Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 5 Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plant (STP)

version 1.0; January 2010

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Board
for the Authorisation
of plant protection products and biocides

Chapter 5 Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plant (STP)

Category: biocides

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the behaviour of a biocide and the active substance in surface water and sediment, and the behaviour in sewage treatment plants (STPs), and which evaluation methodologies are applied for the NL framework (§2 - §2.5).

This chapter consists of two parts, one part about behaviour in surface water and sediment (I), and a second part about behaviour in sewage treatment plants (STPs) (II).

I BEHAVIOUR IN SURFACE WATER AND SEDIMENT

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 serves to determine estimated or measured concentrations in surface water, which are used for risk estimation for organisms that depend on surface water (aquatic organisms, sediment organisms and birds and mammals).

In view of the above, there is a relationship with the following chapters on Ecotoxicology, aquatic organisms (see Chapter 6 Ecotoxicology; aquatic) and Ecotoxicology, terrestrial organisms (see Chapter 6 Ecotoxicology; terrestrial).

The concentration in surface water depends on factors such as direct emissions to surface water or indirect emissions via sewage treatment plants, or the extent to which a substance leaches from treated materials and reaches the water via drainage pipes. Via this last route and specifically the potential application of surplus activated sludge on land, there is a relationship with Chapter 5 Behaviour and fate in the environment; behaviour in soil; Leaching to groundwater. For Dutch communal STP's however, this emission route is not relevant [3].

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various types in emission scenario documents (see the ex-ECB web site [4]). Objective of these emission scenarios is the harmonisation of the annex I inclusion and authorisation process for biocidal products. The emission scenario documents relevant for various product types are briefly summarized 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.

One aspect has been elaborated in the NL framework which has not yet been worked out in EU framework. This further elaboration is presented below. If in EU framework clarity will be provided about these currently not elaborated aspects, these will be followed.

The TNsG on data requirements [5] shows that studies for metabolites should, as regards behaviour in water, be identified that are at any point in time formed in a percentage greater than 10% of the substance applied.
The Biocides Directive as well as the Plant protection products and biocides Act [1] stipulates that no authorisation shall be granted for a biocide if relevant metabolites or breakdown or reaction products in water (or its sediments) have an effect considered unacceptable, unless it is demonstrated that under relevant field conditions there is no unacceptable effect.
No link, however, is made between the definition of relevant metabolites and the 10% mentioned in the TNsG on data requirements.

For the NL framework it is assumed that relevant metabolites are those metabolites that are formed in a percentage greater than 10% of the substance applied at any point in time. This means that behavioural studies must be provided for metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance [6].

2.3. Risk assessment

The methodology for the NL evaluation is identical to the EU methodology. We therefore refer to the EU part §1.3.
Metabolites are handled as described in Chapter 2.2. 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 (= relevant metabolites) should be evaluated. These metabolites are assessed in the same way as the active substances.

Conform Directive 98/83/EC on the quality of water intended for human consumption, pesticides are defined as: “organic insecticides, herbicides, fungicides, nematicides, acaricides, algicides, rodenticides and slimicides, similar products (such as growth regulators) and their respective metabolites and degradation and reaction products”.

For the assessment of the drinking water criterion for biocide applications, the interim decision tree of the Ctgb, as laid down in C-163.5 [7], applies until more guidance is available. The Tier 1 possibility as provided in C-163.5, however, does not apply to uses that emit via STP, since the PIEC in the edge-of-field ditch according to TOXSWA is used as a basis for further calculations. Furthermore, the used travelling time and dilution are also not suitable for surface water receiving discharge water from an STP.

With respect to the assessment of the drinking water criterion in surface water intended for the abstraction of drinking water, active substances can be divided in three classes:

1. **new substances** (< 3 years on Dutch market)
2. **old substances of no concern**
3. **old substances of concern**

For these categories the following methodology is followed:

1. For **new substances** on the Dutch market (< 3 years authorised in NL) pre-

registration modelling is needed. However, no standardized methodology is available for mathematical modelling of the substance concentration at the drinking water abstraction points. Assessment of the drinking water criterion in first tier is evaluated based on the $PEC_{surfacewater}$. The PECsurfacewater, determined at the point of discharge, can be considered as a conservative worst case assessment for the PECsurfacewater at the drinking water abstraction points. Where based on the PECsurface water no exceedance of the 0.1 µg/L criterion is calculated, it is considered that the substance causes no problems at the drinking abstraction point. If predicted concentrations exceed the drinking water criterion, first, emission reducing measures will be proposed. If then the substance still exceeds the drinking water criterion but with a factor < 5, authorisation could be granted under condition of post-registration monitoring. When a risk still cannot be excluded based on this conservative assessment, authorisation cannot be granted unless the applicant submits an acceptable adequate risk assessment (e.g., estimates of dilution factors). This adequate risk assessment will be judged by Ctgb on a case-by-case basis.

2. **Old** (> 3 years authorised in NL) **substances of no concern**: Surface water intended for the abstraction of drinking water is subject to extensive pesticide monitoring, coordinated by Vewin (Association of Dutch Water Companies). On a regular basis, active substances (and metabolites), that exceed the drinking water criterion for surface water are listed by Vewin. The list of substances of concern is yearly updated by the VEWIN and provided to the Ctgb. For substances that have been on the market for over 3 years at the time of the assessment and are not included on the list of substances of concern, there is no need to analyse monitoring data or perform model calculations (a standard paragraph is added to the assessment). The Ctgb holds the view that there are in this case no concrete indications for concern about the consequences of this product, if used in accordance with the Statutory Use Instructions, for surface water from which drinking water is produced. The Ctgb expects no exceedance of the drinking water criterion and the product is considered not to have an effect that is unacceptable for the environment on this point.
3. For **old** substances (> 3 years authorised in NL) that have been indicated as **substances of concern** by the VEWIN, the analysis of post-registration monitoring data is performed in line with C-163.5. The available monitoring data of the VEWIN of the most recent 5 years at all drinking water abstraction points will be analysed.

2.4. Approval

The assessment of the behaviour in water has been laid down in regulations. Under National legislation, the Plant protection products and biocides Act (2006) states in Art. 49, under 1b: “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 existing active substances already included in Annex I, or new substances, has been laid down in the RGB, Chapter 10 [2], in which it is elaborated that these products are evaluated in compliance with the Common Principles.

Metabolites are handled as described in Chapter 2.2. For decision-making on permissibility this means that metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance (= relevant metabolites) should be evaluated. These metabolites are assessed in the same way as the active substance.

2.4.1. Criteria and trigger values

The criteria and trigger values under national legislation correspond with the criteria and trigger values in the Biocides Directive and the TNsG on Annex I inclusion (see EU part §1.4.1). The concentration in surface water and sediment as determined in accordance with the methodologies in this chapter, are used to assess the risk for aquatic organisms. The ecotoxicological criteria and trigger values have been laid down in the part Ecotoxicology; aquatic organisms.
Further to a decision of the College of Beroep voor het bedrijfsleven (CBb, Court of Appeal on Trade and Industry) of 19 August 2005 (AWB 04/37) approval should be judged against the drinking water criterion. The criterion laid down for surface water intended for drinking water production is that the concentration of any pesticide and the metabolites formed from that pesticide must be lower than 0.1 µg/l (Directive 75/440/EEC, Directive 98/83/EC).

2.4.2. Decision on approval

Evaluation complies with the Common Principles of the Biocides Directive.

Substances are evaluated against the criteria for aquatic organisms. This evaluation has been elaborated in the part Ecotoxicology; aquatic organisms (see Chapter 6 Ecotoxicology; aquatic).

For the NL framework it is assumed that metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance (= relevant metabolites) should be evaluated. These metabolites are assessed in the same way as the active substance.

At the national level, further to a decision of the College of Beroep voor het bedrijfsleven (CBb, Court of Appeal on Trade and Industry) of 19 August 2005 (AWB 04/37) approval is judged against the drinking water criterion following an interim decision procedure, described in §2.3 of the NL part.

2.5. Developments

Developments

- For plant protection products a tiered approach for testing against the drinking water criterion is under development. The first tier concerns testing against the drinking water criterion in the field ditch, the last tier is testing against monitoring data. New developed methodologies to estimate dilution, travelling time and substance concentration at the drinking abstraction point may be suitable also for risk assessment of biocides.

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- Methodology for higher tier evaluation of the drinking water criterion for surface water for new substances not yet on the market.

II BEHAVIOUR IN THE SEWAGE TREATMENT PLANT (STP)

3.

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation and 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 evaluated 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 behaviour 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.

Objectives are to determine estimated or measured concentrations in the STP, which are used for risk assessment for micro-organisms in the STP, estimation of the concentration in surface water, which is used for risk assessment for organisms that depend on surface water (aquatic organisms and birds and mammals), and estimation of the concentration in agricultural soil, which is used for risk assessment for organisms that depend on the soil (soil organisms, birds and mammals). The concentration in the STP depends on factors such as direct emissions to the sewage system or indirect emissions via surfaces to the sewage system.

In view of the above, there is a relationship with the following chapters Ecotoxicology aquatic organisms (see Chapter 6 Ecotoxicology; aquatic) and Ecotoxicology terrestrial organisms (see Chapter 6 Ecotoxicology; terrestrial).

2.2. Data requirements

The data requirements for the NL evaluation are identical to the data requirements for the EU. We therefore refer to §1.2 of the EU part, where the NL question codes are given as well.

2.3. Risk assessment

The assessment methodology for the NL situation is identical to the assessment methodology for the EU. We therefore refer to §1.2 of the EU part.

2.4. Approval

2.4.1. Criteria and trigger values

The concentration in an STP is used in the evaluation of the risk for the STP and as starting point for calculation of the concentration in surface water and sediment. The

trigger values have been laid down in the section Ecotoxicology; Risk for an STP and surface water.

2.4.2. Decision on approval

The concentration in an STP is used in the decision making about the risk for the STP and as starting point for calculation of the concentration in surface water and sediment. For effects on an STP we refer to the section Ecotoxicology; Risk for the STP.

2.5. Developments

Developments

- None

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- None

3. APPENDICES

Appendix 1. Explanatory notes decision tree Behaviour in water

1) Data on behaviour in surface water should be submitted for each substance, unless it can be demonstrated that it is ruled out that the substance reaches surface water when the biocide is used in practice consistent with the WG/GA (Statutory Use Instructions/Directions for Use). The standard data requirements should always be submitted in EU framework. This concerns photolysis and hydrolysis in water, biodegradation and adsorption/desorption. For environment, the standard data requirements cannot be waived.

2) Relevant metabolites are metabolites in the aqueous phase or sediment of which in the laboratory or field studies, for photolysis, hydrolysis and biodegradation, the concentration is at any point in time greater than 10% of the substance applied. These metabolites must be identified.

   In EU framework it has not been elaborated how the identified metabolites must be dealt with whereas this has been elaborated for national evaluations. For the NL framework it is assumed that metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance (= relevant metabolites) should be evaluated. These metabolites are assessed in the same way as the active substance.

3) Standard data requirement. A ready biodegradation test is a standard data requirement for determination of biodegradation. A water simulation study is required in case of direct emission to surface water. A ready test does not need to be carried out in that case. A supplementary inherent biodegradability test does not need to be carried our in case a substance is “readily biodegradable”. Inherent tests are usually not suitable for risk evaluation purposes (because these tests are carried out with unrealistic substance-biomass ratios and/or with adapted sludge). A simulation test is therefore preferred over inherent tests. Where an inherent test is available, this can conditionally be used for the initial risk evaluation (see data requirements). It should be noted that these tests only determine the complete degradation to CO_2. Degradation rates of metabolites, if any, are not determined.

4) An initial evaluation is carried out where emission to the environment cannot be ruled out. Input values for the initial PEC calculations are DT_{50} values (half life values for photolysis, hydrolysis and biodegradation (complete degradation) and Kp values (partition coefficient for the partition over water and suspended material) originating from the standard data requirements. These values are entered in the calculation models. Depending on the questions and results of the calculations, further studies must be submitted to specify these values.

5) Standard data requirement. A screening test is sufficient for an initial evaluation. Supplementary data, however, are required for certain product types. Data on the adsorption to soil (see 7.1.3) can be used for assessment of the adsorption of the substance to sludge in a STP or sediment in surface water. To refine the evaluation, the extent of adsorption to active sludge can be determined for substances that are discharged to surface water via an STP.

6) Where direct emission to a compartment (STP, surface water/sediment, salt water environment or exposure to anaerobic conditions) occurs or where the initial PEC/PNEC > 1, supplementary studies as indicated in the flow chart are always required.

   Where the initial evaluation shows that the product is permissible for this aspect, and no direct emission occurs, the flow chart does not have to be followed any further.
   The core data requirements should, however, always be submitted.

7) A study for anaerobic conditions (with a sediment) is, inter alia, required for biocides that are used in animal housings, where emission to manure occurs. This study can also be requested if the largest part of the active substance is adsorbed to sediment, where anaerobic conditions are to be expected.

8) Supplementary data for sediment evaluation. In EU framework it is for a further sediment evaluation not quite clear when a water-sediment study (7.1.2.2.2) must be chosen or an extended adsorption/desorption study (7.1.3). Both studies are required for the NL framework. The amount of bound residue must be determined in these studies. Water-sediment simulation must be carried out for at least 2 different sediments.

9) Initially, the K_p value (coefficient for the partitioning over water and suspended material or sediment) obtained from the screening test can be used for selecting supplementary studies for degradation in an STP. The K_p can be derived from the K_{oc} by means of the formula $K_p = f_{oc} \times K_{oc}$ with a dry matter concentration in raw sewage of 450 mg/L (dwt) and an organic carbon concentration of 30%.

10) Initially, the K_p value (coefficient for the partitioning over water and suspended material or sediment) obtained from the screening test can be used for selecting supplementary studies for degradation in surface water. The K_p can be derived from the K_{oc} by means of the formula $K_p = f_{oc} \times K_{oc}$ with a suspended matter concentration in surface water of 15 mg/L (dwt) and an organic carbon concentration of 10%.

    Refinement of the adsorption/desorption value may be required if induced by the evaluation or if there are indications that the adsorption/desorption values obtained from the screening are not adequate.

11) Assessment of the persistence criterion is relevant for inclusion of the active substance in Annex I. Starting points are laboratory tests in aerobic water/sediment systems (20-25 °C).
    This criterion applies unless it has been demonstrated scientifically that no unacceptable accumulation in sediment occurs under relevant field conditions.

12) The results from the field study (DT_{50} values) are evaluated against the same criteria as the laboratory degradation studies. This is the DT50 >6 months or non-extractable residues >70% and mineralisation rate < 5% after 100 days.

13) The exposure calculation is usually carried out by using emission scenario documents (ESDs) and the Board-authorised version of the exposure models EUSES and MAMPEC (for antifouling paints).

EUSES contains several modules for calculation of the concentration in surface water for emission routes corresponding with different uses. When calculating the concentration in surface water it will have to be investigated for a biocide which uses and emission routes to surface water exist, and a concentration calculation will have to be carried out with the corresponding module.

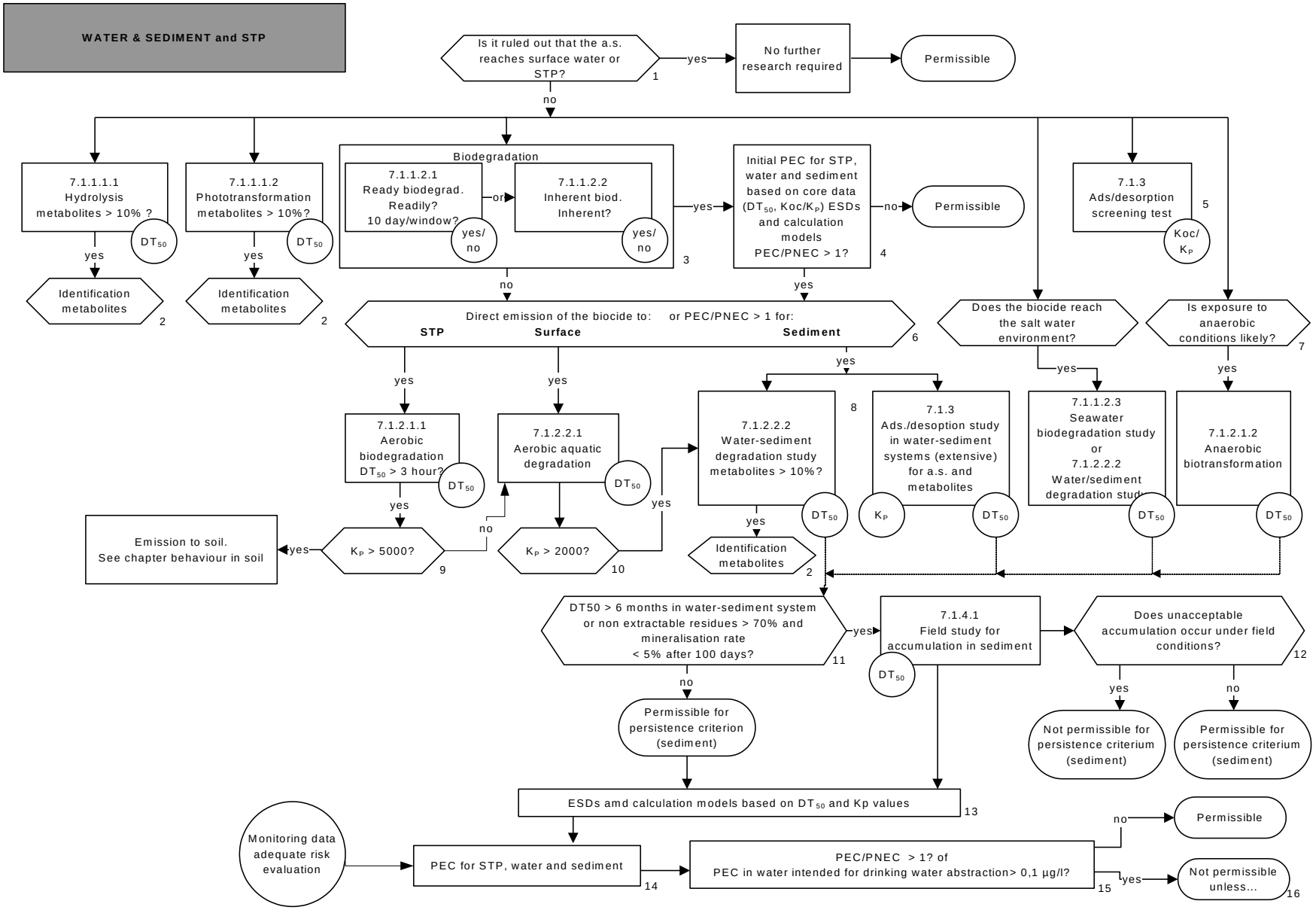
The input data to be used are obtained from degradation and adsorption/desorption studies in laboratory or field.

14) The exposure (Predicted Environmental Concentration (PEC)) is the value calculated by a mathematical model where the emission scenario has been taken into account.
If appropriate, the PEC can be adjusted to adequately measured data (see section 1.3.2 and section 2.2.1 of the TGD).

15) The PEC values for STP, water and sediment can be judged against:
- the calculated PNEC value (see Chapter 6 Ecotoxicology aquatic organisms);
- natural background values of active substances consisting of a metal or a semi-metal element.

16) Not admissible unless it is demonstrated scientifically that this concentration is not exceeded under relevant field conditions.

An active substance consisting of a metal or a semi-metal element is not included in Annex I if its use leads to a significant accumulation exceeding the natural background values.


WATER & SEDIMENT and STP
Is it ruled out that the a.s. reaches surface water or STP?
1
yes
No further research required
Permissible
no
7.1.1.1.1 Hydrolysis metabolites > 10% ?
DT50
yes
Identification metabolites
2
7.1.1.1.2 Phototransformation metabolites > 10%?
DT50
yes
Identification metabolites
2
Biodegradation
7.1.1.2.1 Ready biodegrad. Readily? 10 day/window?
yes/ no
or
7.1.1.2.2 Inherent biod. Inherent?
yes/ no
3
yes
Initial PEC for STP, water and sediment based on core data (DT50, Koc/KP) ESDs and calculation models PEC/PNEC > 1?
4
no
Permissible
yes
7.1.3 Ads/desorption screening test
5
Koc/ KP
no
Direct emission of the biocide to: STP Surface or PEC/PNEC > 1 for: Sediment
6
Does the biocide reach the salt water environment?
Is exposure to anaerobic conditions likely?
7
yes
yes
yes
yes
yes
7.1.2.1.1 Aerobic biodegradation DT50 > 3 hour?
DT50
yes
7.1.2.2.1 Aerobic aquatic degradation
DT50
7.1.2.2.2 Water-sediment degradation study metabolites > 10%?
8
DT50
yes
Identification metabolites
2
7.1.3 Ads./desoption study in water-sediment systems (extensive) for a.s. and metabolites
KP
DT50
7.1.1.2.3 Seawater biodegradation study or 7.1.2.2.2 Water/sediment degradation study
DT50
7.1.2.1.2 Anaerobic biotransformation
DT50
yes
no
yes
Emission to soil. See chapter behaviour in soil
KP > 5000?
9
KP > 2000?
10
DT50 > 6 months in water-sediment system or non extractable residues > 70% and mineralisation rate < 5% after 100 days?
11
yes
7.1.4.1 Field study for accumulation in sediment
DT50
Does unacceptable accumulation occur under field conditions?
12
yes
Not permissible for persistence criterium (sediment)
no
Permissible for persistence criterium (sediment)
no
Permissible for persistence criterion (sediment)
ESDs amd calculation models based on DT50 and Kp values
13
Monitoring data adequate risk evaluation
PEC for STP, water and sediment
14
PEC/PNEC > 1? of PEC in water intended for drinking water abstraction> 0,1 µg/l?
15
no
Permissible
yes
Not permissible unless...
16

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 Handboek Implementatie milieubeleid EU in Nederland. Ministerie VROM.
http://www.eu-milieubeleid.nl/ch05s10.html

4 http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/

5 TNsG on data requirements. Technical guidance document 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. February 2008. In the February 2008 version, Chapter 2.5 of the previous version (October 2002) has been renamed to Part C of Chapter 2. No other changes have been made with respect to the content of the Guidance Document.

6 College (2009) Metabolieten

7 Ctgb decision C-163.5