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and the Environment
Ministry of Health, Welfare and Sport

Guidance for the derivation of environmental risk limits

Part 4. Derivation of ERLs for freshwater and marine
sediments

version 1.0

Colophon

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1 Introduction

1.1 Focus and risk limits considered

Risk limits for sediment are used as a basis for setting environmental quality standards for the protection of benthic ecosystems. Direct exposure of sediment organisms is the only route that is taken into account, because direct contact of humans with sediment is not considered to be critical for risk limit derivation (see also ERL Report 01). The derivation of quality standards for sediment is covered in the guidance developed under the Water Framework Directive (WFD) [1]. However, specific quality standards for Dutch (standard) sediment are not derived within the context of the WFD. Such risk limits are used in other frameworks, e.g. local risk assessment, remediation policy and evaluation of re-use of dredged materials.

The following risk limits are derived:

- the Maximum Permissible Concentration in sediment (MPC_{sed}), in Dutch designated as *Maximaal Toelaatbaar Risiconiveau (MTR)*, and
- the Negligible Concentration in sediment (NC_{sed}), *Verwaarloosbaar Risiconiveau (VR)* in Dutch.
- the Serious Risk Concentration in sediment (SRC_{sed}), *Ernstig Risiconiveau (ER)* in Dutch

The MPC is defined in VROM [2,3] as the standard based on scientific data which indicates the concentration in an environmental compartment for which:

- 1 no effect to be rated as negative is to be expected for ecosystems;
- 2a no effect to be rated as negative is to be expected for humans (for non-carcinogenic substances);
- 2b for humans no more than a probability of death of 10^{-6} per year can be calculated (for carcinogenic substances).

However, as indicated above, risk limits for sediment only refer to ecological risks, so at MPC level, only the $MPC_{sed, eco}$ protecting for direct ecotoxicity ($MPC_{sed, eco, fw}$ and $MPC_{sed, eco, sw}$) and the $MPC_{sed, secpois}$ protecting for secondary poisoning ($MPC_{sed, secpois, fw}$ and $MPC_{sed, secpois, sw}$) are derived.

The NC is defined as $MPC/100$. The factor of 100 is applied to account for combination toxicity. The SRC_{sed} is the concentration in sediment at which possibly serious ecotoxicological effects are to be expected (see also ERL Report 01), and is derived for the freshwater and saltwater sediment compartment, for direct ecotoxicity and, if data are available, for secondary poisoning.

1.2 Relevance of sediment risk limits

The initial cause of sediment contamination is migration of contaminants from the water phase. The partitioning of organic substances between water and sediment is considered to be driven mainly by the

compounds' affinity for organic matter and its hydrophobicity. According to the WFD-guidance, sediment quality standards will be derived when the substance of interest has a $\log K_{oc} \geq 3$, or a $\log K_{ow} \geq 3$, when there is other evidence of accumulation in sediments (e.g. sediment monitoring data), or when there is evidence of high toxicity to benthic organisms [1]. In the framework of Dutch standard setting, these properties will not be used as triggers in a sense that risk limits for sediment will automatically be derived when the triggers are breached, but they may serve as screening tools to determine whether a request for sediment risk limits makes sense in combination with other information (monitoring, effect data) that may be available.

1.3 Equilibrium partitioning and Dutch standard characteristics

For derivation of ecotoxicological risk limits, preference is given to experimental ecotoxicity data on sediment organisms. However, if those data are absent or only available to a limited extent, risk limits for water may be used to derive risk limits for sediment by means of equilibrium partitioning (EqP). The way EqP is used within the framework of standard setting is outlined in ERL Report 09.

The methodology for derivation of ERLs for sediment in this report, makes use of the characteristics for Dutch standard sediment as they have been used in the past for ERL derivations at the Dutch national level. These characteristics are the percentage of organic matter or organic carbon. The principle of EqP is also used to convert all sediment ecotoxicity data to Dutch standard sediment, by normalisation to organic carbon content, if appropriate. Exceptions are e.g. metals or compounds that show irreversible sorption. The final ERLs should be expressed on the basis of Dutch characteristics.

2 Collection, evaluation and selection of sediment ecotoxicity data

2.1 Data collection and evaluation of sediment laboratory toxicity data

Please read the section on general information on data evaluation and data selection for ecotoxicity data in ERL Report 02 (chapter 5). International guidelines exist for performing ecotoxicity studies for a number of species. The most frequently used guidelines are summarised in Appendix 1.

2.1.1 *Data tables for sediment laboratory ecotoxicity studies*

The ecotoxicity data are summarised in data tables. The following sections (2.2.2.1 to 2.2.2.18) discuss the parameters that are reported in the sediment toxicity data tables, examples of which are presented in Table 1 and 2. The aim is to fill the table as complete as possible. The parameters are treated in the same order as they appear in the default toxicity data table.

Separate tables are prepared for freshwater and marine species. Marine species are defined as species living and tested in sediment systems with salt or brackish water. The division between freshwater, brackish water and seawater on basis of salinity is given in ERL Report 03, section 2.1.1. The division in these categories is rather arbitrary and depends on the source used. For the division between freshwater and brackish or saltwater tests, the value of 0.5‰ is defined in the Water Framework Directive [4].

Table 1 Example of a chronic ecotoxicity data table for benthic organisms.

Legend to column headings	
Species properties	ad =adult
Sediment type	origin and sediment type according to US soil classification; art. = artificial
A	test sediment analysed for test substance Y(es)/N(o)
Purity	refers to purity of active substance or content of active substance in formulation; ag = analytical grade; tg = technical grade
pH, OM, clay	pH, organic matter and clay content, latter expressed as % on a dry weight basis
T	Temperature
Value standard sediment	result of test normalised to Dutch standard sediment (10% OM and 25% clay), see ERL rapport 09
Ri	reliability index according to [5]. Valid studies (Ri 2 or higher) are considered for EQS-derivation.

Species	Species properties	Sediment type / location	A	Test compound	Purity [%]	pH	OM [%]	clay [%]	T [°C]	Exp. time	Criterion	Endpoint	Value test sed. [mg/kg _{dwt}]	Value standard sed. [mg/kg _{dwt}]	Ri	Note	Ref.
Annelida																	
<i>Lumbriculus variegatus</i>	ad	natural sediment, Drontermeer, NL	Y	active	98%	6.2	12-14	16	20±1	28	EC50	reproduction	83	64	2	1,2,3	[a]
<i>Lumbriculus variegatus</i>	ad	natural sediment, Drontermeer, NL	Y	active	98%	6.2	12-14	16	20±1	28	EC10	reproduction	33	26	2	1,2,3	[a]
Insecta																	
<i>Chironomus riparius</i>	1 st instar, <24 h	sediment	Y	active	99.5	8.4	9.41		20	28	LC10	mortality	74	79	2	4	[b]
<i>Chironomus riparius</i>	2 d	artificial sediment with alpha-cellulose	Y	active		7.9±0.2	4.75	~30	23±2	10	EC10	mortality	179	377	4	5	[c]

Notes

- Solvent is methanol (<0.4 mg/L); lowest oxygen conc. in test 4.9 mg/L.
- Constant illumination: UV-A+B and visible light, spectrum 91% equal to natural sunlight; UV-A and UV-B intensities are 108 and 6.7 µW/cm²; total intensity approximately equal to 0.5 and 1 m depth in an eutrophic lake; 24 h pre-exposure to anthracene in dark; oxygen concentration 6.9 mg/L.
- Concentration based on actual concentrations; strong decrease in test concentration: 32% recovered after 96 h; initial concentration is 103% of nominal concentration; time weighted average concentration calculated.
- Photoperiod 16:8 h light:dark with an intensity of 75-80 µE/m².s produced by "cool white fluorescent" light; renewal on days 7 and 11; test performed in screw-capped erlenmeyers with about 1/5 headspace.
- Light regime: 16 h light and 8 h dark, at 1086 lux; results expressed as 57% of the water soluble fraction, solubility in test water is 34000 µg/L.

2.1.1.1 Species

All available toxicity data for a given compound are ordered by test organism. Species are grouped in taxonomic groups. A comprehensive list of taxonomic groups is shown in ERL Report 10. Latin names are used for both taxa and species names. Species names within a taxon are listed in alphabetical order.

Species are listed as follows:

Annelida

Tubifex tubifex
Lumbricus variegatus

Crustacea

Corophium volutator
Gammarus pulex
Hyalella azteca

Insecta

Chironomus riparius
etc.

2.1.1.2 Species properties

The most relevant properties of the test organism are mentioned in this column; e.g. age, size, weight, life stage or larval stage. Toxicity data for organisms with different age, size, life stage etc., are presented as individual entries (i.e. one entry in each row) in the data table.

2.1.1.3 Sediment type

In this column, list the sediment type: e.g. fine sandy, organic rich, muddy, etc. Artificial OECD sediment is designated with "OECD art." If percentages of sand, silt and clay are given, the sediment type can be derived using the soil texture triangle of the American Soil Classification System, see Appendix 2. Report sediment type as e.g.: sandy, clay, silt loam. The following websites can be used to check the United States Department of Agriculture (USDA) soil type when the particle size distribution is given:

https://www.nrcs.usda.gov/wps/portal/nrcs/detail/soils/survey/?cid=nrcs142p2_054167

The following particle size limits apply to the USDA system. Percentage sand: >50 µm, percentage silt: 2-50 µm, percentage clay: <2 µm.

2.1.1.4 Analysed

This column reports whether the test compound is analysed during the experiment. Y (Yes) is entered in this column, when the compound has been analysed. When no analysis for the test compound is performed, N (No) is entered in this column.

In some cases the test compound is analysed, but the test results (L(E)C50, EC10, NOEC) are not calculated from the actual concentrations. If the test result is based on nominal concentrations, this is mentioned in a footnote to this study: 'Test result based on nominal concentrations'. When this is valid because measured concentrations are close to initial concentrations (drop in concentration

< 20% over exposure period), 'Test result based on nominal concentrations, measured concentrations were > 80% of nominal' is noted.

If the test compound is analysed but not used for the test results and there is considerable change in the concentration during the test (> 20% loss of test compound), the test result is recalculated using actual concentrations. In such case, in a footnote to this study should be mentioned that tests results were recalculated to actual concentrations.

2.1.1.5 Test compound

This column can be deleted when the compound under consideration has only one structural molecular configuration.

If the tested compound is a metal, the tested metal salt should be reported here.

If the tested compound is a stereoisomer¹, consists of a mixture of isomers, etc., the name of the tested molecule(s) should be reported here. For some stereoisomers it might be preferred to derive individual risk limits. The stereoisomers dieldrin and endrin are an example of such a case.

If the tested compound is a structural isomer, the individual compounds, in general, have different physicochemical and toxicological properties and are, in principle, regarded as different compounds. Examples are ethanol and dimethyl ether or anthracene and phenanthrene. In these cases, each individual isomer will generally be the subject of an ERL derivation. As a rule of thumb, isomers can be regarded as individual compounds when they have different CAS registry numbers. However, for more complex molecules² consultation with an expert or the client (e.g. the Ministry of IenM) might be needed. The use of a formulated product (e.g. biocides, pesticides) should be reported here.

2.1.1.6 Purity

Unit: %

The purity of the test compound expressed as percentage is reported in this column. Alternatively, the following abbreviations may be entered for the designation of chemical purity.

ag	analytical grade
lg	laboratory grade
pa	pro analyse
rg	reagent grade
tg	technical grade

Here, the first four have a relatively high purity, while technical grade is in general somewhat less pure. When the purity of the test compound is

¹ Stereoisomers: geometric isomers (*cis*- and *trans*-isomers or E- and Z-isomers), optical isomers (+ and – isomers or R- and S-isomers) and conformational isomers (e.g. chair and boat structures in cyclohexane ring structures)

² Isomers might be distinguished by CAS nrs., but still be treated (generally) as 'one compound', e.g. 'nonylphenol'. The nonyl chain can have many conformations and different CAS nrs. exist. However, the generic name 'nonylphenol' is mostly used for all para-nonylphenol isomers.

expressed only by an abbreviation, this abbreviation is reported. However, a purity expressed as percentage is preferred.

- 2.1.1.7 pH
Report the pH or the range of pH values, of the test sediment in this column. In sediment pH determinations the use of 0.01 M CaCl₂ or KCl solutions is common. If the method of pH determination is reported, this should be added in a note to the table. pH values determined in pure water (report as pH H₂O) can not be compared directly to values determined with e.g. 0.01 M CaCl₂.
For compounds for which toxicity is pH dependent, consider adding an extra column in order to separate pH H₂O from pH 0.01 M CaCl₂.
- 2.1.1.8 Organic matter (o.m.)
Unit: %
In this column the weight percentage of organic matter in the sediment is reported. When in a study the percentage organic carbon is given, recalculation to percentage organic matter o.m. is necessary according to Eq. 1:
- $$\% \text{ o.m.} = 1.7 \times \% \text{ o.c.} \quad (1)$$
- This is the general conversion between organic matter and organic carbon used throughout the whole process of deriving risk limits. The value of 1.7 is derived from guidance in the REACH framework: standard soil solids in REACH/EUSES have a weight fraction of 0.02 kg_{organic carbon}/kg_{solid} (F_{oc_{soil}}) and 0.034 kg_{organic matter}/kg_{solid} (F_{om_{soil}}; REACH R16, Table R.16-9 [6]).
- 2.1.1.9 Clay
Unit: %
In this column the weight percentage of clay in sediment is reported. The % clay (lutum) is used to convert test results for metals to standard sediment. Further, this gives valuable information on the type of sediment used.
- 2.1.1.10 Temperature
Unit: °C
In this column the temperature at which the test is performed should be reported, preferably a measured temperature. If a temperature range is given, the range is reported.
- 2.1.1.11 Exposure time
The duration of exposure to the toxicant in the toxicity experiment is expressed in this column. The abbreviations listed below in Table 2 can be used. A rule of thumb is to stick to the most common expression of test duration in case of standardised tests (e.g. OECD or ISO tests) where this is possible.

Table 2 Abbreviations and applied ranges for exposure times.

Test duration in	Abbreviation	Duration
Minutes	Min	0-60 minutes
Hours	H	1-120 hours
Days	D	5-56 days
Weeks	W	1-4 weeks
Months	Mo	1-12 months
Years	Y	≥ 1 years

2.1.1.12 Criterion

Follow the extensive information on criteria given in ERL Report 02, section 5.2.

2.1.1.13 Test endpoint

See ERL Report 02, section 5.2.

2.1.1.14 Result test sediment

Unit: mg/kg_{dw}, µg/kg_{dw}

This column shows the result as obtained in the experiment, expressed in weight units per kg dry weight of the test sediment (i.e. not recalculated to standard sediment). The mass unit in which the amount of substance is expressed (mg, µg, etc.) is optional. For reasons of comparison and to avoid errors, the same unit is used throughout all terrestrial data tables.

In general, values are expressed in two or three digits. At most, four significant digits are reported. However, further calculation with these data may be necessary: averaging, dividing the values by an assessment factor, use of the results in SSDs, etc. Further calculation is always performed with the original (not rounded) values.

Toxicity data of metal compounds are always expressed in quantities of the element, not as the salt. For example, a test performed with CoSO₄·7H₂O is expressed as Co²⁺. Test results are recalculated if necessary. A similar approach is followed for all charged substances with a non-toxic counter ion.

2.1.1.15 Result standard sediment

Unit: mg/kg_{dw}, µg/kg_{dw}

This column shows the result recalculated into weight units per kg of standard sediment (dry weight). The mass unit in which the amount of substance is expressed (mg, µg, etc.) is optional. For reasons of comparison and to avoid errors, the same unit is used throughout all terrestrial toxicity data tables.

The bioavailability of compounds in sediment is influenced by properties like organic matter content, clay content, pH, moisture content etc. This hampers direct comparison of toxicity results obtained for the same substance in different sediments. In order to make results from toxicity tests conducted in different sediments more comparable, results should be normalised using relationships that describe the bioavailability of the compound in sediment. Results are converted to Dutch standard sediment, which is defined as having an organic matter content of 10%

(w/w, or 5.88% organic carbon) and a lutum (clay) content of 25%. See also section 2.1.1.8. It should be noted that the lutum content was used historically for normalisation of metal concentrations, but this is no longer current practice (see below).

Organic compounds

For non-ionic organic compounds, it is assumed that bioavailability is determined by organic matter content only. In WFD and REACH guidance (R16), it is advised to recalculate data from toxicity experiments to the standard sediment with REACH characteristics. Within the Dutch national framework, this recalculation of results from individual tests (LC50s, EC50s, EC10s, NOECs, etc.) to Dutch standard sediment is performed according to Eq. 2, with the organic matter content of Dutch standard sediment (see ERL Report 09). E.g. for an EC10:

$$EC10_{\text{Dutch standard sediment}} = EC10_{\text{experimental sediment}} \times \frac{f_{\text{om, Dutch standard sediment}}}{f_{\text{om, experimental sediment}}} \quad (2)$$

Note that the REACH guidance R10 [7] states the following with respect to normalisation to standard soil:

'It should be noted that this recommended normalisation is only appropriate when it can be assumed that the binding behaviour of a non-ionic organic substance in question is predominantly driven by its $\log K_{ow}$, and that organisms are exposed predominantly via pore water.' This also applies to normalisation to standard sediment. However, no guidance is given for those compounds to which the above statement does not apply, e.g. ionisable organic compounds.

Metals

Apart from mode of action, toxicity of metals to sediment dwellers is determined for a large part by bioavailability. However, a general method for bioavailability correction for metals cannot be given. It is proposed, in general, not to normalise toxicity data for metals for the reasons mentioned in Van Vlaardingen and Verbruggen [8], if no improved bioavailability corrections are available in comparison with the older system of 'reference lines'. For ERL derivation, all reliable toxicity results with metals for benthic organisms are grouped in the appropriate data table without normalisation.

However, if a reliable bioavailability relationship is available for a given metal, this method may be applied, but justification of its application needs to be investigated on a case by case basis.

2.1.1.16 Reliability

This column contains a number (1, 2, 3 or 4), indicating the quality of the study summarised according to ERL Report 02, section 2.2.

2.1.1.17 Notes

This column contains references to footnotes that are listed below the toxicity data tables. Numbers are used to refer to footnotes.

2.1.1.18 Reference

The reference to the study from which data are tabulated. All cited references are listed in a reference list. If references are generated using bibliographic software (e.g. Endnote, Procite), it is most convenient to list all references, i.e. those used in the report text as well as those in all data tables, into one single reference list.

2.2 Selection and aggregation of sediment laboratory toxicity data

Where multiple data are available for the same species/endpoint that are obtained under comparable test conditions, individual toxicity data may be aggregated using the same principles as those in Chapter R.10 of the REACH Guidance [7]. This aspect is discussed in general terms in ERL Report 02, Chapter 5.3 and is supplemented here with specific guidance for sediment data. This process is performed separately with toxicity data for freshwater species and marine species (see also 2.3).

For non-standard test species, preference is given to endpoints that are applicable to related standard benthic test species, such as emergence, growth, survival or biomass. If for a species only alternative endpoints are available, these may be used, although this has to be judged on a case-by-case basis.

If endpoints are available for different durations, preference is given to the endpoints from tests that followed the minimum test duration as specified in the guideline, e.g. at least 20-28 days for *C. riparius*.

If there is a clear relationship between test results and abiotic conditions, results are selected that refer to conditions relevant for Dutch surface waters. Any deselection of data should be motivated.

The aggregated data should be presented in a new table, according to the format shown below. It should be indicated whether the presented data were normalised to organic matter content or not. The selected acute and chronic values are presented separately for each species, and a footnote is added to explain how the value is derived from the summary data tables.

Table 3 Example of an aggregated data table with selected chronic ecotoxicity data for benthic organisms.

Taxon	Species	NOEC/EC10 [mg/kg _{standard sediment}]
Annelida	<i>Limnodrilus hoffmeisteri</i>	168 ^a
Annelida	<i>Lumbriculus variegatus</i>	26
Crustacea	<i>Hyalella azteca</i>	167 ^b
Crustacea	<i>Rhepoxynius abronius</i>	122 ^c
Crustacea	<i>Schizopera knabeni</i>	7.8 ^d
Insecta	<i>Chironomus riparius</i>	91 ^e

a: Most sensitive parameter (sediment egestion).

b: Geometric mean of 339, 113, and 122 mg kg_{dw}⁻¹, standard sediment, recalculated to standard sediment with 10% organic matter, for the most sensitive parameter (length).

c: Geometric mean of 125 and 120 mg kg_{dw}⁻¹, standard sediment, recalculated to standard sediment with 10% organic matter.

d: Most sensitive parameter (reproduction).

e: Geometric mean of 84, 114, and 79 mg kg_{dw}⁻¹, standard sediment, recalculated to standard sediment with 10% organic matter for the parameter emergence/mortality in a 28-d study.

2.3 Combining freshwater and marine data sets for ERL derivation

After compiling the aggregated data table, it should be investigated whether toxicity data for freshwater and for marine species may be combined into one (aggregated) data table. The same procedure as for aquatic ecotoxicity tests is used for sediment. This means that marine and freshwater sediment toxicity data may be pooled unless it can be documented that differences in toxicity exists between freshwater and saltwater sediment [1].

If fresh- and saltwater data are pooled, the standards for both freshwater and marine water are derived using the same, combined dataset, but with different assessment factor schemes for the AF- and SSD-approach. By default, an additional assessment factor of 10 is applied for the marine assessment as compared to freshwater assessment. This additional assessment factor can be decreased in a stepwise manner when toxicity data for specific marine species or taxa are available. An additional factor of 5 is used if the dataset contains one typically marine species. The WFD-guidance specifies how this should be interpreted. If two or more specifically marine species are present, the freshwater and marine assessment schemes are similar. Note that this does only apply to the AF- and SSD-approach, and not if mesocosm data are used (see 2.4.2). When the freshwater and marine data cannot be pooled for QS derivation, the separate aggregated data sets are used for QS-derivation.

➔ Location in WFD guidance: Section 3.2.3, p. 35.

➔ Location in WFD guidance: Section 3.3.2.1, p. 46.

➔ Location in WFD guidance: Appendix 1, section A1.3.7.1, p. 151.

2.4 Use of micro- and mesocosm data

2.4.1 General information

The evaluation of aquatic micro- and mesocosms is discussed in ERL Report 03 section 2.6. These test systems usually include a sediment layer and associated organisms. Most studies include observations on aquatic insects and crustaceans that use the sediment layer as a food source and/or as a substrate for part of their life cycle, but in general focus on the water living life-stages. In case exposure via sediment is of particular interest, e.g. because partitioning into sediment is an issue for risk assessment, additional sediment inhabiting species may be included. Since exposure is almost always performed via the water phase, the use of these studies for sediment risk assessment depends on whether the exposure concentrations in sediment are adequately measured. In addition, these studies may provide information that the proposed EQS for water is also protective for sediment.

In the WFD-guidance, reference is made to the use of empirical approaches that link biological responses of benthos to chemical contamination in the field. They are based primarily on field data for which sediment chemistry is linked to biological effects data using statistical approaches. If such data exist, thresholds may be calculated referring to the field concentration at which biological effects are unlikely to occur or are associated with a significant biological impact. As for other compartments, a decision on the use of field data will always be made on a case-by-case basis and heavily relies on expert judgement. No further guidance is given here.

2.4.2 Treatment of freshwater and saltwater data

Little information is present on the representativeness of freshwater mesocosm studies for marine risk assessments. Differences in physico-chemical characteristics, water exchange rate and sensitive taxa may contribute to differences in ecological response. It is therefore advised not to use freshwater mesocosm studies as a basis for a marine risk assessment, and vice versa, unless there is scientific evidence that the ecotoxicological response in both types of systems is comparable.

3 Derivation of risk limits

3.1 Ecotoxicity data used for ERL sediment derivation

Starting point for the derivation of ERLs for sediment are the aggregated ecotoxicity data for sediment organisms, described in section 2.2 containing either pooled or not-pooled freshwater and marine toxicity data (section 2.3). Where applicable, toxicity data normalised to the Dutch standard organic carbon content (5.88% o.c.) are used and the ERL is expressed on the basis of Dutch standard sediment.

3.2 MPC_{sed} – Maximum Permissible Concentration for sediment

3.2.1 MPC_{fw sed, eco} – ecotoxicity for freshwater sediment organisms

→ The MPC_{sed, eco, fw} is derived following WFD EQS guidance, section 5.2.1, page 94.

The assessment factor scheme for derivation of the MPC_{sed, eco, fw} is presented below (Table 4). According to the WFD- and REACH guidance [1,7], if only one or more endpoints from short-term tests with sediment-dwelling organisms are available, an assessment factor of 1000 is applied to the lowest reliable value. The REACH-guidance states that it is not necessary to have three acute sediment tests to apply an assessment factor of 1000, this in contrast to the principle adopted for the aquatic compartment [7]. If only short-term tests are available, the MPC_{sed, eco, fw} should also be derived on the basis of the QS_{fw, eco} using equilibrium partitioning. See ERL Report 03 for the derivation of QS_{fw, eco}. Information on the use of statistical extrapolation by means of species sensitivity distributions (SSDs) is not given in the REACH-guidance. The WFD-guidance notes that in principle, SSDs can be applied to sediment toxicity data in a similar way as for aquatic organisms. It is noted that in practice, the minimum data requirements for an SSD will rarely be met for sediment, even for well-studied compounds like e.g. copper [9].

Table 4 Assessment factors used to derive the MPC_{sed, eco, fw}.

Available data	Assessment factor
Only short-term LC50-values	1000 ^a
At least one long-term NOEC/EC10-value	100
Two long-term NOEC/EC10-values for species representing different living and feeding conditions	50
Three long-term NOEC/EC10-values for species representing different living and feeding conditions	10
Species sensitivity distribution (SSD) method (≥ 10 NOEC/EC10-values)	5-1 (to be fully justified case by case)
Field data or model ecosystems	Reviewed on a case by case basis

a: if only short-term tests are available, the MPC_{sed, eco, fw} is also derived from the QS_{fw, eco} using EqP.

3.2.2 $MPC_{sw\ sed, eco}$ – ecotoxicity for saltwater sediment organisms

→ The $MPC_{sed, eco, sw}$ is derived following WFD EQS guidance, section 5.2.4, page 105.

The derivation of the $MPC_{sed, eco, sw}$ basically follows the same approach as described for freshwater sediments, taking into account additional assessment factors in a similar way as is done for the $QS_{sw, eco}$ (see ERL Report 03, section 2.3) and WFD guidance Section 3.3.2.1 [1]. The assessment factor scheme for derivation of the $MPC_{sw\ sed, eco}$ is presented below (Table 5).

Table 5 Assessment factors used to derive the $MPC_{sed, eco, sw}$.

Available data	Assessment factor
One acute freshwater or marine LC50-value	10000 ^a
Two acute LC50-values including a minimum of one marine test with an organism of a sensitive taxon	1000a
One long-term NOEC/EC10 from a freshwater sediment test	1000
Two long-term NOEC/EC10-values from freshwater tests for species representing different living and feeding conditions	500
Two NOEC/EC10-values from one long-term freshwater and one saltwater test representing different living and feeding conditions	100
Three long-term NOEC/EC10-values for species representing different living and feeding conditions	50
Three long-term NOEC/EC10-values for species representing different living and feeding conditions including a minimum of two tests with marine species	10

a: if only short-term tests are available, the $MPC_{sed, eco, sw}$ is also derived from the $QS_{sw, eco}$ using EqP.

The WFD-guidance further states that the general principles of notes c and d to the assessment scheme for marine aquatic organisms shall also apply to sediment data (see Table 3.3 in the WFD-guidance). Notes c and d are quite extensive, but basically deal with situations where the assessment factors of 500 and 100 may be lowered because additional information is present indicating that additional long-term data will not lead to a lower endpoint. This may be the case when acute tests on saltwater species indicate that those species are not more sensitive than related freshwater species, and it is unlikely that chronic tests with these species will result in lower NOEC-values than already available. In general, where there is convincing evidence that the sensitivity of marine organisms is adequately covered by that available from freshwater species, the assessment factors used for freshwater sediment data may be applied. Such evidence may include data from long-term testing of freshwater and marine aquatic organisms, and must include data on specific marine taxa.

As for freshwater sediment, EqP should be applied when the experimental data originate from short-term ecotoxicity tests only. Apart

from the situations mentioned in the assessment factor scheme in Table 2, other combinations of data are possible. Therefore, the additional guidance as mentioned in [8] also applies:

- an assessment factor of 500 is applied if only one long-term marine but no freshwater test is available,
- if two long-term tests with marine species representing different living and feeding conditions are available, but there are no freshwater tests, an assessment factor of 100 is applied,
- an assessment factor of 1000 might only be applied to a short-term toxicity test if the lowest value available is for a marine species.

In addition, if the $MPC_{fw\ sed, eco}$ is derived using an SSD, the following applies to the derivation of the $MPC_{sw\ sed, eco}$ [8]:

$MPC_{sed, eco, sw} = MPC_{sed, eco, fw}$ if at least two marine species are represented,

$MPC_{sed, eco, sw} = MPC_{sed, eco, fw} / 2$ if one marine species is represented,

$MPC_{sed, eco, sw} = MPC_{sed, eco, fw} / 5$ if no marine species are represented.

3.2.3

MPC_{sed, secpois} – Maximum Permissible Concentration based on secondary poisoning

In some cases, direct ecotoxicity to sediment dwelling organisms is not the key driver of the ERL-derivation. For some hydrophobic organic substances such as polychlorobiphenyls (PCBs), polychlorodibenzo-dioxins (PCDDs) or furans (PCDFs), predatory fish or mammals may be the primary concern for setting sediment risk limits. While according to the WFD-guidance biota standards are most appropriate in this case, sediment ERLs may be useful from the viewpoint of monitoring and/or management options. If that is the case, the $MPC_{sed, secpois}$ may be derived from a biota standard, using Biota to Sediment Accumulation Factors (BSAFs) to back-calculate the biota standard into equivalent concentrations in sediment. Since the biota standard is likely to be different between freshwater and saltwater due to the longer food chain to be protected in the latter compartment, different MPC values result:

$$MPC_{sed, secpois, fw} = \frac{QS_{biota, secpois, fw}}{BSAF} \quad (3)$$

$$MPC_{sed, secpois, sw} = \frac{QS_{biota, secpois, sw}}{BSAF} \quad (4)$$

$QS_{biota, secpois, fw}$ and $QS_{biota, secpois, sw}$ are derived according to ERL Report 03, section 3.5.1. The trophic level of the species used to derive a specific BSAF value determines the type of predator that is protected. E.g. using a BSAF studies on benthic Annelids (oligochaetes) will result in an MPC protecting birds feeding on Annelids. The use of BSAF values determined for species of a higher trophic level than Annelids, e.g. fish, will lead to a standard that also protects predators that consume fish at that trophic level. Food-web modelling studies may also yield information to derive $MPC_{sed, secpois}$.

3.2.4

Selection of the MPC_{fw sed} and MPC_{sw sed}

The lowest of the routes direct ecotoxicity and secondary poisoning is selected as the MPC_{sed}. However, in most cases only the former will be derived, and the MPC_{sed, eco, fw} and MPC_{sed, eco, sw} will be used as MPC_{sed, fw} and MPC_{sed, sw}, respectively.

3.3

NC_{sed} – Negligible Concentration for sediment

The NC_{sed} is derived by dividing the MPC_{sed} by a factor of 100. When different MPCs are derived for the freshwater and saltwater compartment, separate NCs are derived accordingly, termed NC_{sed, fw} and NC_{sed, sw}.

3.4

SRC_{sed} – Serious Risk Concentration for sediment

See ERL Report 01, section 4.6 for general guidance on the SRC. The SRC_{sed, eco} is the geometric mean of all available chronic toxicity data. If not enough chronic toxicity data are available, the SRC_{sed, eco} is calculated as the geometric mean of all (aggregated) acute data, divided by an assessment factor of 10. The two values are compared and the lowest value is selected as SRC_{sed, eco}.

3.4.1

SRC_{sed, eco} – ecotoxicity for freshwater and saltwater sediment organisms

For derivation of the SRC_{sed, eco}, the same aggregated data tables with acute and chronic sediment ecotoxicity data are used as for derivation of the MPC-values, using the assessment factor scheme in Table 6. In case a pooled data set for freshwater and marine toxicity data is used for QS derivation (see section 2.3), the pooled (aggregated) data set is also used for SRC derivation. In this case, one SRC_{sed, eco} is derived that is valid for both the freshwater and the marine compartment. No additional assessment factor is used for derivation of the SRC_{sed, eco, sw}. When the freshwater and marine data have not been pooled for QS derivation, the assessment factor scheme in Table 6 is applied to the separate freshwater and marine aggregated data sets to derive an SRC_{sed, eco, fw} and SRC_{sed, eco, sw}. The following scheme applies:

Table 6 Assessment factors used to derive the SRC_{sed, eco}.

Available data	Additional criteria	SRC _{sed, eco} based on	Assessment factor
only LC50 value(s) and no NOECs or EC10s	comparison with EqP ^a	geometric mean of LC50s	10
1 NOEC value ^b	comparison with EqP and acute toxicity data ^c	NOEC value	1
≥ 2 NOEC values ^{b,d}	–	geometric mean of NOEC values	1

a: If only acute data are available, the SRC_{sed, eco} is also calculated on the basis of equilibrium partitioning. The lowest of both values is selected as SRC_{sed, eco}.

b: This may also be (an) EC10 value(s).

c: If chronic toxicity data are available for only one trophic level, the SRC_{sed, eco} is also calculated from the acute toxicity data, if available, and on the basis of equilibrium partitioning. The lowest of these values is selected as SRC_{sed, eco}.

d: When chronic data are available, these data prevail and acute data are no longer used in SRC_{sed, eco} derivation if these NOECs are from different trophic levels.

The following explanation is taken over from [8]:

- In principle, an acute-to-chronic ratio (ACR) of 10 is applied to the acute toxicity data to compare acute LC50s with chronic NOECs (or EC10s). In the future, one may deviate from this factor of 10 if more information on the ACR for the specific compound or endpoint can be obtained [10].
- For the sediment compartment, comparison between chronic data and acute data is not performed when chronic data are available for two species, each of which should represent a different trophic level, e.g. molluscs and crustaceans.
- For sediment, the SRC_{eco} derived from a NOEC or EC10 for only one trophic level is also compared with a value derived by EqP (using the appropriate SRC for water, $SRC_{eco, fw}$ or $SRC_{eco, sw}$). This is done since in the derivation of the SRC_{eco} no assessment factor is applied. This differs from the derivation of MPC_{sed} , where a comparison with EqP is no longer made when chronic toxicity data are available, even if this is only one NOEC or EC10.
- When the SRC_{eco} is to be reported with confidence limits, the computer program ETX 2.0 [11] is used to calculate the median HC50 and its 90% confidence interval. The HC50 is equal to the geometric mean of non transformed toxicity data.
The SRC_{eco} is always taken as the geometric mean of (either acute or chronic) toxicity data, irrespective of whether these data are log-normally distributed or not. If the data from which the SRC_{eco} is calculated do not fit a normal distribution, it suffices to note this briefly in the report section where the SRC_{eco} derivation is presented.
- Derivation of the SRC for metals will be further elaborated on in the ERL report for metals that is under preparation.

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List of abbreviations

ACR	acute to chronic ratio
ad	adult
AF	assessment factor
ag	analytical grade
art	artificial
BSAF	biota to sediment accumulation factor
CAS	Chemical Abstract Service
d	days
EC	European Commission
ECHA	European Chemicals Agency
EC50	concentration at which 50% effect is observed
ECx	concentration at which x% effect is observed
EqP	equilibrium partitioning
EQS	(Environmental) Quality Standard
ER	Ernstig Risiconiveau
ERL	Environmental Risk Limit
EUSES	European Uniform System for the Evaluation of Substances
HC50	Hazardous Concentration for 50% of the species
h	hours
IenM	Dutch Ministry of Infrastructure and the Environment
ISO	International Organisation for Standardisation
K _{oc}	Organic carbon partitioning coefficient
K _{ow}	Octanol/water partitioning coefficient
lg	laboratory grade
LCx	Lethal Concentration for x% of the tested organisms
MPC	Maximum Permissible Concentration
min	minutes
mo	months
MTR	Maximum Toelaatbaar Risiconiveau
NC	Negligible Concentration
NOEC	no observed effect concentration
o.c.	organic carbon
OECD	Organisation for Economic Cooperation and Development
o.m. or OM	organic matter
pa	pro analyse
PCB	polychlorinated biphenyls
PCDD	polychlorodibenzo-dioxins
PCDF	polychlorodibenzo-furans
REACH	Registration, Evaluation and Authorisation of Chemicals
Ri	reliability index
SRA	Serious Risk Addition
SRC	Serious Risk Concentration
SSD	species sensitivity distribution
tg	technical grade
USDA	United States Department of Agriculture
UV	ultra violet
VR	Verwaarloosbaar Risiconiveau (negligible concentration; NC)
VROM	former Ministry of Spatial Planning, Housing and Environmental Protection, now Ministry of Infrastructure and the Environment

w	weeks
WFD	Water Framework Directive
y	years

Appendix 1. Established guidelines for sediment ecotoxicity tests

→ Location in WFD guidance (sediment): Appendix 1, section A1.3.4, p. 146-148.

Insecta

OECD 218. Sediment-Water Chironomid Toxicity Test Using Spiked Sediment. This is a chronic toxicity study with a chironomid species. The measured endpoints are the total number of adults emerged and the time to emergence. Additionally, larval survival and growth after a ten-day period are recommended endpoints.

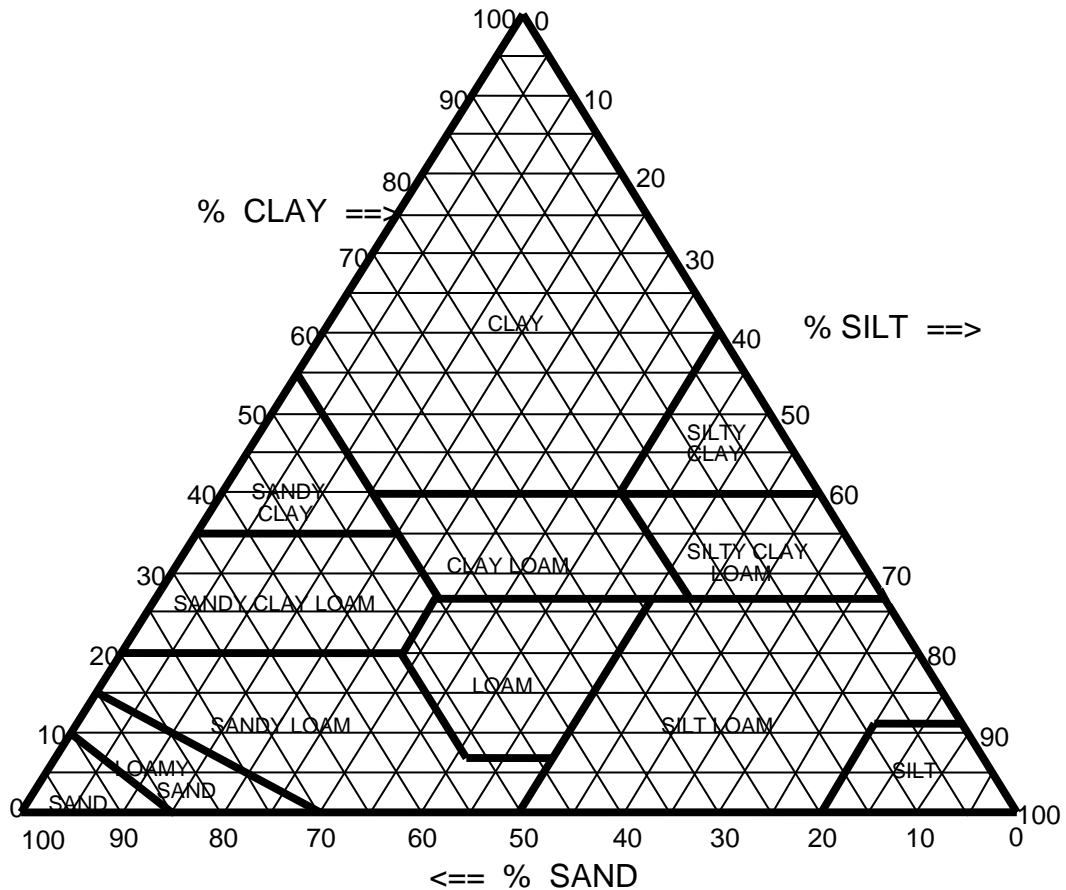
OECD 219. Sediment-Water Chironomid Toxicity Test Using Spiked Water. Endpoints from this test can only be used for sediment ERLs if it is possible to express the endpoint on the basis of measured concentrations in sediment.

OECD 233. Sediment-Water Chironomid Life-Cycle Toxicity Test. This test is an extension of OECD 218 and 219 (see above) and covers the early part of the 2nd generation. Measured endpoints are the total number of adults emerged (for both 1st and 2nd generations), development rate (for both 1st and 2nd generations), sex ratio of fully emerged and alive adults (for both 1st and 2nd generations), number of egg ropes per female (1st generation only) and fertility of the egg ropes (1st generation only). This guideline requires determination of sediment, water and pore water concentrations. If effects are or can be expressed on the basis of concentrations in the sediment phase over the duration of the test, the results can be used as a basis for ERLs.

Annelida

OECD 225. Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment. Test to assess the effects of prolonged exposure to sediment-associated chemicals on the reproduction and the biomass of the endobenthic oligochaete *Lumbriculus variegatus* (Müller).

Appendix 2. Soil classification system



Textural classes of mineral soils according to the US soil classification.

Particle size classes:

sand > 50 μm

silt $\geq 2 - \leq 50 \mu\text{m}$

clay < 2 μm

The interactive soil texture triangle can also be used at the following

URL:

http://www.pedosphere.com/resources/bulkdensity/triangle_us.cfm?190,215

or use:

http://www.pedosphere.com/resources/bulkdensity/worktable_us.cfm

Particle size distribution of test soils reported using the German system may also be encountered. The German system uses the size classes:

sand > 63 μm ,

silt $\geq 2 - \leq 63 \mu\text{m}$ and clay < 2 μm .

The following rule may be used to translate a particle size distribution according to the German system to the USDA system. It is based on work presented by Nemes et al. [12] for Dutch soils as explained in Van Vlaardingen and Smit [13].

In order to extrapolate particle size estimations performed using the German system to the USDA system, add 5% to the sand fraction determined using the German system and subtract 5% from the silt fraction determined using the German system.

Example.

*Particle size distribution
using German system:*

sand (>63 µm):	65%
silt (≥ 2 µm and ≤ 63 µm):	25%
clay (<2 µm):	10%

*Becomes using particle size limits of
the USDA system*

sand (>50 µm):	70%
silt (≥ 2 µm and ≤ 50 µm):	20%
clay (<2 µm):	10%