Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; aquatic organisms sediment organisms

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Board for the Authorisation of plant protection products and biocides

Chapter 6 Ecotoxicology; aquatic organisms

Category: biocides

II SEDIMENT ORGANISMS

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to sediment organisms of a biocide and the active substance, and which evaluation methodologies are applied for the EU framework (§1 - §1.5).

1. EU FRAMEWORK

The procedure for inclusion of active substances in Annex I to Biocides Directive 98/8/EC [1] is described under EU framework (§1 - §1.5) where only the procedure laid down in the EU is described. The NL procedure for evaluation of a substance, described in the NL part §2 - §2.5, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risk to sediment organisms.

This chapter has a relationship with Chapter 5, Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plants (STPs), where estimation or measurement of the concentrations in sediment are described.

Described are the guidelines for assessment of the aspect sediment organisms are described in the Technical Guidance Document on Risk Assessment [3] and the TNsG on Data Requirements [2]. including addenda and additional guidance agreed at Technical Meetings, endorsed at Competent Authority meetings.

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types in emission scenario documents (see the ex-ECB web site [4]). Objective of these emission scenarios is the harmonisation of the annex I inclusion and authorisation process for biocidal products. They are briefly described in Appendix A to the environmental section.

A decision tree with corresponding explanatory notes is included in Appendix 1.
This decision tree summarises the evaluation system for sediment organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The National further provisions can also be used for inclusion of an active substance in Annex I to 98/8/EG.

1.2. Data requirements

The data requirements laid down in the TNsG on data requirements [2] corresponding with the Biocides Directive (98/8/EC) are listed below; the data requirements for the active substance and the product for evaluation of the risk to sediment organisms. This is the verbatim text of the Directive (grey frames). Numbering of the studies corresponds with the numbering of the TNsG on data requirements. Numbering in square brackets follows the numbering of the Biocides Directive. Where relevant, the result of the study has been added.

The data requirements are divided into standard data requirements (core data) that apply for each product type.
In addition, product-type-specific data should be submitted for different product types. The different product types are elaborated in the relevant chapters. Additional data must be submitted in case a higher tier evaluation must be carried out.

The TNsG on data requirements stipulates a number of principles, that reason the requirement of a data set including the data quality:

- The ability of the active substance or its degradation product(s) to damage the function and structure of biotic systems is to be clarified with a selection of ecotoxicity tests. Effects in the ecologically functional groups of producers, consumers and decomposers in relevant media (water, soil, and air) are addressed in these tests.

- There is a need to report all potentially adverse effects found during routine eco-toxicological investigations and to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported.

- In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits. Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

- In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.

- As required by EC test methods, concentrations of the test substance should be measured at least at the beginning as well as at the end of the test. Normally, however, it will be necessary to monitor the concentrations more frequently. The LC50's, EC50's and NOEC’s should be calculated based on the measured concentrations. However, where the measured concentrations are close to the nominal concentrations (i.e. > 80% of nominal), it is acceptable to calculate the LC50's, EC50's and NOEC’s based on nominal concentrations of the tested substance. In other cases, the geometric average measured concentrations should be used.

It should be noted that legislation is not clear as regards the definition of relevant metabolites. It is neither clear when these data on relevant metabolites must be submitted and how these should be evaluated.
This lacuna is for the NL framework elaborated in the NL part §2.2 and appendix C. As long as this lacuna has not been elaborated in EU framework, the description in the NL part §2.2 is followed.

The TNsG on data requirements [2] reads as follows about the submission of saltwater toxicity data:

The species tested should be relevant to the environments likely to be affected due to the manner of use or disposal of the substance. Seawater species should be used if the substance is likely to influence directly or indirectly only estuarine or marine

environments. If a marine or brackish water environment is affected but it is not the only aquatic target environment, then a toxicity test in a marine or in a brackish water species, respectively is required in addition to the fresh water tests (see Part C of Chapter 2).

Data requirements for the active substance

Standard data requirements
There are no standard data requirements for sediment organisms.

Product-type-specific and additional data

Toxicity research sediment organisms
Product-type-specific and additional data for the active substance are required for a number of product types. Toxicity data must also be submitted if the risk to soil sediment organisms cannot be ruled out on the basis of log Kow and the equilibrium partitioning method.

The study as described in the TNsG on data requirements [2] is summarised below.

7.4.3.5.1 Effects on sediment dwelling organisms

- A test in sediment dwelling organisms is required if due to the partition to and persistence of the active substance in aquatic sediments the exposure of sediment dwelling organisms is likely and if effects on sediment dwelling invertebrates are likely. Testing might be required for certain Product types (cf. Part C of Chapter 2) or if the risk assessment for sediment based on the equilibrium partition method indicates a possible risk to the benthic compartment.
- The risk assessment strategy will indicate whether one or several tests are necessary cf. EC (1996)
- The selection of test species can be made on the basis of their habitat and feeding strategy, to reflect different routes of exposure among sediment organisms.
  In this context one could make a distinction between epibenthic deposit feeders, (*Chironomids*) and endobenthic sediment ingesters (*Oligochaetes*).
  To make a distinction between sediments of different composition rather than different species, it is also recognised that the variability of sediment could be as relevant for the outcome of the test as species sensitivity.
- Organisms should be exposed to spiked sediment. The presence of spiked sediment is essential because the substances for which testing is required are very hydrophobic substances or substances that bind covalently to sediment. Long-term tests should be performed and one long-term NOEC should be sufficient at the first stage. The NOEC will be based on the measured bulk sediment concentration. If further refinement of the PNEC would be necessary, test species with different habitat and feeding strategy should be preferred to reflect the possible different ways of exposure.
- The following recommendations can be made with respect to the test species.
  The recommended species are complementary to each other with respect to feeding strategy and habitat.

1. - Long Term Chironomid Toxicity Test Using Spiked Sediment

- Two draft guidelines are under development within the OECD: (1) Chironomid Toxicity Test Using Spiked Sediment and (2) Chironomid Toxicity Test Using Spiked Water. Only the test using spiked sediment is considered appropriate for the purpose of testing here. This test should be considered first, when further testing is required.

2. - Long Term Oligochaete Test Using Spiked Sediment

- If further testing is needed, preference should be given to an endobenthic sediment ingester to reflect the different habitat and feeding strategy. Oligochaetes (*Tubifex or Lumbriculus*) would be suitable candidates. Standardised tests have been described for these species in the international literature (E.g. ASTM method E 1383).

3. - Long Term Test Using Spiked Sediment and *Gammarus* or *Hyalella*

- Finally a test with a third species could be considered to lower the assessment factor. Suitable species would be *Gammarus* or *Hyalella.* These are again epibenthic deposit feeders, but the difference with *Chironomus* is that they spent their whole life cycle on the sediment. Also for these organisms standardised tests have been described (e.g. ASTM E 1383). Instead of testing of a third species, testing with a second sediment could be considered.

Result:
→ NOEC sediment organisms
→ EC_{10} sediment organisms

In the TGD as part of the further testing strategy the following recommendations are included:

If no long-term test with sediment organisms is available and the PEC/PNEC ratio established via the equilibrium partitioning method or from short-term tests shows concern for the sediment compartment, further testing is necessary. When selecting test species, the behaviour of the substance together with the feeding strategy of the test species should be considered. The following species are recommended:
• long-term test with *Lumbriculus variegatus* using spiked sediment;
• long-term test with *Chironomus riparius* or *Chironomus tentans* using spiked sediment;
• long-term test with a further benthic species using spiked sediment.
The selection of the test species should depend on the properties of the test substance.

The species mentioned represent different habitats and feeding strategies and are therefore exposed to sediment-bound substances by different exposure pathways. *Lumbriculus variegatus* is a true sediment feeder, while *Chironomus* sp. is a collector-gatherer that feeds mainly on material deposited on submerged substrate. The two species belong to different benthic taxa and the tests involve different life stages. Selection of the third test species should supplement the first two species in these aspects. Other test methods are quoted in Appendix VI.

In addition to the described tests with benthic invertebrates, consideration can be given to sediment tests with other benthic species that are important for the sediment compartment, e.g. microorganisms and plants. A prerequisite would be that the tests are true sediment tests and that all relevant exposure pathways are covered. Especially the tests with microorganisms must essentially cover endpoints / degradation processes relevant for the sediment compartment (e.g. respiration, nitrification, denitrification, nitrogen fixation, methane formation). In general, tests with microorganisms and plants should be used only as the third sediment test, i.e. to lower the assessment factor to 10. As standardized sediment tests for microorganisms and plants are not yet available, further research and development is needed in this field.

An alternative to the testing of a third species could be a test with a second sediment performed with the most sensitive of the species already tested, provided that the characteristics of the second sediment, which determine bioavailability for the substance

in question (e.g. organic carbon content, composition, grain size, …), are very different from the first one.

Supplementary feeding of the organisms during the test should be avoided otherwise it may reduce the ingestion of contaminated sediment particles. Tests with species that need supplementary feeding should be designed in such a way that food taken up via the sediment by the test organisms is also spiked or contaminated with the test substance. To solve this problem e.g. an artificial sediment with pulverized leaves as carbon source as proposed by Oetken et al. (2000) could be used.

The organic carbon content of the sediment may influence the bioavailability and therefore the toxicity of the test substance. Therefore, for comparison of sediment tests, the organic carbon content of the test sediment should be within a certain range. The draft OECD guideline 218 (2001e) for the test with Chironomus using spiked sediment recommends an organic carbon content of the test sediment of 2 % (+/- 0.5 %). In Table 5 the organic carbon content of a standard sediment is set to 5 %. *It is recommended that the organic carbon content of the test sediments is between these two values* ***(recommended organic carbon content in sediment between 2 % and 5 %).***

Various techniques can be used to spike sediments, e.g. wet spiking and dry spiking. A flexible approach should be adopted due to variations in physico-chemical properties of test substances. However, it has to be guaranteed that the substance will not desorb from the sediment particles during the test as this would lead to an underestimation of the toxicity. To limit such desorption **an *adequate equilibration period before the start*** of the test is recommended. ***In addition the actual concentration of the test substance in the sediment should be monitored at least at the beginning and at the end*** of the test to check the efficiency of the contamination technique and the stability of the test substance concentration.

Microcosm or mesocosm study
Submission of a microcosm or mesocosm study is an option for a further (adequate) risk assessment.
This study can be submitted if the calculated concentration in sediment exceeds the criterion. In the TGD
It has in EU framework biocides not yet been indicated which guidelines must be followed for execution of a microcosm or mesocosm study. This lacuna is for the National framework elaborated in the NL part §2.2. As long as this lacuna has not been elaborated in EU framework, the description under §2.2 is followed.

Result:
→ NOEC ecosystem
→ NOEAEC ecosystem

Data requirements for the product
There are no specific data requirements for the product for sediment organisms but the TNsG on data requirements [2] gives the following general information about the submission of data for the product:

Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself [Ann. IIB, VII.7.2.]
- Required, for example, if the composition (formulation) of or the application technique for the product is suspected to influence the degradation and transformation, mobility

and adsorption properties or effects on aquatic or terrestrial organisms in a way that may considerably alter the conclusions of the risk characterisation. For instance, assessment by an expert on the effect of formulation on the ecotoxicology of the active substance should be submitted (see Chapter 1.2, point 4). Guidelines of the Council Directive 88/379/EEC (as amended) on assessing the effect of a single substance in causing hazard in a preparation may be partly applicable here.

- In addition, a qualitative or, preferably, a quantitative estimate on the possibility of formation of by-products of the active substance during normal use should be submitted on the basis of available data on the active substance and the intended use of the biocidal product.
- Ecotoxicology testing with a product might be required in those cases where a direct release of a product to a compartment is possible (see Part C of Chapter 2).

1.3. Risk assessment

The risk assessment for sediment organisms has been elaborated in the following documents:
Technical Guidance document [3] (TGD):
- Part 2, Chapter 3.5: Effects assessment for the sediment.

TNsG on data requirements [2]:
- Part C of chapter 2: Important compartments are indicated per product type.
- p.112: Effects on aquatic organisms.

Introduction
The risk evaluation for sediment organisms follows a tiered approach. The first tier is, if no toxicity data are available, based on model data as regards exposure and on the log Kow value and the equilibrium partitioning method as regards toxicity. This is a general conservative evaluation of the behaviour and toxicity of the substance in the environment. Where the trigger values of the first tier of the evaluation are not met, the applicant is offered the opportunity to submit supplementary data for conducting a refined risk evaluation (higher tier).

General evaluation system Risk to sediment organisms
Research into the behaviour of an active substance in sediment is relevant for a correct estimation of the concentration of this active substance in sediment (PEC = Predicted Environmental Concentration).
This PEC is an important parameter in the risk assessment for sediment organisms.
The PEC is calculated according to the TGD [3] and the Emission Scenario Documents [4].
Additional guidance is developed concerning rapidly degrading substances [5].The proposed approaches are to be used for the determination of the mean exposure concentration in acute or chronic tests where a substance can be shown to degrade significantly over the course of a test (< 80 % of nominal reported).The guidance in this document only apply to robust tests conducted to guidelines where the substances tested CANNOT be maintained through techniques such as semi-static or flow-through. These rules do not allow for endpoints to be derived from unacceptable or poor quality studies. Depending of the rate of degradation of the active substance it is decided to calculate a geometric mean concentration or time weighted average (TWA) concentration.

A criterion (PNEC) is also established on the basis of the data submitted on (the toxicity to) sediment organisms (log Kow, data from the equilibrium partitioning method, EC_{10}, NOEC).

A number of aspects have not yet been elaborated in EU framework; in the NL part §2.3 these lacunas are elaborated (how to deal with metabolites, establishing PNEC by means of microcosm or mesocosm studies, etc.). As long as these lacunas have not been elaborated in EU framework, the guidance as described in the NL part §2.3 and appendix C is followed. When in EU framework these currently not yet elaborated aspects will have been worked out, these will be followed.

Determination PNEC

The PNEC can be determined as follows:

- If no toxicity data on sediment organisms are available, the equilibrium partitioning method and the toxicity data on aquatic organisms are used to identify whether a potential risk for sediment organisms exists.
- If only acute toxicity data on sediment organisms are available, the risk is determined on the basis of these toxicity data by applying an assessment factor of 1000 as well as on the basis of the equilibrium partitioning method. The lowest PNEC is used to estimate the risk.
- If chronic toxicity data on sediment organisms are available, these form the basis for calculating a PNEC by applying assessment factors.

Determination PNEC by means of the equilibrium partitioning method

Derivation of a $PNEC_{sediment}$ according to the equilibrium partitioning method proceeds as follows:

$PNEC_{sediment} = (K_{susp\text{-}water} / RHO_{susp}) \times (PNEC_{water} \times 1000)$

$PNEC_{water}$	Predicted No Effect Concentration in water	$[mg.L^{-1}]$
RHO_{susp}	bulk density of wet suspended matter	$[kg.m^{-3}]$
K_{susp}	warter partition coefficient suspended matter water	$[m^3.m^{-3}]$
$PNEC_{sed}$	Predicted No Effect Concentration in sediment	$[mg.kg^{-1}]$

$K_{susp\text{-}water} = Fwater_{susp} + Fsolid_{susp} \times (Kp_{susp} / 1000) \times RHOsolid$
$Kp_{susp} = Foc_{susp} \times Koc$

RHO_{susp} = 1,150 [kg (ww) / m^3]
RHOsolid = 2,500 [kgsolid / msolid]
Fwatersusp = 0.9 [$mwater^3$ / $msusp^3$]
$Fsolid_{susp}$ = 0.1 [$msolid^3$ / $msusp^3$]
Foc_{susp} = 0.1 [kg_{oc} / kg_{solid}]

$PNEC_{sed}$ is calculated on wet weight basis. Recalculation to dry weight can be derived from $PNEC_{sed,\ dw} = 4.6 \times PNEC_{sed,\ ww}$

The TGD [3] mentions a number of assumptions and remarks as regards the equilibrium partitioning method.

If log Kow > 5, an additional assessment factor of 10 should be applied. This additional assessment factor accounts for the possible uptake via sediment.

The table below summarises different types of available data and elucidates how these are to be used in the risk assessment for sediment organisms.

PEC sediment	PNEC sediment	Risk assessment

$C_{pore\ water}$	None	$C_{pore\ water}$ / $PNEC_{water}$
C_{bulk}	None	(C_{bulk} x RHO_{susp}) /($K_{susp\text{-}water}$ x $PNEC_{water}$ x 1000)
None	$PNEC_{sediment}$	($K_{susp\text{-}water}$ x PEC_{water}x1000) / ($PNEC_{sediment}$ x RHO_{susp})
$C_{pore\ water}$	$PNEC_{sediment}$	($K_{susp\text{-}water}$ x $C_{pore\ water}$x1000) / ($PNEC_{sediment}$ x RHO_{susp})
C_{bulk}	$PNEC_{sediment}$	C_{bulk} / $PNEC_{sediment}$
$C_{pore\ water}$ concentration in sediment pore water (mg/l) C_{bulk} concentration in total sediment (mg/kg sediment) $K_{susp\text{-}water}$ suspended matter-water partition coefficient (m^3/m^3) RHO_{susp} bulk density of suspended matter (kg/m^3)		

Remark: If the ratio (PEC / PNEC) is greater than 1, study 7.4.3.5.1 (Total sediment tests with sediment organisms (using spiked sediment)) should be carried out.

Determination PNEC by applying an assessment factor to the EC_{10} and NOEC value(s)
A criterion is established by applying an assessment factor to the data submitted about the toxicity to sediment organisms (EC_{10}, NOEC).
The PNEC is derived from the lowest available NOEC/EC_{10} obtained from chronic tests by application of the assessment factors.

Freshwater organisms
The assessment factors for freshwater organisms (TGD 3.5.4) are presented in the table below

Available test result	**Assessment factor**
One long-term test (NOEC or EC_{10})	100
Two long-term tests (NOEC or EC_{10}) with species representing different living and feeding conditions	50
Three long-term tests (NOEC or EC_{10}) with species representing different living and feeding conditions	10

Remark:
If only acute toxicity data on sediment organisms are available, the risk is determined on the basis of a factor 1000 to the lowest toxicity value as well as on the basis of the equilibrium partitioning method. The lowest PNEC is used to estimate the risk.

See the TGD [3] for elucidation of the table above.

Marine sediment organisms
The assessment factors for marine sediment organisms (TGD 4.3.2.4) applied to the lowest LC50/NOEC/EC10 value are presented in the tables below.

Short-term sediment toxicity tests

Available test results	**Assessment factor**	**$PNEC_{marine\ sediment}$**
One acute freshwater or marine test	10,000	Lowest of LC_{50} /10,000 and equilibrium partitioning method
Two acute tests including a minimum of one marine test with an organism of a sensitive taxa	1000	Lowest of LC_{50} /1000 and equilibrium partitioning method

Long-term sediment toxicity tests

Available test results	Assessment factor
One long-term freshwater sediment test	1000
Two long-term freshwater sediment tests with species representing different living and feeding conditions	500 (c
One long-term freshwater and one saltwater sediment test representing different living and feeding conditions	100 (d
Three long-term sediment tests with species representing different living and feeding conditions	50
Three long-term tests with species representing different living and feeding conditions including a minimum of two tests with marine species	10

c) An assessment factor of 500 applies to the lowest of two NOECs covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOECs have been generated covering those trophic levels showing the lowest L(E)C50 in the short-term tests with these species. Consideration can be given to lowering this factor in the following circumstances:
- It may sometimes be possible to determine with a high probability that the most sensitive species covering fish, crustacea and algae has been examined, that is that a further longer-term NOEC from a third taxonomic group would not be lower than the data already available. In such circumstances an assessment factor of 100 would be justified;
- a reduced assessment factor (to 100 if only one short-term test, to 50 if two short-term tests on marine species are available) applied to the lowest NOEC from only two species may be appropriate where:
- short-term tests for additional species representing marine taxonomic groups (for example echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive group, and;
- it has been determined with a high probability that long-term NOECs generated for these marine groups would not be lower than that already obtained. This is particularly important if the substance does not have the potential to bioaccumulate. An assessment factor of 500 also applies to the lowest of three NOECs covering three trophic levels, when such NOECs have not been generated from the taxonomic group showing the lowest L(E)C50 in short-term tests. This should, however, not apply in the case where the acutely most sensitive species has an L(E)C50 value lower than the lowest NOEC value. In such cases the PNEC might be derived by applying an assessment factor of 1000 to the lowest L(E)C50 in the short-term tests.

d) An assessment factor of 100 will be applied when longer-term toxicity NOECs are available from three freshwater or saltwater species (algae, crustaceans and fish) across three trophic levels. The assessment factor may be reduced to a minimum of 10 in the following situations:
- where short-term tests for additional species representing marine taxonomic groups (for example echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive group, and it has been determined with a high probability that long-term NOECs generated for these species would not be lower than that already obtained;
- where short-term tests for additional taxonomic groups (for example echinoderms or molluscs) have indicated that one of these is the most sensitive group acutely and a long-term test has been carried out for that species. This will only apply when it has been determined with a high probability that additional NOECs generated from other taxa will not be lower than the NOECs already available. A factor of 10 cannot be decreased on the basis of laboratory studies only.

See the TGD[3] for elucidation of the table above.

Determination PNEC by means of statistical extrapolation techniques (SSD method)

The procedure for the SSD method is the same as for aquatic organisms; see chapter

Aquatic organisms.

1.4. Approval

According to the Directive of the European Parliament and the Council of 16 February 1998 concerning the placing of biocides on the market (98/8/EG) it should be investigated whether biocides have, when approved, no unacceptable effect on the environment and in particular the health humans and animals (consideration 8) if used properly for the envisaged purpose, in the light of the current scientific and technical knowledge.

Article 5, 1, b ii), iii) and iv) stipulates that Member States may only authorise a biocide if the product, when used consistent with the authorisation and taking into account:
- all conditions under which the biocide is normally used,
- the way in which material treated with the product can be used,
- the consequences of use and removal,

ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,
(iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater,
(iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:
- its fate and distribution in the environment; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water,
- its impact on non-target organisms;

1.4.1. Evaluation

The Common Principles (Annex VI to 98/8/EC) present the starting points for evaluation as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for the risk to sediment organisms are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to Directive 98/8/EC.

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.
37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.
38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds ` may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:
- any indications of bioaccumulation potential,
- the persistence characteristics,
- the shape of the toxicity/time curve in ecotoxicity testing,

- indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
- data on structurally analogous substances,
- endocrine effects.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).
41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

    The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indicationsgiven in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC(*).
    (*) OJ L 227, 8.9.1993, p. 9.
42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.
43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.
44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
    - adequately measured exposure data,
    - the form in which the product is marketed,
    - the type of biocidal product,
    - the application method and application rate,
    - the physico-chemical properties,
    - breakdown/transformation products,
    - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
    - the frequency and duration of exposure.
45. Where adequately measured, representative exposure data are available, special

consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.
47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

1.4.2. Decision making

The Common Principles (Annex VI to 98/8) present the starting points for decision making as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for risk to sediment organisms are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to Directive 98/8/EC.

81. The Member State shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.
88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:
    - the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use;

    By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which this Directive enters into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

In line with the TGD [3] and described in EU part §1.3, the PNEC can be calculated in different ways. The PEC is calculated and established as described in the chapter ‘Behaviour in water and sediment’.

A
To avoid extensive testing of chemicals a log Koc or log Kow of < 3 indicates that a

sediment effects assessment is not necessary.

B
If no toxicity data are available the equilibrium partitioning method is used to identify whether a potential risk for sediment organisms exists.
a. if log Kow > 5: 10 x (PEC / PNEC) ≤ 1, or
b. if log Kow < 5: PEC / PNEC ≤ 1.
The criteria for toxicity sediment organisms are met.

C
If only acute toxicity data for sediment organisms are available, the risk is determined on the basis of a factor 1000 (or 10,000 for marine, but a reduction to 1000 is possible if Two acute tests including a minimum of one marine test with an organism of a sensitive taxa is available, see table on assessment factors for PNEC saltwater organisms in §1.3) to the lowest value as well as on the basis of the equilibrium partitioning method (see A). The lowest criterion (PNEC) is used to estimate the risk.

If B or C are not met or if chronic toxicity studies are already available earlier, D, E or F apply:

D
If one chronic toxicity study is available:
PNEC = NOEC or EC_{10} for sediment organisms / 100 (or 1000 for marine)
PEC (chronic)/PNEC ≤ 1: The criteria for toxicity sediment organisms are met.

E
If two chronic toxicity studies are available with species that represent different living and feeding conditions:
PNEC = lowest NOEC or EC_{10} for sediment organisms / 50 (or 500 for marine, but a reduction to 100 is possible see note c) factors for PNEC saltwater organisms in §1.3)
PEC (chronic) / PNEC ≤ 1 The criteria for toxicity sediment organisms are met.

F
If three chronic toxicity studies are available with species that represent different living and feeding conditions:
PNEC = lowest NOEC or EC_{10} for sediment organisms / 10 (or 100 for marine, but a reduction to a minimum of 10 is possible see note d) factors for PNEC saltwater organisms in §1.3)
PEC (chronic) / PNEC ≤ 1: The criteria for toxicity sediment organisms are met.

Further (adequate) risk assessment
If the criteria under D, E or F are not met, the use in question is considered as non-permissible unless a further (adequate) risk assessment shows that there are no unacceptable direct or indirect effects on sediment organisms under relevant field conditions.

If a microcosm or mesocosm study shows that PEC / PNEC ≤ 1, the criteria for toxicity sediment organisms are met. the use in question can part of the Annex I inclusion.

If PEC / PNEC > 1, the criteria are not met and the use in question cannot be part of the Annex I inclusion.
If for all proposed uses a risk is identified and thus there is no accepted use, then the

substance should be recommended for non Annex I inclusion.

An additional option for an adequate risk assessment is the inclusion of mitigation measures / restrictions. The applicant must, however, provide evidence that the proposed mitigation measures / restrictions are realistic and will result in an acceptable risk.

1.5. Developments

Developments

- There are no current developments.

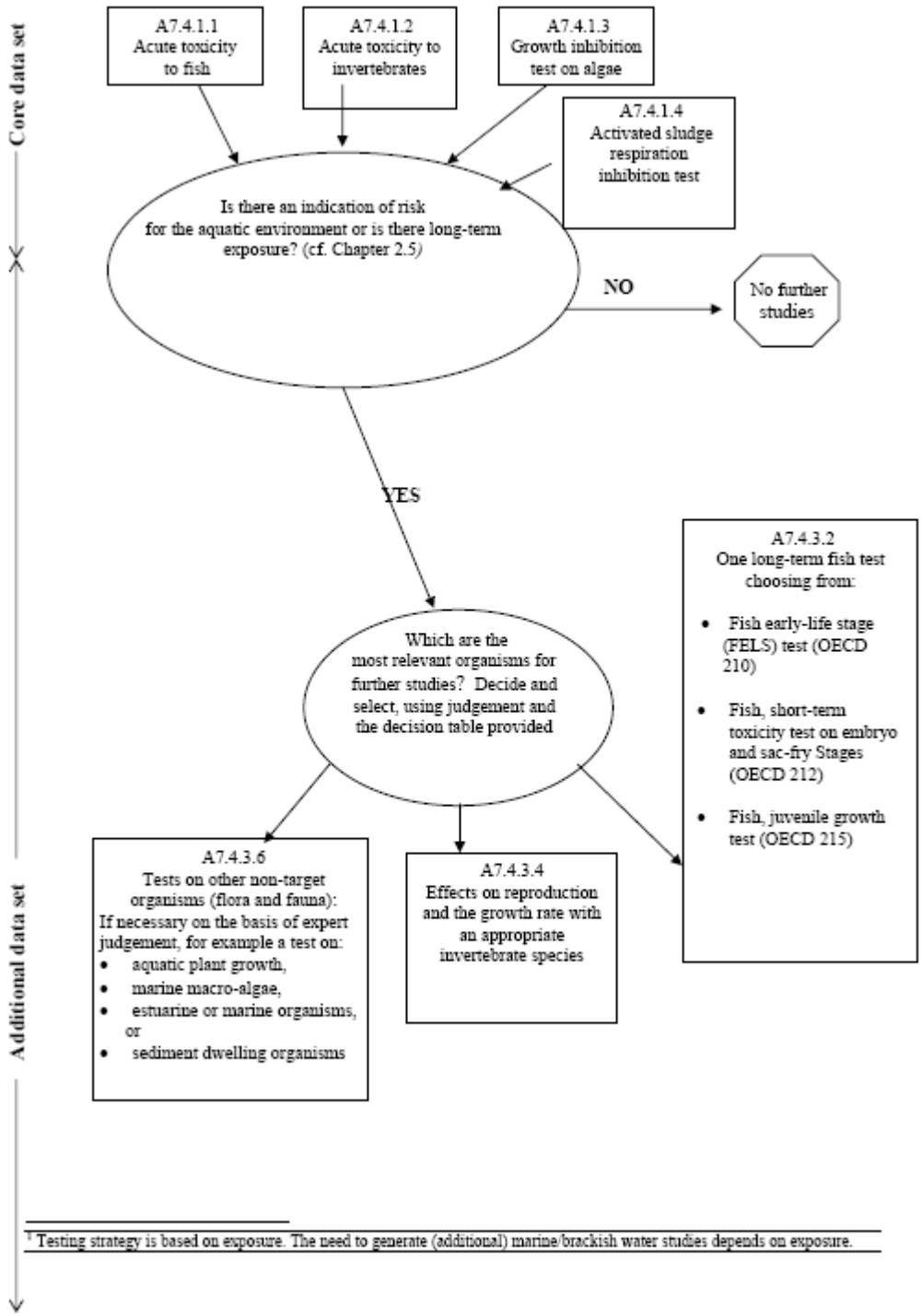
EU developments will be followed.

Lacunas

- It is not clear what is to be understood by relevant metabolites. It is neither clear when data on relevant metabolites must be provided and how these must be evaluated.
- The procedure for conducting an adequate risk assessment has not yet been elaborated in EU framework.

2. APPENDICES

Appendix 1 TESTING STRATEGY FOR AQUATIC STUDIES[1] (FIG 3.1 from [2])



[1] Testing strategy is based on exposure. The need to generate (additional) marine/brackish water studies depends on exposure.

3. REFERENCES

1 Biocides Directive (98/8/EC).
2 Technical notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products. October 2002.
3 Technical Guidance document in support of Commission Directive 93/67/EEC on Risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, part II, April 2003.
4 Emission Scenario Documents for Biocides: Ex-European Chemicals Bureau : > Biocides > ESDs > ESD PER PRODUCT TYPE. E.g. Emission scenarios for all 23 product types of EU Directive 98/8/EC, report RIVM 601450009/2002. P. van der Poel en J. Bakker & Development of Environmental Emission Scenarios for active substances used in Biocidal Products. Final Report, January 2004. European Commission DG ENV, RIVM Service contract B4-3040/2001/326154/Mar/C3.
5 [Guidance_rapidly_degrading_substances_TWA_2009]. Environmental effects assessments for biocidal active substances that rapidly degrade in environmental compartments of concern. This document was endorsed at the 32nd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (18-20 February 2009).