REACH24H CRAC 2022 by REACH24H Consulting Group

14th Chemical Regulatory Annual Conference

Virtual Forum

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EU REACH Compliance Requirements and future update plans

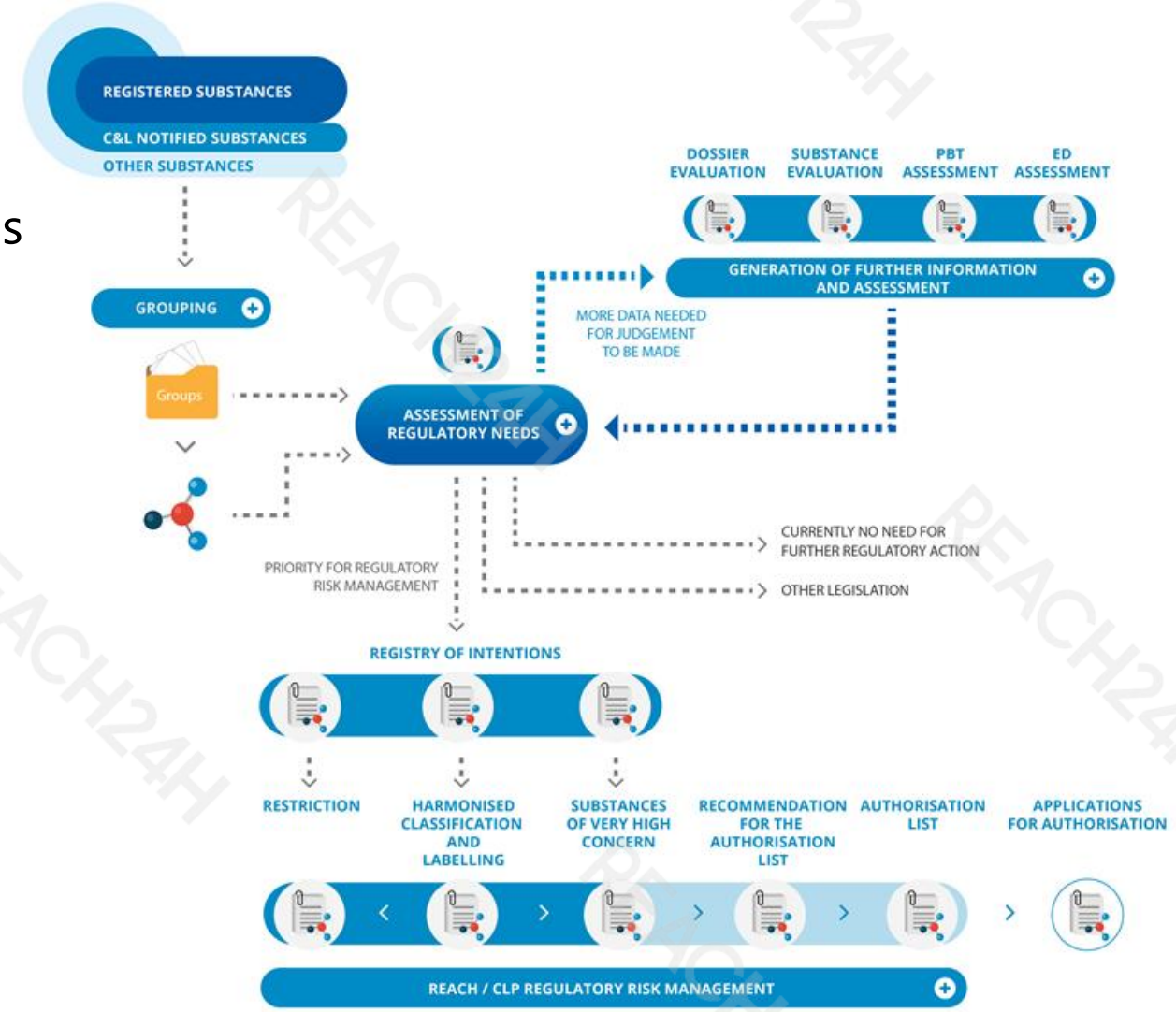
European Chemicals Agency
Catherine Cornu

2022.12.15

Contents

ECHA's Integrated Regulatory Strategy

Compliant registrations are key



- '[Chemical universe]' to track progress on registered substances
  - >100 tonnes
  - 1-100 tonnes
- Grouping approach: work on groups of substances

Safeguarding the environment and protecting health

Update on registration and evaluation

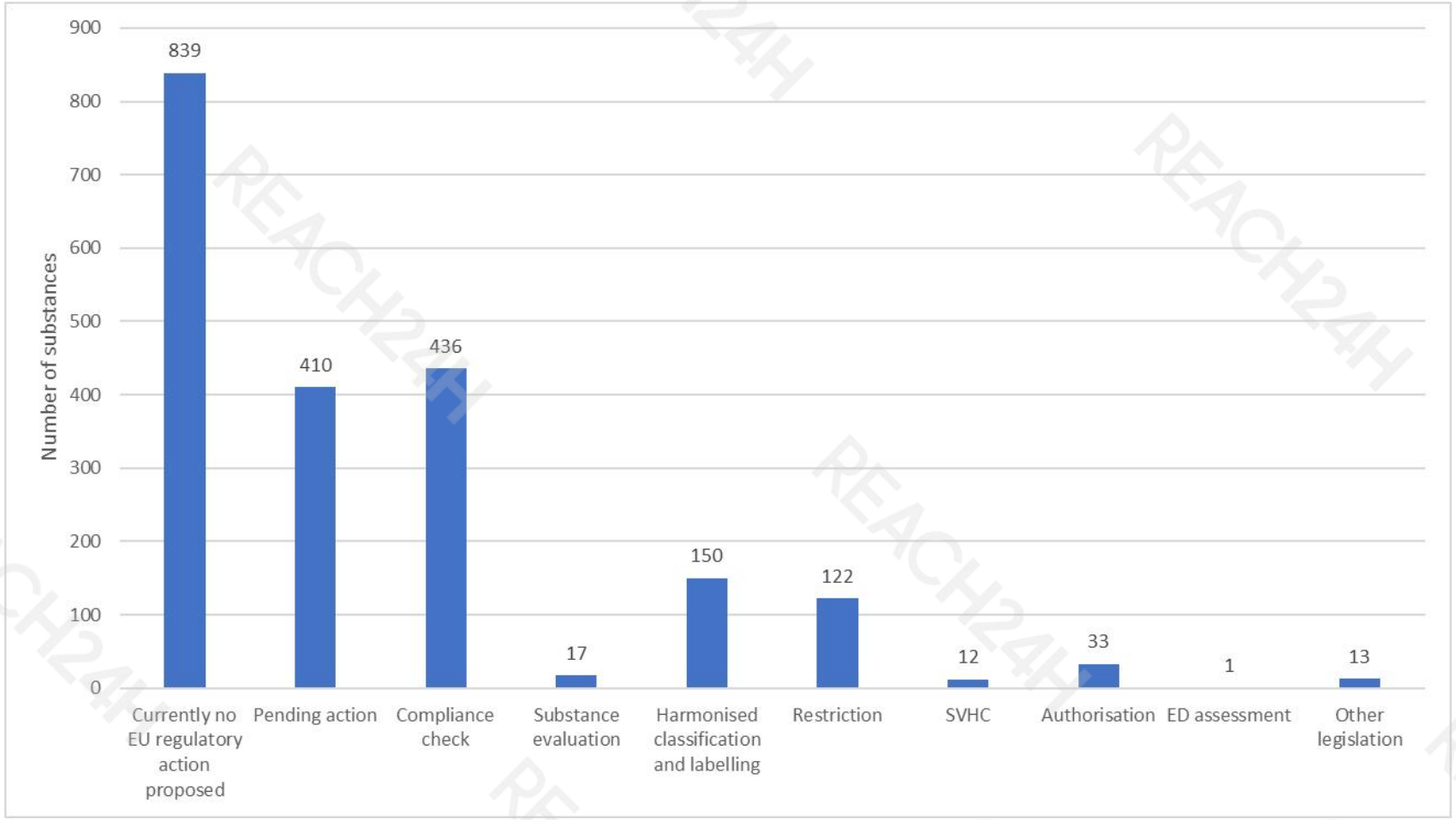
- ECHA's Integrated regulatory strategy work in 2021
- Clarification of REACH information requirements (applying as of 2022)
- Dossier update Implementing Regulation
- What's next?

ECHA's Integrated regulatory strategy work in 2021

- >1900 substances assessed
- EU regulatory risk management actions expected for ~30% of assessed substances
- Assessment of Regulatory Needs (ARNs) are the main source of candidates for EU regulatory risk management
- Most need further data generation/confirmation first
- Group assessment work has identified over 400 substances for CCH in 2021

https://echa.europa.eu/documents/10162/5641810/irs_annual_report_2021_en.pdf

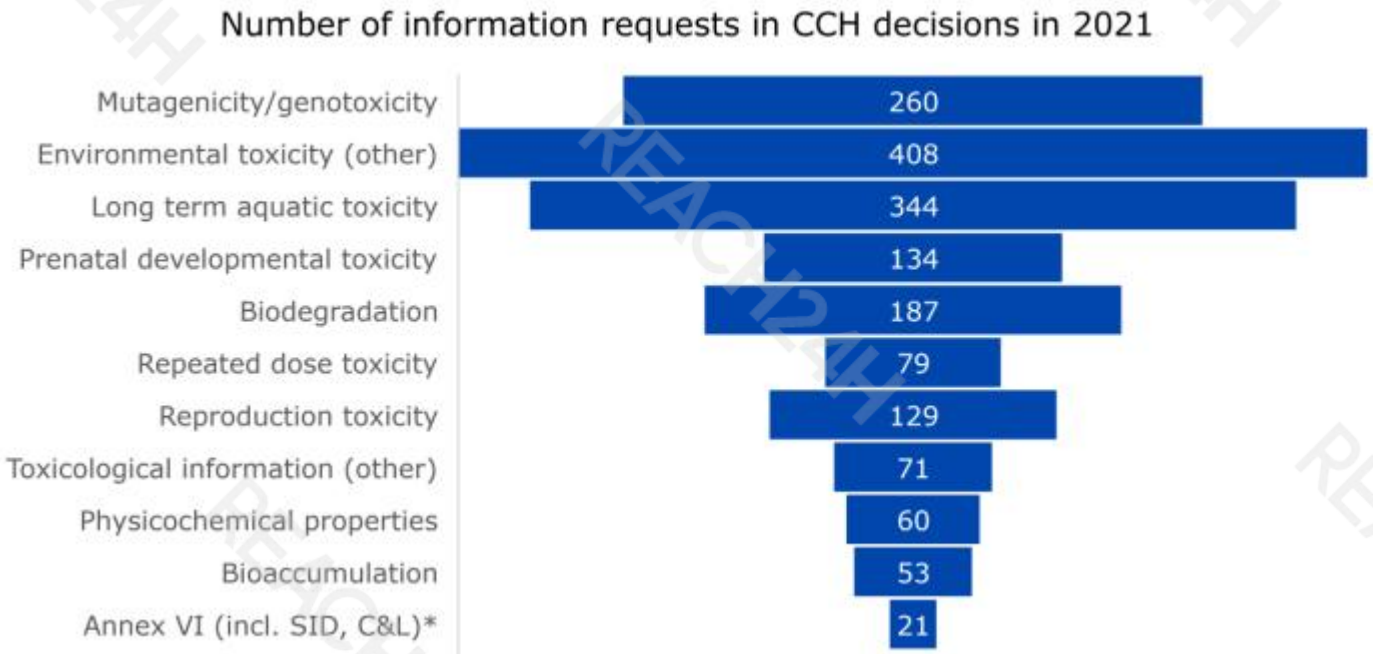
Next action for 2021 groups



https://echa.europa.eu/documents/10162/5641810/irs_annual_report_2021_en.pdf

Main reasons for non-compliance

- Adaptations (data waiving, read-across, QSAR, weight of evidence approach) not justified in line with the regulation or failing due to lack of documentation
  - leading to data gaps for higher tier information requirements



- Documentation insufficient
  - e.g. insufficient level of detail in robust study summaries to allow for an independent assessment

https://echa.europa.eu/en/recommendations-to-registrants

Clarification of REACH information requirements

Action 1 changes entered into application 8 January 2022

- Physico-chemical properties: new specific rules for adapting for dissociation constant and viscosity
- New adaptation rules for environment endpoints: fate and behaviour in the environment based on a low octanol-water partition coefficient
- Eye and skin irritation, repeated dose toxicity, reproductive toxicity, further clarifications for human health and environmental testing to be performed at appropriately high dose levels
- Annex XI

Clarification of REACH information requirements

Action 2 changes entered into application 14 October 2022

- Mutagenicity
- Reproductive toxicity
- Environmental endpoints
- substance identification

Only representatives had to identify the non-EU manufacturer: done for over 95% of OR registrations!

Resulting amendments to the completeness check & IUCLID formats

- Annex VI: substance identification
  - New checks to improve information in boundary composition

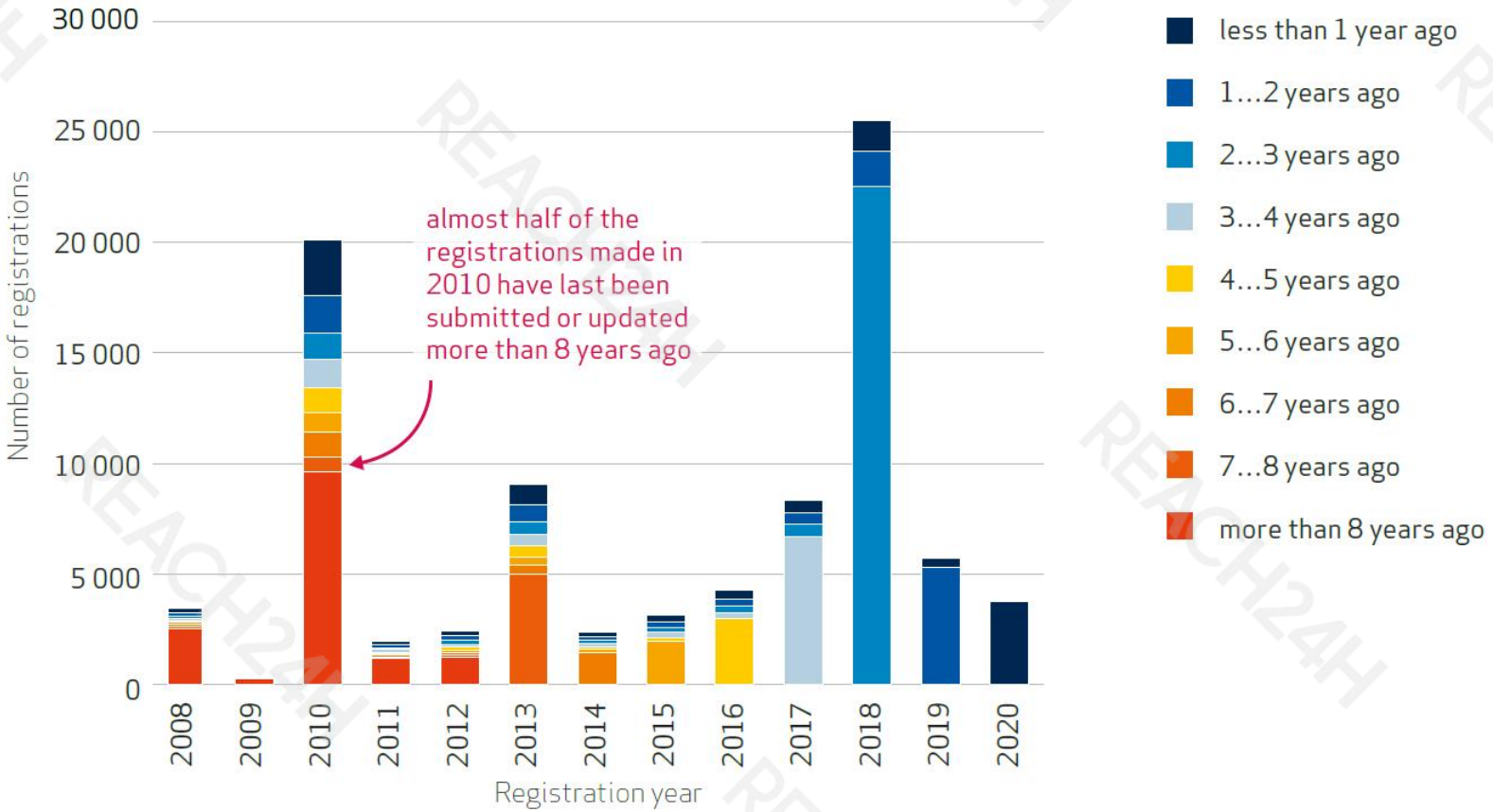
- Annexes VII-XI information requirements
  - New and updated data waiving picklist values, in line with the Column 2 adaptation options
  - Long term aquatic toxicity and degradation: alignment with the interpretation of the Column 2 provision related to the outcome of the CSA
  - New IUCLID document to justify the weight of evidence approach in a structured manner
  - Mutagenicity – clarifications related to the data requirements applicable for Annexes VII-X

Support on the amendments to the completeness check

- Webinar on 8 February 2023
- Updated information on the TCC webpages
- Updated rules available in the IUCLID Validation assistant and in the registration manual as of April 2023
- Plan the timeline for your submissions: submit before May 2023 or only after you have updated your IUCLID and addressed the changes using the support materials and tools

- Questions: contact us via the contact form

Dossier updates



Dossier updates

Updating is a legal obligation (Article 22)

- On your own initiative, without undue delay, after changes in:
  - company status
  - composition of the substance
  - tonnage band
  - new identified uses
  - new risks of the substance to human health and/or the environment
  - classification and labelling of the substance
  - …
- When the Agency requests an update of the registration after a dossier or substance evaluation decision
- After an authorisation or a restriction for the substance

Dossier update Implementing Regulation

- Applies since October 2020
- Clarifies the concept of 'without undue delay' for updates on your own initiative, i.e. sets update deadlines for different changes (3-6-12 months)
- Although the responsibility is with industry, ECHA ran 2 supporting dossier update campaigns in 2021-2022 to raise awareness:
  - Registrations of substances listed on Annex XIV, requiring authorisation to be used after their sunset date
  - Registrations of substances for which the classification has been harmonised

https://www.echa.europa.eu/web/guest/keeping-your-dossier-up-to-date

What's next?

- Chemicals Strategy for Sustainability envisages
  - Zero tolerance for non-compliance
  - Registration of certain polymers
  - New (alternative method) information requirements
  - …

- REACH revision has been postponed in the Commission's 2023 work programme to Q4 2023

- No certainty as to when the final revised REACH will be adopted by the European Parliament and the Council

Contents

EU enforcement project on REACH registration (REF-7)

- Scope: REACH registration duties
  - Imports controlled in cooperation with customs
  - 28 EU and EEA countries involved
- Timeline: Inspections in 2019, report in end of 2020
- Results
  - 1420 substances controlled in 813 companies
  - 15% overall non-compliance with all duties checked
  - ~7% of substances missing required registration

EU enforcement project on REACH registration (REF-7)

Issues detected for only representatives (ORs)

- 8% of ORs found to be non compliant due to:
  - Lack of updated information on overall quantities of the substance imported per year
  - Lack of updated information on covered importers (DUs)

https://echa.europa.eu/documents/10162/17088/project_report_ref-7_en.pdf

Pilot project on control of imports

- Scope: control imports for REACH restrictions and CLP labelling in cooperation with customs
- Timeline: Inspections in 2019, report in 2020
- Results
  - 1389 imported products controlled
  - 23% of all checked imported products were non-compliant
  - 17% overall rate of non-compliance for restrictions
  - 64% of non-compliance with CLP labelling/packaging duties
  - 74% of non-compliant products found originated from China

https://echa.europa.eu/documents/10162/17086/customs2_project_report_en.pdf

EU enforcement project on control of REACH imports (REF-12)

- Scope: Control of imports for Registrations, Restrictions and Authorisation in cooperation with customs

- Purpose:
  - Strengthen control of imports to ensure level playing field
  - Improve cooperation with customs

- Timeline:
  - Preparation 2023
  - Inspections 2024
  - Report 2025, Follow-up 2026

https://echa.europa.eu/en/-/next-eu-wide-reach-enforcement-project-to-focus-on-imported-products

Contents

Know your registration duties

- Recommendations for registrants (ORs)
  - Regularly and pro-actively verify own compliance with registration duties
  - Enforcement project questionnaire* may help to prepare for controls
  - Put more attention to keep registrations up to date and synchronised with actual company operations (e.g. monitoring systems)

- Recommendations for non-EU manufacturers
  - Regularly inform the OR about importers which receive the substance and quantities they receive per year

* https://echa.europa.eu/documents/10162/17088/project_report_ref-7_en.pdf

Know the responsibilities of registrants during evaluation

- How to act during dossier evaluation
  - Read the updated practical guide
  - Keep your contact details in REACH-IT up to date
  - Before a draft decision is sent, substances are listed in the Dossier Evaluation status pages and in PACT (ECHA's public activities coordination tool)
  - If your substance is listed, get in touch with your co-registrants to get organised
- Tonnage band downgrades
  - Dossiers are expected to be up-to-date on tonnages and uses
  - Tonnage band changes may now be taken into account during dossier evaluation
- Collaborate with co-registrants on generating the requested data
- Ceasing import
  - If between draft decision and final decision: registration becomes invalid
  - If after final decision: need to comply with requests in the decision

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Take-home messages

- Be aware that – through the Integrated Regulatory Strategy – registrations are the starting point for regulatory actions on substances
- Invest in a good registration: complete and compliant
- Have procedures in place to identify if changes in your registration are needed and keep your registration up-to-date. Contribute to the review of the information (including data waivers and read-across) by the co-registrants
- Through grouping ECHA is speeding up the assessments. Keep track of authorities' intentions on substances that need action via PACT
- Be prepared for your registration being checked, and that your OR will need to work together with co-registrants to generate data for your substances
- Legislation evolves: follow ECHA on our comms channels for regular updates

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THANKS