Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 6 Ecotoxicology; aquatic and terrestrial bioconcentration

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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 and terrestrial bioconcentration

Category: biocides

III BIOCONCENTRATION

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk of bioconcentration 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 bioconcentration 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 as regards bioconcentration.

This chapter has a relationship with Chapter 5, Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plants (STPs).

Guidelines for evaluation of the aspect bioconcentration are described in the Technical Guidance Document on Risk Assessment [3], the TNsG on data Requirements [4] and the TNsG on Annex I inclusion [5].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 [6]). 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 the NL Part to §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 and part of the Annex I inclusion may trigger the requirement of 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 in water, 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) 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. This also includes the risk to non-target organisms in these 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 bioconcentration must be provided for metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance.

2.3. Risk assessment

For the evaluation methodology for aquatic organisms 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:

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 bioconcentration. These metabolites are evaluated in the same way as active substances.

2.4. Approval

Evaluation of the risk of bioconcentration 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 the evaluation of the biocide against the criteria for the risk to aquatic organisms in line with the procedures described in the EU part on Bioconcentration as follows:

A on basis of indicative BCF:
Indicative BCFs are calculated on the basis of log Kow. One BCF for aquatic organisms and one BCF for terrestrial organisms. Surface active, dissociating or inorganic substances (e.g. metals) require studies for BCF derivation.

The derived BCF is used to test the requirement for a secondary poisoning assessment and for the evaluation of the PBT criteria (see B3).

Aquatic organisms
If it is expected on the basis of these calculations that the substance is not bioaccumulating for aquatic organisms and there is no risk via secondary poisoning, the criteria for bioconcentration for aquatic organisms are met. Evaluation is performed against the following trigger values:

- BCF ≤ 1000 for substances that are readily biodegradable or;
- BCF ≤ 100 for substances that are not readily biodegradable.

Terrestrial organisms
If it is expected on the basis of these calculations that the substance is not bioaccumulating for soil organisms and there is no risk via secondary poisoning, the trigger values for bioconcentration for soil organisms are met. Evaluation is performed against the following trigger values [3]:

In summary: if, at base-set level, a substance:

- has a log Kow ≥ 3, or;
- is highly adsorptive, or;
- belongs to a class of substances known to have a potential to accumulate in living organisms, or;
- there are indications from structural features;
- and there is no mitigating property such as hydrolysis (DT50 < 12 hours).

there is an indication of bioaccumulation potential.

If risk via secondary poisoning is expected or if the substance is possibly bioaccumulating, the risk is determined by means of experimental studies.
See B for aquatic organisms and C for soil organisms.

B. on basis of BCFs from experimental studies with aquatic organisms
The experimental BCF is used for PBT assessment. Furthermore the BCF is tested against trigger values for bioconcentration for aquatic organisms and the BCF is used to determine the risk to birds and mammals via secondary poisoning.

B1 Based on the result of experimental studies. If:
- BCF is lower than or equal to 1000 for readily biodegradable substances or;
- BCF is lower than or equal to 100 for substances that are not readily biodegradable.

The criteria for bioconcentration are met.

If:
- BCF is greater than 1000 for readily biodegradable substances or;
- BCF is greater than 100 for substances that are not readily biodegradable.

The criteria for bioconcentration are not met unless the risk assessment clearly shows that there are under field conditions, when the biocide is used consistent with the proposed instructions for use, no direct or indirect effects on the viability of exposed organisms, including marine and estuarine organisms in seas and river mouths.

B2, B3 or B4 must be met as well (see below).

B2 - Based on the results of the experimental studies. If:
- BCF is lower than or equal to 2000 ánd there is no risk of secondary poisoning.

The criteria for bioconcentration are met.
If the active substance does not meet the trigger value above, the criteria for bioconcentration are not met.

B3 - Based on the results of the experimental studies. If:
- BCF is between 2000 and 5000, the PBT approach should be followed.

	PBT-criteria	**vPvB-criteria**
P	Half-life > 60 d in marine water or > 40 d in freshwater* or half-life > 180 d in marine sediment or > 120 d in freshwater sediment*	Half-life > 60 d in marine- or freshwater or >180 d in marine or freshwater sediment
B	BCF > 2000	BCF > 5000
T	Chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects	Not applicable

For more information about the PBT criteria see TGD [3].

If the active substance meets the trigger values above, the criteria for bioconcentration are not met.
If the active substance does not meet the trigger values above, the criteria for bioconcentration are met.

B4
Based on the results of the experimental studies. If:
- BCF is greater than 5000,

The criteria for bioconcentration are not met.

C. soil organisms
If risk is expected via secondary poisoning or if the substance is possibly bioaccumulating, the risk is determined by means of experimental studies.
For soil organisms it is not clear how further evaluation must be carried out if the trigger values mentioned under A are not met; the BCF, however, is used to determine the risk to birds and mammals via secondary poisoning.

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 aquatic organisms
These metabolites are assessed in the same way as the active substances.

Assessment of Endocrine Disruption (ED)

Assessment of Endocrine disruption is part of the PBT assessment, but can be considered a lacuna that has not yet been elaborated in EU framework and therefore partially has been elaborated in NL framework. The further elaboration is presented below:

Identification of a potential endocrine disrupter is based on the assessment of the following information:

1. Check whether the substance is listed in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706).
2. Evaluate the mode of action as described in doc IIB section 2 efficacy of the product and whether there is a link to a endocrine disruption working mechanism.
3. Collect and evaluate information on endocrine disruption (both environment and human health related);

If the available information provide evidence of potential endocrine related effects then it must be dertermined to whether these effects are non-threshold. At present there is, however, no agreed approach on how to implement the aspect of endocrine disruption in the risk assessment.

2.5. Developments

The criteria for the PBT assessment are under discussion. In future the assessment probably will be based on guidance from Reach.

It is not clear how evaluation for soil organisms must be carried out if the calculations show that risk is expected via secondary poisoning or if the substance is possibly bioaccumulating.

3. APPENDICES

Appendix 1 Explanatory notes decision tree bioconcentration (EU)

1) Indicative BCFs are calculated on the basis of data of 3.9, 6.2, 7.4.2 and 7.5.5. One BCF for aquatic organisms and one BCF for terrestrial organisms.

   Surface active substances (surface tension lower than 50 mN/m), dissociating or inorganic substances such as metals require data on bioaccumulation from e.g. toxicokinetic studies (including metabolism), residue studies or monitoring data on aquatic organisms (e.g. data on residues in tissues of aquatic organisms and on concentrations in the environment) or a relevant study available.

   On the basis of these calculated BCFs it is investigated whether the substance may possibly be bioaccumulating or whether there is a risk via secondary poisoning. See §2.4.2 for trigger values.

2) If the substance is not bioaccumulating and there is no risk of secondary poisoning, the substance is permissible for this aspect.

3) If a risk via secondary poisoning is expected or if the substance is possible bioaccumulating (or on other grounds) studies into bioaccumulation must be carried out.

For aquatic organisms

4) Based on the results of the experimental studies. If:
   - BCF is lower than or equal to 1000 for substances that are readily biodegradable or
   - BCF is lower than or equal to 100 for substances that are not readily biodegradable,

   the criteria for bioconcentration are met.

5a) Based on the results of the experimental studies. If:
   - BCF is lower than or equal to 2000 ánd there is no risk of secondary poisoning

   the criteria for bioconcentration are met.

5b) If the BCF is lower than or equal to 2000 and there is a risk of secondary poisoning, the criteria for bioconcentration are not met.

6) Based on the results of indicative BCF (7.2.4) or the experimental BCF studies (7.4.3.3.1 and 7.4.3.3.2) the PBT approach must be followed:

Criterion	PBT-criteria	VPvB-criteria
P	Half-life > 60 d in marine or > 40 d in freshwater* or half-life > 180 d in marine sediment of > 120 d in freshwater sediment*	Half-life > 60 d in marine or freshwater or > 180 d in marine or freshwater sediment
B	BCF > 2,000	BCF > 5,000
T	Chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects	Not applicable

* For the purpose of marine environmental risk assessment half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.

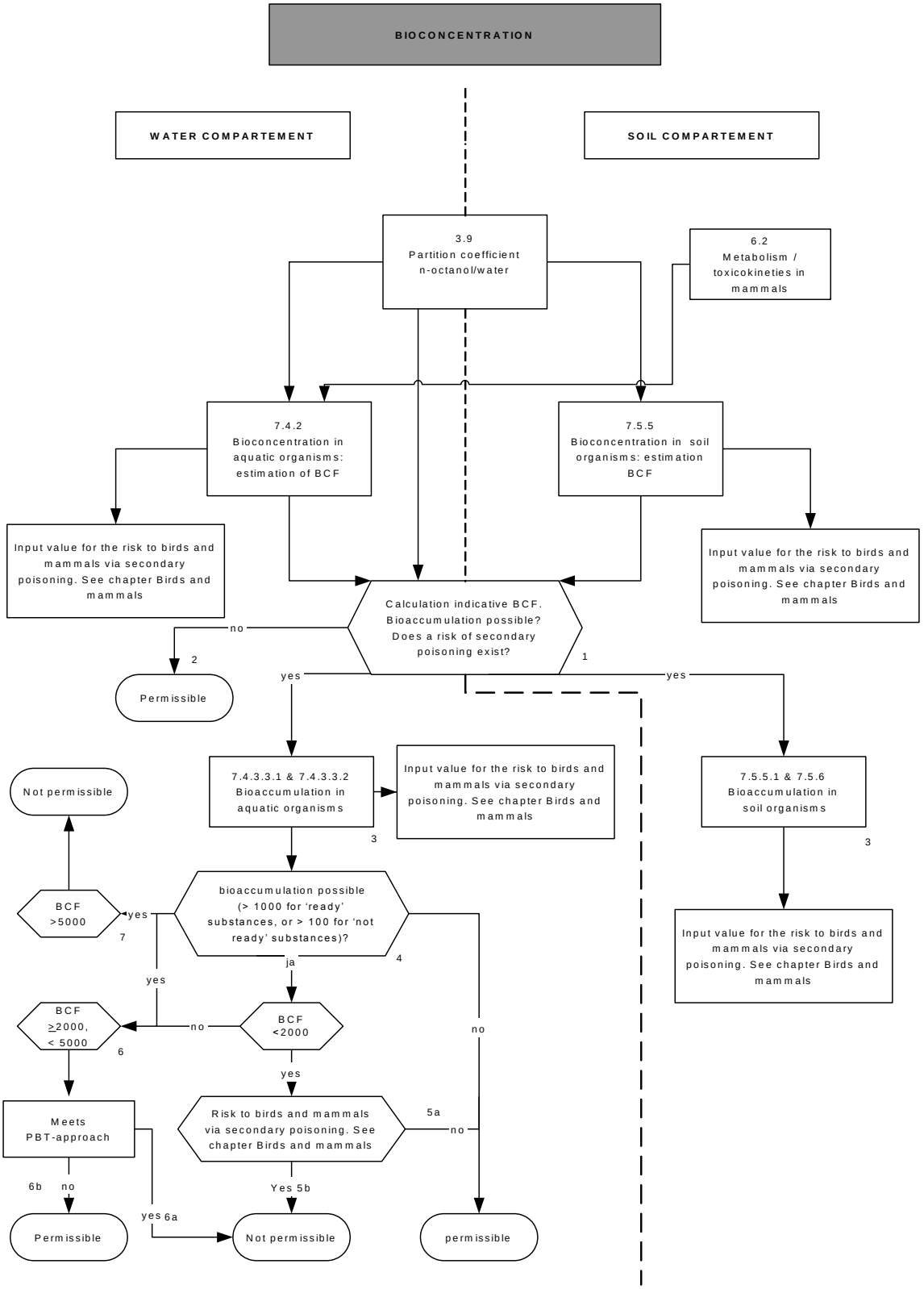
6a) If the active substance meets the trigger values in the table above, the criteria for bioconcentration are not met.

6b) If the active substance does not meet the trigger values above, the criteria for bioconcentration are met.

7) Based on the results of the experimental studies. If:
- BCF is greater than 5000,

The criteria for bioconcentration are not met

For soil organisms
No trigger values for evaluation.


BIOCONCENTRATION
WATER COMPARTEMENT
SOIL COMPARTEMENT
3.9
Partition coefficient n-octanol/water
6.2
Metabolism / toxicokineties in mammals
7.4.2
Bioconcentration in aquatic organisms: estimation of BCF
7.5.5
Bioconcentration in soil organisms: estimation BCF
Input value for the risk to birds and mammals via secondary poisoning. See chapter Birds and mammals
Input value for the risk to birds and mammals via secondary poisoning. See chapter Birds and mammals
Calculation indicative BCF. Bioaccumulation possible? Does a risk of secondary poisoning exist?
1
no
2
Permissible
yes
yes
7.4.3.3.1 & 7.4.3.3.2
Bioaccumulation in aquatic organisms
3
Input value for the risk to birds and mammals via secondary poisoning. See chapter Birds and mammals
7.5.5.1 & 7.5.6
Bioaccumulation in soil organisms
3
Input value for the risk to birds and mammals via secondary poisoning. See chapter Birds and mammals
Not permissible
BCF >5000
yes
7
bioaccumulation possible (> 1000 for 'ready' substances, or > 100 for 'not ready' substances)?
4
ja
yes
BCF ≥2000, < 5000
no
6
BCF <2000
no
yes
Meets PBT-approach
Risk to birds and mammals via secondary poisoning. See chapter Birds and mammals
5a
no
6b
no
Yes 5b
yes 6a
Permissible
Not permissible
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 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 TNsG on Annex I inclusion. 2002. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB. April 2002

6 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.