

REACH Compliance Project “Availability of Health and Environmental Data for High Tonnage Chemicals under REACH” – Introduction to the project

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REACH Compliance Project

Availability of human health and environmental data for high tonnage chemicals under REACH

1. Data availability of REACH registrations on chemicals **≥1000 tpa** (High tonnage band)
2. Data availability of REACH registrations on chemicals **100-1000 tpa** (Medium tonnage band)

REACH Compliance Project

Methodology

Registration dossiers of lead registrants and (opt-out) individual registrants

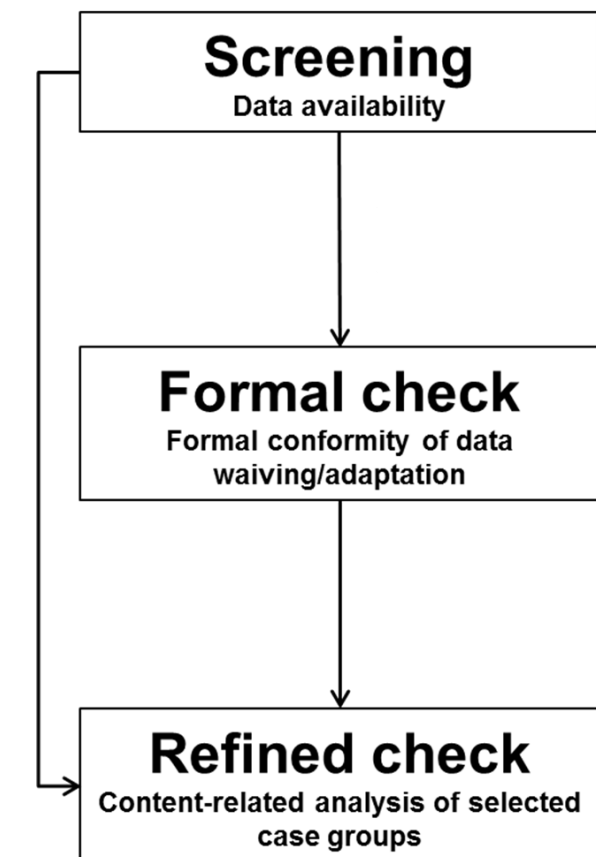
Art. 10 Information to be submitted

Standard data requirements in

- REACH Annex VII-X **≥1000 tpa**
- REACH Annex VII-IX **100-1000 tpa**

Standardised approach, tiered procedure on the available data

- Screening (decision trees on each endpoint)
- Evaluation of formal conformity of data waiving / adaptation
- (In-depth) Refined analysis



Selected Endpoints

Endpoints of particular importance for high tonnage chemicals

Human health:

- Repeated dose toxicity
- Mutagenicity
- Developmental toxicity
- Reproductive toxicity

Environment:

- Abiotic degradation
- Biotic degradation
- Bioaccumulation
- Ecotoxicity
- Environmental exposure

Dossier Evaluation

Number of lead and individual registrations

≥1000 tpa **1814 Dossiers** (Date of submission by March 2014)

100-1000 tpa **2053 Dossiers** (Date of submission by March 2017)

The project did not consider dossier updates

- **For reasons of comparability, dossiers under investigation were ,frozen‘ at the date of submission**
- **Nevertheless, results could be taken as informative**
 - ECHA (2016) 64% of 29,000 dossiers have never been updated since registration**
 - Others updated to various degrees**

REACH Compliance Project

1. Data availability of REACH registrations on chemicals **≥1000 tpa**

- **Project I 2014 – 2015**
 - **Screening approach**
- **Project II 2015 – 2016**
 - **Formal conformity of data waiving and adaptation with REACH requirements**
- **Project III 2016 – 2018**
 - **Refined analysis of endpoints without conclusion after project I and II for selected endpoints**

2. Data availability of REACH registrations on chemicals **100-1000 tpa**

- **Project III 2016 – 31 Oct 2018**
 - **Screening (completed)**
 - **Evaluation of formal conformity (ongoing for Mutagenicity and Ecotoxicology)**
 - **Refined analysis (pending)**
 - **ECHA database extractions**

Project contributions to the workshop

REACH Compliance – A workshop on data quality in registration dossiers

BfR-Workshop
23 – 24 August 2018, Berlin



1. **Reporting of the results on 100-1000 tpa**
2. **Comparison with final results on ≥ 1000 tpa**

*Data quality of human health data in registrations
(Anika Brüning)*

*Data quality of environmental endpoints in
registrations (Angelika Oertel)*

3. **BfR Pilot project**

*Data on consumer uses and exposure in
registrations (Christian Jung)*

Project Aims

- Generate an **overview of the availability of data** in representative numbers of registrations
- Estimate the **status of compliance** (‘**data quality**’) with the REACH requirements in as many registrations as achievable
- Identify **major causes of non-compliance**

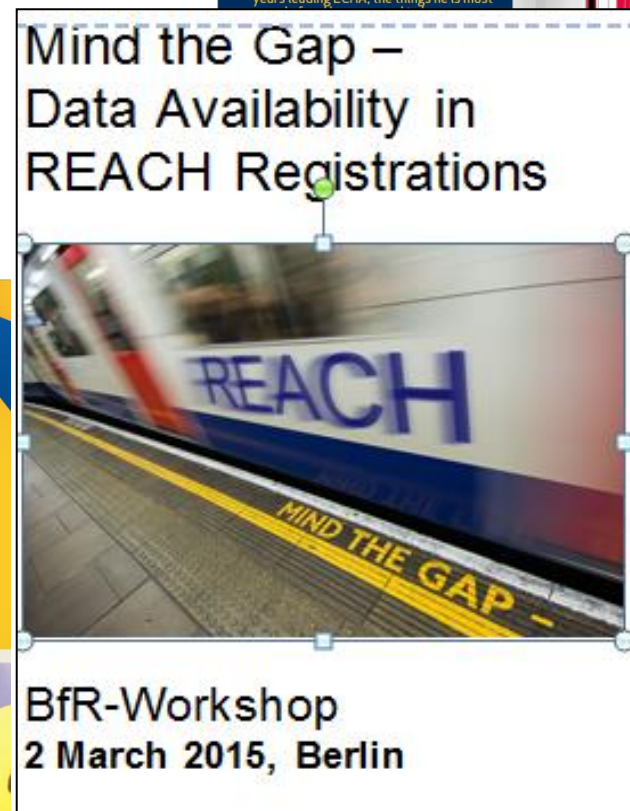
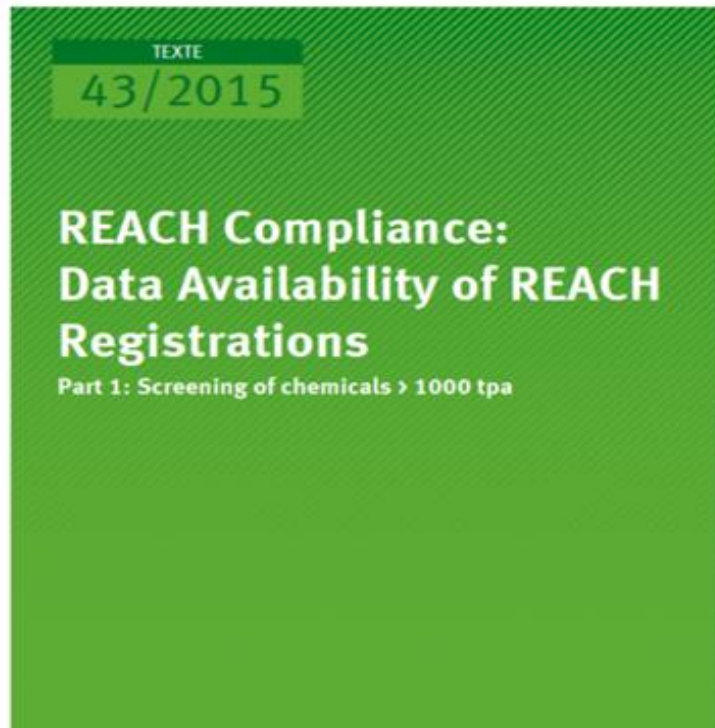
Project Aims

Based on the project results it is intended to

- Indicate whether there is a **need for improvement in REACH registrations**
- Develop **recommendations for registrants** on how to improve their dossiers
- Use **results for priority setting** for further regulatory actions

Note: Project methodology is not identical to the Compliance Check by ECHA

Communication on the Project



<https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-of-reach>

Thanks to all contributing to the project

REACH Compliance Project (2014-2018)

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

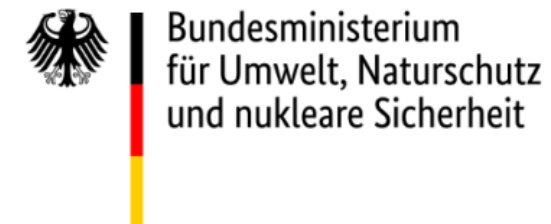
ECHA Directorate Evaluation



UBA Division IV Chemical Safety



BMU Directorate IGII Environmental Health, Chemical Safety



Thank you for your attention

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