Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; aquatic organisms
Micro-organisms in the STP

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Board
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Chapter 6 Ecotoxicology; aquatic

Category: biocides

IV MICRO-ORGANISMS IN THE STP

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to micro-organisms in sewage treatment plants (STP) 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 of this chapter, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risk to micro-organisms in an STP.

This chapter has a relationship with Chapter 5 Behaviour and fate in the environment; behaviour in surface water, sediment and STP.

Guidelines for assessment of the aspect micro-organisms in an STP are described in the Technical Guidance Document on Risk Assessment [3] and the TNsG on Data Requirements [2].

The points described in this chapter concern further elaborations of the EU procedure. When the aspects mentioned below will be elaborated in the EU, these will be followed

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types in the context of EUBEES. These are briefly described in Appendix A to the environmental section.

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/EC.

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 micro-organisms in an STP. 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.
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.
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.
Because no test methods are available for determination of the concentration of the metabolites in an STP (the PEC) it is not possible to make a PEC/PNEC calculation. It is therefore not meaningful to request toxicity studies for the relevant metabolites. This means that no risk of metabolites on micro-organisms in an STP can be estimated.

Data requirements for the active substance

Standard data requirements
The studies as described in the TNsG on data requirements [2] are summarised below.

7.4.1.4 Inhibition to microbiological activity [Ann. IIA, VII.7.4. and Ann. IIIA, VII.3]
- For example, test according to the EC method C.11. or the corresponding OECD guideline 209 (Activated sludge, respiration inhibition test).
- Relevant efficacy data may be available from industry.

Result:
→ NOEC, ECx

Product-type-specific and additional data
There are no product-type-specific and additional data requirements.

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

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 Chapter 2.5, part B).

1.3. Risk assessment

The risk assessment for micro-organisms in an STP has been elaborated in the following documents:
Technical Guidance Document [3] (TGD):

- Part 2, Chapter 3.4: Effects assessment for micro-organisms in sewage treatment plants (STP).

Introduction
The risk assessment for micro-organisms in an STP is carried out by comparing the PNEC with the PEC.

General evaluation methodology Risk to micro-organisms in an STP
Research into the behaviour of an active substance in an STP is important for a correct estimation of the concentration of such an active substance in a STP (PEC = Predicted Environmental Concentration).
This PEC is an important parameter for the risk estimation for micro-organisms in an STP. The PEC is calculated in accordance with the TGD [3] and the Emission Scenario Documents [4].
The data submitted about the toxicity to micro-organisms in an STP (EC_{50}, NOEC) are used to establish a criterion by application of a assessment factor (PNEC).

The chapter “Behaviour and fate in the environment, sediment and STP” describes how the PEC is determined with the submitted data.
In the decision tree “Risk to micro-organisms in an STP” (Appendix 1 of this chapter) the PEC is related to the toxicity data on the different micro-organisms in an STP.

The procedure for dealing with metabolites has not yet been elaborated in EU framework.

Establishment PNEC

Establishment PNEC by means of a assessment factor on the EC_{50} and NOEC value(s)
The data submitted about the toxicity to micro-organisms in an STP (EC_x, NOEC) are used to establish a criterion by application of a assessment factor.

The assessment factors (TGD chapter 3.4) are presented in the table below

Test	Available value	Assessment factor
Respiration inhibition tests **EU Annex V C.11; OECD 209 (1984f)** ISO 8192 (1986)	NOEC or EC_{10}	10
	EC_{50}	100
Inhibition control in standardised biodegradation tests Ready biodegradability tests EU Annex V C.4 A-F; OECD 301A-F (1992f) 92/69/EEC C4 (1992) ISO-7827 (1994), -9439 (1999), -10707 (1994), -9408 (1999) Inherent biodegradability tests EU Annex V C.9; OECD 302 B-C (1981d-1992g) 88/302/EEC (1988) ISO-9888 (1999)	The tested concentration at which toxicity to the inoculum can be ruled out with sufficient reliability (cf. corresponding text section above) could be considered as a NOEC for the toxicity to microorganisms of a STP	10
Inhibition of nitrification ISO-9509 (1989)	NOEC or EC_{10}	1
	EC_{50}	10
Ciliate growth inhibition tests (preferably with *Tetrahymena,* cf. OECD, 1998a) 1)	NOEC or EC_{10}	1
	EC_{50}	10
Activated sludge growth inhibition tests ISO-15522	NOEC or EC_{10}	10
	EC_{50}	100
Pilot scale activated sludge simulation tests **OECD 303A (2001b)** ISO-11733	Based on case-by-case expert judgement, the tested concentration not impairing proper functioning of the CAS [2] unit could be considered as NOEC for microorganisms in STPs	Case-by-case down to 1
Growth inhibition test with *Pseudomonas putida* NF EN ISO 10712 (1995)	NOEC or EC_{10}	1
	EC_{50}	10
	To be used if no other tests are available	
Pseudomonas fluorescens (Bringmann and Kühn, 1960)	Not usable as it uses glucose as substrate	
Escherichia coli (Bringmann and Kühn, 1960)	Not usable as it uses glucose as substrate	
Vibrio fischeri (MICROTOX) NF EN ISO 11348-1, -2, -3 (1999)	Not relevant for STP as the bacterium is a saltwater species	

Notes
1) Ciliate testing would be required as the guideline becomes available
2) CAS: Continuous Activated Sludge

The TGD [3] reads as follows about what to do if PEC/PNEC >1.

If on the basis of the $PNEC_{microorganisms}$ derived using the procedures described above the PEC/PNEC ratio for industrial / domestic sewage treatment plants is above 1, the following procedure is proposed for refining the $PNEC_{microorganisms}$:

- If on the basis of a test with nitrifying bacteria, a PEC/PNEC ratio above 1 is derived for a specific industrial STP, a revised $PNEC_{microorganisms}$ for this specific site can be derived from a nitrification inhibition test using sludge from this site's STP. The revised $PNEC_{microorganisms}$ for a specific industrial STP is derived from this test using the assessment factors described for nitrifying bacteria. For domestic STPs a revision of the PNEC is not possible in this way - sludge from one STP can not be regarded as being representative (in comparison with the single species test) of all domestic STPs with respect to the nitrifying activity;
- If on the basis of a respiration inhibition test, a PEC/PNEC ratio above 1 is derived for a specific industrial STP, a revised $PNEC_{microorganisms}$ for this specific STP can be derived from a respiration inhibition test using sludge from this site's STP (the result from such a test is sometimes already available). A revised $PNEC_{microorganisms}$ for a specific industrial STP is derived from these tests using the assessment factors described above for respiration inhibition tests. A $PNEC_{microorganisms}$ for domestic STPs can not be derived on the basis of results from respiration tests that use industrial sludge as the source of inoculum;
- If on the basis of a respiration inhibition test, a standardised biodegradation test or an activated sludge growth inhibition or simulation test, a PEC/PNEC ratio above 1 is derived for a specific industrial sewage treatment plant, a revised $PNEC_{microorganisms}$ for this site can be derived from an appropriate pilot scale simulation test using activated sludge from the site's STP as a source of inoculum;
- If on the basis of a single species test with ciliated protozoa a PEC/PNEC ratio above 1 is derived for municipal or industrial sewage treatment plants, a test reflecting the integrity of the native ciliate population in (industrial or domestic) sewage sludge is necessary. The exception to this is where it can be shown that for the industrial STP under consideration protozoa are not relevant. The ability of the protozoan community to eliminate external bacterial food supply should be considered as a possible endpoint in this test. At present a standard protocol for a test based on ciliated protozoa which can be used to provide data for revising a $PNEC_{microorganisms}$ is not available.

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 micro-organisms in an STP 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 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 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 micro-organisms in an STP 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.

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

1.5. Developments

Developments

- None
- EU developments will be followed.

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- It is not clear what is to be understood by relevant transformation products. It is neither clear when data on relevant transformation products must be provided and how these must be evaluated.

2. 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 2000.
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 Document for Biocides: Hyperlink: [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.