

Concluding remarks and closing

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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**

Project on Data Availability in REACH Registrations

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“

Project on Data Availability in REACH Registrations

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?

Registration Deadline 31 May, 2018: Aftermath

Conclusions:

- Industry provided information on all current chemicals in the market (>88,000 registrations on >21,000 substances; caveat: 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

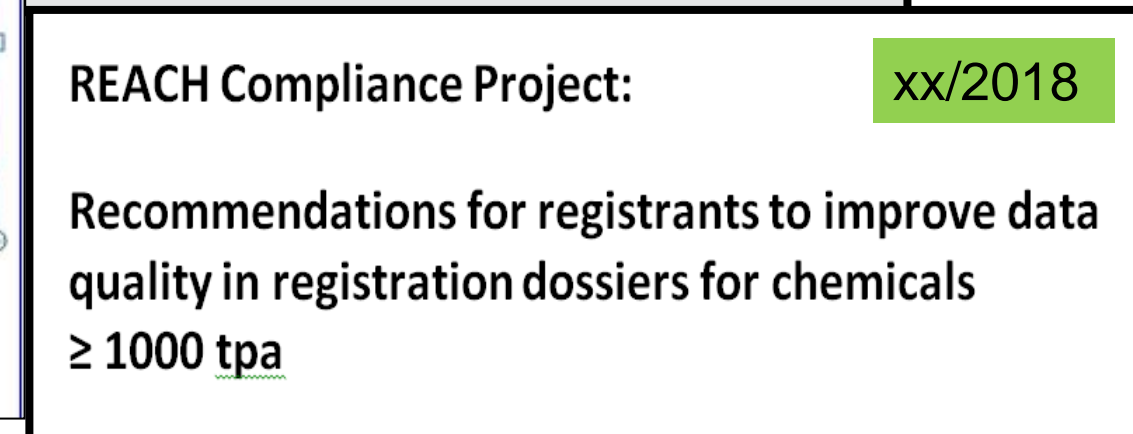
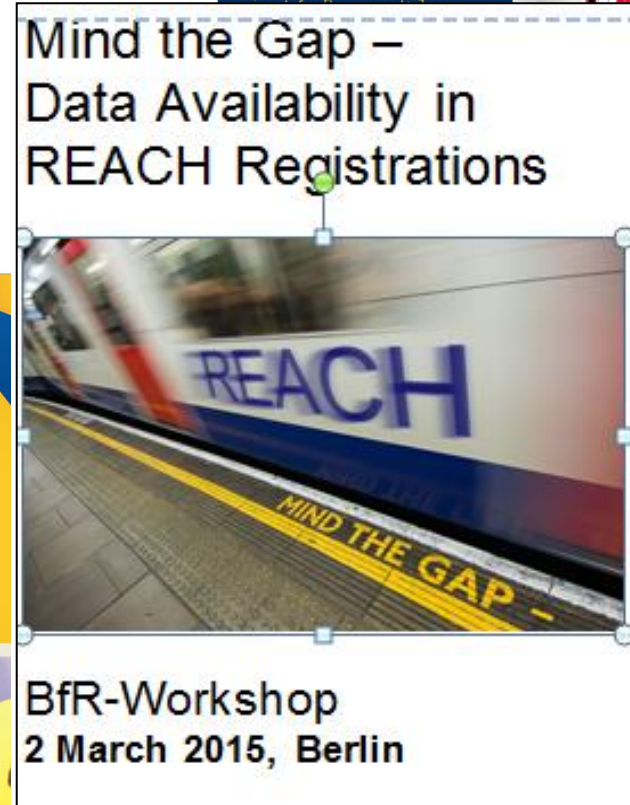
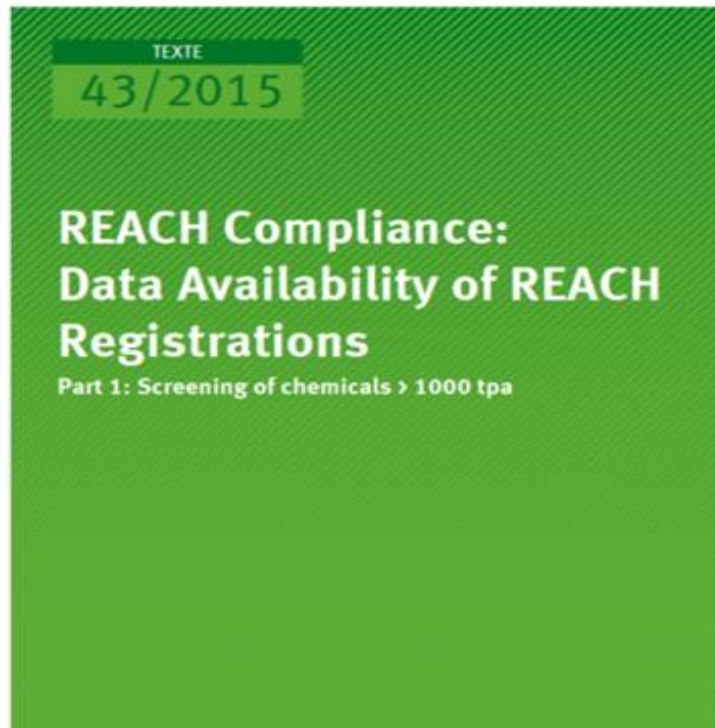
→ Time to address data gaps or inappropriate data waiving/adaptations

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



Thanks to all Contributors of the Project

REACH Compliance Project (2014-2018)

“Availability of Health and Environmental Data for High Tonnage Chemicals under REACH”

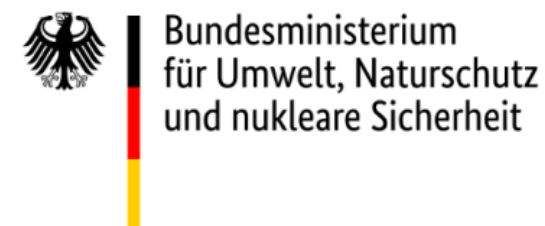
ECHA Directorate Evaluation



UBA Division IV Chemical Safety



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Thank you!

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