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für Umwelt, Naturschutz,
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Introduction

Data Availability in REACH Registration Dossiers

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- Lack of knowledge in 2001
- Liability
- REACH
  - Time table for implementation
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- Status of the Evaluation Work

White Paper 2001

Lack of knowledge

- There is a general lack of knowledge about the properties […] of existing substances.

- … existing substances amount to more than 99% of the total volume of all substances on the market.

- Problem with the pre-REACH legislation: …further testing of substances […] can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof.

White Paper 2001

Liability

- Current liability regimes are insufficient to remedy the problems […]
- […] in order to be held liable, it is generally required that a causal connection be proven between the cause and the resulting damage.
- This is virtually impossible for injured parties if cause and effects occur far apart in time and if adequate test data are not available.

REACH

Implementation – time table

- 2006: REACH was adopted
- 2007: ECHA was founded
- 2010: Phase-in (existing) substances > 1000 tons per year registered
- 2013: Phase-in substances 100 - 1000 tons per year registered
- 2018: Phase-in substances 1 - 100 tons per year registered

REACH

Provisions on testing

- The Regulation sets standard testing/information requirements

- The requirements are tonnage dependent. The higher the tonnage the more testing is required. Full testing is required for substance above 1000 tons per year.

- Deviation from the standard requirements is possible:
  - If registrants believe that testing is not necessary
  - If authorities believe that additional testing /information is needed.

- Deviation requires justification!

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REACH

Registration and Evaluation

Registration:

- A producer or importer submits a dossier for a substance to ECHA
- ECHA checks **completeness** and assigns a registration number
- The completeness check does **not** include an in-depth assessment of the quality or the adequacy of any data or justifications

Evaluation (compliance check):

- In-depth assessment of (parts of) the registration dossier
- ECHA must check at least 5 % of the registration dossiers for each tonnage band

Project Data Availability

Scope of the Project

- Registrations for all phase-in substances above 1000 tons per year
- Endpoints addressed:
  - Repeated dose toxicity
  - Reproductive Toxicity
  - Mutagenicity
  - Ecotoxicity
  - Biotic and abiotic degradation
  - Bioaccumulation
  - Exposure of the environment

Status of the Evaluation Work

- ECHA already carried out a compliance check for more that 5 % of the dossiers for substances above 1000 tons per year
- ECHA has consumed the fee income from registration dossiers > 1000 tons.

Recital of the Fee Regulation: The fees for the registrations should also take into account the work that may be done pursuant to Title VI (Evaluation) of the REACH-Regulation.

➢ If ECHA is asked to do more work on the registration dossiers a finance mechanism is necessary .

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Summary

- Liability regimes are insufficient to trigger testing for chronic/long-term effects.
- REACH requires systematic testing for these effects.
- The project focuses on substances above 1000 tons per year.
- It assesses the availability of data relevant for the identification of chronic/long-term effects.
- This information is most relevant to identify substances of very high concern.
- The registration fees for phase-in substances above 1000 tons per year have been spent.

Thank for your attention