Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; aquatic organisms

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Board
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Chapter 6 Ecotoxicology; aquatic organisms

Category: biocides

I AQUATIC ORGANISMS

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to aquatic 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 of 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 of this chapter, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risks to aquatic 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 the estimated or measured concentrations in surface water are determined.

Described are the guidelines for assessment of the aspect aquatic organisms in the Technical Guidance Document on Risk Assessment [2] and the TNsG on Data Requirements [3], 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 the NL part in Appendix 1, which is fully in line with the decision process in the EU. This decision tree summarises the testing framework for aquatic 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 of 98/8/EC.

1.2. Data requirements

The data requirements laid down in the TNsG on data requirements [3] 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 aquatic 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 group. In addition, product-group-specific data should be submitted for different product groups. The different product groups are elaborated in the relevant

chapters (see Appendix 1 in underlying document, the testing strategy for aquatic studies).
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.

In addition to the latter approach for the derivation of concentrations from tests guidance developed for rapid degrading substances [5]

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 [3] reads as follows about the submission of salt water 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

Acute toxicity research aquatic organisms

Studies should be carried out according to standardised methods with representatives of at least 3 trophic levels, i.e.: phytoplankton (algae), invertebrates (crustaceans) and vertebrates (fish). These are the standard test organisms. These data are required for the active substance.

These studies as described in the TNsG on data requirements [3] are summarised below.

7.4 Effects on Aquatic Organisms

7.4.1 Aquatic toxicity, initial tests

- The tests should provide the acute toxicity values related to mortality, immobilisation or growth and growth rate, NOEC values, and details of observed effects.
- When carrying out toxicity tests on aquatic organisms, it is useful to test information on the solubility and stability of the substance in the test medium, as it may differ from the result obtained under the water solubility test (paragraph A3.5, data set for the active substance).

7.4.1.1 Acute toxicity to fish [Ann. IIA, VII.7.1.]

- Should be studied with one species and a fresh water species is preferred or, if different aquatic environments are exposed, with two species (cf. Part C of Chapter 2). The two species selected should represent fresh water and marine environments. *Cyprinodon variegatus* may be used as marine species.
- Test according to the EC method C.1 or the corresponding OECD guideline 203 (where test with *Cyprinodon variegatus* is also possible), or for a marine species e.g. US-EPA guideline OPPTS 850.1075 (US-EPA 1996a).

Result
→ LC_{50} fish

7.4.1.2 Acute toxicity to invertebrates [Ann. IIA, VII.7.2.]

- Test according to the EC method C.2 on freshwater crustacea (*Daphnia*) or the corresponding OECD guideline 202.
- Test on marine/brackish crustacea according to, for instance, the ISO standard ISO/DIS 14669 (still a draft) with marine/brackish crustacea may be appropriate or e.g. the US-EPA guidelines OPPTS 850.1035 (marine mysids) and 850.1045 (marine paneid shrimps) may be used. OPPTS 850.1035 may also be conducted in brackish water, if relevant.
- Tests on marine/brackish molluscs e.g. short-term tests on embryos of e.g. *Mytilus edilus* according to ASTM E724 can be performed. Tests can also be conducted with the brackish water mollusc *Macoma baltica* (Bryant et al. 1985 as quoted in OECD DRP on Aquatic Testing Methods for Pesticides and Industrial Chemicals, 1998).

Result
→ EC_{50} invertebrate

7.4.1.3 Growth inhibition test on algae [Ann. IIA, VII.7.3.]

- Should be studied with one species and a fresh water species is preferred or, if different aquatic environments are exposed, with two species. For instance, in addition to a test in a fresh water species a test in a salt or brackish water species (e.g. the marine diatom, *Skeletonema costatum*, or the blue-green algae - or cyanobacterium, *Anabaena flos-aquae*, suitable both for fresh and brackish water) should be submitted if relevant, see Part C of Chapter 2.
- Test according to EC method C.3 or the corresponding OECD guideline 201, or for a marine species a test according to for instance the ISO standard ISO 10253 (ISO 1995). For a marine or brackish water species e.g. the US-EPA guideline OPPTS 850.5400 (US-EPA 1996d) may be used.
- For certain product types industry may have efficacy data relating to the effects on algae.

Result
→ NOEC algae/EC_{50} algae

Product-type-specific and additional data

Chronic toxicity studies aquatic organisms
Chronic toxicity data for the active substance are mandatory for a number of product groups. These are the so-called product-type-specific data. In addition, chronic toxicity data must be submitted in the following cases (see TGD 3.3.1.1 [2]):

- chronic (prolonged) exposure;
- log Kow > 3 and/or BCF > 100;
- PEC > 1/100th of the water solubility;
- PEC/PNEC > 1 on the basis of the acute data.

N.B. In the TGD Chapter 6.3 Refinement Of PNEC: Strategy For Further Testing of the TGD the following additional guidance is given:
Where L(E)C50 > 100 mg/L, chronic studies are not required; this does not apply for substances with a water solubility < 1 mg/L.

Chronic toxicity studies must be carried out with representatives of crustaceans and fish. Different chronic studies can be carried out for fish. Which is test is most suitable is decided on a case-to-case basis.

These studies as described in the TNsG on data requirements [3] are summarised below.

7.4.3.2 Effects on reproduction and the growth rate on an appropriate species of fish

- Test required according to decision table in Appendix 1.
- *Fish early-life stage (FELS)* test (OECD 210)1 This test is considered as the most sensitive of the fish tests, covering several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth. This is felt to cover most, but not all, of the sensitive points in the life-cycle, and it is the only suitable test currently available for examining the potential toxic effects of bioaccumulation, apart from the full life cycle test. It is, however, a long test typically 60 days post hatch for rainbow trout (*Oncorhynchus mykiss*), or approximately 30 days post-hatch for warm water fish, and is consequently the most expensive of those available. It should be requested where long-term fish toxicity data are required and the substance has the potential to bio-accumulate. For marine environments, the test can be performed with

Cyprinodon variegatus.

- *Fish, Short-term Toxicity test on Embryo and Sac-fry Stages* (OECD 212) This test measures the sensitive early life stages from the newly fertilised egg to the end of the sac-fry stage. It is considerably shorter, and hence cheaper, than the FELS test but is also considered to be less sensitive. It offers an alternative to the FELS test for substances with log Kow less than 4. The conditions under which the egg and sac-fry stage test can be used in place of the FELS test may be clarified following the further discussions at the OECD. For marine environments, the guideline proposes several species, e.g. *Cyprinodon variegatus*.
- *Fish, Juvenile Growth Test* (OECD Guideline 215) This test measures the growth of juvenile fish over a fixed period, and it is considered a sensitive indicator of fish toxicity. Although it is considered to be of insufficient duration to examine all the sensitive points in the fish life cycle, it provides a .....shorter and cheaper option to FELS test for substances of log Kow < 5.

Result
→ NOEC fish

7.4.3.3 Effects on reproduction and growth rate with an appropriate invertebrate species

- Test required according to decision table in Appendix 1 or if chronic exposure is expected.
- Test according to OECD guideline 211. For marine environments, a long-term test with *Nitocra spinipes* can be performed (Danish standard 2209). Tests have also been performed with *Macoma baltica* (Bryant et al. 1985 as quoted in OECD DRP on Aquatic Testing Methods for Pesticides and Industrial Chemicals, 1998).
- For marine environments, a test with *Mysidopsis bahia* according to US-EPA method OPPTS 850.1350 can also be performed.

Result
→ NOEC invertebrates

Other toxicity data aquatic organisms

The studies as described in the TNsG on data requirements [3] are summarised below.

7.4.3.1 Prolonged toxicity to an appropriate species of fish [Ann. IIIA, XIII.2.1.]

- Usually this test is not required, as it does not add information as needed in the risk assessment. The existing test guidelines are not sufficient.
- Test according to OECD guideline 204

Result
→ NOEC fish

7.4.3.5 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk [Ann. IIIA, XIII.3.4.]

- Such testing may be required if tests on other non-target organisms are needed on the basis of intended use(s) and results from the other tests in section A7 (data set for the active substance) or a preliminary risk assessment compiled in accordance with point A10. For instance, tests on sediment dwelling organisms, aquatic plant growth (including macro-algae), accumulation and elimination in shellfish or tests on marine macro-algae or other additional tests on estuarine and marine organisms may be needed.

- The decision on the need of such further studies should be decided case-by-case after consulting with the competent national authority (see Chapter 1.2, point 4) for those product types not specifically mentioned below.

Result
→ $L(E)C_{50}$
→ NOEC

7.4.3.5.2 Aquatic plant toxicity
- Test with *Lemna spp*. , e.g. according to US-EPA guideline OPPTS 850.4400 (US-EPA 1996b) An OECD guideline is in preparation. For marine/eustarine higher plants, *Zostera spp* could be tested.

Result
→ NOEC aquatic plant/EC_{50} aquatic plant

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 surface water exceeds the criterion.
It has in EU framework biocides not yet been indicated which guidelines must be met 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 in the NL part §2.2 is followed.

Result:
→ NOEC ecosystem
→ NOEAEC ecosystem

Data requirements for the product
The TNsG on data requirements [3] reads as follows 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).

Besides the studies that must also be submitted for the active substance (7.4.1.1, 7.4.1.2,

7.4.1.3), the following data must be submitted as additional product data in some situations. Product data are required if the submitted data on the active substance give insufficient information or if there are indications of risks to be ascribed to specific properties of the product.

7.7	Effects on aquatic organisms
7.7.1	In case of application on, in, or near to surface waters.
7.7.1.1	Particular studies with fish and other aquatic organisms.
7.7.1.2	Residue data in fish concerning the active substance and including toxicological relevant metabolites. • Possible monitoring data or results of residues studies including toxicologically relevant metabolites, if these cause harmful effects on human health.
7.7.1.3	The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2, 2.3, and 2.4 may be required for relevant component of the biocidal product.
7.7.2	If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions.

1.3. Risk assessment

The risk assessment for aquatic organisms has been elaborated in the following documents:
Technical Guidance Document [2] (TGD) :
- Part 2, Chapter 3.3: Effects assessment for the aquatic compartment.

TNsG on data requirements [3]:
- Part C of Chapter 2: it is indicated per product group which compartments are important.
- p.115: Testing strategy for aquatic toxicity studies.
- p.118: Effects on aquatic organisms.
- p.126: Further ecotoxicological studies.
- p.131: Appendix 1: Decision table for additional aquatic toxicity testing (also included in appendix 1 of underlying document).

<u>Introduction</u>
The risk evaluation for aquatic organisms follows a tiered approach. The first tier is based on model data as regards exposure and on laboratory data 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).

<u>General evaluation system Risk to aquatic organisms</u>
Research into the behaviour of an active substance in water is relevant for a correct estimation of the concentration of this active substance in surface water (PEC = Predicted Environmental Concentration).
This PEC is an important parameter in the risk assessment for aquatic organisms. The

PEC is calculated according to the TGD [2] and the Emission Scenario Documents [4]. The data submitted on the toxicity for aquatic organisms (LC_{50}, EC_{50}, NOEC) also form the basis for establishing a criterion by application of an assessment factor (PNEC). 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 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). As long as these lacunas have not been elaborated in EU framework, the guidance as described in NL part is followed. When in EU framework these currently not yet elaborated aspects will have been worked out, these will be followed.

Establishment PNEC

Establishment PNEC by means of an assessment factor on the endpoint
The data submitted on the toxicity for aquatic organisms (LC_{50}, EC_{50}, NOEC) also form the basis for establishing a criterion by application of an assessment factor.

Freshwater organisms
The assessment factors for freshwater organisms (TGD 3.3.1.1) are summarised in the table below.

Available data	**Assessment factor**
At least one short-term L(E)C50 from each of three trophic levels of the baseset (fish, Daphnia and algae)	1000 a)
One long-term NOEC (either fish or Daphnia)	100 b)
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 c)
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 d)
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case)
Field data or model ecosystems	Reviewed on a case by case basis

a) The use of a factor of 1000 on short-term toxicity data is a conservative and protective factor and is designed to ensure that substances with the potential to cause adverse effects are identified in the effects assessment. It assumes that each of the uncertainties identified above makes a significant contribution to the overall uncertainty. For any given substance there may be evidence that this is not so, or that one particular component of the uncertainty is more important than any other. In these circumstances it may be necessary to vary this factor. This variation may lead to a raised or lowered assessment factor depending on the available evidence. A factor lower than 100 should not be used in deriving a PNECwater from short-term toxicity data except for substances with intermittent release (see TGD Section 3.3.2).
There are cases where the base-set is not complete: e.g. for substances that are produced at <1 t/a (notifications according to Annex VII B of Directive 92/32). At the most the acute toxicity for

Daphnia is determined. In these exceptional cases, the PNEC should be calculated with a factor of 1000.
Variation from a factor of 1000 should not be regarded as normal and should be fully supported by accompanying evidence.

b) An assessment factor of 100 applies to a single long-term NOEC (fish or Daphnia) if this NOEC was generated for the trophic level showing the lowest L(E)C50 in the short-term tests. If the only available long-term NOEC is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus the effects assessment is based on the short-term data with an assessment factor of 1000. However, the resulting PNEC based on short-term data may not be higher than the PNEC based on the long-term NOEC available.
An assessment factor of 100 applies also to the lowest of two long-term NOECs covering two trophic levels when such NOECs have not been generated from that showing the lowest L(E)C50 of the short-term tests. This should, however, not apply in cases 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 using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests.
c) An assessment factor of 50 applies to the lowest of two NOECs covering two trophic levels when such NOECs have been generated covering that level showing the lowest L(E)C50 in the short-term tests. It also applies to the lowest of three NOECs covering three trophic levels when such NOECs have not been generated from that trophic level showing the lowest L(E)C50 in the short-term tests.
This should however not apply in cases 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 using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests.
d) An assessment factor of 10 will normally only be applied when long-term toxicity NOECs are available from at least three species across three trophic levels (e.g. fish, Daphnia, and algae or a non-standard organism instead of a standard organism).
When examining the results of long-term toxicity studies, the PNECwater should be calculated from the lowest available NOEC.
Extrapolation to the ecosystem effects can be made with much greater confidence, and thus a reduction of the assessment factor to 10 is possible. This is only sufficient, however, if the species tested can be considered to represent one of the more sensitive groups. This would normally only be possible to determine if data were available on at least three species across three trophic levels.
It may sometimes be possible to determine with high probability that the most sensitive species has been examined, i.e. that a further long-term NOEC from a different taxonomic group would not be lower than the data already available. In those circumstances, a factor of 10 applied to the lowest NOEC from only two species would also be appropriate. This is particularly important if the substance does not have a potential to bioaccumulate. If it is not possible to make this judgement, then an assessment factor of 50 should be applied to take into account any interspecies variation in sensitivity. A factor of 10 cannot be decreased on the basis of laboratory studies.
e) Basic considerations and minimum requirements as outlined in TGD Section 3.3.1.2.
f) The assessment factor to be used on mesocosm studies or (semi-) field data will need to be reviewed on a case-by-case basis.

See the TGD [2] for elucidation of the table above.

If the PEC/PNEC > 1, supplementary toxicity studies can be submitted for refinement of the PNEC derivation. Further test options are presented in the table below, which in TNsG on data requirements [3] is referred to as Appendix 1 Decision Table For Additional

Aquatic Toxicity Testing.

Variation in acute toxicity tests	**Further possibilities for testing**	**Data available for assessment**	**Assessment factor [(a)]**
No significant differences between the L(E)C_{50} values of fish, daphnia and algae	Chronic fish study + chronic daphnia study + determination NOEC algae.	FBS + algae + daphnia + fish	10
Fish LC_{50} more than 10 x lower than L(E)C_{50} of daphnia and algae.	Chronic fish study + determination NOEC algae. If S/L [(b)] ratio for fish > 20: chronic daphnia study [(c)]	FBS + algae + fish FBS + algae + daphnia + fish	50 10
Daphnia L(E)C_{50} more than 10 x lower than L(E)C_{50} of fish and algae.	Chronic daphnia study + determination NOEC algae. If S/L [(b)] ratio for daphnia > 20: chronic fish study [(c)]	FBS + algae + daphnia FBS + algae + daphnia + fish	50 10
Algae L(E)C50 more than 10 x lower than L(E)C50 of fish and daphnia.	Test with different algae species + chronic fish/daphnia studies	FBS + 2 algae + daphnia / fish	10 (d)
Fish LC_{50} more than 10 x higher than L(E)C_{50} of daphnia and algae.	Chronic daphnia study + determination NOEC algae. If S/L [(b)] ratio for Daphnia > 20: chronic fish study [(c)]	FBS + algae + daphnia FBS +algae + daphnia + fish	50 10
Daphnia L(E)C_{50} more than 10 x higher than L(E)C_{50} of fish and algae.	Chronic fish study + determination of NOEC algae. If S/L [(b)] ratio for fish > 20: chronic daphnia study [(c)]	FBS + algae + fish FBS + algae + fish + daphnia	50 10
Algae (E)C_{50} more than 10 x higher than L(E)C_{50} of fish and daphnia.	Chronic fish study + chronic daphnia study + determination NOEC algae.	FBS + algae + daphnia + fish	10

FBS = Full Base Set

(a) the assessment factor must be applied to the lowest NOEC available at this stage, including the NOEC from the algae test.

(b) S/L refers to the short-term to long-term ratio, i.e. the ratio between the L(E)C50 from a short-term test and the NOEC from a long-term-test.

(c) Generally testing of a third species will be unnecessary since the toxicity results from the first species should be protective. However, this cannot be a fixed rule given the toxicity variations within taxonomic groups as well as between them. Thus if a short-term L(E)C50: long-term NOEC ratio > 20 is found for the species tested, or from the algae study, then the further testing of a third species might be necessary. The use of long-term fish or Daphnia QSARs could help in deciding which species needs to be tested (see Chapter 4 "Use of QSARs" in the EC, 1996 [6]). It is considered that such a ratio may be indicative of an abnormal level of toxicity or of a specific mode of action, and thus the acquisition of additional evidence is justified in order to

improve confidence in the calculated PNECwater. Other factors such as the shape of the toxicity time curve and the presence of sub-lethal effects in the short-term toxicity study for the second species may also be considered. An assessment factor of 10 may be applied to the lowest of the three NOECs. Before a toxicity study on a third species is requested, due consideration should be given as to whether the resultant NOEC will lead to a further revision of the PNECwater.

(d) This table is based on the presumption that an NOEC for algae is available at the base set. If this is not the case, an assessment factor of 50 should be used.

Saltwater organisms

The assessment factors for saltwater organisms (TGD 4.3.1.3) are summarised in the table below.

Data set	**Assessment factor**
Lowest short-term L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels	10.000 [a)]
Lowest short-term L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels, + two additional marine taxonomic groups (e.g. echinoderms, molluscs)	1.000 [b)]
One long-term NOEC (from freshwater or saltwater crustacean reproduction or fish growth studies)	1.000 [b)]
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500 [c)]
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100 [d)]
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + one long-term NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs)	50
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels + two long-term NOECs from additional marine taxonomic groups (e.g. echinoderms, molluscs)	10

Evidence for varying the assessment factor should in general include a consideration of the availability of data from a wider selection of species covering additional feeding strategies/ life forms/ taxonomic groups other than those represented by the algal, crustacean and fish species (such as echinoderms or molluscs). This is especially the case, where data are available for additional taxonomic groups representative of marine species. More specific recommendations as with regard to issues to consider in relation to the data available and the size and variation of the assessment factor are indicated below.

When substantiated evidence exists that the substances may be disrupting the endocrine system of mammals, birds, aquatic or other wildlife species, it should be considered whether the assessment factor would also be sufficient to protect against effects caused by such a mode of action, or whether an increase of the factor would be appropriate.

a)
The use of a factor of 10,000 on short-term toxicity data is a conservative and protective factor and is designed to ensure that substances with the potential to cause adverse effects are identified in the effects assessment. It assumes that each of the identified uncertainties described above makes

a significant contribution to the overall uncertainty.
For any given substance there may be evidence that this is not so, or that one particular component of the uncertainty is more important than any other. In these circumstances it may be necessary to vary this factor. This variation may lead to a raised or lowered assessment factor depending on the evidence available. Except for substances with intermittent release, as defined in TGD Section 2.3.3.4, under no circumstances should a factor lower than 1000 be used in deriving a PNECwater for saltwater from short-term toxicity data.
Evidence for varying the assessment factor could include one or more of the following:

- evidence from structurally similar compounds which may demonstrate that a higher or lower factor may be appropriate.
- knowledge of the mode of action as some substances by virtue of their structure may be known to act in a non-specific manner. A lower factor may therefore be considered. Equally a known specific mode of action may lead to a higher factor.
- the availability of data from a variety of species covering the taxonomic groups of the base set species across at least three trophic levels. In such a case the assessment factors may only be lowered if multiple data points are available for the most sensitive taxonomic group (i.e. the group showing acute toxicity more than 10 times lower than for the other groups).

There are cases where a complete short-term dataset even for freshwater algal, crustacean and fish species will not be available, for example for substances which are produced at < 1 t/a (notifications according to Annex VII B of Directive 92/32). In these situations, the only data may be short-term L(E)C50 data for Daphnia. In these exceptional cases, the PNEC should be calculated with a factor of 10,000.
Variation from an assessment factor of 10,000 should be fully reported with accompanying evidence.

b)
An assessment factor of 1000 applies where data from a wider selection of species are available covering additional taxonomic groups (such as echinoderms or molluscs) other than those represented by algal, crustacean and fish species; if at least data are available for two additional taxonomic groups representative of marine species.
An assessment factor of 1000 applies to a single long-term NOEC (freshwater or saltwater crustacean or fish) if this NOEC was generated for the taxonomic group showing the lowest L(E)C50 in the short-term algal, crustacean or fish tests.
If the only available long-term NOEC is from a species which does not have the lowest L(E)C50 in the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus, the effects assessment is based on the short-term data with an assessment factor of 10,000. However, normally the lowest PNEC should prevail.
An assessment factor of 1000 applies also to the lowest of the two long-term NOECs covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOECs have not been generated for the species showing the lowest L(E)C50 of the short-term tests.
This should not apply in cases 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 of the short-term tests.

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.

Pooling of endpoints from freshwater and marine water studies

Regarding the use of freshwater and/or marine data, the TGD (4.3.1.2 Evaluation of data) states: ‘The use of freshwater acute effects data in lieu of or in addition to saltwater effects data for risk assessment purposes is not contra-indicated by the empirical data reviewed. Use of pooled data is therefore recommended. Under such circumstances, PNEC values should be derived from the most sensitive endpoint regardless of the medium.’ Additionally at TMI08 it was concluded that ‘for the derivation of a PNEC for freshwater or saltwater the available toxicity data for freshwater and saltwater organisms can be pooled. Before pooling these data the differences in sensitivity has to be considered: in general if the difference is more than a factor 10 the data cannot be pooled. In addition, the mode of action of the substance under evaluation has to be considered.’ It should be noted that in CAR a PNEC for marine waters is only addressed in case emission of the active substance to marine water is to be expected.

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

Introduction

Species usually show a wide variation in sensitivity to biocides. This variation can be described by a sensitivity curve.
In the scientific literature this approach is referred to as the ‘Species Sensitivity

Distribution' (SSD) method. An SSD is a statistical distribution, based on a collection of toxicity data on different species, visualised by means of a cumulative distribution curve (see Figure 1). The normally used toxicity data have been obtained from so-called 'single species lab tests'.

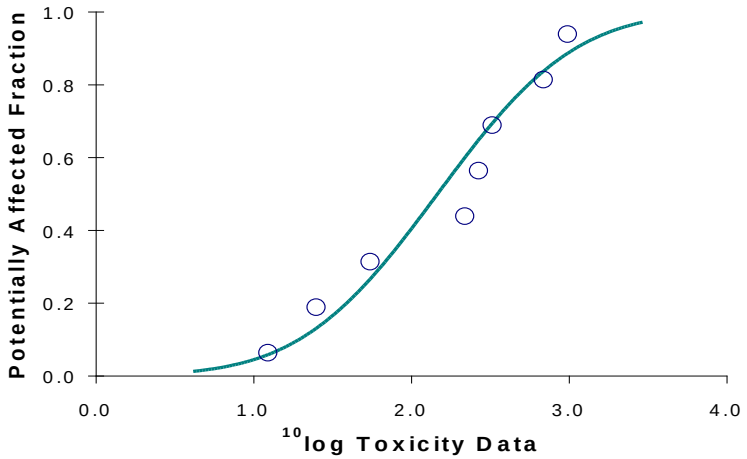


Figure 1: Example of a cumulative SSD curve. The X axis represents the concentration corresponding with the relevant toxicity endpoint (e.g., NOECs or EC50s) of the different species; the Y axis represents the potentially affected fraction.

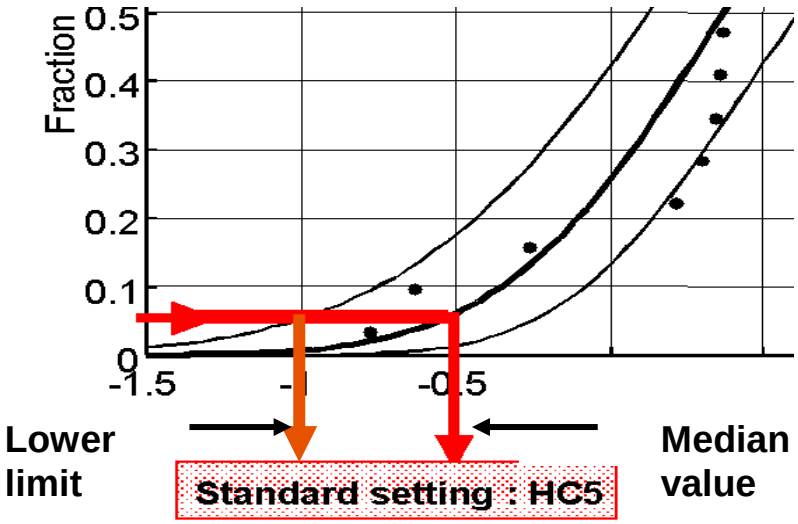


Figure 2: Visualisation of the calculation of the HC5 from a cumulative SSD curve and the corresponding 95% confidence intervals.

SSD curves can be used to calculate the concentration at which a certain fraction of the collection of species is affected.

The TGD [2] reads as follows about the SSD method:

The effect assessment performed with assessment factors can be supported by a statistical extrapolation method if the database on Species Sensitivity Distributions (SSDs) is sufficient for its application. If a large data set from long-term tests for different

taxonomic groups is available (OECD, 1992d), statistical extrapolation methods may be used to derive a PNEC.
In general, the methods work as follows: long-term toxicity data are log transformed and fitted according to the distribution function and a prescribed percentile of that distribution is used as criterion.

The TGD [2], Chapter 3.3.1.2 gives more information about:
- input of the data;
- which taxonomic groups are in any case required;
- minimum number of available data (at least 10 NOECs of 8 taxonomic groups);
- procedure for dealing with several data for one species?;
- 'fitting' to a correct distribution.

The PNEC is calculated as follows:

PNEC = 5%SSD(50%c.i.) / AF

N.B.: 5%SSD(50%c.i.) is the median estimate of the 5^{th} percentile of the SSD. The TGD [2] reads as follows about the assessment factors and the SSD method:

AF is an appropriate assessment factor between 5 and 1, reflecting the further uncertainties identified. Lowering the AF below 5 on the basis of increased confidence needs to be fully justified. The exact value of the AF must depend on an evaluation of the uncertainties around the derivation of the 5th percentile.

The TGD [2] indicates which points need to be taken into account when establishing the assessment factor (AF). A number of recommendations are made as well.

The exact value of the AF must depend on an evaluation of the uncertainties around the derivation of the 5th percentile. As a minimum, the following points have to be considered when determining the size of the assessment factor:
- the overall quality of the database and the endpoints covered, e.g., if all the data are generated from "true" chronic studies (e.g., covering all sensitive life stages);
- the diversity and representativity of the taxonomic groups covered by the database, and the extent to which differences in the life forms, feeding strategies and trophic levels of the organisms are represented;
- knowledge on presumed mode of action of the chemical (covering also long-term exposure);
- statistical uncertainties around the 5th percentile estimate, e.g., reflected in the goodness of fit or the size of confidence interval around the 5th percentile, and consideration of different levels of confidence (e.g. by a comparison between the 5% of the SSD (50%) with the 5% of the SSD (95%));
- comparisons between field and mesocosm studies, where available, and the 5th percentile and mesocosm/field studies to evaluate the laboratory to field extrapolation.

<u>Establishment PNEC by means of microcosm or mesocosm studies</u>
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 surface water exceeds the criterion.
The EU framework biocides does not yet indicate how microcosm or mesocosm studies should be evaluated. This lacuna is for the national framework elaborated in the NL Part

§2.3. As long as this lacuna has not been elaborated in EU framework, the description in the NL part §2.3 is followed.
The assessment factor to be applied will be decided case by case.

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/EC) 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) and iii) 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 of 98/8) 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 aquatic organisms are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI of 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 indications given 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 of 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 aquatic organisms are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI of 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 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’.

The following procedure applies for the biocide and relevant metabolites:

A
If only acute toxicity data are available:
PNEC = lowest L(E)C_{50} for fish and crustacean and algae / 1,000 (10,000 for marine, which can be lowered to 1,000 if two additional L(E)C_{50} are available for marine taxonomic groups (e.g. echinoderms, molluscs)

PEC (acute) / PNEC ≤ 1
the criteria for toxicity aquatic organisms are met.

B
If acute toxicity data and one chronic NOEC (fish or crustaceans) are available.

If the NOEC value has been derived from that trophic level at which the lowest L(E)C50 was found in the acute studies:
PNEC = lowest NOEC for fish and crustacean / 100 (or 1,000 for marine)

PEC (chronic) /PNEC ≤ 1 ,
the criteria for toxicity aquatic organisms are met

If the NOEC value has been derived from a species that did not have the lowest L(E)C50 value in the acute studies:
See A.
The criterion (PNEC) based on the acute toxicity data may, however, not be higher than the available criterion based on the chronic data. If this is the case, the lowest criterion is taken.

C
If acute toxicity data and two chronic NOEC values (fish and/or crustaceans and/or algae) are available.

If the NOEC values have been derived from those trophic levels at which the lowest L(E)C50 were found in the acute studies:
PNEC = lowest NOEC for fish ánd crustacean, or, fish ánd algae, or crustacean and algae / 50 (or 500 for marine, but a reduction to 100 or 50 is possible see note c to table on assessment factors for PNEC saltwater organisms in §1.3)

PEC (chronic) / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

If the NOEC vales have been derived from species that did not have the lowest L(E)C50 values in the acute studies:
PNEC = the lowest NOEC for fish ánd crustacean, or, fish ánd algae, or crustacean and algae / 100 (or 1,000 for marine)

PEC (chronic) / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

If the most sensitive organism has a lower L(E)C_{50} value than the lowest NOEC value, the criterion (PNEC) should be derived with a safety factor of 100 (or 1,000 for marine) to the lowest L(E)C_{50} value.

D
If acute toxicity data and three chronic NOEC values (fish and crustaceans and algae) are available.

If the NOEC values have been derived from those trophic levels at which the lowest L(E)C50 were found in the acute studies:
PNEC = lowest NOEC for fish and crustaceans and algae / 10 (or 100 for marine, but a reduction to a minimum 10 is possible see note d to the table on assessment factors for PNEC saltwater organisms in §1.3)

PEC (chronic) / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

If the NOEC values have been derived from species that did not have the lowest L(E)C50 values in the acute studies:
PNEC = lowest NOEC for fish and crustacean and algae / 50 (or 500 for marine)

PEC (chronic) / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

If the most sensitive organism has a lower $L(E)C_{50}$ value than the lowest NOEC value, the criterion (PNEC) should be derived with a safety factor of 100 to the lowest $L(E)C_{50}$ value.
PNEC = lowest $L(E)C_{50}$ for fish and crustaceans and algae / 100 (or 1,000 for marine)

PEC (acute) / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

The following remark is still made in the TGD [2] (note d of Table 16):

It may sometimes be possible to determine with high probability that the most sensitive species has been examined, i.e. that a further long-term NOEC from a different taxonomic group would not be lower than the data already available. In those circumstances, a factor of 10 applied to the lowest NOEC from only two species would also be appropriate. This is particularly important if the substance does not have a potential to bioaccumulate. If it is not possible to make this judgement, then an assessment factor of 50 should be applied to take into account any interspecies variation in sensitivity. A factor of 10 cannot be decreased on the basis of laboratory studies.

E
If at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups are available then the SSD-method can be applied (see §1.3). This method calculates a point (5%SSD (50%c.i.) below which 5% of the species is at risk with a 50% confidence interval (c.i.) as an intermediate value in the determination of a PNEC.
PNEC = 5%SSD(50%c.i.) / (assessment factor between 5 and 1).
In the TGD the SSD method is worked out only for freshwater PNEC derivation. Furthermore in note d to the table on assessment factors for PNEC saltwater organisms in §1.3 is indicated the assessment factor of 10 cannot be decreased on basis of laboratory studies only, which implies that the minimum assessment factor applied to the SSD method is 10 for deriving the PNEC for saltwater organisms.

PEC / PNEC ≤ 1, the criteria for toxicity aquatic organisms are met.

A full justification should be given for the method used to determine the PNEC.

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

For a further adequate risk assessment data must be submitted which give cause for adjustment of the calculated concentration in surface water or for adjustment of the effect concentration under field conditions; here, (semi) field experiments (such as mesocosm studies) are possible, where a more realistic exposure is mimicked, or laboratory studies with additional species that are representative of surface water.
The assessment factor to be used on mesocosm studies or (semi-) field data will need to be reviewed on a case-by-case basis.

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.

If the adequate risk assessment shows that PEC / PNEC ≤ 1, the use in question can part of the Annex I inclusion.
If the adequate risk assessment shows that PEC / PNEC > 1, the use in question recommended for non Annex I inclusion.

1.5. Developments

Developments

- The Water Framework Directive came into force on 23 October 2000 (Directive 2000/60/EC). This Directive aims at mapping the chemical and ecological water quality by means of a standardised monitoring and reporting protocol. In addition, the desired future water quality is described, together with the path to reach this new situation. There is a link with the Biocides Directive 98/8/EC in view of the burdening of surface water with biocides. The consequences for the authorisation policy of biocides are not yet clear.

- A new testing strategy is developed for fish toxicity tests to reduce the number of fish required. The Commission has asked to carefully consider changes before implementing them.

- EU developments will be followed.

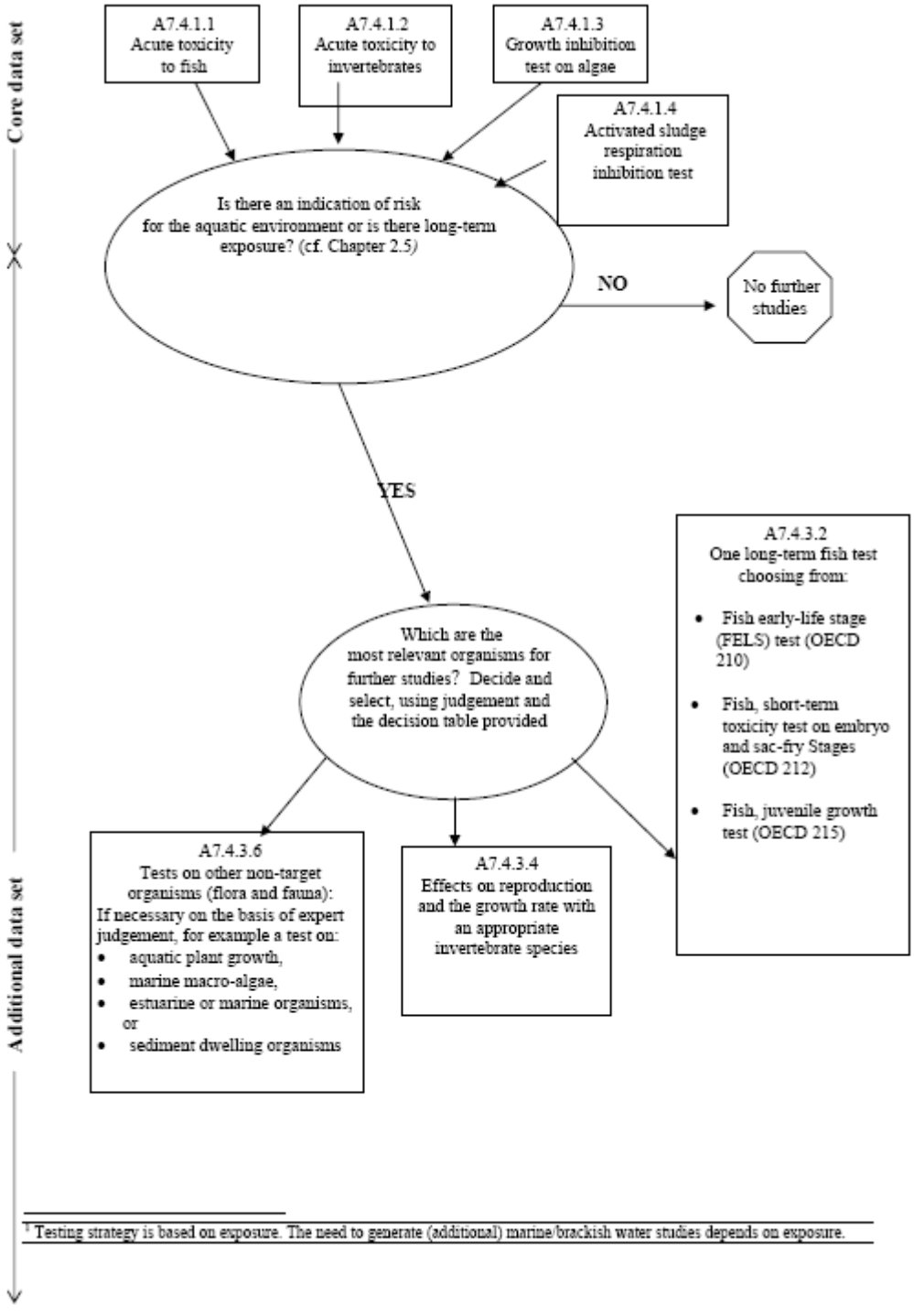
Lacunas

- The procedure for evaluating a microcosm or mesocosm study has not yet been indicated in EU framework. This still needs to be elaborated.

- 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.

2. APPENDICES

Appendix 1 TESTING STRATEGY FOR AQUATIC STUDIES[1] (FIG 3.1 from [3])



[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 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
3. 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.
4. Emission Scenario Document for Biocides (esd) > Documents > Emission scenario Documents > 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).

6 Technical Guidance Document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. Part III. Chapter 4 Use of (Quantitative) Structure Activity Relationships ((Q)SARs). ISBN 92-827-8013-9.