



Federal Ministry  
for the Environment, Nature Conservation  
and Nuclear Safety

# **Workshop**

# **REACH compliance - Introduction**

Jörg Lebsanft



# The REACH Regulation

- Registration
- Evaluation
- (Restriction)
- (Authorisation)



# Registration

- Submission of registration dossiers for all substances above 1 t/a to the European Chemicals agency ECHA
- Following a superficial completeness check a registration number is assigned.



# Evaluation

- Assessment of dossier compliance by ECHA
- Assessment of substances by Member States in case of a concern requiring further information
- Limitation: Under evaluation, only additional information/testing may be requested and decisions may only be addressed to registrants (manufacturers and importers)
- The administrative burden to authorities is high



# What means compliance under REACH?

- Compliance means that all information according to Article 10 is included into the registration dossier, e.g.
  - description of the substance identity
  - the classification and labelling of the substance
  - summaries of all required studies; the higher the tonnage, the more information is required
  - Justifications in case of adaptations (standard studies have not been performed)



## **Why is incompliance unacceptable?**

- Serious hazardous properties may be missed
- Users of the substance may falsely assume the use of substances to be safe
- Ignorance of serious long-term effects of widely used substances may have disastrous consequences



# **Compliance - a challenge to industry and ECHA**

- Detailed information requirements are laid down in Annexes VI to XI
- REACH tries to minimise animal testing and testing cost to industry
- REACH contains many options to avoid testing (waiving of standard tests)
- Expert judgement is often necessary to decide whether standard testing is necessary
- Divergence of views among experts is frequent
- There is a substantial risk that ECHA decisions are appealed against or challenged in court



# **Economic incentives to comply with REACH?**

- Liability regimes promote testing for short-term effects
- However, they do not promote testing for long-term effects - rather the contrary





## **White Paper - Strategy for a future Chemicals Policy (2001)**

Liability is usually based on the principle that those who cause damage should pay compensation for that damage. However, 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 often virtually impossible for injured parties **if cause and effect occur far apart in time** and if adequate **test data** on the effects of substances **are not available**.



## **REACH regulation, article 41(5)**

To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, **no lower than 5 % of the total** received by the Agency for each tonnage band, for compliance checking.

Is there a need to check more than 5% of the dossiers for compliance?

The BfR projects presented at this workshop feed into the political debate on future priorities under REACH