

REACH Regulatory Framework for Sediment Risk Assessment under dossier evaluation

Anne-Mari Karjalainen¹ and Francesca Pellizzato¹

¹ECHA, Annankatu 18, FI-00121 Helsinki, FINLAND



Background

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. Consequently toxic effects may be exerted in sediment studies even if in a water study no effects were seen, possibly as no equilibrium was reached (ECHA Guidance R7B). In addition, sediments integrate the effects of surface water contamination over time and space and may thus present a 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 R10).

Objectives

This poster provides the REACH regulatory context for sediment risk assessment. The REACH information requirements concerning the sediment compartment are given. The derivation of Predicted No Effect Concentration for sediments (PNEC_{sed}) through an integrated testing strategy for toxicity to sediment organisms and its residual uncertainty is illustrated.

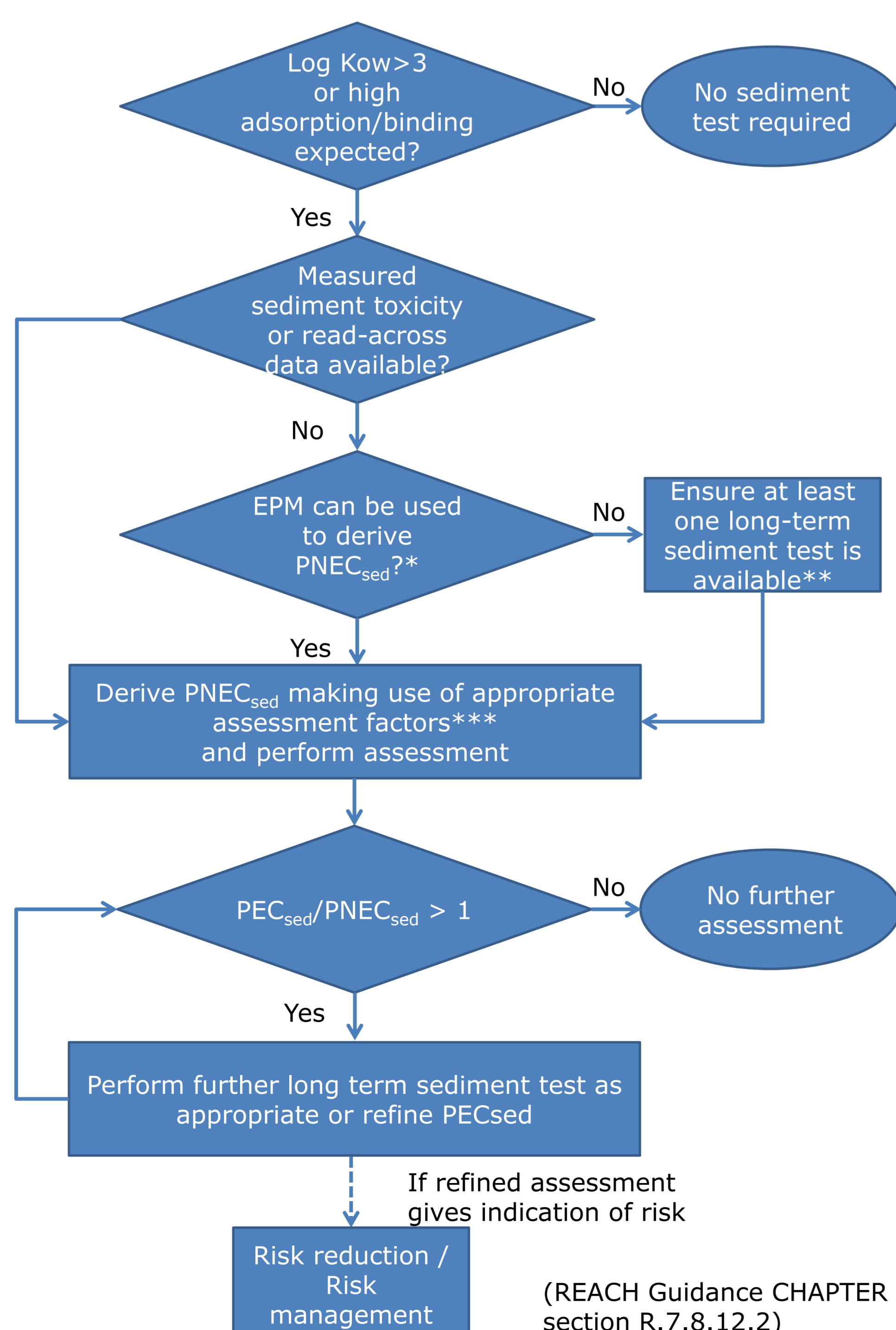
REACH information requirements for sediment

	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: <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none"> – 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.

Annex I Requirements

3. ENVIRONMENTAL HAZARD ASSESSMENT 3.3. Step 3: Identification of the PNEC	3.3.1. Based on the available information, the PNEC for each environmental sphere shall be established.
6. RISK CHARACTERISATION	6.3. The risk characterisation consists of: a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs

Integrated Testing Strategy (ITS) for toxicity to sediment organisms



PNEC_{sed} derivation for freshwater sediment compartment

*EPM cannot be used for highly insoluble substances for which no effects were observed in aquatic studies.

**If no adequate long-term (LT) sediment tests are available, a test with preferably either *Lumbriculus variegatus* or *Chironomus* spec. using spiked sediment should be performed first.

*** results from:

- only short-term tests -> AF 1000 (EPM also to be used)
- 1 LT test → AF 100
- 2 LT tests → AF 50
- 3 LT tests → AF 10

Predicted Effect Concentrations (PEC_{sed}) derivation

(REACH Guidance PART R.16, section R.16.6.6.3)

The local concentration in sediment during the release episode can be calculated as:

$$PEC_{local\ sed} = K_{susp-water} / RHO_{susp} * PEC_{local\ water} * 1000$$

PEC local water: concentration in surface water during release episode
 K_{susp-water}: suspended matter-water partitioning coefficient
 RHO_{susp}: bulk density of suspended matter
 PEC local sed: predicted environmental concentration in sediment

Risk Characterization Ratio (RCR) calculation

PEC_{local} to be compared with the PNEC for sediment dwelling organisms:

$$RCR = PEC_{sed} / PNEC_{sed}$$

- PEC_{sed} is the concentration in freshly deposited sediment, therefore the properties of suspended matter are used.
- However, benthic organisms are exposed via the sediment not via the suspended matter
 - estimation of exposure to organisms via PEC suspended matter accurate?
- Highly adsorptive substances may not be considered adequately with this approach as they are often not in equilibrium between water and suspended matter.
 - If LogKow > 5, the PEC_{sed}/PNEC_{sed} ratio is increased by a factor of 10 to take uptake via ingestion of sediment into account.