Current Status of Sediment Risk Assessment in the Regulatory Context: EU REACH

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## REACH Information Requirements for Sediment

<table>
<thead>
<tr>
<th>Annex</th>
<th>COLUMN 1 STANDARD INFORMATION REQUIREMENT</th>
<th>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annex X (&gt;1000 tpa)</td>
<td>9.5.1. Long-term toxicity to sediment organisms</td>
<td>9.5.1. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.</td>
</tr>
<tr>
<td>Annex IX (100-1000 tpa)</td>
<td>9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)</td>
<td>9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.</td>
</tr>
<tr>
<td>Annex IX (100-1000 tpa)</td>
<td>9.3.2. Bioaccumulation in aquatic species, preferably fish</td>
<td>9.3.2. The study need not be conducted if: — the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes, or — direct and indirect exposure of the aquatic compartment is unlikely.</td>
</tr>
</tbody>
</table>
Substances that are potentially capable of depositing on or sorbing to sediments to a significant extent have to be assessed for toxicity to sediment-dwelling organisms.

- For such substances uptake from sediment or food may be more important than uptake from water.

Sediments integrate the effects of surface water contamination over time and space.

- Potential hazard to aquatic communities (both pelagic and benthic, also via the food chain), not directly predictable from concentrations in the water column alone.
ECHA Guidance – Conceptual Model (2)
Integrated Testing Strategy (ITS) for toxicity to sediment organisms

Log Kow>3 or high adsorption/binding expected?  
Yes

Measured sediment toxicity or read-across data available?  
No

EPM can be used to derive PNEC_{sed}?*  
Yes  
Derive PNEC_{sed} making use of appropriate assessment factors*** and perform assessment  
No

Log Kow>3 or high adsorption/binding expected?  
No

No sediment test required

PEC_{sed}/PNEC_{sed} > 1  
Yes

Perform further long term sediment test as appropriate or refine PEC_{sed}

No further assessment

PEC_{sed}/PNEC_{sed} > 1  
No

Risk reduction / Risk management

Ensure at least one long-term sediment test is available**

*Not for highly insoluble substances with no effects in aquatic studies. If LogKow>5 or high adsorption/binding expected, apply extra factor of 10 for PEC/PNEC_{sed}.

**New test with preferably *L. variegatus*, *Chironomus* sp. on spiked sediment

*** AF derivation, slide 6
PEC sediment is estimated from PEC water and (ad)sorption processes

PEC sediment is the concentration in freshly deposited material, thus properties of suspended matter are used

Estimation of exposure to organisms via PEC suspended sediment problematic as benthic organisms exposed via the sediment not via the suspended matter?

PECsed derivation

**Local concentration in sediment during a release episode can be calculated as:**

\[
\text{PEC local sed} = \frac{\text{Ksusp-water}}{\text{RHOsusp}} \times \text{PEC local water} \times 1000
\]

<table>
<thead>
<tr>
<th><strong>PEC local water</strong></th>
<th>concentration in surface water during release episode</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ksusp-water</strong></td>
<td>suspended matter-water partitioning coefficient</td>
</tr>
<tr>
<td><strong>RHOsusp</strong></td>
<td>bulk density of suspended matter</td>
</tr>
<tr>
<td><strong>PEC local sed</strong></td>
<td>predicted environmental concentration in sediment</td>
</tr>
</tbody>
</table>
### ECHA Guidance – Effect Assessment

#### Chapter R10

PNECsed derivation for freshwater sediment compartment

<table>
<thead>
<tr>
<th>Available test result</th>
<th>Assessment factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>One short-term test</td>
<td>1000 (&amp; EPM)</td>
</tr>
<tr>
<td>One long-term test (NOEC, EC10)</td>
<td>100</td>
</tr>
<tr>
<td>Two long-term tests (NOEC, EC10) with species representing different living and feeding conditions</td>
<td>50</td>
</tr>
<tr>
<td>Three long-term tests (NOEC, EC10) with species representing different living and feeding conditions</td>
<td>10</td>
</tr>
</tbody>
</table>

### Guidelines used for sediment toxicity testing

- OECD 218: 13.1%
- OSPARCOM guidelines: 37.2%
- Method not reported: 24.6%
- Other: 9.5%
- EPA OPPTS 850.1735: 3.0%
- OECD 225: 3.9%
- ASTM E1525-94a: 2.1%
- ASTM E1706-95b: 1.3%
- ASTM E1383-94: 1.6%
- ASTM E1383-94: 1.6%
- ASTM E1306-04: 0.5%
- EPA OPPTS 850.1740: 0.3%
- EPA OPPTS 850.1800/EPA OTS 797.1995: 0.3%
- ASTM E1611-04: 0.2%
- ASTM E1688-96: 0.2%

### Species tested

- Corophium volutator: 33.1%
- Corophium volutator: 33.1%
- Lumbriculus variegatus: 7.4%
- Chironomus tentans: 2.5%
- Chironomus riparius: 6.9%
- Chironomus sp.: 5.7%
- Hyalella azteca: 5.9%
- Tubifex tubifex: 2.1%
- Caenohabditis elegans: 1.3%
- Corophium sp.: 0.8%
- Leptocheirus plumulosus: 0.7%
- Rana arvalis: 0.7%
- None or empty: 18.9%
- Other: 12.3%
ECHA Guidance – Risk Characterisation

Risk Characterisation Ratio, \( RCR = \frac{PEC_{sed}}{PNEC_{sed}} \)

- An \( RCR < 1 \) indicates that risks are adequately controlled
- Higher \( RCR \) require refinement or risk management measures

- If the equilibrium partitioning method is used:
  - Highly adsorptive substances may not be considered adequately as they are often not in equilibrium between water and suspended matter
  - If \( \log K_{ow} > 5 \), the \( PEC_{sed}/PNEC_{sed} \) ratio is increased by a factor of 10 to account for uptake via ingestion of sediment.
ECHA Posters and a Case Study

Topic 1: Risk Assessment: Problem definition and conceptual model
- Poster: REACH Regulatory Framework for Sediment Risk Assessment under dossier evaluation
  Anne-Mari Karjalainen and Francesca Pellizzato
- Poster: REACH perspective under dossier evaluation on a sediment assessment of a NONS substance
  Laurence Deydier Stephan
- Case study: EU RAR CSR Comparison
  Anne-Mari Karjalainen

Topic 3: Effect assessment
- Poster: Sediment Risk Assessment: REACH perspective under dossier evaluation
  Francesca Pellizzato and Anne-Mari Karjalainen
Thank You.