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

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REACH Information Requirements for Sediment

Annex	COLUMN 1 STANDARD INFORMATION REQUIREMENT	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
Annex X (>1000 tpa)	9.5.1. Long-term toxicity to sediment organisms	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.
Annex IX (100-1000 tpa)	9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	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.
Annex IX (100-1000 tpa)	9.3.2. Bioaccumulation in aquatic species, preferably fish	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.

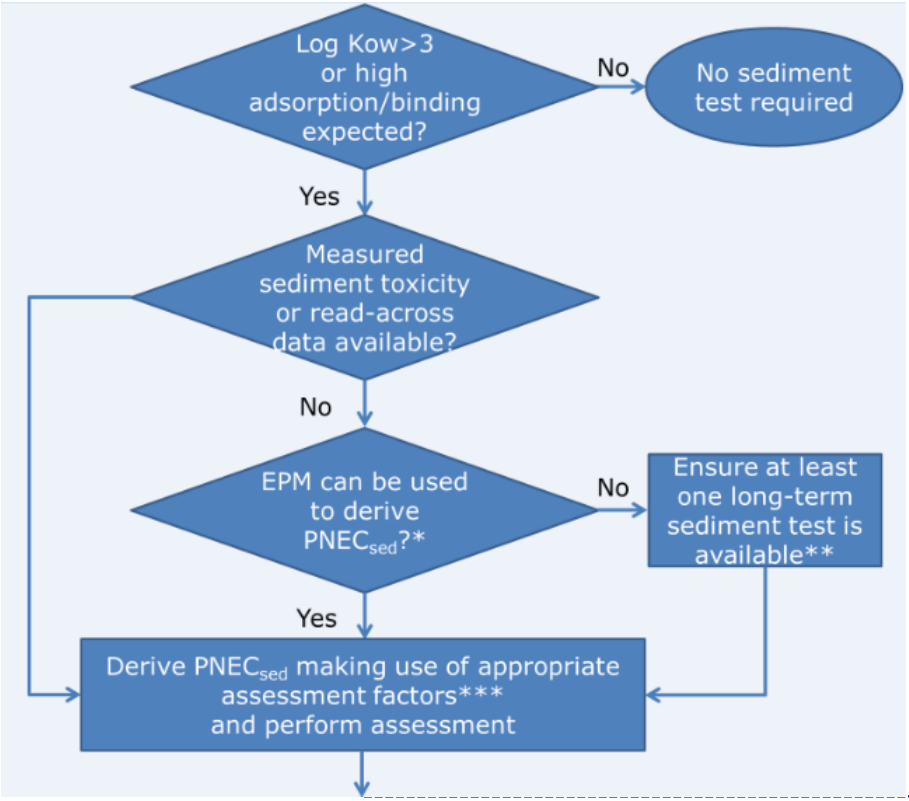
ECHA Guidance – Conceptual Model (1)
Chapter R7B Endpoint specific guidance

- 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.

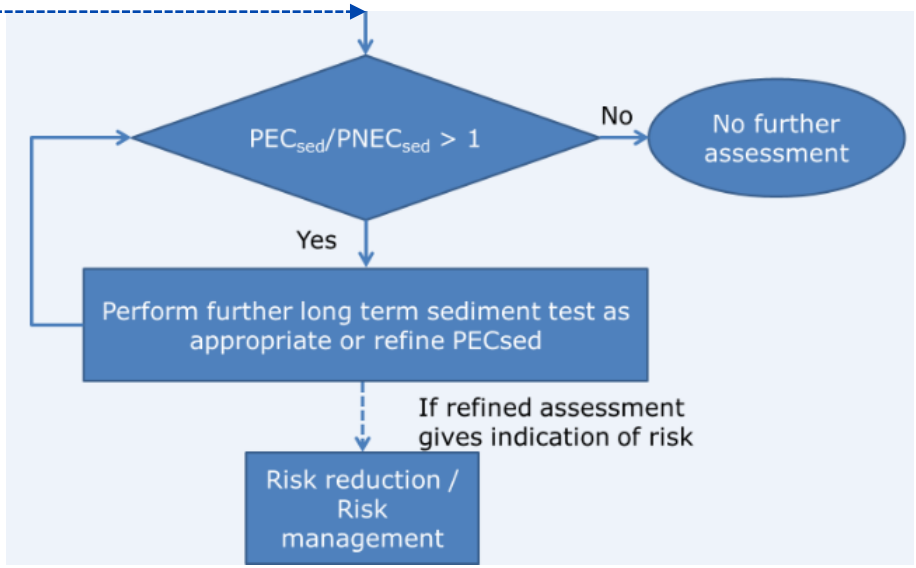
- Sediments integrate the effects of surface water contamination over time and space
  - Potential hazard to aquatic communities (both pelagic and benthic, also via the food chain), not directly predictable from concentrations in the water column alone

ECHA Guidance – Conceptual Model (2)

Integrated Testing Strategy (ITS) for toxicity to sediment organisms



(ECHA Guidance R.7B, section R.7.8.12.2)



*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/PNECsed.

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

*** AF derivation, slide 6

ECHA Guidance – Exposure Assessment
Chapter R16

- 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

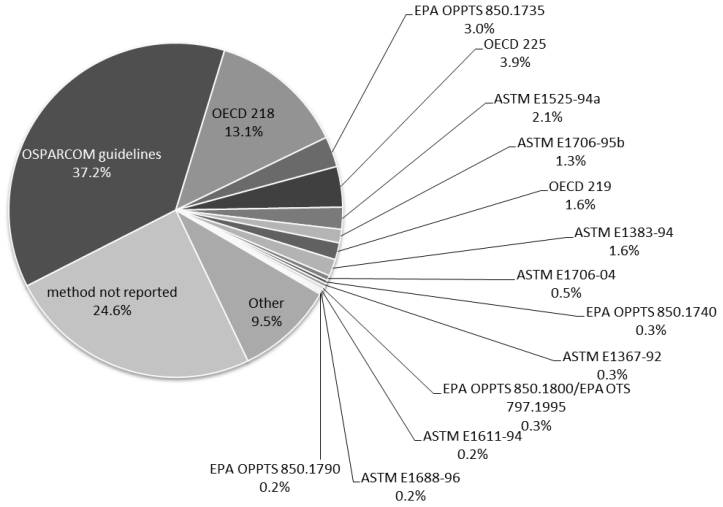
Local concentration in sediment during a release episode can be calculated as:	
*PEC local sed = Ksusp-water / RHOsusp * PEC local water * 1000*	
PEC local water	concentration in surface water during release episode
Ksusp-water	suspended matter-water partitioning coefficient
RHOsusp	bulk density of suspended matter
PEC local sed	predicted environmental concentration in sediment

ECHA Guidance – Effect Assessment
Chapter R10

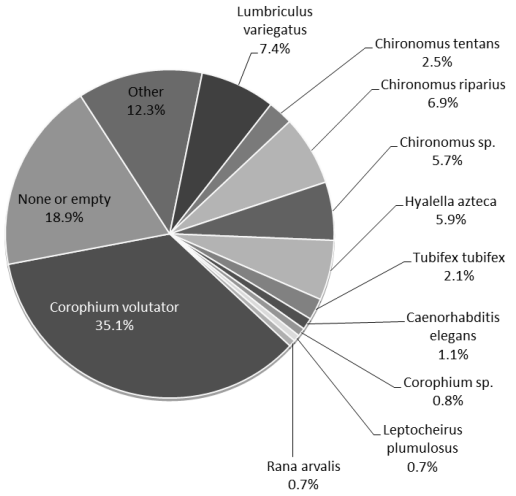
PNECsed derivation for freshwater sediment compartment

Available test result	Assessment factor
One short-term test	1000 (& EPM)
One long-term test (NOEC, EC10)	100
Two long-term tests (NOEC, EC10) with species representing different living and feeding conditions	50
Three long-term tests (NOEC, EC10) with species representing different living and feeding conditions	10

Guidelines used for sediment toxicity testing



Species tested



ECHA Guidance – Risk Characterisation

Risk Characterisation Ratio, RCR=PECsed/PNECsed

- 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 LogKow > 5, the PECsed/PNECsed 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

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Thank You.