HESI/JRC/SETAC workshop on bioaccumulation assessments

REACH Implementation Project 3.3

Steve Dungey

Chemicals Assessment Unit

Chair of Endpoint Working Group 10 on bioconcentration, bioaccumulation and avian toxicity

Project overview

- Provision of the Technical Guidance Document to Industry on the Information Requirements for REACH
- Based on scoping study (“Phase 1”) report of July 2005 & 13 December version of REACH
- Final draft required by end of December 2006.

Phase 1 report ("TAPIR")

- Contract between COM and CEFIC + several partner organisations
- Explored how *in vitro*, (Q)SAR, read-across & category data could help to fill data gaps:
  - General decision making framework
  - IWGs reviewed state of science (Exposure considerations, Testing methods and Non-testing methods)
  - 4 EWGs: ITS developed for aquatic toxicity, degradation, reproductive/developmental toxicity and irritation/corrosivity

Phase 1 lessons

- Good starting point but not yet guidance
- No single general decision-making framework can cope with the diversity of all of the scientific aspects for every endpoint
- Endpoint ITS need more work – more examples and guidance needed on all alternative methods and weight-of-evidence
- Need better definition of “low” exposure and consistent application
- Tools that consider uncertainty will be required

Deliverables for Phase 2

- Guidance on strategies for generation of information on relevant inherent properties
- The guidance should explain and illustrate:
  - How to find and use existing information (including non GLP studies and non-standard test methods);
  - How to implement the rules for adaptation (waiving) as provided in the different annexes, especially for substances at higher tonnages;

Deliverables for Phase 2 (cont.)

- When and how to use *in vitro* methods;
- When and how to use QSARs;
- When and how to apply grouping and read-across;
- When testing is technically impossible;
- How to apply a weight of evidence approach;
- When testing can be adapted based on exposure considerations.

- Extranet: http://rip3-3.cefic.org

Task 1 – Overview of information

- General introduction to TGD and guidance on generic (cross-cutting) aspects
  - Templates for EWGs
  - Generic guidance on how to interpret Annex IX, to include
    - How to identify information sources and how to ensure the reliability of the information used
    - Exposure aspects
    - Substance-tailored testing strategies
    - Weight of evidence

Task 2 – Endpoint Specific Guidance

- 10 working groups will provide guidance on
  - How to identify information sources and ensure the reliability of the information used
  - When and how to use alternative information (instead of (animal) testing) including guidance on what is “adequate and reliable documentation”
  - Test strategy to provide information sufficient for classification, risk assessment & PBT assessment

Task 3 – Categories

- OECD/ECB lead to provide guidance on how to build, justify and use read-across or category approach including a format to report the “adequate information” to justify the category

- The Guidance should be based, as far as appropriate, on the OECD guidance.

Task 4 – Final guidance

- Cefic to edit all inputs from Working Groups into a TGD for RIP 3.3 - for agreement by a project management group
  - Consider IT aspects so that the structure of the guidance is amenable to an IT solution
  - Develop the guidance in a structured way to allow easier understanding of requirements by the user (possibly two levels)

Non-standard substances

- Separate working group led by Eurometaux with input from CONCAWE, to provide guidance on:
  - when deviation from the testing strategy for standard substances may be needed for metals and complex hydrocarbons
  - an appropriate testing strategy where necessary (to be discussed with EWG leader)

EWG10 timeline

- Kick-off meeting March 2006
- Initial report by mid-June
- Presentation to stakeholder expert group (SEG) in July
- Final report following SEG input by end September