

**Topical Scientific Workshop on  
Risk Assessment for the Sediment Compartment  
7-8 May 2013**

**“Thought starter” background document on:**

**Risk assessment:  
Problem definition and conceptual model**

This thought starter paper has been prepared by ECHA with the support of the Scientific Committee following a structured expert consultation process. Workshop participants were requested to respond to three sets of questions covering three main discussions areas:

- Problem definition and conceptual model for sediment Risk Assessment
  - Protection goals and ecological relevance
  - Risk characterisation and environmental impact assessment
- Exposure assessment
  - Environmental fate and transfer of chemicals between water, suspended matter and sediment
  - Behaviour processes, within sediment distribution, ageing, bioavailability estimations
- Effect assessment
  - Effect assessment for epi-benthonic organisms, relevant taxonomic groups and experimental tools
  - Effect assessment for benthonic organisms, relevant taxonomic groups and experimental tools

This document reflects the feedback obtained from the participants regarding the first area. Additional information has been obtained from the guidance documents, a review of available scientific literature and the input received from other experts in the field.

**Disclaimer:** This compilation has been prepared as a background document for facilitating the workshop discussions and does not represent a position of the European Chemicals Agency.

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## **1. Problem formulation and protection level in sediment risk assessment**

The examples above and the additional legislative frameworks developed in other jurisdictions clarify the particular relevance of a clear problem formulation in sediment risk assessment. For example, in the US, one of the main motivating factors for sediment assessment was the development of tools for dredged material management, which tends to be limited in terms of scope to the local scale. Within Europe, this issue is relevant for some countries while at the EU level, chemicals management is a major driver, and as we see in the global recognition of chemical safety regulations such as REACH, it is likely that other regulatory risk assessment processes will follow precedents set by REACH. For specific chemicals such as pesticides, sediment is also part of the environmental assessment in pre-marketing authorisation which are common world-wide. It is therefore extremely important to appropriately establish the scope of assessments for the sediment compartment. Sediment ecosystem risk assessments can be thought of more holistically within the context of overall freshwater, marine, or estuarine environment of interest to the environmental problem being addressed. This means not thinking of the assessment as a series of complementary but separate risk assessments for pelagic organisms and for the sediment compartment.

The protection of benthic communities or populations (rather than individuals) should be considered as part of the approach for the aquatic compartment. It may be possible to consider the protection of ecosystem services, rather than specific organisms, although the traditional ecotoxicity testing approaches are unlikely to be able to provide this information. A healthy sediment should provide sufficient capacity to carry a pelagic ecosystem (i.e., benthic-pelagic coupling) and functions such as organic matter breakdown and sediment reworking. It should also reflect background geochemical properties for similar sediments found in a region, should support similar levels of biodiversity, and have similar nutrient assimilative capacity. The risk assessment should focus on how chemical substances might compromise these key properties and processes. It is noted that the general guidances on how to protect ecosystem services are not that detailed and more general than the guidances on how to derive PNEC<sub>sediment</sub> or EQS<sub>sediment</sub> values.

Sediment should not be considered as an isolated compartment, but as an integral component of the aquatic ecosystem. Both, pelagic and sediment communities are inter-linked and should be protected. Essentially, the question is under what circumstances is a risk assessment on the sediment compartment necessary.

Three generic problem formulations can be used as examples for covering the most relevant regulatory needs:

- 1 Predictive risk assessments for marketing of chemicals, such as REACH or the authorisation of pesticides, biocides, etc.
- 2 Setting Quality Standards and criteria for sediment, to be compared with measured values (chemical and/or biological) from monitoring programmes covering potentially contaminated sediments, such as in WFD, or similar legislations.

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- 3 Assessments for supporting risk management of contaminated sediments, including the evolution of the sediment status and the potential risks for other compartments due to the management decisions.

Other problem formulations can be covered as combinations of these general three formulations. For example, discharge/emission permit authorisation combine setting quality standards (as in 2) with exposure estimations predicting the expected concentration in sediment from a point emission to water (which is part of the exposure assessment under 1). Retrospective assessments for liability, diagnosis and source identification are a combination of current status assessments (as in 3) and exposure assessment from potential sources (as in 1).

All three of these assessments may be generic or site-specific.

<b>Elements for discussion</b>
Should we focus the workshop in these three general problem formulations?
Should we remove/add others?

The level of protection is a management question, not a scientific one as protection of ecosystem functions can be achieved through different sets of management decisions. Which one to choose depends upon the economics, human health and ecological concerns, and aesthetics of the local system. For defining what level of protection is needed we first need to define what we are protecting and what the protection goals are. Protection of human health from consumption of contaminated fish and shellfish is often the leading driver for sediment remediation in USA at Superfund sites (as compared to ecological risk). Therefore in this case, a healthy sediment ecosystem will support a healthy fishery that can be utilized to support human sustenance and/or recreation with low to negligible risks. Fish and shellfish tissues that are at these low acceptable or negligible levels of contamination should be defined in a risk assessment for secondary poisoning to adverse effects to human health. A similar approach can be extended to wildlife; and, in fact, the associated terrestrial ecosystems, and particularly the terrestrial vertebrates feeding on aquatic organisms, are included as elements to protect in the EU Water Framework Directive. Ecological receptors associated with the sediments should also be protected from sediment contamination because they serve as the base of the food chain and are important to matter and energy flow through the aquatic freshwater and marine environments. Design the conceptual model is easier when the problem formulation defines clearly the protection goals and level of protection desired; this is rarely defined in clear or quantitative terms in the regulation, but may be included in the implementation guidance. In the USA, a 20% effect concentration is often used to establish a threshold for effects relative to reference or control conditions. That said, if one documents a 10% loss of ecological value, the Natural Resource Damage Assessment and Restoration (NRDAR) program, administered through the Department of the Interior (DOI) or through National Oceanic and Atmospheric Administration (NOAA) allows for seeking compensation for any ecological loss. For Species Sensitivity Distribution approaches the HQ5, protective for 95% of the tested species, is frequently used as departure point. Once the protection goal is defined at the policy/managing level, scientific support is needed for implementing this decision into measurable/predictable effects and expected impacts. A physiological and ecological relevance scale can be defined

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that considers four response levels: homeostasis (=healthy system), compensation (=apparently healthy system but under pressure), disturbance (=system structure and/or functionality no longer within the homeostatic range), and failure (=system is deteriorating and services collapsing). It is possible to set the protection level based on an abundance drop, reduction of number of species, and/or decline in the number of functional groups. These will give different thresholds, from which risk managers can use all of them for risk assessment purposes and provide a range of predictions indicating different levels of stress to the ecosystem. The current risk assessment scheme is somewhat arbitrary in the way that it chooses to assess the risk to sediment organisms. The sediment compartment first needs to be examined using an approach such as the ecosystem services approach to define what we are aiming to protect on a species, population, and ecosystem levels as well as and on what spatial and temporal scale.

The levels of protection should fit the ecological level target, and the uses of the water body. The ecological level targets for the sediments should fit the water body ecological level targets. An integrated risk assessment approach will cover all risks for aquatic ecosystems as complementary elements. The sediment assessment should focus on those cases when the benthic community is expected to trigger the overall assessment. In fact, many guidance documents include thresholds for triggering the sediment assessment (e.g., based on the binding potential of the chemical). If waterborne exposure is expected to be the most significant exposure route, the assessment of the pelagic community may be sufficiently protective to also protect the benthic community. Further, the chemical properties may suggest the potential relevance of other routes triggering the sediment assessment. An option is to include organisms with additional exposures through contact or feeding on sediments, which cover a number of pelagic organisms. The sediment risk assessment should be based on species representative for different trophic levels, feeding strategies, and habitats. As many benthic organisms are exposed and affected by overlying waters, this exposure compartment must be considered (includes interface, overlying waters + suspended materials). In addition, it is important to consider the organism life -history and ecology that can modify the exposure. For example, some organisms build tubes which means that, although they live in the sediments, they are not exposed to the sediments or pore water directly but rather to the overlying water as they bioirrigate their burrows. Others live on top of not in the sediments. Ecology is critically important to understanding exposure and too often overlooked.

**Elements for discussion**

Should sediment assessment be triggered by information suggesting that contact or feeding exposure routes could represent a significant addition to waterborne exposure?

If YES, are current thresholds, based on partition under equilibrium conditions, proper indicators?

How the ecology and habitats of benthic and epi-benthonic organisms should be considered?

Are similar triggers and indicators useful for non-animal receptors, such as plants and microorganisms?

Should also other indicators, for example; e.g. high toxicity in aquatic

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invertebrates, indications of phytotoxicity, or high toxicity for microbial functions be used as triggers for launching sediment assessments?

## 2. Selection of relevant taxonomic groups and ecological functions

Most sediment risk assessments focus on benthic invertebrates. Rooted aquatic plants are currently poorly covered. Microorganisms are also barely considered. OECD Test Guidelines are limited to two invertebrate groups, and this may be a main constraint in some regulatory contexts.

Regarding the invertebrate community, sediment quality assessments should cover different functional groups; in particular, infaunal organisms (i.e., detritivores, filter-feeders and predators), each of them representing different energy pathways and different trophic levels in aquatic food webs, and hence may express different responses to chemical exposures. In addition, there are many pelagic organisms feeding on sediment and deposited materials.

Sediment is not as simple compartment as currently considered. In most risk assessments sediments contain complex micro-environments that can vary in space and time. For example, anaerobic zones may start as little as 2 mm below the surface layer. Aerobic niches created by burrowing organisms (e.g., sediment reworking) will complicate the chemical dynamics and exposure. Anaerobic degradation has been identified as a key primary degradation route for some chemicals, and although the assessment of relevant degradation products is part of the legal requirements in many jurisdictions, in practice this is not really covered in most risk assessments.

The functions provided by infaunal sediment communities include nutrient cycling, sediment stability, support for pelagic food chain, and maintenance of habitat for pelagic organisms. Carbon and nitrogen cycling are clearly relevant. Recovery of nutrients and removal or breakdown of excess nutrients and compounds should be also considered as should any function relevant to reducing the impact of eutrophication on dissolved oxygen levels. Functions generally relevant and expected to be indirectly impacted by chemicals include the grazing potential and availability of providing habitat for resident and transient populations; these functions are only covered in higher tier assessments.

Regarding contaminated sediments and the link between sediment quality and ecosystem functions, SedNet offers relevant information<sup>1</sup>.

### **Elements for discussion**

Should the focus be on function, on structure or on both?  
Is the coverage based on benthic invertebrates sufficient?  
If NOT, which other critical ecological receptors should be considered? For example, should epi-benthonic invertebrates such as grazing molluscs and filter-

<sup>1</sup> See: <http://www.sednet.org/download/J-Brils.pdf> and [http://www.sednet.org/download/Sednet\\_booklet\\_final.pdf](http://www.sednet.org/download/Sednet_booklet_final.pdf)

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feeders, plants, micro-organisms, pelagic species feeding on sediment and at the water/sediment interface, or other groups always considered in a sediment assessment?

Is the SSD an appropriate approach to integrate laboratory data for multiple species/endpoints?

A typical approach is to consider structure for animals and plants and function for effects on micro-organisms, is this approach suitable for sediment?

If function is considered more relevant, which functions should be considered?

Sediment assessments are conducted on freshwater, transitional (e.g., estuarine and coastal lagoons) and marine systems. In broad terms, all systems share similar functions and taxonomic groups, but when entering into details, obvious differences are observed, e.g., insects in freshwater systems *versus* echinoderms in marine systems. In estuarine environments, species can be distributed through a very wide salinity range. Overall, there is greater diversity of species presented in marine waters, but this should be put in the context that oceans represent over 70% of the Earth surface and about 97% of the Earth waters, while freshwater systems represent less than 1%; thus, the complexity of a particular aquatic ecosystem depends on a myriad of factors, not just on its allocation as freshwater, transitional (estuarine) or marine.

At a screening level, the same ecological receptors may be viewed as relevant to the different environments (i.e., marine, estuarine, freshwater), although separation of the different environments may be worthwhile where adequate data are available to assess each separately. Data availability may be a major consideration, as there are likely to be relatively few substances with sufficient data to do independent assessments for the different systems.

Data collected in one compartment may inform on another. The relevance of knowledge on the mechanisms of action and key drivers in one system (e.g., freshwater) for the other systems (e.g., estuarine/marine) can be considered, for example in order to identify particularly sensitive groups or functions. Over all, the possibility for combinations and/or extrapolation among the different systems may be assessed using the following considerations: 1) sediments perform similar functions in each environment; 2) whether or not there are important and predictable differences in sensitivities among representative benthic groups from each system; 3) major taxonomic differences exist among environments (e.g., how representative are data on insects to estuarine/marine benthic communities, and how representative are data on polychaetes/echinoderms to freshwater communities); and, 4) differences in the geochemical features of the sediment processes that influence bioavailability / exposure to the various types of sediment organisms?

Regarding consideration 1, the same general ecological receptors and functions noted above are suitable for all three environment types, thus the discussion is more at the "ecotype" level (e.g., rooted aquatic macrophytes are particularly important in some ecosystems, including some estuaries and coastal lagoons, but also some coastal and riverine areas, ponds and shallow lakes).

Regarding consideration 2 and 3, for chemicals with generic narcotic-type modes of action, based on thermodynamic or critical body burden theory there should not be major differences regarding toxicity at equilibrium. Nevertheless, due to



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species specific feeding strategies, habitat or exposures there could be differences prior to equilibrium being reached. For chemicals with specific mechanisms of action (e.g., neurotoxins), from several papers it seems that the sensitivity distributions of taxonomically similar freshwater and marine species to organic pesticides do not differ significantly (Maltby et al, 2005; Brock et al 2008; Klok et al 2012)<sup>2</sup>. For chemicals with insecticidal activity, a particularly relevant issue is the relative sensitivity of aquatic insects, including sediment dwellers such as chironomids, *versus* other arthropods, such as crustaceans; but also marine non-crustacean arthropods, such as horseshoe crabs and sea spiders. An equivalent assessment is needed for other biologically active chemicals.

Finally, for consideration 4, two complementary factors should be considered, first those related to chemical interactions and the influence of salinity, pH, redox reactions, and other general conditions on the chemical speciation, dissociation, etc. which may affect bioavailability. Secondly, the biological adaptations which may affect uptake and elimination but also other toxicokinetic and toxicodynamic elements. The estuarine environments are especially challenging because across the salinity gradient there is a transition from a freshwater to a marine species dominated biological diversity. This gradient is characterized by species with a freshwater background that have developed adaptations and/or tolerances to the saltwater environment and vice versa. This can be achieved in various ways and may result in differences in sensitivity between freshwater and saltwater representatives of the same taxonomic groups. Also, the capacity of organisms to adapt to a salinity gradient can be very different resulting in certain species being more sensitive when closer to their limit of tolerance within the gradient.

**Elements for discussion**

Is an extrapolation assessment based on responses to the four considerations above a suitable solution?

For generic assessments (e.g., REACH, pesticides/biocides authorisation, setting quality standards), are there some specific ecological receptors (taxa or function) and essential information requirements for freshwater, transitional or marine systems?

**3. Risk characterisation tools and metrics**

Risks can be assessed from: (i) a chemical perspective (e.g. frequency or probability to exceed regulatory thresholds); (ii) an ecotoxicological perspective (e.g., deviation of an ecotox response in comparison to a reference sediment); and (iii) an ecological perspective (e.g., deviation of an ecological state in comparison to a reference site). To aggregate these Lines of Evidence, MultiCriteria Decision Analysis (MCDA) should be developed/improved (eventually including new tools like bioavailability, biomarkers); the tools would depend on the problem definition and should be included in the conceptual model. The same approaches that are used for any environmental compartment can be used for the sediment compartment. Different risk characterisation tools are needed for

<sup>2</sup> See EFSA Literature review on the sensitivity and exposure of marine and estuarine organisms to pesticides in comparison to corresponding fresh water species "<http://www.efsa.europa.eu/en/supporting/pub/357e.htm>

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Screening Level Risk Assessments and for Detailed Level Risk Assessments: Generic (local and regional/water basin) and site specific. Deterministic tools (e.g., Risk Quotients, Exposure-Toxicity Ratios) are appropriate for screening-level analyses. Sediment quality standards are also useful as initial screens, or for permitting purposes (e.g., discharges). For detailed level assessments, preference should be given to probabilistic risk characterisation tools (e.g., Monte Carlo analysis, Bayesian approaches, probability bounds, etc.). Geospatial analysis tools can be used to produce risk maps. A deterministic approach is often sufficient to perform a practicable assessment for the sediment compartment. On the other hand, if sufficient data are available, probabilistic tools may be possible. However, normally not enough data are available to use probabilistic tools.

For lower tier screening type assessments, there are no primary conceptual differences regarding risk characterisation tools between predictive and prospective assessments, but the departure points may differ as the exposure and effect tools may be significantly different. At this lower-tier level, there should not be substantial differences, other than scale and the associated factors, such as interconnections and global change contributions, between local and regional assessments. For highly hydrophobic industrial substances, local ERA will be driven by suspended solids released particularly from Waste Water Treatment Plants (WWTPs). Depending on the area of release, there could be near complete movement of suspended solids (SS) to the sediment compartment (e.g., in a lake system) or almost complete transport to a distant zone (e.g., fast flowing river). In estuaries the deposition/resuspension of sediment is very high. Current methods taking into account adsorption at equilibrium at local sites are therefore not always meaningful but at least cover worst case situations. Local exposure will be from a point source whereas regional exposure will be more diffuse. The processes driving the exposure and distribution of the substances in these two situations will differ, in particular, degradation and distribution processes are taken into account; however, these processes are more relevant in the regional scale. For chemicals with direct (e.g., pesticides, fertilizers) or indirect (e.g., though soil applications of WWTP sludge) releases in the terrestrial compartment, run-off, drainage and soil erosion may be relevant pathways at the river basin level. In some regional scale assessments, the concentration of the substance is assumed to be constant without changes over the time but these assessments should take into account how chemicals are transported. One element for discussion is the need for considering specific ecotypes accounting for different sediment transport properties (e.g., the rhithron (upper part with high slope and fast and turbulent flow) and potamon (downstream part, warmer, slower and finer in substrate) zones of rivers, shallow and deep lakes, delta-type and fjord estuaries) for generic risk assessments. Regional-level monitoring often helps to identify and/or prioritize areas of concern that might need a more specific and directed study to inform environmental management decisions.

**Elements for discussion**

For screening and lower tier assessments:

Should sediment risk characterisations be performed independently from the pelagic characterisation or integrated into a single aquatic assessment?

Should they be performed using default assumptions or focused to the specific concerns that trigger the assessment, (e.g., additional exposure due to intake of particles; high persistence in sediment)?

Are local and regional estimations based on equilibrium conditions always over-



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protective or can be under-protective in some circumstances?  
Which emission routes should be considered for local generic assessments?  
Which emission routes should be considered for regional assessments?

For higher tier confirmatory assessments, the risk characterisation tools are driven by the methods used for presenting the exposure and effect assessments. There are also significant differences between generic and site-specific assessments. Sediment quality standards should be used as initial screens and for permitting purposes (e.g., discharges). For remedial decision making site specific assessments should be considered. Local-scale assessments require a much more intimate examination of physical, chemical, and biological elements of the aquatic system. It might be expected that more is known of local biodiversity and ecosystem services provisions in conservation / resource supply areas (e.g., fisheries) than at the regional level, whereas in other areas, proxy measures may be required to establish 'at-risk' receptor classes. Regional assessments should focus on large-scale processes which include diffuse and widely dispersive sources (e.g., near and far-field emissions and transport of materials), and should set broad 'regional norms' for key ecosystem properties, where sufficient knowledge is available. A combination of tools is essential in these cases as they each measure different things and have associated strengths/limitations. Key tools include habitat characterization, indigenous biotic metrics, toxicity/bioassays (laboratory and in situ), chemistry (including bioavailable fractions) of each sediment compartment. Whole sediment toxicity tests with field collected sediments or with spiked sediments can be used to develop generic or site specific sediment quality guidelines (SQGs). These SQGs can be generated using concentrations of contaminants in either whole sediment or in pore water. Normalising the water or sediment concentrations to factors influencing bioavailability and toxicity are also needed. The potential for sediment transport may lead to significant differences between local and regional exposures. In some cases, substances which partition to sediments may result only in relatively localised contamination, meaning that only the local exposure scenarios are of real ecological relevance.

One of the main challenges in sediment assessments is the heterogeneity in sediments (e.g., organic carbon; particle size; etc.) and associated biota. Local assessments can account for these differences, especially as they affect bioavailability, and can focus on the specific organisms that are present in that location. Regional risk assessments have to account for the range in variability that is present, and develop a risk estimate that is sufficiently protective of vulnerable areas without being overly protective of other locations. This can best be accomplished using a spatially-explicit approach that essentially captures the heterogeneity of the region, with sub-assessments for local conditions. If only a single approach is used, then some consideration needs to be given for using it as a starting point, so that local assessments can deviate from the regional risk value (i.e., either be at greater or lesser risk). The concept of ecoregions should be extended to sediments such that regional assessments make ecological (not political) sense. This would include, at a minimum, consideration of sediment characteristics (i.e., as above – organic carbon, grain size); depth of water; temperature (i.e., cold-water versus warm-water systems); and lakes versus streams/rivers. Freshwater, estuarine, and saltwater would be treated separately and not included in one regional assessment. In a regional risk assessment, the

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overall risk assessment, including the different point and diffuse emissions, should be included in order to evaluate if protection goals are achieved. It may be difficult to apply the ecological recovery option in a regional risk assessment, and the ecological threshold level seems more appropriate for cumulative exposures covering all relevant sources and chemicals.

**Elements for discussion**

For confirmatory and higher tier assessments:

Should sediment risk characterisations be performed independently from the pelagic characterisation or integrated into a single aquatic assessment?

It is feasible to develop generic conceptual models or it is always case-specific?

#### **4. Screening identification and extrapolation tools**

Some regulatory approaches include screening methods to trigger the sediment assessment or to conduct assessments when no ecotoxicological information is available. The Equilibrium Partitioning Method (EPM) is used for REACH and biocides in Europe. Equilibrium partitioning and solubility-based approaches are very useful (for organic substances), as they use physical-chemical properties to bound what is possible in terms of exposure. The Kow also provides an indication of the potential for bioaccumulation. The Koc is very useful for understanding the role that organic carbon plays in the sequestration of the chemical in sediments whereas water solubility limits the amount of chemical available to the biota. Taken together, these metrics can qualitatively and quantitatively describe the amount of chemical that will be available in the sediment to which the biota may be exposed. They can be used to categorise and screen chemicals, and then be applied to make adjustments for site-specific differences. These methods are all useful and all have limitations. Particular limitations include site-specific differences in key bioavailability controls.

The EPM method appears to be better for the sediment compartment than for soil. It provides a valuable screening approach for use in the absence of sediment effects information, although the predictions provided are uncertain. Relative to uncertainty, the EPM approach provides a good estimate of whether a specific chemical, or class of chemicals (e.g., PAHs), is likely to have any effect. However, most chemicals in sediments are present in mixtures and the EPM is currently not capable of estimating the adverse effects of all of the combined effects of all of the chemicals in the mixture. The EPM based on just organic chemicals partitioning into sediment organic carbon (KOC) tend to over-predict exposures and therefore is over-predictive. When the EPM model includes sediment organic carbon and black carbon (KBC), it tends to under-predict exposures and therefore is under-protective. This probably occurs because we don't have good methods for determining the types of black carbon that are in the sediment and we have limited KBC for individual types of black carbons (e.g., coal fly ash, diesel soot, char). The EPM model has the advantage of being simple and easily applied in the absence of measured data in prospective assessments, it can also be used in retrospective assessments based on sediment concentrations of contaminants ( $\mu\text{g/g}$  dry) and the organic carbon concentration in the sediments ( $\text{g OC/g dry}$ ). It should therefore be used as a first tier which can be applied to see if risk is predicted to be very high or very low. An approach used under the US EPA

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Superfund and applicable here is to link the need for further information with the outcome of the risk characterisation considering the uncertainty. For example, if the RCR is close to 1 (i.e., say between 0.5 and 1), requirements for further studies or more exposure information will automatically be triggered. Nevertheless, the extra factor of 10 applied to the RCR for substances with  $\log K_{ow} > 5$  and equivalently highly adsorptive substances is not validated; for substances with a high  $K_{oc}$ , tests with spiked sediments should be a data requirement. Certain surfactants (notably cationics, but not only) are very poorly estimated by these methods and an alternative approach should be sought for evaluating such materials.

More guidance on the applicability of the EPM-method would be useful. This should include a critical review/discussion on the use of the EPM-method. For instance, the following questions should be addressed: 1) How does the EPM - method, presuming that the method is based on the assumption that the pore water concentration and the concentration in the pelagic are equivalent, reflect reality? 2) How to use the information when the assumption is that the contaminants are at equilibrium between the interstitial waters, sediments and organisms but not with the overlying water (e.g., using the value ( $\Pi = \text{pie}$ ) to express the dis-equilibria between the benthic exposure and the water column exposure)? Taking into consideration that sediments can act as sinks (and sources) of substances, in many cases equilibrium between overlying pelagic water masses/water column and the pore water is not achieved, and the concentrations in pore water are expected to be higher. 3) How to address ionisable substances? How to take into account the effect of pH and salts (K, Mg, Na,  $\text{SO}_4$ , Cl) on the properties, especially  $\log K_{ow}$  values? 4) More information on the applicability of the AVS-SEM method (acid volatile sulphides - simultaneously extracted metals) for predicting bioavailability of metals is needed. In many situations, the sediment is a dynamic system that is affected by currents causing turbulence, and benthic organisms also cause the mixing/turbulence of sedimentary material resulting in the potential for an exchange of gasses; the AVS also varies seasonally around the year. The upper sediment level is typically expected to be aerobic, which may limit the use of the AVS-SEM approach for estimating the bioavailability of certain metals; however, based on experience, if AVS-SEM  $> 0$  the concept can be used because the aerobic phase is highly influenced/dependent of the metal binding capacity of the nearby anaerobic phase (with a pool of free AVS which can bind (precipitate) metals). As the Ni case study shows, we can also begin to consider empirically-based bioavailability models, which are based on EPM concepts but consider the dynamics of sediment phases and the species-specific interactions between organism and sediment-associated contaminants.

Another issue needing exploration is bound residues, both for metals and organic substances. It is not clear today whether unextractable bound residues should really be considered as a concern to the sediment compartment as they will not be bioavailable; however, the uncertainty lies in the degree to which an otherwise unavailable chemical may (with time) become available due to (for example) diagenetic processes.

The physico-chemical properties of the contaminants can also be used for identifying if the substance can absorb or adsorb to sediment. If not, a more detailed assessment is not useful. If yes, the assessment can be either

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quantitative or qualitative. Guidance documents should also be improved by proposing methodologies according to one of the three following scales: ecosystem, effluent or substance.

For screening and EPM lower tier assessment based on equilibrium conditions, the same processes and values are used for estimating the PEC<sub>sed</sub> and PNEC<sub>screening</sub>, the result is that the same risk quotients (PEC/PNEC ratios) are obtained for water and for sediments in some cases (e.g., log K<sub>ow</sub> between 3 and 5 under REACH), the added value of this approach is therefore questionable.

**Elements for discussion**

It is feasible to develop simple indicators triggering the need for sediment assessment?

If the main exposure route is water and pore-water, what is the added value of conducting assessments for the sediment compartment?

Are ecological taxa or functions particularly relevant for the sediment assessment but of much lower relevance for the pelagic community (e.g., gastropods or sediment microbial functions)?

What are the main advantages and limitations of the EPM approach in relation to other alternatives? Is it sufficiently validated? Are additional EP related developments needed?

**5. Risk characterisation for impact assessment and informing decision making**

In the regulatory context, the risk assessment is conducted as one of the elements for the decision making. The specific conditions for using the risk characterisation outcome in the decision making process depends on each regulatory process. Ecoregion variability in physicochemical and biological characteristics will cause the risks, and the expected impacts on the sediment community and the associated pelagic community, to vary dramatically. A key element for regulatory risk assessments should be a weight-of-evidence (WoE) approach that is based on independent lines of evidence that include laboratory field toxicity data, mechanistic information that supports these data, incorporation of refinements such as bioavailability modelling, and good monitoring information that demonstrates widespread exposure of the contaminant in question to benthic, infaunal communities. Elements that are recommended for consideration when using the outcome of the sediment risk assessment in a regulatory context are:

- 1) concentration-effects relationships (i.e., toxicity data) that include site-specific data when specific locations or contaminated sites are at issue;
- 2) food-chain bioaccumulation and consumption risks to humans and/or ecological receptors;
- 3) bioavailability of sediment contaminants;
- 4) sources of contaminants to the sediments;
- 5) system dynamics of the sediment environment (e.g., sediment stability, transport, contaminant flux) and how that may affect exposures; and
- 6) what the realistic future uses and ecological conditions of the water body are expected to be given the environmental setting (e.g., pristine, industrialized, urban, abandoned industrial, agricultural, many other

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- types);  
7) How to incorporate ecosystem services in the assessment.

These essential elements should be explained and justified in the risk assessment presented to a risk manager or politician:

- A. How realistic and relevant is the exposure input?
- B. How realistic and relevant is the effects input?
- C. Are appropriate temporal and spatial scales covered?
- D. Are assessment factors and other methods used to deal with uncertainties and variability sufficient without being under- or overprotective?

The use of distributions of data (rather than single point) in the risk assessment will offer the regulator more information for comparison in a cost-benefit approach of the control or remedial clean up measure.

Taking into consideration that sediments can act as sinks (and sources) of substances, it is particularly important to distinguish between preventive assessments, aiming to avoid sediment pollution, and corrective assessments, aiming to mitigate the effects of contaminated sediments. This distinction directly affects decisions about the choice of available tools, e.g. sediment toxicity tests (1) conducted with spiked sediments to assess the toxicity and bioavailability of contaminants in sediment in the case of preventive risk assessments versus (2) those conducted with field-collected sediments to assess the site-specific aspects of sediment contamination (e.g., measuring directly the effects of potentially toxic concentrations) in the case of retrospective/corrective risk assessments. Monitoring programmes with risk-based sediment quality standards represent the intermediate category.

In the regulatory context, it is important to know if sediment is going to be a relevant compartment for each specific use. If there is risk for one use, mitigation measures should be established. The use of toxicity data for setting generic sediment safety standards, or for discharge permitting, necessarily means being protective but not predictive. This will result in over-protection of most areas in order to be protective of the more sensitive ecosystems. This is one reason to have different standards and approaches for freshwater, estuarine, and saltwater systems (i.e., to reduce the underlying variability and therefore reduce the amount of over-protection). Also, it is helpful to develop risk-based standards that are equations, rather than single numbers, so they can be easily adapted to site-specific conditions that affect bioavailability and/or chemical fate. It should be assumed that initial hazard and risk assessments will be more conservative (cautious) than in higher tier assessments and in field situations, with the caveat that there may, at times, be exceptions to this rule due to emergent properties of environmental interactions that are not predicted from laboratory studies. The starting element for these sediment risk assessments should be a risk quotient (e.g., PEC/PNEC ratio or TER) based on sediment tests. Results from risk assessments based on EPM should only be used as screening; however, no regulatory consequences, other than requesting further information and testing, should be derived from EPM based assessment. To derive quality standards, the PNEC based on sediment test results can be used. The protection of populations and ecological functions should be used as the protection goal. Broader ecological values such as biodiversity, species richness, endemism, etc. and ecosystems



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services are not directly addressed and should be difficult to address until much more high performance population models are available. The adaptation of the SPEAR assessment tool to make a link between the sediment and the organisms might be considered. Putting more emphasis on mesocosm and field data (i.e., benthic species monitoring) adds ecological relevance to the assessment. For decision making, many elements beyond those covered by a generic risk assessment need to be considered. The risk assessment should inform issues such as contaminant load and toxicity evolution, residence times, extent of water-mixing, and on the expected consequences for related activities such as fisheries, aquaculture or bathing. In addition, local permitting authorities need to consult national legislation (on e.g., dredging limit values). It is highly essential to develop site-specific sediment quality guidelines (EQSs) for more accurate and robust risk assessment, while it is equally important to validate the EQS via field validation studies. This will provide a check and balance for the risk assessment process.

Sediments may be a key compartment for PBT/vPvB (Persistent Bioaccumulative and Toxic/very Persistent and very Bioaccumulative) substances, and it would be useful to give more specifications on the applicability of the criteria for sediment. The OECD TG 308 is the test method mostly used, but there are other elements requiring further guidance (e.g., for  $K_{ow}$ , to clarify temperature, how to address bound residues). Certain substances of potential concern (not fitting PBT/vPvB criteria but with certain elements of these) and expected to be highly present and persistent in sediments and potentially bioavailable could be highlighted for monitoring (e.g., under the WFD).

Broader ecological values such as biodiversity, species richness, endemism, etc., can be addressed at this point and considered in the integrated assessment of sediment quality (e.g., by comparing appropriate metrics to a "reference condition" - meaning that no one set is applicable - and must be hydrologic type/ecoregion type dependent following the AQEM/STAR approach developed for the EU). The consideration of issues such as biodiversity and species richness ideally needs to be considered alongside tools which are able to describe these factors under unstressed conditions. This is due to the fact that different environments and habitats may support different levels of diversity and species richness under unimpacted conditions. Tools such as RIVPACS are able to provide indications of benthic macroinvertebrate communities under reference conditions, although many of the assessments performed so far suggest that these communities respond predominantly to exposures via the overlying water. Sediment quality triads and diversity indices (e.g., based on dominance or information approaches), should be also considered. Ecological metrics focusing on biodiversity, species richness, endemism, etc. (or improvements to them) could be included in the long-term ecological goals for the recovery of a contaminated sediment ecosystem. However, these types of ecological measurements are not often useful as leading lines of evidence to inform decision-making because it is difficult to adequately link them to contamination levels due to the confounding influence of numerous other environmental factors and stressors that affect populations and communities of organisms. However, these ecological measurements can be used to complement or augment a clean-up decision that is itself based upon dose-response data, especially in cases where a risk range is determined from the risk assessment. In some cases, these "confounding factors" can either attenuate or exacerbate the effects of chemicals.



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An important area for future research is to understand how co-occurring stressors interact so that decision-making in risk assessments might be better informed. A risk assessment for managing/recovering contaminated sediments should not only be defined according to the compliance of a threshold, but also by taking into account the local features (e.g., such as biodiversity, endemism, species richness) by local surveys, or by including qualitative parameters. The evolution of the ecological compartments can also be a key factor to be compared with the initial studies.

Expressing the uncertainty is a key element for any assessment and should be addressed and explained differently in each case. The overall uncertainty should be reflected in a weight of evidence approach with qualitative tools, as, unfortunately, no suitable/informative numerical tools are available; ranging from low to high with indications of what are the key components driving uncertainty and hence providing the basis for moving forward and addressing them. The risk assessor should also add their own professional opinion about the certainty of the assessment in a qualitative discussion. There are however statistically based methods covering some assessments or processes (e.g., for full probabilistic risk assessments, for comparing reference vs. test site conditions, for developing species sensitivity distributions, for covering parametric uncertainty based on probability Density Functions for parameters in case of modelling and generic scenarios, etc.). There are also many tools and approaches available to perform higher-level uncertainty analysis such as Monte Carlo analysis, interval analysis, Bayesian methods, second-order Monte Carlo, probability bounds analysis, and many others. These should be considered when weighing options for risk management. The EFSA's Scientific Committee approach on describing Uncertainties in RA<sup>3</sup> can partly be applied to risk assessment for the sediment compartment. Whenever possible, uncertainty and variability should be addressed independently; if this is not possible and both aspects are combined, it is important to indicate at least which elements have been considered and how both aspects have been combined.

**Elements for discussion**

Are points 1 to 7 and A to D above clear and sufficient?  
Should the focus of the sediment assessment be part of a full aquatic systems assessment, the structure of the sediment community, or both?  
Is it feasible and desirable to move into "ecosystem services" approaches for addressing the impact of chemicals on the sediment compartment?  
In which cases should broader ecological values such as biodiversity, species richness, endemism, etc. be considered?  
Is a qualitative assessment of the uncertainty in the weight of evidence approach sufficient? What is the role of expert judgement in the uncertainty assessment for sediment?

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<sup>3</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/438.htm>

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**Annex. Questions for TOPIC 1 Risk Assessment: Problem definition and conceptual model**

1. The standard RA structure includes complementary risk assessments for pelagic organisms and for the sediment compartment: Which elements/receptors should be covered by the sediment compartment? How should the water/sediment interface and the exposure via suspended matter be included in the sediment RA?
2. Which taxonomic groups and ecosystem functions should be considered as key ecological receptors<sup>4</sup> in sediment RA?
3. Are the same ecological receptors suitable for freshwater, estuarine and marine sediment compartments?
4. Which level of protection is required for the different ecological values<sup>5</sup> in the sediment compartment? How should this level of protection be defined and quantified?
5. Which qualitative, deterministic and probabilistic tools can be used for the characterisation of sediment compartment risks?
6. What are the main conceptual and methodological differences for conducting local and regional assessments of the sediment compartment?
7. Are the approaches described in the current guidance documents<sup>6</sup> on sediment assessment useful and sufficient? Are current tiered protocols and screening methods, particularly the EPM<sup>7</sup> and prioritization/exclusion criteria<sup>8</sup> suitable and validated? Which are the main elements requiring improvement or scientific update? )
8. Which key elements should be considered when using the outcome of the sediment risk assessment in a regulatory context? Which issues are particularly relevant for specific processes such as generic sediment safety assessments for marketing/authorisation/restriction<sup>9</sup>; setting environmental quality standards/criteria; or local permits authorisations)?
9. How can biodiversity, species richness, endemism, and other ecological concerns be included and considered in the risk characterisation for the

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<sup>4</sup> Ecological receptors refer to species, taxonomic groups, trophic levels and ecological functions that could be adversely affected by the stressor and for which exposure and risk should be assessed

<sup>5</sup> Ecological values refer to the services provided by a healthy sediment community

<sup>6</sup> Please, include the list of sediment assessment guidance documents you have used

<sup>7</sup> Equilibrium Partitioning Method estimating the risk to sediment by comparing the predicted pore water concentration with the predicted no effect concentration for pelagic organisms

<sup>8</sup> E.g. criteria for conducting or not a sediment assessment based on solubility, Kow and Koc thresholds

<sup>9</sup> E.g. those related to REACH, or pesticides, biocides, pharmaceuticals regulations

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sediment compartment?

10. Are there ways available for expressing the overall uncertainty of the risk assessment performed in the sediment compartment?

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