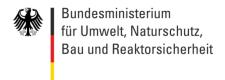


Introduction

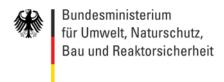
Data Availability in REACH Registration Dossiers

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Content

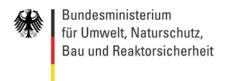
- Lack of knowledge in 2001
- Liability
- REACH
 - Time table for implementation
 - Provisions on testing
 - Registration and evaluation
- Project on data availability
- Status of the Evaluation Work



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

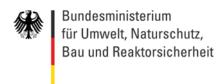
- Current liability regimes are insufficient to remedy the problems [...]
- [...] in order to be held liable, it is generally required that a causal connection be proven between the cause and the resulting damage.
- This is virtually impossible for injured parties if cause and effects <u>occur far</u>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



REACH

Implementation – time table

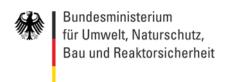
- 2006: REACH was adopted
- 2007: ECHA was founded
- 2010: Phase-in (existing) substances > 1000 tons per year registered
- 2013: Phase-in substances 100 1000 tons per year registered
- 2018: Phase-in substances 1 100 tons per year registered



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!



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 <u>not</u> include an in-depth assessment of the quality or the adequacy of any data or justifications

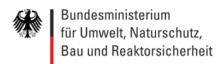
Evaluation (compliance check):

- 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

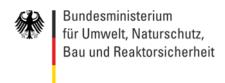


Status of the Evaluation Work

- 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.

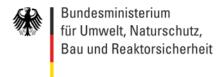
Recital of the Fee Regulation: The fees for the registrations should also take into account the work that may be done pursuant to Title VI (Evaluation) of the REACH-Regulation.

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



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/longterm 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