ECHA's Topical Workshop on Sediment Risk Assessment: outcome and implication on prioritisation of chemicals

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Disclaimer:

The presentation gives an overview of the draft outcome of the sediment workshop held at ECHA. It does not represent the REACH and Biocides regulatory consequences and their implementation by ECHA.

The presentation represents the opinion of the author and is not an official position of the European Chemicals Agency.

Outline

- Outcome of ECHA's sediment workshop
- Implications for chemicals prioritization
- Prioritization of chemicals under Substance Evaluation
- Conclusions

ECHA Topical Scientific Workshop on Risk Assessment for the Sediment Compartment (May 2013)

- Structure: Scientific discussion in a broad regulatory context, on
  1. Problem formulation and conceptual model
  2. Exposure assessment
  3. Effect assessment
- Aim: Review the state of the art in prospective and retrospective sediment risk assessment
- Output: Workshop Proceedings*, contribution towards guidance updates (ECHA and others)

*http://echa.europa.eu/documents/10162/13639/environmental_risk_assessment_final_en.pdf

Conceptual model (1/2)

- Clear presentation of the conceptual model needed
  - Identification of the traits, functions, services and their indicators for protection
  - Inclusion of sources, transport, key receptors or effects and exposure pathways (dissolved, contact, dietary)
  - Coverage of an adequate suite of the population diversity
    - Including communities living within the Pelagic-Epibenthic-Benthic gradient
- Consideration to more ecological and physiological aspects for the selection of species (micro-habitat, life cycle, feeding strategy…)

Conceptual model (2/2)

- Sediment Assessment triggered by combination of factors (exposure routes, bioavailability, partitioning, persistence)
- Ecological versus pragmatic approach
  - Integrated assessment between pelagic and benthic/sediment compartments
  - Separate assessments
- Extrapolation between marine and freshwater environments
  - - *Scientifically not acceptable*
  - √ *Possible if differences between the two environments addressed*
- Need to have high number of species/taxa diversity (rooted plants, aquatic insects, meiobenthos, biofilm, periphyton, microbial community)

Exposure - modelling

- Fate and exposure are key factors in decision making
- Need for transparency, validation
- Realistic worst case scenarios for regulatory purposes
- More refined/realistic exposure models for higher tier assessment (biotransformation, kinetics, dietary exposure, bioaccumulation)
- Reflect spatial and temporal variability
- Consideration to speciation, bioaccessibility and bioavailability (e.g. for metals)
- Inclusion of degradation, aging, burial and resuspension of sediments

Equilibrium Partitioning (EqP)

- Equilibrium conditions can be used in some generic local and regional assessment as **starting point**
  - ➢ To be improved using probabilistic approaches of exposure and effects, considering also resuspension and other diagenitic processes
- EqP not applicable when no information on pelagic toxicity or metabolites
- EqP not generally applicable at higher tiers
- At higher tiers kinetic processes should be considered (site specific information, experimental Kd values)

Effect assessment

- Traits approach more and more important
- Test guidelines currently available too limited to cover complexity of benthic community
- Need for development of further internationally recognised test methods to include more of the diverse sediment community
  - Identifying which functions are essentials
  - Accounting for variability in: taxonomy, lifestyle, dietary, feeding behaviour…
  - Incorporating: wide range of traits and functions
- Need to review relevance of AFs
- SSD – in principle applicable in sediments (issue of species coverage, number of species to be used…)

Risk characterisation and impact assessment

- A tiered approach should be considered, the first step is to identify the relevance of the sediment compartment
  - The relevance assessment should consider e.g. all emission routes and pathways relevant to the identified uses
- Even for screening a more integrated approach needed
  - Including diet exposure for all relevant groups
  - Using corrections to physicochemical parameters
- A case-specific higher tier approach may be required for covering the relevant non-aquatic exposures
  - e.g. dietary, contact, root intake etc.

Implications for prioritisation

- New regulatory approach to risk assessment of sediments
  - Ecosystem service approach
  - Identifying ecological receptors of concern
  - How chemicals compromise these key properties and processes
  - More research needed to establish relationships between regulatory protection goals and ecosystem service performance
- More integrated approach (pelagic – benthic)
- Filling data gaps:
  - New species to be tested
  - Read across marine to freshwater
- EPM as first tier – screening on the risk (high or low)
- More realistic exposure models should be developed
- Effects assessment on the species traits more important for the benthic community (not for the taxonomy per se)

Prioritization of chemicals under Substance Evaluation

Industrial chemicals - REACH

- Registrants responsible for:
    - generation of data
    - Chemical Safety Assessment (risk assessment)
- ECHA evaluates if all information is present
- Among all registration received some substances are prioritized
- Prioritized substances are evaluated by Member States in the Substance Evaluation process

Aim of Substance Evaluation

- To clarify whether a substance constitutes risk to human health or environment
- Triggered when there is a concern or missing information
- For substances on the Community Rolling Action Plan (CoRAP)
- Potential formal outcome of substance evaluation:

  - Request for further information to clarify risk (a decision)
- Performed by Member States and coordinated by ECHA

Criteria used for selection of substances for CoRAP

Risk-based criteria*

1. Hazard criteria
   - Known/Suspected PBT/vPvB, PBT-like substances
   - Known/Suspected CMRs
   - Suspected EDs
   - Known/Suspected sensitisers
2. Exposure criteria
   - Wide dispersive use
   - Consumer use
   - Aggregated tonnage
3. RCR>1 or cumulative exposure from structurally related substances with critical hazardous properties

*http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

Challenges

- Consider the aggregated cumulative exposure for aggregated sources/emissions
- Find the substances for which exposure assessment is not adequate or is incorrectly made
- Find substances with exposure to sensitive subpopulations
- Inconsistency between uses / exposure assessment / outcomes
- Consider the effects of coincidental mixtures of various substances in the environment

Conclusions

- Science for sediment assessment has evolved, new scientific concept need to be considered
- The workshop identified recommendations for further improvements in sediment risk assessment
- Implications for prioritization of chemicals
- Prioritization of chemicals under Substance Evaluation and its challenges

Thank you!

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