Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 6 Ecotoxicology; aquatic organisms sediment organisms

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Author:
Peter Okkerman, MSc

Co-ordination:
Werner Pol, MSc, BSc

Lay-out:
Jiske de Wolf

ctgb

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 NL framework (§2 - §2.5).

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation evaluation of biocides based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the EU Member States on 14 May 2000.
The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and biocides Act) 2006 [1] are met. The product is tested against the Plant Protection Products and Biocides Regulations (RGB) [2]. The evaluation dossiers must meet Annex IIA, IIB, IIIA and IIIB to 98/8/EC

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national evaluation system or where the national evaluation system has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for inclusion in Annex I in case no EU procedure has been described.

2.1. Introduction

This chapter describes the data for sediment organisms for which specific rules apply in the NL framework or where the NL evaluation system has been elaborated in more detail than the EU framework. In addition this chapter describes newly accepted guidance commissioned in the Regulations on Plant Protection Products and Biocides.

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.

Guidelines for evaluation of the aspect aquatic organisms are described in the Technical Guidance Document on Risk Assessment [3], the TNsG on data Requirements [4] and the Guidance Document on Aquatic Ecotoxicology in the context of Directive 91/414/EEC [5]. Additionally in the “wijzigingsregeling RGB deel B [2]” the following methods are designated for the authorisation of biocides: College (2009) Combinatie toxicology, College (2009) Metabolieten and Ctb (2005).

In case of lacunas in the EU assessment methodology for biocides, and if relevant methods exist within the Plant Protection Products framework (PPP), then these PPP methods can be used for the assessment of a biocide, with a supportive argumentation.

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]). These emission scenarios are briefly described

in Appendix A to the environmental section. Additionally in the “wijzigingsregeling RGB deel B [2]” USES 2.0 and MAMPEC 2.5 are included as designated models.

The points discussed 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.

2.2. Data requirements
The data requirements for the NL evaluation are identical to the data requirements for the EU. We therefore refer to the EU part §1.2.

It should be emphasised that a type of use (including use concentrations, dosages and frequencies) proposed by the applicant deviating from the type of use assessed in the EU CAR as part of the Annex I inclusion may trigger additional studies.

A number of lacunas that have not yet been elaborated in EU framework have been elaborated in NL framework. These further elaborations are presented below.

Metabolites
The TNsG on data requirements [4] shows that metabolites should, as regards behaviour, be identified if formed in a percentage greater than 10% of the substance applied.
Legislation (Biocides Directive) stipulates that no authorisation is granted for a biocide if relevant reaction products (= metabolites) have in water (and its sediments), soil and air an effect on non-target species that is considered unacceptable unless it is scientifically demonstrated that there is under relevant field conditions no unacceptable effect.
No link, however, is made between the definition of relevant transformation products and the 10% mentioned in the TNsG on data requirements.
For the NL framework the data requirements for metabolites is elaborated in appendix C.

This means that studies on sediment organisms must be provided for metabolites that that are at any point in time formed in a percentage greater than 10% of the applied substance.

Microcosm or mesocosm study
Submission of a microcosm or mesocosm study is a possible option for a further (adequate) risk assessment.
Such a study can be submitted if the criterion for sediment organisms is exceeded.
The Guidance Document on Aquatic Ecotoxicology in the context of Directive 91/414/EEC [5] is followed for the execution of a microcosm or mesocosm study.

Result:
→ NOEC ecosystem
→ NOEAEC ecosystem

2.3. Risk assessment
For the evaluation methodology for sediment organisms for the national authorisation we refer to the EU framework. There are, however, a number of lacunas in the EU, which are elaborated nationally. This concerns the following supplements:

Metabolites
Metabolites are dealt with as described in §2.2, data requirements and appendix C. For the evaluation methodology this means that metabolites that are formed in a percentage exceeding 10% of the applied substance at any point in time should be evaluated as

regards sediment organisms. These metabolites are evaluated in the same way as active substances.

Determination PNEC by means of microcosm or mesocosm studies.
Submission of a microcosm or mesocosm study is a possible option for a further (adequate) risk assessment.
Such a study should be submitted if the calculated concentration in surface water exceeds the criterion.
The Guidance Document on Aquatic Ecotoxicology in the context of Directive 91/414/EEC [5] is followed for evaluation of a microcosm or mesocosm study.

Combination toxicity
Combination products are formulated biocides that contain more than one active substance. When evaluating the side effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances.
There is no European guidance as regards combination toxicology.

It is possible to base the risk assessment of a combination product on toxicity tests with the formulation. The *acute* toxicity test can lead to variable results because the quantity and the quality of the co-formulants may not be constant and the formulation may alter the availability of the active substances. For the acute risk assessment, the combination toxicity on the basis of the tests with the product is compared with the combination toxicity based on the toxicity research with the separate active substances.
The lowest combination toxicity value or criterion exceedance (see below) is then used in the risk assessment.
The fact that the ratio between the active substances changes by differences in sorption and degradation rate plays a role in establishing *chronic* toxicity. This means that the concentration of the combination product in the environment (the PEC) cannot be predicted because the separate active substances may behave differently after application. For chronic risk assessment it is therefore preferred to determine the toxicity of the combination product on the basis of toxicity research with the separate active substances.

Combination toxicity is determined on the basis of concentration addition.
In theory, three different effects are to be expected when two or more substances are used in a mixture:
- the substances may weaken each others' toxic effects (antagonism)
- the effects of the substances may be additive
- the substances may potentiate each others' toxic effects (synergism).

Although the effects of mixtures of active substances in Biocidal products have only been studied to a very limited extent and toxicological endpoints have not been studied for all relevant species it is expected that active substances in a combination product together contribute to the toxicity of that product. The extent to which the active substances are contributing is poorly known.
The available data indicate that also in case of partial addition the extent of combination toxicity does not deviate strongly from concentration addition. In view of these considerations the evaluation of the toxicity data of combination products is based on concentration addition. In case of concentration addition each substance contributes to the total toxicity of a mixture in proportion to its concentration. The calculation method is given in Appendix B to the environmental section.

The following applies for determination of the combination toxicity:
- where one application is concerned, determination of the acute combination toxicity is based on the ratio of the substances in the product;
- where several applications are concerned, determination of the acute combination toxicity is based on the ratio of the substances on the basis of the calculations of the concentrations after the last application;
- chronic toxicity is always based on the ratio of the substances on the basis of calculations of the concentrations over a certain period.

The above means that for both last-mentioned options the exceedance factors of the individual substances can be added up for evaluation against the criterion.
For the first-mentioned option, acute combination toxicity for one application, this it not possible because the ratio between the substances in the product is the basis here.

Endpoint derivation for biocidal active substances that rapidly degrade.
Newly accepted guidance listed in the Regulations on Plant Protection Products and Biocides, published in the Government Gazette 16551 of 14 October 2010, that come into effect on 1st January 2011 concerns environmental effects assessments for biocidal active substances that rapidly degrade [6]. Additional information on the incorporation of this guidance is presented in the Evaluation manual, Chapter 6 Ecotoxicology; aquatic organisms.

2.4. Approval

Evaluation of the risk to sediment organisms has been laid down in regulations.
The Wgb (Plant protection products and biocides Act) 2006 [1] stipulates in Art. 49 (1) (b3 and b4): “a pesticide will only be authorised if this has no effect that is unacceptable for the environment”.

The evaluation of products on the basis of old active substances already included in Annex I, or new substances, has been laid down in the Plant Protection Products and Biocides Regulations (RGB) [2] in which it is elaborated that these products are evaluated in compliance with the Common Principles.

2.4.1. Criteria and trigger values

The criteria and trigger values in the RGB correspond with the criteria and trigger values in the Biocides Directive, see EU part §1.4.1.

2.4.2. Decision on approval

Decisions on approval are taken in accordance with the Common Principles of the Biocides Directive.
The Board evaluates the biocide against the criteria for the risk to sediment organisms as follows.
As 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’. In line with the TGD [3] and EU part on sediment organisms §1.4.2.approval of a certain use is obtained if PEC / PNEC ≤ 1, thus the criteria for toxicity aquatic organisms are met.

Metabolites

Metabolites are handled as described in Chapter 2.2 Data requirements. For the risk assessment this means that metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance should be evaluated as regards sediment organisms
These metabolites are assessed in the same way as the active substances.

2.5. Developments

There are no lacunas and developments.

3. APPENDICES

Appendix 1 Explanatory notes decision tree on sediment organisms

Route determination
If no toxicity data are available for sediment organisms, choose route A. If only acute toxicity data for sediment organisms are available, choose route B. If chronic toxicity data of sediment organisms are available, choose route C.

Route A:
If no toxicity data are available for sediment organisms, the equilibrium partition method is used to identify whether a potential risk exists for sediment organisms.

1a) If log Kow > 5 an additional assessment factor must be applied: PEC x 10 / PNEC.
1b) If log Kow ≤ 5 this additional assessment factor does not need to be applied: PEC / PNEC.

2) If the ratio PEC/PNEC or 10 x (PEC / PNEC) is lower than or equal to 1, the substance is permissible.

3) If the ratio is greater than 1, study 7.4.3.5.1 (Total sediment tests with sediment organisms (using spiked sediment)) should be carried out. Alternatively, if the PNECsediment is based on acute data, can be refined by aquatic (chronic) toxicity tests and applying the EP method.

4) If the ratio PEC/PNEC is lower than or equal to 1, the substance is permissible.

5) If the ratio is greater than 1, the use in question is considered as not permissible unless a further (adequate) risk assessment shows that there are no unacceptable direct or indirect effects for sediment organisms under relevant field conditions. A further risk assessment may, e.g., consist of a microcosm or mesocosm study or the SSD approach.

Route B:

6) 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 partition method (see also point 1 of route A). The lowest PNEC is used to estimate the risk.

7) If the PEC/PNEC ratio is lower than or equal to 1 is, the substance is permissible.

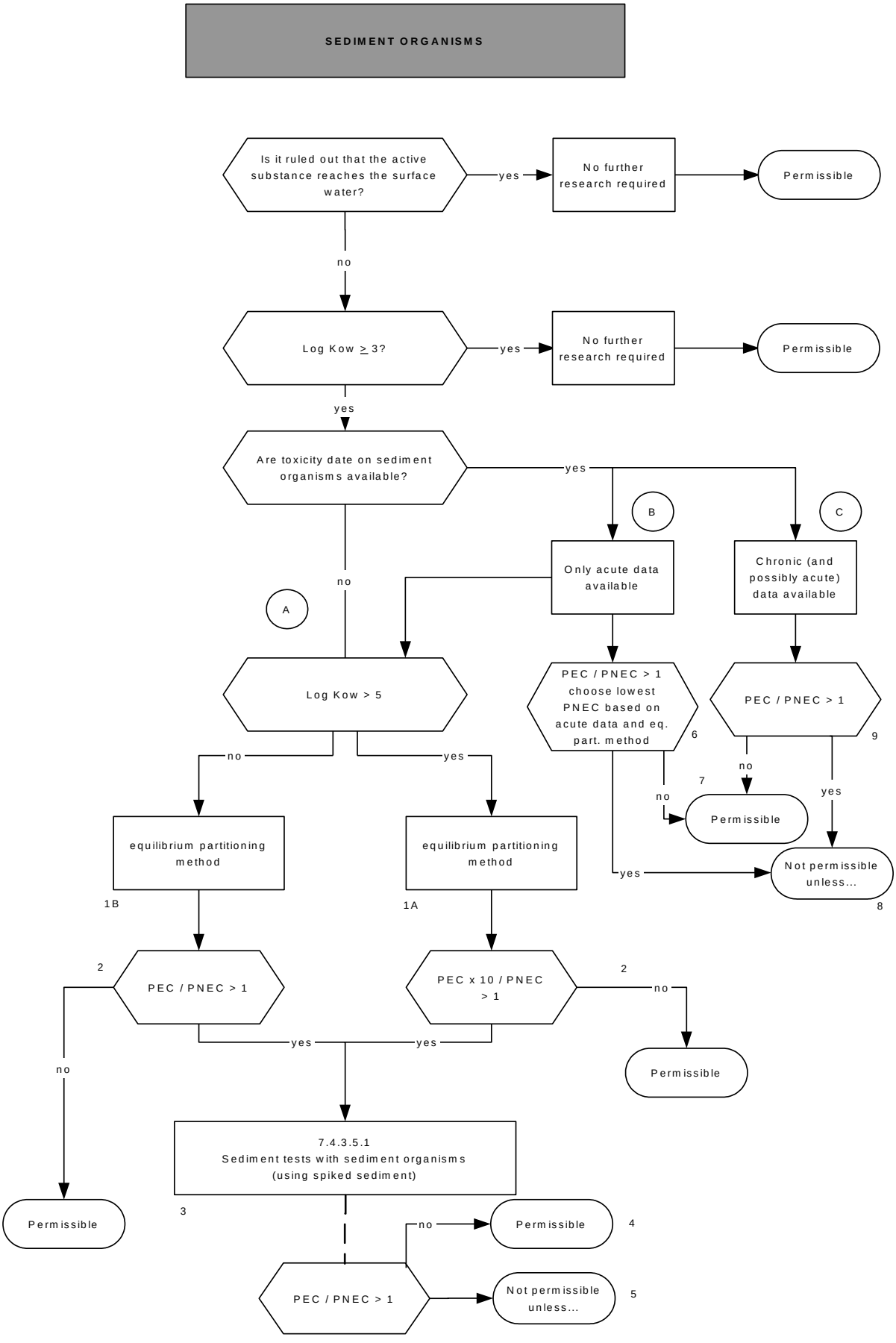
8) If the ratio is greater than 1, the use in question is considered as not permissible unless a further (adequate) risk assessment shows that there are no unacceptable direct or indirect effects for sediment organisms under relevant field conditions. A further risk assessment may, e.g., consist of a microcosm or mesocosm study or the SSD approach.

Route C:

9) If chronic toxicity data for sediment organisms are available, a PNEC is calculated on the basis of these values by applying the assessment factors.

7) If the PEC/PNEC ratio is lower than or equal to 1, the substance is permissible.

8) If the ratio is greater than 1, the use in question is considered as not permissible unless a further (adequate) risk assessment shows that there are no unacceptable direct or indirect effects for sediment organisms under relevant field conditions. A further risk assessment may, e.g., consist of a microcosm or mesocosm study or the SSD approach.


SEDIMENT ORGANISMS
Is it ruled out that the active substance reaches the surface water?
yes
No further research required
Permissible
no
Log Kow ≥ 3?
yes
No further research required
Permissible
yes
Are toxicity date on sediment organisms available?
yes
B
C
Only acute data available
Chronic (and possibly acute) data available
no
A
Log Kow > 5
PEC / PNEC > 1 choose lowest PNEC based on acute data and eq. part. method
6
PEC / PNEC > 1
9
no
yes
7
no
no
Permissible
yes
Not permissible unless...
8
yes
equilibrium partitioning method
1B
equilibrium partitioning method
1A
2
PEC / PNEC > 1
PEC x 10 / PNEC > 1
2
no
yes
yes
no
Permissible
no
7.4.3.5.1
Sediment tests with sediment organisms (using spiked sediment)
3
Permissible
no
Permissible
4
PEC / PNEC > 1
Not permissible unless...
5

4. REFERENCES

1 Regeling voor de toelating, het op de markt brengen en het gebruik van gewasbeschermingsmiddelen en biociden (Wet gewasbeschermingsmiddelen en biociden) (Plant protection products and biocides Act, Wgb 2006);
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/;

2 Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 26 september 2007, nr. TRCJZ/2007/3100, houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Regulations (RGB), published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 Oktober 2007;
including
Regeling van 20 oktober 2009 tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met de aanwijzing van beoordelingsmethoden), published in the Government Gazette (Staatscourant) 16032 of 26 Oktober 2009 came into effect on 1 January 2010;
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/

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 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.

5 European Commission (2002). Guidance Document on Aquatic Ecotoxicology in the context of Directive 91/414/EEC (SANCO/3268/2001 rev 4 final, 17 October 2002).

6 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).