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

Introduction to the EU regulatory framework for sediment risk assessment

This summary of the EU regulatory framework for sediment risk assessments presents examples of the linkage between the scientific developments and regulatory decision-making in this field. It will be also facilitate the understanding by participants not fully familiar with the EU regulatory system.

Disclaimer: This summary has been prepared as a background document for facilitating the workshop discussions and does not represent a position of the European Chemicals Agency. Readers are referred to the legal texts and guidance documents produced by the responsible European Institutions (a summary of relevant guidance documents is also available as workshop background material).

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1. Introduction

Environmental risk assessments (ERA), including sediment assessments, are typical tools for supporting decision making in the regulatory context, and cover all kinds of spatial situations, from local to world-wide assessments, under very different regulatory contexts. Typical extremes for chemical ERAs are the purely predictive and generic assessments conducted for marketing chemicals (e.g., substances under REACH, or pre-marketing authorisations for pesticides, biocides, pharmaceuticals, etc. existing in many jurisdictions) and the retrospective site-specific assessments conducted on contaminated areas as diagnosis tools in the identification of ecological effects and the responsible stressors. In between these two extremes, there are several regulatory processes using risk- based tools or risk assessment elements for prospective and monitoring purposes. These; include the processes for setting ecological quality standards/criteria, the emission-permit authorisations, the assessment of risk associated with contaminated sediments and its management, etc.

All these processes have common elements as well as specificities. This workshop is intended to create consensus around the available scientific tools, needs and challenges regarding the risk assessment of the sediment compartment in all these different regulatory processes.

The EU regulatory system can be used as an example for the identification of the different regulatory needs, and therefore the main elements of this system and the current guidelines are summarised in this introduction.

2. Sediment risk assessment under REACH

Except when covered by an exception, all substances marketed or imported in the EU above 1 tonne per year must be registered under REACH. For the registration, the company must gather information according to a set of regulatory requirements and demonstrate a safe use. The information requirements are linked to the annual tonnage. Sediment specific requirements are only mandatory above 100 (fate data) and 1000 tonnes/year (ecotoxicity data), respectively; and can be waived due to justified specific and general adaptations. The ECHA guidance[1] offers default emission factors and a generic environmental fate scenario based on the previous TGD (Technical Guidance Document for Risk Assessment, see reference to biocides in the next section). It allows a generic predictive assessment based on the tonnage, use and operational conditions, standardised through a set of use descriptors, particularly the Environmental Release Categories (ERC). ERCs are linked to conservative default release factors to be used as a starting point for a first tier environmental exposure assessment. The physical-chemical and fate properties of the substance are then used to

[1] **REACH Guidance documents on Chemical Safety Assessment:**
Chapter R7. Endpoint specific guidance
Chapter R.10. Characterisation of dose [concentration] - response for environment
Chapter R.16. Environmental exposure estimation
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

predict the behaviour of the chemical in the Sewage Treatment Plant (STP) (e.g., using the model SimpleTreat 3.10). For the local assessment, the release of treated wastewater is the only sediment exposure route considered relevant. The exposure is quantified as the Predicted Environmental Concentration in sediment (PEC_{sed}). The concentration in freshly deposited sediment is taken as the PEC for sediment, estimated from the PEC in water and experimental or estimated partitioning rates to suspended matter. The guidance offers default values for all relevant parameters, thus a generic local PEC_{sed} can be calculated and considered applicable to all local emissions in Europe, although the default values can be adapted to specific conditions if justified. The local risk for wide-dispersive uses (e.g., from consumers or small, non- industrial companies) is estimated for a default STP serving 10000 inhabitants. In addition, a regional assessment is conducted for a standard area, a region represented by a typical densely populated EU-area located in Western Europe (i.e., about 20 million inhabitants, distributed in a 200 x 200 km^2 area). For calculating the regional PEC_{sed}, a multi-media fate-modelling approach is used (e.g., the SimpleBox model). All releases to each environmental compartment for each use are, assumed to constitute a constant and continuous flux, are summed and averaged over the year, and steady-state concentrations in the environmental compartments are calculated. The regional concentrations are used as background concentrations in the calculation of the local concentrations.

The effect assessment is based on the estimation of the Predicted No Effect Concentration ($PNEC_{sed}$) In the absence of ecotoxicological data for sediment-dwelling organisms, the $PNEC_{sed}$ may be provisionally calculated using the equilibrium partitioning method (EPM). This method uses the $PNEC_{water}$ for aquatic organisms and the suspended matter/water partitioning coefficient as inputs. If ecotoxicity data on sediment dwelling organisms is available, the PNEC is calculated using the lowest value and an Assessment Factor (AF) related to the amount of information. The default AFs are 100, 50 and 10 for freshwater (for one, two or three long-term NOECs from sediment invertebrate species representing different living and feeding conditions) and range between 10000 and 10 for the marine environment. There are no recommendations for using Species Sensitivity Distributions (SSD) or other higher-tier approaches; thus, registrants should develop and justify the cases for using these methodologies.

In the risk assessment, the PEC_{sed} is compared to the $PNEC_{sed}$ simply through the Risk Quotient Ratio (RQR=PEC/PNEC). For substances with a log Kow greater than 5 (or with a corresponding Kpsed value) the PEC/PNEC ratio resulting from the EPM is increased by a factor of 10 in order to take into account of possible uptake via ingestion of sediment. This approach is considered as a screening level assessment of the risk to sediment dwelling organisms. If with this method, a PEC/PNEC ratio greater than 1 is derived then tests, preferably long-term (i.e., chronic), with benthic organisms using spiked sediment have to be conducted for a more realistic risk assessment.

3. Vertical premarketing legislations: Plant Protection Products.

The guidance for Biocidal Products is also based on the TGD[2] and the provisions are similar to those presented for REACH, but take into account the different pathways for environmental release associated with the variety of use patterns for biocides. However, a different approach is used for pesticides under the Plant Protection Products legislation.

The current practice for pesticides is based on the Guidance Document on aquatic risk assessment (Sanco/3268/2001 rev.4 (final) 17 October 2002) but is under revision. According to the current aquatic GD, the assessment of risk to sediment organisms is triggered by the results of a water/sediment dissipation study conducted with the radiolabelled substance. Sediment assessment is required for active substances which appear with more than 10% of applied radioactivity (AR) in the sediment. *Chironomus* sp. (*Insecta, Diptera, Chironomidae, Chironominae*) is the required freshwater test organism to assess potential effects on sediment-dwelling organisms. To prevent unnecessary testing with substances of low toxicity to invertebrates, the water-only NOEC in the chronic *Daphnia* test (or in a comparable study with insects when this group of organisms is more sensitive) must be < 0.1 mg/l for testing with sediment dwelling organisms to be warranted. For persistent substances (see EU-Guidance-Document 9188/VI/97), it may be justified to require a life-cycle test on chironomids to generate data on reproduction effects. It is well-established that for non-polar organic compounds of log K_{ow} up to 5 that in such a system at equilibrium, adequate predictions of toxicity in sediment can be made from the concentration in the water phase (DI TORO et al., 1991).

The exposure of active substances is evaluated using ten FOCUS surface water (SW) scenarios[3]. Each of these scenarios should apply to the 90th percentile of the exposure concentration in a large region. At the time of the development of the FOCUS SW scenarios, comprehensive databases for checking this assumption were not available, so it is not currently clear if the FOCUS scenarios are good predictions of this 90th percentile. EFSA (European Food Safety Authority) has developed a consistent methodology for scenario derivation that could be applied to improve the exposure assessment[4].

The FOCUS calculation partitions the substance between water and sediment and assumes that equilibrium exists (i.e., worst-case because in nature dilution would be expected). The concentration in the water phase will reflect the 'bioavailable' concentration in the sediment. Consequently, using the appropriate water phase concentration, *Daphnia* toxicity data and the standard Annex VI triggers for invertebrates, it is possible to determine whether there is potential for sediment toxicity.

The risk characterisation is performed through the Toxicity/Exposure ratios (TERs). If the Toxicity/Exposure ratios (TERs) (based on the maximum exposure concentration from the FOCUS SW modelling) for *Daphnia* are less than 100 or 10

[2] EU-TGD Part 2
http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd/tgdpart2_2ed.pdf
[3] http://viso.ei.jrc.it/focus/sw/index.html
[4] http://www.efsa.europa.eu/en/efsajournal/doc/2562.pdf

for acute or chronic endpoints, respectively, then testing of sediment dwelling organisms should be required, if the sediment exposure triggers are met. For insecticides, where it is possible that *Daphnia* are not a representative test organism (e.g., neonicotinoids), acute toxicity data for *Chironomus riparius* can also be used to trigger long-term sediment studies. If the TER resulting from the maximum PEC at Step 2 and the *C. riparius* 48 h LC_{50} is less than 100, then long-term sediment testing is required, if the sediment exposure triggers are met. Although data requirements specify *Chironomus* sp. as the test organism, and survival and development (including emergence of adults) as endpoints, no further guidance is included on the type of study to be conducted (e.g., the "spiked-sediment" toxicity test (OECD 218) or the "spiked water" toxicity test (OECD 219)). There has been some debate about under which circumstances the "spiked water" or "spiked sediment" method is most appropriate. Data generated using either method should be judged on its own merits, although the spiked water test may be seen as providing a more realistic exposure scenario for most cases. However, data from spiked sediment studies can be particularly useful for addressing risks from exposure to contaminated sediment, particularly if there is an accumulation of the compound in the sediment over time (e.g., from multiple applications and/or via different exposure routes). For sediment toxicity tests, the concentrations in the pore water, the overlying water, and the sediment should be measured. There are some reservations with respect to the OECD 219 which includes the fact that analytical measurements in sediment are not routinely conducted. It can be argued that such analyses are not necessary if suitable data on the partitioning of the substance from a water-sediment study are available. Therefore, reasoned cases which include the estimation of likely levels in sediment, utilising data from the water-sediment study, may also be acceptable. In such situations, the notifier should demonstrate that the conditions in the water-sediment study are comparable to those in the "spiked water" test. The estimation of levels should include consideration of metabolites present in the sediment where this is relevant for the risk assessment. Additional analytical measurements in a study may sometimes be valuable to decide on the validity of a test and may help to avoid additional testing with living organisms. NOEC values from "spiked water" studies that are expressed as initial concentrations in the water phase should be compared to initial PECs for the water column, and those from "spiked sediment" tests should be compared to PECs in sediment. Since both studies are long-term tests, the appropriate trigger for further evaluation is 10. If the trigger is not passed, a range of higher-tier studies are possible to further refine the risk assessment. Toxicity to sediment-dwelling invertebrates may also be addressed in a suitably designed microcosm or mesocosm study.

In addition to the above guidance given in the GD, the following practice regarding sediment risk assessment has become a standard practice: Modelling exposure with FOCUS SW provides both exposure data for water and sediment. If an active substance is very lipophilic and used repeatedly, exposure may build up in the sediment (i.e., predicted by FOCUS SW tool). If only a spiked-water test with *Chironomus* is provided, the derived endpoint from the water phase is transformed to an equivalent concentration in the sediment and *visa versa*.

The Aquatic GD for risk assessment of pesticides is currently under revision. As a first step, a revision of the guidance for pelagic organisms at 'edge-of-field' is due in the middle of 2013. A revision of the sediment effect assessment for pesticides

is expected to be initiated by EFSA in Autumn 2013. In the draft new aquatic 'edge-of-field' GD, the following guidance is given on sediment/soil dwellers in relation to sediment risk assessment: "This GD has its focus on a tiered risk assessment procedure for aquatic organisms living in the water column in edge-of-field surface waters". Nevertheless, also a preliminary (Tier 1) risk assessment procedure for sediment-dwelling organisms on the basis of the 28-d water-spiked water-sediment test with *Chironomus riparius* or *Lumbriculus* spp. is incorporated, since this concerns a data requirement under the PPP regulation. A later PPR Scientific Opinion in the series mentioned above will deal in detail with the effect assessment for sediment-dwelling organisms by paying attention to a wider array of sediment-dwelling species. For standard toxicity tests with aquatic organisms, the EC_{10} is recommended as a substitute for the NOEC. When accumulation of an active substance in aquatic sediments is indicated or predicted by environmental fate studies, the impact on a sediment-dwelling organism shall be assessed. The chronic risk to *Chironomus riparius* (OECD 218, 219) or *Lumbriculus* spp (OECD 225) shall be determined. An appropriate alternative test species may be used where a recognised guideline is available. The active substance should be applied to either the water or the sediment phase of a water/sediment system and the test should take into account of the major routes of exposure. The key endpoint from the study should be presented in terms of mg substance/kg dry sediment and mg substance/L water. The PPR Panel recommends a preference for conducting a water-spiked study. Sediment-spiked studies could be part of higher tier testing. This GD focuses on exposure via the water phase. A scientific opinion addressing the effect assessment for sediment organisms in detail will be developed by the PPR Panel in the near future.

The existing GD and the draft revised GD so far only include exposure via water and does not include exposure by food. This route may be important for sediment browsers – especially for organic compounds partitioning to the sediment surface. New tools are needed to consider effects and exposure.

4. Environmental control and monitoring: The Water Framework Directive (WFD).

The WFD establishes management by river basin - the natural geographical and hydrological unit - as the best model for a single system of water management. For each river basin district - some of which will traverse national frontiers - a "river basin management plan" should be established and updated every six years. The WFD has the objective to achieve the good ecological and chemical status for all waters within 2015. There are a number of objectives in respect of which the quality of water is protected. The key ones at the European level are general protection of the aquatic ecology, specific protection of unique and valuable habitats, protection of drinking water resources, and protection of bathing (swimming) water. These protection goals are similar to those considered in other jurisdictions, for example under the Clean Water Act in the USA. All these objectives must be integrated for each river basin. It is clear that the last three - special habitats, drinking water areas and bathing water - apply only to specific bodies of water (i.e., those supporting special wetlands; those identified for drinking water abstraction; those generally used as bathing areas). In contrast, ecological protection should apply to all waters: the environment should be protected to a high level in its entirety.

The sediment assessment is part of the "Surface water" protection, which includes three levels, ecological protection, chemical protection and the protection of specific uses.

The classification of the surface water bodies is based on the ecological and the chemical status.

A general requirement for ecological protection, and a general minimum chemical standard, was introduced to cover all surface waters. These are the two elements "good ecological status" and "good chemical status". Good ecological status is defined in terms of the quality of the biological community, the hydrological characteristics and the chemical characteristics (included specific pollutants relevant at national or river basin level). Because of ecological variability, no absolute standards for biological quality can be set which apply across the entire Community, thus the controls are specified as allowing only a slight departure from the biological community which would be expected in conditions of minimal anthropogenic impact, as determined by relevant reference sites. A set of procedures for identifying the ecological status of a water body has been developed. The ecological status is defined through a set of ecoregions and ecotypes, comparing the situation in the water body with those of relevant reference sites. A set of inter-calibration exercises have been conducted for ensuring a common understanding regarding the application of the general principles. The ecological status is based on the direct assessment of the biological community, which includes macrophytes and phytobenthos as well as benthic invertebrate fauna for rivers and lakes, and macroalgae, angiosperms and benthic invertebrate fauna for coastal and transitional waters.

The chemical status protection is defined in terms of compliance with all the Ecological Quality Standards (EQS) established for the prioritised chemical substances of the European list of priority (currently 33 + 8). THE EQS are concentrations derived in water column, sediment and biota that should protect human health and the environment. The Directive 2008/105/EC, published in compliance with the art. 16 of the WFD, gives a useful role to sediment: Member States have the possibility to derive environmental quality standard for the priority substances in sediment compartment for specific water bodies. Furthermore the analysis of sediments for specific priority substances is useful for the analysis of the trend.

A large set of Guidance Documents[5] have been developed in the context of the common implementation strategy of the WFD. Guidance No 25 - Chemical Monitoring of Sediment and Biota and Guidance No 27 - Deriving Environmental Quality Standards are the most relevant for the sediment compartment.

Guidance No 25 - Chemical Monitoring of Sediment and Biota and Guidance, describes the conditions for monitoring chemicals in sediments, including sampling design, passive sampling methods, chemical analysis, etc. In addition

[5] https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:_idcl=FormPrincipal:libraryContentList:pager&page=1&FormPrincipal_SUBMIT=1&org.apache.myfaces.trinidad.faces.STATE=DUMMY

the guidance provides indications for the use of ecotoxicity methods in a Triad approach, combining the three assessment methods: chemical, bioassay, and ecology. Specific references are made to Toxicity identification evaluation (TIE) and effect-directed analysis (EDA), which combine biological and chemical analysis with physicochemical manipulation and fractionation techniques.

Guidance No 27 describes the derivation of the Environmental Quality Standards. These values are compared with the measured concentrations for determining the chemical status of the water body in relation to the priority pollutants. A log K_{oc} or log K_{ow} of ≥3 is used as a trigger value for sediment effects assessments for organic chemicals. Some substances can occur in sediments even though they do not meet these criteria so, in addition, evidence of high toxicity to aquatic organisms or sediment-dwelling organisms or evidence of accumulation in sediments from monitoring, would also trigger derivation of a sediment EQS. The methodology is also based on the TGD but has been updated with additional guidance, including that developed for pesticides. The QS for the sediment is derived using the EPM or the AF method as described for REACH, and there are additional recommendations for using mesocosms studies and higher tier methods. Furthermore the EQS Guidance includes guidance on derivation of a maximum allowable concentration (MAC-EQS) besides the derivation of an annual average concentrations (AA-EQS) (the latter of which is equivalent with the PNECsed - derivation in REACH). It should be noted that the sediment EQS can be used only for the first tier assessment; if the measured concentrations exceed the sediment EQS, and the sediment EQS is not scientifically robust for taken the final decision, site-specific assessments of the benthic community, including the use of bioassays, are conducted for assessing the ecological status.

5. Other relevant European legislation

In addition to those described in the previous sections, there are many other pieces of European legislation which may benefit from the update of sediment risk assessment protocols. These include the IPPC and Industrial Emissions Directives, which establishes the principles for setting emission permits, the Environmental Liability Directive, the Seveso Directives on major accidents, the Waste Directive, etc. Indirectly and on certain cases, sediment assessments may be relevant for the Habitats Directive which establishes basic principles for the protection of areas of high ecological value. No specific guidance for sediment risk assessment has been developed.

6. Management of contaminated sediments

There is no specific EU legislation regarding handling of contaminated sediments but the WFD and other general regulations offer some basic principles[6]. In addition to the Community legislations, most site-specific assessments are conducted under national law. This is the case for the assessment of contaminated sediment for remediation or dredging purposes.

[6] See for example : http://www.sednet.org/download/Sednet_booklet_final.pdf