemented and finalised
- Minimisation of animal testing
- Reduced costs for studies

Benefits to authorities

- Industry committed to generate hazard data
  - Proof of lower tier and other supporting data generation
  - Testing proposals for higher tier endpoints
- Data gaps filled without the need to open formal compliance checks
- New data facilitates further regulatory work
  - Confirmation of low hazard substances
  - Potential regulatory risk management processes
- Minimised animal testing

Grouping by ECHA

- Grouping by ECHA is different from grouping by industry
  - see earlier presentation on ECHA Grouping
- ECHA addresses groups of structurally similar substances holistically
  - More efficient compared to a single substance approach
  - Avoids regrettable substitution
  - Still possible to address substances one-by-one and open compliance checks on individual substances

Things to take into account with grouping

- Companies must share data and costs, and follow consortia agreements
- Category hypothesis may change based on newly-generated supporting or higher-tier data
- If category hypothesis does not hold, ECHA may need to open compliance checks
- Resource-intensive for companies and ECHA
- Process will be reviewed at end of 2021, together with Cefic

How to get involved

- Sign up for the Cefic plan
- Contact other registrants, establish/review data- and cost-sharing contracts
- Make sure substance identity is clear
- Check whether you have enough supporting data. If not, generate it (no need for ECHA's decision)
- Develop a category read-across hypothesis based on available data and refine later based on supporting data results
- Inform ECHA about your group
- Follow ECHA’s advice

Summary

- Cefic Voluntary Action Plan is your chance to improve compliance of your dossiers
- Support available from ECHA
- Reduce costs and minimise animal testing

Links

- ECHA and Cefic websites
  - https://echa.europa.eu/echa-cefic-collaboration-on-dossier-compliance
  - https://cefic.org/policy-matters/reach-dossier-improvement-action-plan/
- ECHA web page on grouping and read-across
  - https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
- ECHA's chemical universe
  - https://echa.europa.eu/universe-of-registered-substances
- ECHA recommendations for registrants
  - https://echa.europa.eu/recommendations-to-registrants

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Thank you!

sampo.karkola(at)echa.europa.eu

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