Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

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

version 1.0; January 2010

Authors:
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

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 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 of 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 micro-organisms in an STP 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.

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. Estimated or measured concentrations in surface water are determined in this chapter.

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 [4].

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 emission scenarios are briefly described in Appendix A to the environmental section.

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.

2.3. Risk assessment

For the evaluation methodology for micro-organisms in an STP for the national authorisation we refer to the EU framework. There is, however, a lacuna in the EU, which is elaborated nationally. This concerns the following supplement:

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.

2.4. Approval

Evaluation of the risk to micro-organisms in an STP 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 conducts evaluates a biocide against the criteria for the risk to micro-organisms in an STP 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 [**Fout! Bladwijzer niet gedefinieerd.**] and EU part on STP §1.4.2.approval of a certain use is obtained if PEC / PNEC ≤ 1, thus the criteria for toxicity to micro-organisms in the STP are met. This applies for both the biocide and relevant metabolites:

If:
$PEC \leq PNEC_{micro\text{-}organisms}$
the criteria for toxicity micro-organisms in an STP are met.

If the active substance does not meet the trigger values above, the criteria for toxicity micro-organisms in an STP are not met.

2.5. Developments

There are no developments.
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.

3. 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.