Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 6 Ecotoxicology; terrestrial organisms birds and mammals

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Chapter 6 Ecotoxicology; terrestrial organisms

Category: biocides

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II BIRDS AND MAMMALS

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to birds and mammals 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 birds 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 risks to birds and mammals.

This chapter has a relationship with Chapter 4, Human toxicology of the Evaluation manual Biocides as regards data concerning mammals; Chapter 5, Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plants (STPs) as regards data concerning the concentration in water, and Chapter 6, Ecotoxicology, aquatic of the Evaluation manual Biocides as regards data concerning bioconcentration (BCF).

This chapter has a relationship with the following EU documents:

- Technical Guidance Document [**Fout! Bladwijzer niet gedefinieerd.**] ;
- CA-Nov06-Doc.4.3 [3]: Addendum relevant to Biocides to the TGD on Risk Assessment $PNEC_{oral}$ derivation for the primary and secondary poisoning assessment of anti-coagulant rodenticides
- TNsG on data requirements [4];
- Guidance Document on Risk Assessment for Birds and Mammals [6].
- Additionally in the “wijzigingsregeling RGB deel B [2]” the following methods are designated for the authorisation of biocides: College (2009) Combination toxicology, College (2009) Metabolites 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 [5]). These are briefly described in Appendix A. product type 14, Rodenticides [4] is in particular relevant.

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.
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.

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.

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 where the risk assessment shows that the active substance, a substance giving cause for concern or a degradation or reaction product (= metabolite) entails an unacceptable risk in one of the environmental compartments – water (including sediment), soil and air. This also includes the risks to non-target organisms in those compartments.
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 birds and mammals must be provided for metabolites that that are at any point in time formed in a percentage greater than 10% of the applied substance. For birds and mammals this concerns metabolites formed in the soil (for secondary poisoning by eating soil organisms) and in surface water (directly and for secondary poisoning by eating aquatic organisms).

Further adequate risk assessment
Submission of a higher tier study is possible in the context of a further (adequate) risk assessment. This needs to be provided if the PEC exceeds the criterion. For the possibilities of a higher tier study we refer to the European Guidance Document on Risk Assessment for Birds and Mammals [6].

2.3. Risk assessment

For the evaluation methodology for birds and mammals 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 birds and mammals. For birds and mammals these are metabolites that are formed in the soil (for secondary poisoning by eating soil organisms) and in surface water (directly and for secondary poisoning by eating aquatic organisms).
These metabolites are evaluated in the same way as active substances.

Further adequate risk assessment
Submission of a higher tier study is possible in the context of a further (adequate) risk assessment. For the way in which a field study must be evaluated, we refer to the European Guidance Document on Risk Assessment for Birds and Mammals [6].

Exposure via granules
See Evaluation Manual Plant protection products Chapter 7; ecotoxicology; terrestrial.

Furthermore, the procedure for dealing with combination toxicity, a national matter, has been elaborated.

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.

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 for birds and mammals 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 birds and mammals as described in the EU Part §1.3, the PNEC can be calculated in different ways. Additionally the PEC is calculated and established as described in the EU Part §1.3. In line with the TGD [**Fout! Bladwijzer niet gedefinieerd.**] and the addendum [3] and EU part on aquatic 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 birds and mammals.
These metabolites are assessed in the same way as the active substances.

2.5. Developments

There are no lacunas and developments.

3. APPENDICES

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Appendix 1 Explanatory notes decision tree for birds and mammals

Exposure via direct poisoning

1) Qualitative assessment: A PEC is calculated as described in the section "Exposure via direct poisoning" (TIER 1 and 2). The LD50 acute is derived. PEC and LD50 are compared
2) Quantitative assessment: A PEC is calculated as described in the section "Exposure via direct poisoning" (TIER 1 and 2). A PNEC is calculated by applying safety factors. The PEC/PNEC ratio is then calculated.

3) If PEC/PNEC ≤ 1, the criteria are met.

4) If PEC/PNEC > 1, the use cannot be permitted unless a further (adequate) risk assessment shows that the criteria are not exceeded under relevant field conditions.

Exposure via secondary poisoning

Target species as food -→ see A
Fish as food ---> see B
Earthworms as food ---> see C

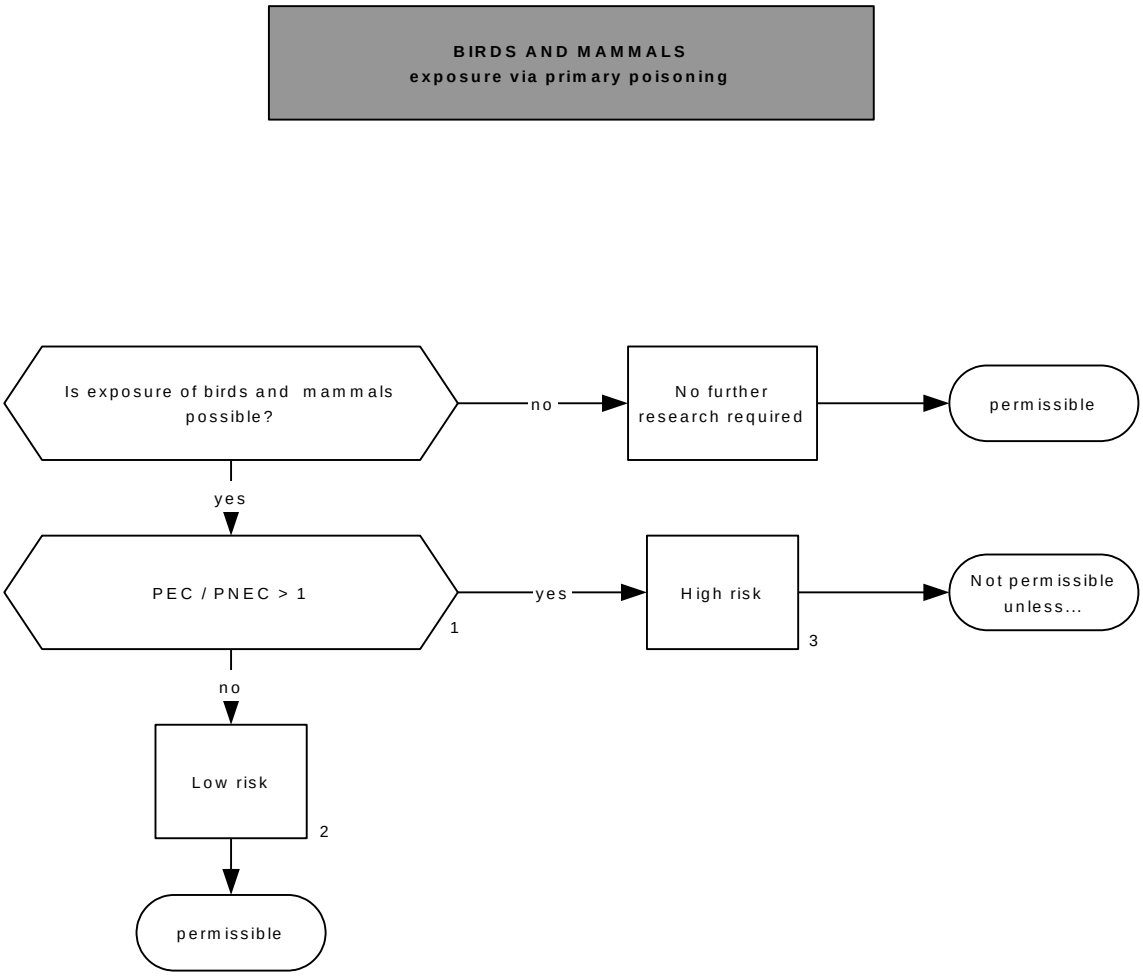
1) Qualitative assessment: A PEC is calculated as described in the section "Exposure via secondary poisoning" (TIER 1 and 2). The LD50 acute is derived. PEC and LD50 are compared
2) Quantitative assessment: A PEC (TIER 1 and 2) and a PNEC are calculated as described in the section "exposure via secondary poisoning". The PEC/PNEC ratio is then calculated.

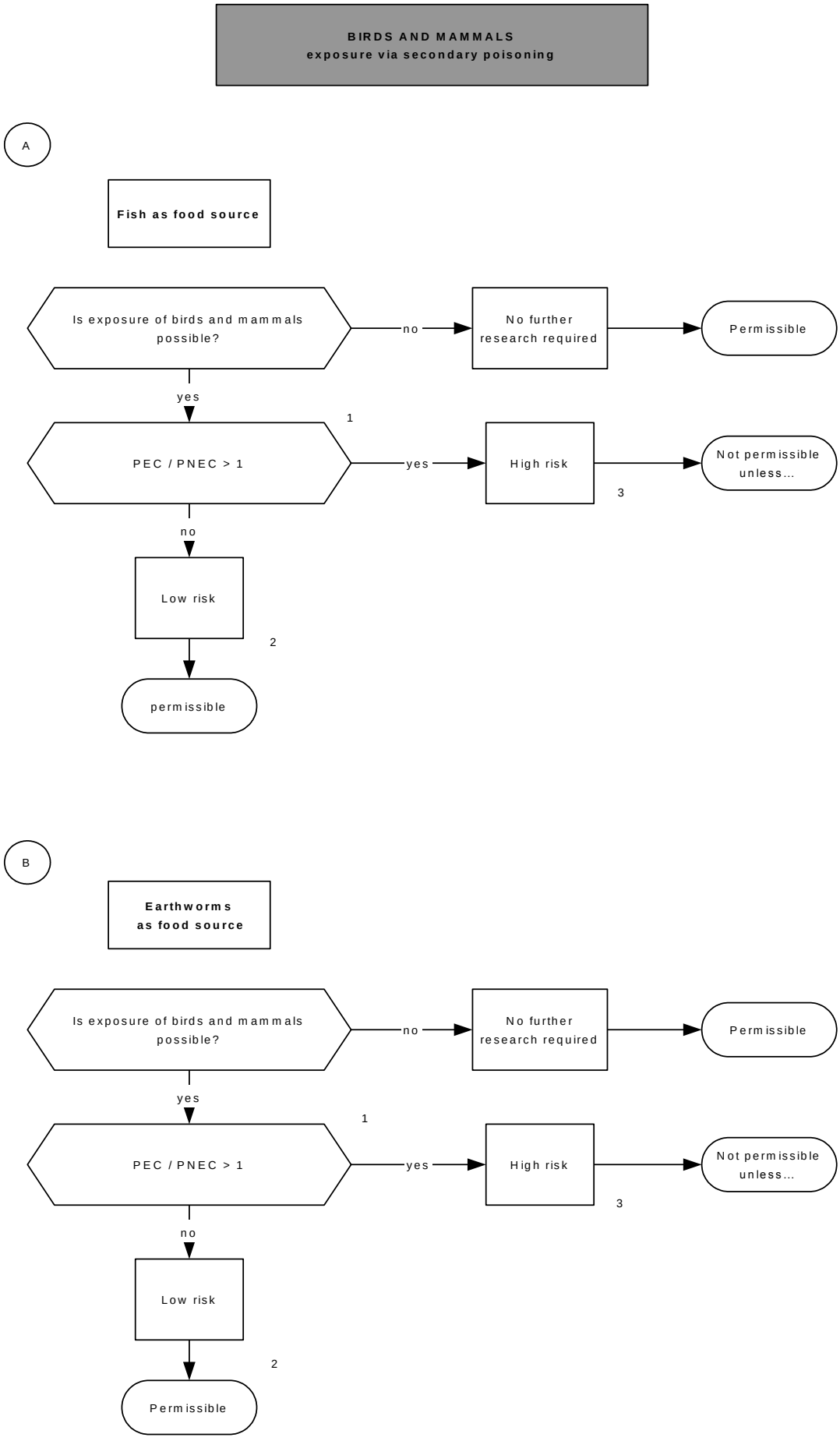
2) If PEC/PNEC ≤ 1, the criteria are met.

3) If PEC/PNEC > 1, the use cannot be permitted unless a further (adequate) risk assessment shows that the criteria are not exceeded under relevant field conditions.

Exposure via granules

See EU part Evaluation manual §1.4.2 and plant protection products Chapter 7: Ecotoxicology; terrestrial.


BIRDS AND MAMMALS
exposure via primary poisoning
Is exposure of birds and mammals possible?
no
No further research required
permissible
yes
PEC / PNEC > 1
yes
High risk
Not permissible unless...
1
3
no
Low risk
2
permissible


BIRDS AND MAMMALS
exposure via secondary poisoning
A
Fish as food source
Is exposure of birds and mammals possible?
no
No further research required
Permissible
yes
1
PEC / PNEC > 1
yes
High risk
3
Not permissible unless...
no
Low risk
2
permissible
B
Earthworms as food source
Is exposure of birds and mammals possible?
no
No further research required
Permissible
yes
1
PEC / PNEC > 1
yes
High risk
3
Not permissible unless...
no
Low risk
2
Permissible

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 CA-Nov06-Doc.4.3. Addendum relevant to Biocides to the TGD on Risk Assessment PNECoral derivation for the primary and secondary poisoning assessment of anti-coagulant rodenticides.

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 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.

6 The European Guidance Document on Risk Assessment for Birds and Mammals, SANCO/4145/2000, 25 September 2002.