Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 5 Behaviour and fate in the environment; behaviour in soil; persistence

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Board for the Authorisation of plant protection products and biocides

Chapter 5 Behaviour and fate in the environment; behaviour in soil; persistence

Category: biocides

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the persistence 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 testing 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 testing framework or where the national testing framework 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 the soil, and the aspect persistence insofar as specific rules apply in the NL framework or where the NL testing framework has been elaborated in more detail than the EU framework.

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 supplementary soil photolysis study shall be carried out in case of indirect emission via the air to the soil and if photolysis is an important degradation route in the phototransformation study in water (standard data requirement). A photolysis DT50 of 10 days is applied as threshold. When the aspects mentioned above will be elaborated in the EU, these will be followed.

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.
The results of the environmental fate tests consist of DT_{50} values for the active substance and possible metabolites that at any point in time account for a concentration >10% of the substance applied. These data are used to calculate PEC (Predicted Environmental Concentration) values. Use of representative measured data is an alternative.
The evaluation methodology for determination of the DT_{50} and PEC soil for the NL evaluation is identical to the EU methodology. We therefore refer to the EU part §1.3.

When the aspects mentioned above will be elaborated in the EU, these will be followed.

2.4. Approval

The risk assessment for soil 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 and the TNsG on Annex I inclusion; see EU part §1.4 and §1.4.1. Derivation of PNEC trigger values is described in Chapter 6 Ecotoxicology; terrestrial.

2.4.2. Decision on approval

Testing is in accordance with the Common Principles of the Biocides Directive.
The aspect persistence is tested against the criteria mentioned in §2.4.1 and EU part §1.4.1. Further testing of calculated or measured PEC_{soil} values against criteria has been elaborated in Chapter 6 Ecotoxicology – terrestrial organisms.

2.5. Developments

Developments

- None

Lacunas

- For metals and semi-metals it should be investigated which data should be applied as natural background values.

3. APPENDICES

Appendix 1 Explanatory notes decision tree Persistence

1) Data on behaviour in soil should be submitted for each substance, unless it can be demonstrated that it is ruled out that the substance reaches the soil when the biocide is used in practice in accordance with the WG/GA (Statutory Use Instructions/Directions for Use). The standard dossier 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. Whether certain emission routes are relevant has been elaborated in emission scenario documents.

2) Cooling water biocides are examples of products for which deposition from air to soil can be relevant. This deposition can also play a role in the waste phase of biocides. The way in which 10% deposition of an applied product to soil must be determined has not yet been elaborated.

3) A supplementary soil photolysis study is carried out in case of indirect emission via the air to the soil and if photolysis is an important degradation route in the phototransformation study in water (standard data requirement). A photolysis DT_{50} of 10 days is applied as limit value.

4) An initial risk assessment is carried out if it cannot be ruled out that emission to soil occurs, but direct emission to the soil is not expected. If the product is found to be not permissible in de initial risk assessment or if the results of 7.1.1.1.2, 7.1.1.2.1, 7.1.1.2.2 give cause for this, supplementary studies as indicated in the decision tree are required. The exposure (Predicted Environmental Concentration (PEC)) is the model-calculated value in which the emission scenario has been taken into account.
The exposure calculations are generally carried out with the Board-authorised version of the exposure model EUSES. EUSES contains several modules for calculating the concentration in soil for emission routes corresponding with various uses. When calculating the concentration in soil the uses and emission routes of a biocide to soil will have to be established and a concentration calculation shall be carried out with the corresponding module.

5) Direct emission to soil is: that a product is applied directly on the soil or is directly emitted to soil or reaches the soil in the waste phase. Indirect emission is, e.g., the application of STP sludge with biocides on the soil or deposition from air to soil.

6) A ready biodegradability test is a standard data requirement for determination of biodegradation. If a substance is “readily biodegradable”, a supplementary inherent biodegradability does not need to be carried out. Usually, inherent tests are not suitable for risk assessment purposes (because these tests are carried out with unrealistic substance/biomass ratios and/or adapted sludge). A simulation test is therefore preferred for inherent tests. Where an inherent test is available, this can conditionally be used in the initial risk assessment (see data requirements Behaviour in water).

7) An anaerobic degradation study is required if anaerobic conditions are to be expected at the place where the active substance or the product is to be applied. The TNsG on data requirements mentions as example biocides that may after application in animal housing get into the manure and subsequently into manure storage, where anaerobic conditions may occur.

8) The aerobic transformation route shall be determined in a laboratory study with at least 1 soil type. Transformation products must be identified in this study; for the active substance and transformation products >10%, transformation rates must be established and the amounts of soil-bound residue and mineralisation rate should be determined.

9) Supplementary aerobic or anaerobic research is required if:
   - Or if for the active substance the DT_{50} >21 days and the PEC/PNEC in soil >1. Derivation of PNEC trigger values is described in Chapter 6 Ecotoxicology.
   - Or if there is a risk for groundwater (see Chapter Leaching);
   - Or refinement of the risk evaluation is required. Refinement of the risk evaluation is, e.g., required if an initial transformation study shows that the DT50 is >180 days.

10) The transformation rate should be established in laboratory studies in three relevant soils at 20^{o}C and 1 soil at 10^{o}C. This determines the DT_{50} of the active substance and the formation of relevant metabolites. If at any point in time metabolites are formed in an amount >10% of the substance applied, supplementary research shall be carried out into the transformation rate of these metabolites and DT_{50} values shall be determined.

11) If bound residue is formed in a concentration >10% of the substance applied, further research into the nature and properties of the bound residue is required. Further research shall be combined with supplementary soil degradation studies (7.2.2.1)

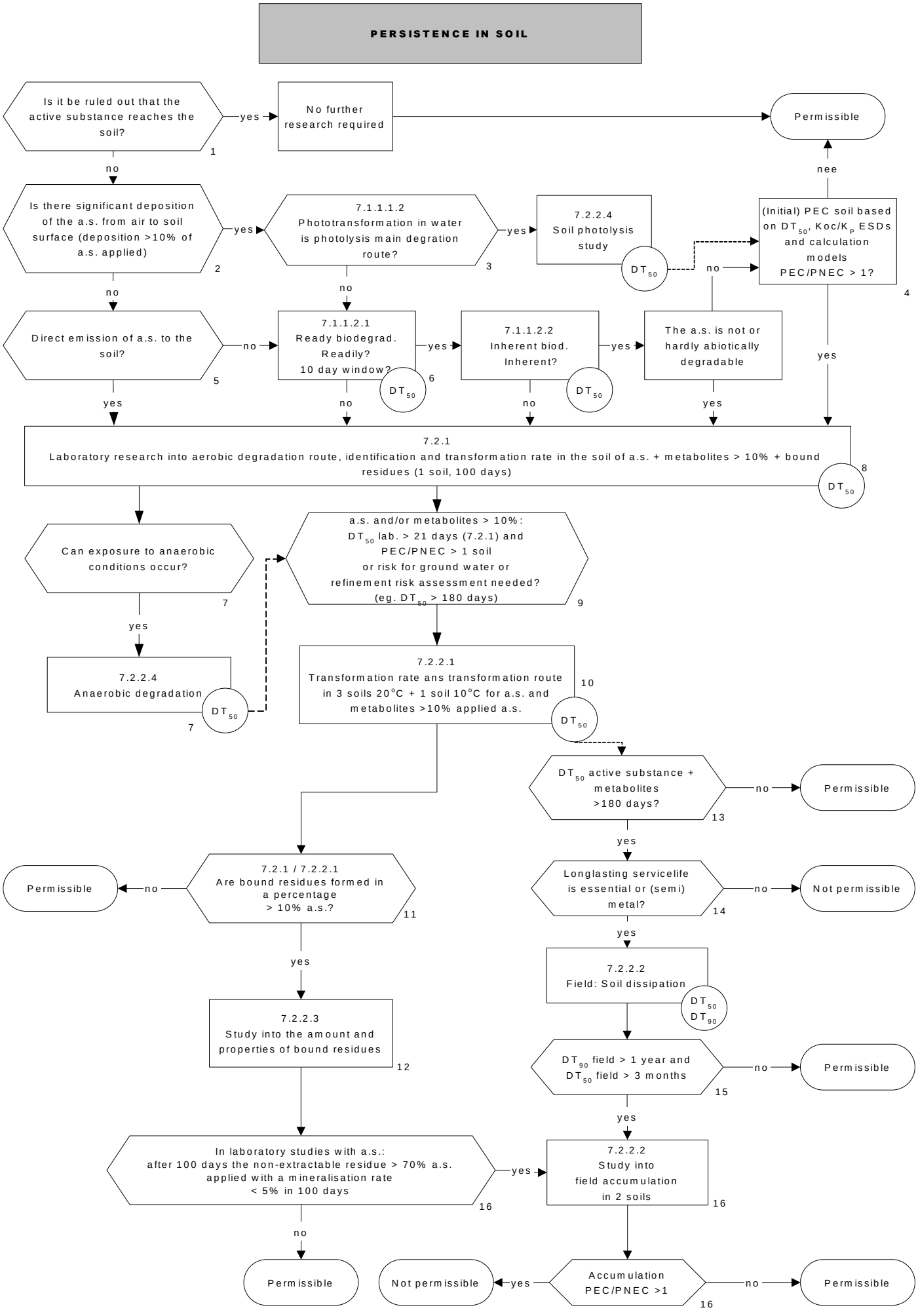
12) Further research into the amounts and properties of the bound residue serves to gain the best possible characterisation of the residue.

13) DT_{50} values of the active substance and metabolites obtained from studies with aerobic and anaerobic soils (7.2.1, 7.2.2.1) are tested against the 180 day criterion. If the DT_{50} values are ≤180 days for the active substance and metabolites with a concentration >10% of the substance applied, the active substance meets the persistence criterion and the product can be authorised for the use given in the WG/GA. An active substance that does not meet the 180 day criterion is not permissible if the “unless clause” is not applicable.

14) The “unless clause” is applicable for products of which a prolonged activity is required and for (non degradable) metals and semi-metals.

15) Condition for the unless clause is that it should be demonstrated that in a field dissipation study the DT_{50} field ≤3 months and the DT_{90} field ≤1 month.

16) If a substance does not meet the criteria in a dissipation study, it should be demonstrated on the basis of field accumulation studies in 2 soils under field conditions that the PEC/PNEC <1 during the use phase of a biocide-treated product. See chapter 6 Ecotoxicology – soil for derivation of the PNEC.
    For (semi)metals the PEC may not exceed the natural background concentration. A field accumulation study should also be carried out if laboratory studies with the active substance show that after 100 days the non-extractable residue >70% of the substance applied with a mineralisation rate of <5% in 100 days.


PERSISTENCE IN SOIL
Is it be ruled out that the active substance reaches the soil?
1
yes
No further research required
Permissible
no
Is there significant deposition of the a.s. from air to soil surface (deposition >10% of a.s. applied)
2
yes
7.1.1.1.2 Phototransformation in water is photolysis main degration route?
3
yes
7.2.2.4 Soil photolysis study
DT50
(Initial) PEC soil based on DT50, Koc/Kp ESDs and calculation models PEC/PNEC > 1?
4
nee
no
no
Direct emission of a.s. to the soil?
5
no
7.1.1.2.1 Ready biodegrad. Readily? 10 day window?
DT50
6
yes
7.1.1.2.2 Inherent biod. Inherent?
DT50
yes
The a.s. is not or hardly abiotically degradable
yes
yes
no
no
yes
7.2.1 Laboratory research into aerobic degradation route, identification and transformation rate in the soil of a.s. + metabolites > 10% + bound residues (1 soil, 100 days)
DT50
8
Can exposure to anaerobic conditions occur?
7
yes
7.2.2.4 Anaerobic degradation
DT50
7
a.s. and/or metabolites > 10%: DT50 lab. > 21 days (7.2.1) and PEC/PNEC > 1 soil or risk for ground water or refinement risk assessment needed? (eg. DT50 > 180 days)
9
7.2.2.1 Transformation rate ans transformation route in 3 soils 20°C + 1 soil 10°C for a.s. and metabolites >10% applied a.s.
DT50
10
DT50 active substance + metabolites >180 days?
13
no
Permissible
yes
7.2.1 / 7.2.2.1 Are bound residues formed in a percentage > 10% a.s.?
11
no
Permissible
yes
Longlasting servicelife is essential or (semi) metal?
14
no
Not permissible
yes
7.2.2.3 Study into the amount and properties of bound residues
12
7.2.2.2 Field: Soil dissipation
DT50 DT90
DT90 field > 1 year and DT50 field > 3 months
15
no
Permissible
yes
In laboratory studies with a.s.: after 100 days the non-extractable residue > 70% a.s. applied with a mineralisation rate < 5% in 100 days
16
yes
7.2.2.2 Study into field accumulation in 2 soils
16
no
Permissible
Not permissible
yes
Accumulation PEC/PNEC >1
16
no
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/