REACH Chemical Safety Assessment: concepts and relationship with CSR & ES

Environmental risk

TNO | Knowledge for business

Test Plans for Art. 10 substances >1000t(2010)

- A complete Annex VII and VIII dossier is required
  - full set of phys-chem,
  - basic environmental data
  - toxicity screening data up to and including a 28d study in rats
- For Annex IX and X, a data gap analysis and test plan are required
- The test plan will be evaluated by ECHA and approval for the proposed tests given, further conditions on achieving completeness may be set
- Test plan evaluation may require ECHA to examine the dossier in some detail - waiver arguments are generally complex
- There may be an impact on prioritization for later full evaluation of the dossier
- EU manufacturers are not allowed to test to fill Annex IX and X, this restriction does not apply to Japanese manufacturers
- The more complete the dossier at submission, the less chance of dossier evaluation

Completeness & compliance

- A completeness tool is expected in Q1 2009
- This will allow an automated check of an IUCLID 5 file
  - a) by the company submitting beforehand
  - b) by ECHA following submission

- Completeness means that the dossier has all the necessary data present
  - It does not mean that those data are acceptable and in compliance with the regulation

- Compliance means that the data is fit-for-purpose and supports the arguments control of risk in the dossier

- The test plan evaluation involves completeness and compliance issues

TNO

- Dossier preparation & technical support for
  - Industry consortia
  - Chemicals manufacturers
- Chemical Safety Assessment and Reports
- Test plan preparation
  - Waivers and scientific statements
  - Communication with ECHA, pre- and post-submission
- Annex IX and X testing
  - 90d toxicity studies
  - 2-generatrion toxicity studies and teratology
  - Kinetics & metabolism