How to bring your registration dossier in compliance with REACH

Tips and Hints - Part 5

Sediment Toxicity

Anne-Mari Karjalainen
Anna Wik
Benoit Dilhac

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Sediment toxicity testing

REACH Information Requirement

Annex X	COLUMN 1 STANDARD INFORMATION REQUIREMENT	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.5.1	Long-term toxicity to sediment organisms	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 degradation products on sediment organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment.

ECHA Guidance on Sediment Toxicity (1)

- According to ECHA Guidance sediment toxicity assessment is needed:
  - for substances that are *potentially capable of depositing on* or *sorbing to sediments to a significant extent*.
  - a log Kow/Koc of ≥3 should be used as a trigger value for sediment effects assessment.
- ECHA considers that Registrants should provide a PNECsediment also for non-classified and non PBT substances.

(ECHA Guidance R.7.B, version 1.2. November 2012, Section R.7.8.7.)

ECHA Guidance on Sediment Toxicity (2)

Equilibrium partitioning method (EPM)

- If no sediment data is available the EPM may be used as a screening approach to derive a PNECsediment
  - If the resulting RCR=PECsed/PNECsed >1
    - ➢ The sediment hazard assessment needs to be refined and tests with sediment organisms may be required

- For substances with logKow >5 or corresponding high adsorption or binding behaviour
  - ➢ PECsed/PNECsed ratio is multiplied by 10 to account for uptake via sediment

- The EPM cannot be used for substances that are *highly insoluble* and for which *no effects are observed in aquatic studies*
  - ➢ For such substances at least one sediment study has to be performed

ECHA Guidance on Sediment Toxicity (3)

Effect assessment and Guidelines to be used

- There are 3 OECD guidelines that are recommended for long-term sediment hazard assessment:
  - Sediment-water Chironomid toxicity using spiked sediment (OECD 218)
  - Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225)
  - Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) (*new Guideline not yet included in ECHA Guidance document R7B)*

➢ Each covers ecologically relevant long-term toxicity endpoints and thus generates information appropriate for the fulfilment of the information requirements of Annex X 9.5.1. Long-term toxicity testing on sediment organisms

➢ Nevertheless the OECD 233 is the most comprehensive as it covers all relevant reproductive endpoints and offers a more complete level of information. *The relative sensitivity of TG 218 and TG 225 is substance dependent.*

ECHA Guidance on Sediment Toxicity (4)

Effect assessment and Guidelines to be used (cont.)

- ECHA considers that it is the Registrants responsibility to choose the most appropriate test protocol(s) based on, for example, substance properties/uses of substance and to give justification for the choice.

  - Registrants have the choice to carry out more than one of the tests if further testing is required, for example to lower the assessment factor used for PNEC derivation.

ECHA Guidance on Sediment Toxicity (5)

Effect assessment and Guidelines to be used (cont.)

- Long-term whole sediment tests account for all possible routes of exposure, whereas tests with water only systems may be only used for screening purposes in combination with the EPM

- Spiking methodology should be considered in detail and be performed as realistically as possible
  - For highly lipophilic compounds or other substances that adsorb to particles, uptake from food or sediment may contribute to overall exposure
  - When using OECD 218 or OECD 233 Registrants should specifically consider the feeding recommendations for testing strongly adsorbing substances established in paragraph 31 of the guidelines

Adaptation Possibilities for Sediment Toxicity (1)

- Chapter R7b: Column 2 adaptation may be possible when

  Chemical safety assessment does not indicate the need to investigate further the effects on sediment organisms

- Effects seen in aquatic studies for a substance that does not show strong binding/adsorption behaviour
  - ➢ PNECaquatic derived and used as basis for deriving the PNECsediment via EPM
  - ➢ RCR=PECsediment/PNECsediment < 1 in all exposure scenarios

    - ➢ Further sediment tests most likely not needed

  - ❖ To note: substances that do not exhibit a toxic effect when tested in water only test systems because equilibrium was not reached during exposure phase may nevertheless exert significant toxic effects in sediment tests.

Adaptation Possibilities for Sediment Toxicity (2): Annex XI Adaptations

- The requirements set in the relevant section of Annex XI need to be fulfilled

- Weight of evidence (Annex XI, 1.2)
  - At least 2 independent pieces of evidence
  - One study record for each piece of evidence
  - Endpoint summary: your own conclusion

- Grouping of substances and read-across approach (Annex XI, 1.5)
  - Adequate and reliable documentation
  - Scientifically sound arguments
  - Assumptions supported with (experimental) data

- Exposure based adaptations (Annex XI, 3 – please see slide 10)

Adaptation – examples (1)

Adaptation based on lack of exposure

In accordance with Column 2 Adaptation of REACH Annex X section 9.4 the studies do not need to be conducted if direct and indirect exposure of the specific environmental compartment is unlikely.

Justification for waiving the sediment toxicity test based on lack of direct/indirect exposure, but:

- In the Exposure Assessment PECs are given for sediment
  - There is exposure (no RCRs given to assess the actual risks)
  - the given adaptation is **unacceptable** and sediment study/studies according to the standard information requirement are requested

- Any adaptation based on exposure considerations need to fulfil the criteria set in Annex XI section 3
  - ”adequate justification and documentation shall be provided”, and
  - ”the justification shall be based on a thorough and rigorous exposure assessment”

Adaptation – examples (2)

Adaptation based on the application of the EPM

In accordance with Column 2 of REACH Annex X, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to sediment organisms.

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Justification for waiving the sediment toxicity test based on EPM, but:

- no effects seen in aquatic studies, not possible to derive PNECaquatic
  - not possible to use the EPM to derive PNECsediment screen
  - the given adaptation is **unacceptable** and sediment study/studies according to the standard information requirement are requested

Adaptation – examples (3)

Although the substance has potential to adsorb to sediment (Log Kow >5), toxicity to sediment organisms is expected to be low based on the chemical composition of the substance and its low toxicity towards aquatic organisms. In addition, column 2 of REACH Annex X states that testing shall be proposed if the results of the chemical safety assessment indicate the need for this. For this substance no Exposure assessment was performed.

Justification for waiving the sediment test based on chemical properties, low toxicity and CSA not showing the need, but:

- Substance has low water solubility, high Kow, no effects in aquatic studies
  - According to ECHA Guidance R7B for such substances at least one sediment study has to be performed
- no exposure assessment is submitted as part of CSR
  - Not possible to further assess whether Column 2 adaptation applicable

- The given adaptation is **unacceptable** and sediment study(ies) according to the standard information requirement under Annex X is requested

REACH Information Requirements –

Sediment Toxicity Guidance

Guidance on Information Requirements and Chemical Safety Assessment

- Chapter R.7b: Endpoint specific guidance
- Chapter R.10: Characterisation of dose [concentration] – response for environment
- Chapter R6: QSARs and grouping of chemicals

http://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Practical Guides:

http://echa.europa.eu/web/guest/practical-guides

- Practical Guide 2: How to report weight of evidence
- Practical Guide 4: How to report data waiving
- Practical Guide 6: How to report read-across and categories

Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time): http://echa.europa.eu/contact/helpdesk-contact-form