

Sediment Risk Assessment: REACH perspective under dossier evaluation

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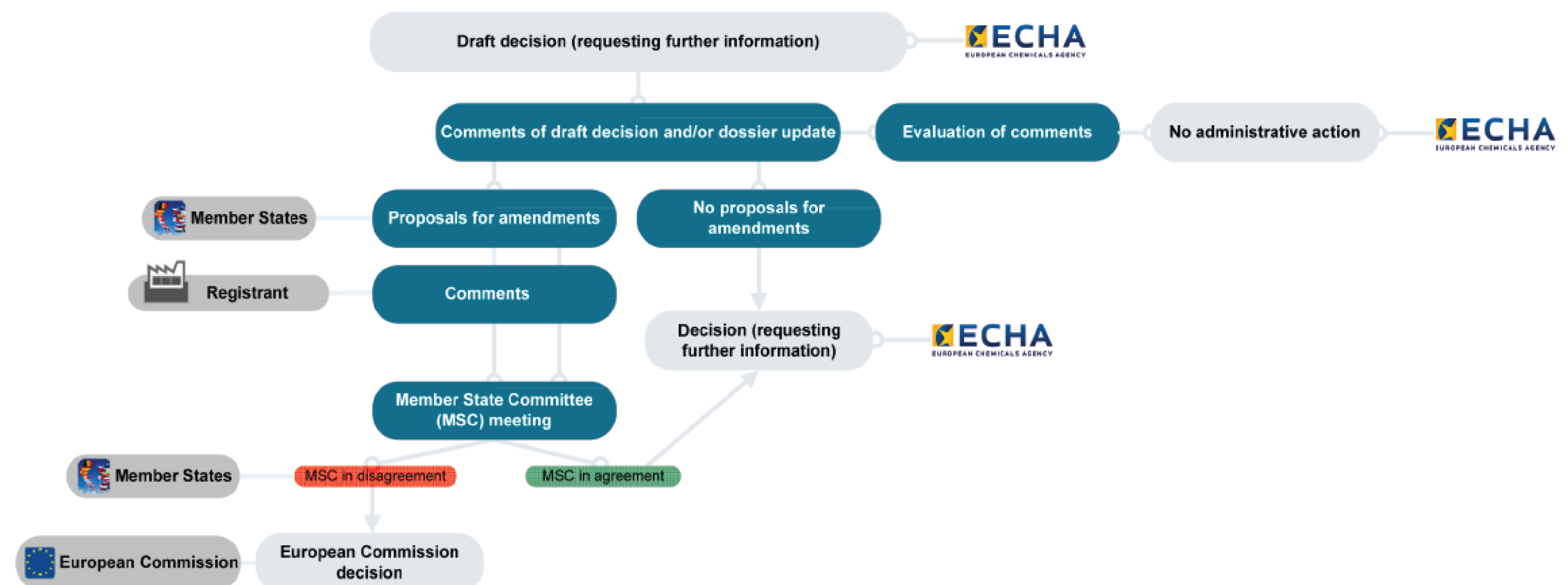
Background

Sediments integrate the effects of surface water contamination over time and space and may thus present a hazard to pelagic and benthic organisms not directly predictable from concentrations in the water column. Effects on benthic organisms are of concern because they constitute an important link in the aquatic food chain and play a role in the recycling of detritus material. Therefore, sediment risk assessment is an integral part of a chemical risk assessment.

Objectives

This poster provides two examples of sediment risk assessment from dossier evaluations. The main challenges and open questions arising from the two case studies are discussed.

Dossier evaluation process overview after ECHA's initial scientific evaluation



Case study 1:

Organic UVCB substance

logKow >4 (20 °C, pH=10),

Ws 1 mg/L (20 °C, pH=6-10)

Not readily biodegradable

C&L: aquatic acute and chronic toxicity 1

PNEC: EPM not applied as according to the Registrant this approach is not recommended for this kind of substance. Instead, the Registrant proposes to determine the PNEC_{sed} when the results of the OECD 218 test proposed are available.

Testing proposals for OECD 305, later changed to OECD 315, and OECD 218.

Outcome of ECHA scientific evaluation

TP for OECD 305, later changed to OECD 315:

- 1st proposal: OECD 305 due to high sorption potential. Proposal accepted as according to ECHA Guidance a fish dietary bioaccumulation test should be used for substances with low water solubility and log P > 6. Here Log P is reported to be >4.
- 2nd proposal: in a dossier update the Registrant changed the guideline proposed from OECD 305 to **OECD 315 Bioaccumulation in Sediment-dwelling Benthic Oligochaetes**
 - Fish bioconcentration study seen practically as very difficult to perform
 - the benthic is regarded as the compartment of concern
 - Organisms might rather be exposed via food than by direct contact
- ECHA amended the DD and **accepted this 2nd proposal**.

TP for OECD 218:

- Registrant considered that effects on sediment organisms may occur. Therefore the OECD 218 test on spiked sediment is proposed to improve the hazard profile of the substance.
- In the **first DD ECHA accepted the TP** as due to substance properties sediment exposure seen relevant.
- One of the prerequisites for an OECD 315 is to have toxicity information on oligochaete species. The OECD 218 examines toxicity on chironomids, whereas the OECD 225 on oligochaetes. Therefore ECHA saw the need to **amend the DD** and give Registrant **two options; the OECD 218 or the OECD 225**.

Case study 2:

Organic UVCB substance

logKow 5.6 (20 °C, pH=7),

Ws ca. 7 mg/L (20 °C)

Not readily biodegradable. Potential PBT

C&L: aquatic chronic toxicity 1.

PNEC: no sediment toxicity data available, EPM applied, for RCR derivation extra AF of 10 used

RCR_{freshwater} <0.01, RCR_{marine} <0.06

Testing proposals for OECD 305 and OECD 218.

Outcome of ECHA scientific evaluation

TP for OECD 305:

- Initially ECHA had no reasons to not to accept the bioaccumulation study on fish as proposed.
- After registrant updated their testing strategy to address the toxicity of benthic rather than pelagic organisms, ECHA considered whether the Registrant should be given the choice between the OECD 305 and the OECD 315.
- Decision was taken to not to give this option as it was not indicated by the Registrant and fish is the preferred species according to legal text. **ECHA request in FD OECD 305.**

TP for OECD 218:

- OECD 225 also referred to in CSR, not in technical dossier
- Initially Registrant proposed to carry out a LT daphnia study (OECD 211), but later the OECD 218 as sediment organisms were seen to be the most likely target of potential effects.
- ECHA considered further the possibility of conducting either the OECD 218, 225 or 233 as any may be seen to fulfil the information requirement of sediment long-term testing.
- In amended **DD ECHA** gives the Registrant the **option** to carry out one of the three; **OECD 218, 225 or 233**. If either OECD 225 or the 233 is chosen the Registrant should consider the feeding recommendations for testing strongly adsorbing substances established in paragraph 31 of those test guidelines.

Challenges and open questions arising from the case studies

- What would be the most appropriate toxicity test to assess the effects of chemicals on sediment dwelling organisms?
 - Are the OECD 218, 225 and 233 interchangeable?
 - Should the criteria for choosing one over the others be defined in ECHA Guidance?
- When should the OECD 315 oligochaete bioaccumulation study be used instead of, or in addition to, the OECD 305 fish bioconcentration study?
- Can a sediment study be sufficient to complete the risk assessment for the aquatic compartment?
 - Can the results from an OECD 218 be used to back-calculate NOEC_{water} using the EPM approach as advised by ECHA Guidance R.11. (p. 33-24)? Can this result be used to conclude on PBT assessment?

