Concluding remarks and closing

Andreas Luch
Registration Dossiers

Registration data are of crucial importance in chemical safety management

REACH Regulation requires …

1. Completeness of standard information on the substance properties (& exposure)

2. Appropriate quality of data (OECD TG)
Project on Data Availability in REACH Registrations

... for the endpoints assessed:

- **compliant**: 44% of dossiers (100-1000 tpa) / 31% (≥1000 tpa) of dossiers (contain the standard information or appear compliant by alternative data/justifications)

- **non-compliant**: 19% / 32%

- **complex**: 37%
  (Need of further case-by-case assessment)

→ Trend for improved justification on data waiving and adaptations / higher compliance rates
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Findings

Frequent use of data waiving / adaptation - On average 71% for the assessed endpoints

- Major cause of „non-compliance“: inappropriate justification of data waiving / adaptations
- Majority of Read Across approaches properly applied
- Majority of (Q)SAR approaches formally „non-compliant“
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Possible Usage / Value?

By Authorities
- To set priorities on dossier evaluation
- As supporting information for ECHA's screening activities
- For priority setting on further regulatory actions

By Industry
- To analyze possible weaknesses and data gaps in the registration dossier
- To improve justifications of data waiving / adaptation
ECHA Responsible for Dossier Evaluation

Art. 41

• Project results are not identical to the conclusions from Compliance Check (CCH) by ECHA

• Project outcome and scrutiny by ECHA's CCH may differ at the single dossier level

• Need for higher rate of CCH by ECHA (currently 200/yr → 5% rate)? Priority setting? Perspective?
Options to Improve Dossier Quality – Obligation and Desire?

Updating – New information
• REACH Article 22
• Obligation to update (new data, to meet regulatory requirements)

Updating – Improving dossier quality
• Currently legally not foreseen
• Options? Update as follow up to Compliance Check (increase of CCH?), new data after evaluation decision

Revise REACH Article 22?

Implementation of regular updating of registrations by other means?
Conclusions:
• Industry provided information on all current chemicals in the market (>88,000 registrations on >21,000 substances; cave: new upcoming compounds)
• Industry takes responsibility for the safe use of all chemicals on the market
• A high number of (previous) registration dossiers at high tonnage level requires improvement

→ Time to address data gaps or inappropriate data waiving/adaptations

Questions:
• How to initiate and support improvement?
• How to urge/support the registrants for more engagement?
• CEFIC’s Helsinki declaration as a starting point for joint activities?
• Withdrawal of the registration as an option?
• Workshop support?
Communication

REACH Compliance: Data Availability of REACH Registrations
Part 1: Screening of chemicals > 1000 tpa

Workshop on Data Quality in Registration Dossiers

Mind the Gap – Data Availability in REACH Registrations

BfR-Workshop
2 March 2015, Berlin

REACH Compliance Project:
Recommendations for registrants to improve data quality in registration dossiers for chemicals ≥ 1000 tpa

Luch, 24.08.2018, REACH Compliance – Workshop on Data Quality in Registration Dossiers
Thanks to all Contributors of the Project

REACH Compliance Project (2014-2018)
“Availability of Health and Environmental Data for High Tonnage Chemicals under REACH”

ECHA Directorate Evaluation

UBA Division IV Chemical Safety

BMU Directorate IGII Environmental Health, Chemical Safety
Thank you!

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