Evaluation Manual
for the Authorisation
of Plant Protection Products and Biocides

NL part

Plant Protection Products

Chapter 6 Fate and behaviour in the environment: behaviour in soil; persistence

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Board
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of Plant Protection Products and Biocides

Chapter 6 Fate and behaviour in the environment; behaviour in soil; persistence

Category: Plant Protection Products

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the persistence in the soil of a Plant Protection Product and its active substance and how reference values are derived in the NL framework (§2 - §2.5).

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant Protection Products based on existing substances, included in Annex I, and new active substances.
A new substance is a substance not authorised in any of the Member States of the EU on 25th of July 1993.
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 II and III of Directive 91/414/EEC
(see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

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 approval framework or when the national framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter can also be used for evaluation of a substance for inclusion in Annex I where no EU procedure has been described

2.1. Introduction

This chapter describes the data requirements and evaluation methodologies for persistence in the soil for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

The risk of persistence of Plant Protection Products in the soil is assessed to prevent that products that present an unacceptable environmental risk to reach the NL market.

The questions from the part ‘Fate and behaviour’, raised in the EU part §1.2.1 and 1.2.2, are relevant for the persistence (residence time) and accumulation of Plant Protection Products in the soil. Data concerning the nature of the metabolites and the degradation rates of active substance and metabolites are covered. These data are also used to assess the risk of leaching to groundwater (see Chapter 6 Fate and behaviour in the environment; behaviour in soil; leaching to groundwater).

Ecotoxicological data coming under the data requirements for other aspects than persistence are used in the higher tier persistence evaluation, when determining the MPC_{soil} (see §2.3.2). This concerns sublethal data for earthworms, data for soil micro-organisms and data for terrestrial non-target plants (see Chapters 7 Ecotoxicology; terrestrial; soil organisms and non targets).

A decision tree with explanatory notes is presented in Appendix 2 to this chapter.
This decision tree summarises the decision scheme for persistence.

2.2. Data requirements

The data requirements for chemical Plant Protection Products are in agreement with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.
NL-specific data requirements and further clarifications of the EU data requirements are given in the text below.

Experiments carried out after 25 July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 6

<u>NL-specific data requirements and further clarification of EU data requirements</u>
The soil types for determination of the route and rate of transformation (A7.1.1.1.1a, b and A7.1.1.2.1b, c and P09.1.1.1a) are preferably chosen from soil types 1, 2 and 3 from Annex A7.1a to the supplementary instruction of the Application Form; this Annex is added to this Chapter as Appendix 3.

Field studies (A7.1.1.2.2b - d and P9.1.1.2b - d) should be carried out under climatological and soil conditions that are comparable to NL conditions. Information about NL soil conditions is given in GeoPEARL [3, 4]. Evaluation of the suitability of field studies as regards the other aspects is based on expert judgement.

2.3. Risk assessment

2.3.1. First tier assessment

The first tier of the national soil persistence evaluation of Plant Protection Products follows the EU framework (see §1.3 of the EU part) while specific aspects that have not been elaborated in the EU framework are elaborated in more detail.

<u>Further elaboration of EU evaluation framework</u>
No European method for calculation of the concentration in the soil has been elaborated for seed dressings or treated propagation material; the calculation method presented in Appendix 4 to this chapter is therefore proposed as further elaboration. The method is briefly summarised below.

A *homogeneous distribution* of the active substance in spherical spheres of influence around the seed is assumed. Analogous to the distribution depth for a spray formulation, it is assumed that the radius of the *sphere of influence* is 5 cm. Two scenarios are proposed. Superficially drilling of small seeds with a radius < 0.5 cm such as cereals, carrots or radish is assumed in the first scenario. The sphere of influence then has the form of a half spheroid. Drilling/planting of larger seeds at ≥ 5 cm depth, e.g., beet, maize, potatoes or bulbs is assumed in the second scenario. The sphere of influence has the form of a full spheroid. For both scenarios a maximum volume of 500 m^3 per ha is assumed as maximum volume of the sphere of influence of the seeds. The calculation method has been elaborated in Appendix 4 to this chapter.

2.3.2. Higher tier assessment: MPC_{soil}

A higher tier assessment must be carried out where the DT50 (field) in the soil is longer than 3 months and[8] DT90 > 1 year or where in laboratory studies after 100 days the percentage active substance or metabolites in the soil-bound residue ≥ 70% of the initial dose, together with a mineralisation rate ≤ 5%.

The relevant circumstances are described in the European framework. For temperature a reference temperature of 20 degrees is prescribed and for moisture content pF2. For the determination of DT50, besides SFO also 'best fit' kinetics can be as degradation kinetics.

Article 2.8 (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant Protection Products and Biocides Regulations (Rgb) describes the authorisation criterion persistence. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC-INS[9] method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM[10]-report 601782001/2007[11].

Concentration of substance and degradation products in soil

The maximum expected concentration of the sum of the active substance and its degradation products in soil should be calculated using one of the two following steps:

1) Calculation on the basis of laboratory data;
2) Calculation on the basis of field studies

The first step is always presented, the second step is an option and depending on the results of step 1 and the available data. After each step a decision is possible.

Step 1. Calculation on the basis of laboratory data

For all active substances and metabolites occurring in a percentage equal or larger then 10% the calculation of the concentration in soil is based on experiments on DT_{50} (A7.1.1.2.1b) and K_{OM} values (A7.1.2a).
The geometric mean DT_{50}- and Kom-values are used as input data in the PEARL model.
To achieve a uniform assessment all input parameters, except DT_{50} en Kom, are kept constant.
On the basis of PEARL, the expected percentage of the dose is calculated present one year after application in the top 20 cm of the soil (at the place of application), at an effective load of the soil of 1 kg/ha (i.e. 1 kg/ha reaches the soil surface).
For substances with spring application, calculations are performed with the Dutch standard spring scenario (period 1 March – 31 August).
For substances with autumn application, calculations are performed with the Dutch standard autumn scenario (period 1 September – 28 (29) Februari).

[8] In the revised UB the word 'and' is replaced by 'or'. In reality this was already used because the triggers based on linear degradation are nearly the same. If other degradation kinetics than SFO are accepted, like FOMC (first order multi compartment), DFOP (double first order in parallel) and DFOS (double first order in serie) a persistent substance will not be triggered and there is a need to use 'or' instead of 'and'.
[9] INS: international and national quality standards for substances in the Netherlands.
[10] RIVM: National institute of public health and the environment.
[11] 601782001/2007: P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'.

In the calculation of the concentration in soil a correction for interception by crop is applied according to appendix 1 of the EU part. This appendix is in line with FOCUS Degradation Kinetics [5].

The calculation of expected percentage of the dose present one year after application in the top 20 cm of the soil of the Dutch standard scenario must be carried out with the FOCUS PEARL model [6, 7, 8]
Another model which is based on the same assumptions concerning adsorption and degradation, accounting for the hydrolitical situation in The Netherlands (among dispersion) and which is validated in the relevant leaching range.
In practice however, the most recent version of PEARL available on the FOCUS website is used, available at: http://focus.jrc.ec.europa.eu/gw/index.html.

The actual exposure of the soil (within one season) is determined according to relation 1:

$$B_{e,ai} = F. ((100-I)) / (100) D_{m,ai} \qquad (1)$$

In which:
$B_{e,ai}$ the actual exposure of the soil (kg ha^{-1}) of the active substance
F the maximum frequency as mentioned on the label (dimension less) (within one season).
I the interception percentage (%) by the crop (as percentage of the single dose) according to the FOCUS Groundwater report (see Appendix 4, EU part chapter 6 Fate and behaviour in the environment: behaviour in soil; persistence).
$D_{m,ai}$ the maximum single dose (kg ha^{-1}) as mentioned on the label.

The expected concentration of the active substance in soil in the top 20 cm of the soil after one year of application is determined according to relation 2:

$$G_{p,ai,1} = B_{e,ai} (R\%_{ai}) / (L\rho) \qquad (2)$$

In which:
$G_{p,ai,1}$ the concentration (mg kg-1) after one year of application of the active substance in the plough layer of the soil (within a parcel)
$R\%_{ai}$ the percentage of active substance that is still present in the plough layer one year after application, as calculated with the PEARL model
L thickness (m) of the layer under consideration (default : L = 0.2 m)
ρ dry bulk density (kg m-3) of the soil (default ρ = 1500 kg m-3).

Determination of R% from the PEARL report:
1.
If the following line from the PEARL report is used:
The mass content of substance in the plough layer at 365 days after application was x (mg.kg-1)
This result must be divided by 0.38 and multiplied by 100 to get the R%.

2.
If the bottommost line from the PEARL report is used:
This is equivalent with an areic mass of x (kg.ha-1)
The result must be multiplied by 100 to get the R%.

Option 2 contains less rounding off error.

Determination of R% for metabolites:
For metabolites also the 1 kg parent /ha calculation in the relevant NL-scenario is used including the metabolic pathway and a formation fraction of 1.

In case of a calculation for a metabolite (all metabolites > 10 which are persistent) also a correction for relative molecular mass of the metabolite compared to the active substance is needed. This can be determined according relation 3:

$$B_{e,op} = (M_{op}) / (M_{ai})\ B_{e,ai} \qquad (3)$$

In which:
$B_{e,op}$ he exposure of the soil (kg/ha) of the metabolite
M he molar mass, $_{op}$ = metabolite, $_{ai}$ = active substance.

$G_{p,10}$ calculation
The expected concentration of the metabolite in soil in the top 20 cm of the soil after one year of application is determined according to relation 4:

$$G_{p,op,1} = B_{e,op}\ (R\%_{op}) / (L\rho) \qquad (4)$$

In which:
$G_{p,op,1}$ he concentration (mg kg-1) after one year of application of the metabolite in the plough layer of the soil (within a parcel)
$R\%_{op}$ he percentage of metabolite that is still present in the plough layer one year after application, as calculated with the PEARL model.

Plan protection products and/or their metabolites can accumulate in soil if there is repeated exposure of a compound. "Repeated" means that the compound is used in different growing seasons at the same parcel. Multiple application within one year is already covered by the frequency (relation 1). The amount of substance in the plough layer one year after the last application is calculated by relation 5:

$$X_n = (f_r(1-f_r^{\,n})) / (1-f_r) \qquad (5)$$

In which:
X_n the fraction of the yearly exposure of the soil present in the plough layer one year after the last application
f_r the fraction present in the plough layer one year after application (during one year) (= R% / 100)
$_n$ the number of applications.

For the calculation of the (total) concentration in the plough layer the concentration extractable residues two year after the last application is relevant. Ten years of application are considered.

The concentration two years after the last (tenth) application is determined by relation 6:

$$G_{p,10} = (B_e X_{10} R\%) / (L\rho) \qquad (6)$$

waarin:
$G_{p,10}$ he concentration (mg kg^{-1}) of a single substance (active substance or metabolite) two years after the last (tenth) application in the plough layer of the soil (within a parcel)
B_e the exposure of the soil (kg/ha) of the substance (see relation 1 and 3)
X_{10} the fraction of the yearly exposure of the soil present in the plough layer one year after the last (tenth) application.

In the assessment against the MPC a yearly release of 5% of the total present bound residue can be taken into account.
An univocal approach is not available, therefore this is ignored. Only in border line cases the argument of release of bound residue can be used to raise additional questions.

For substances for which an assessment against the MPC is relevant because of an soil bound residue ≥ 70% in combination with a mineralisation speed of ≤ 5% a concentration in soil will be based on expert judgement.

Based on specific information on the application of the Plant Protection Product revised calculations are an option and can give advanced understanding in relation to the risk assessment.

Step 2. Calculation on the basis of field data
In step 1 the expected concentration in soil is calculated based on a standard scenario and laboratory data on degradation and sorption. Possibly revised calculations are considered based on specific information.
In reality other processes can contribute to the dissipation of the substance. Also other kinetics of processes used in the standard scenario can be relevant. For a revised assessment field experiments or (field)lysimeters studies are needed.
Adequate field studies, if a SFO DegT50 can be derived, can be used for PEARL calculations to achieve a R% value.

Monitoring data
If monitoring data is available, according to article 2.10b of the Plant Protection Products and Biocides Regulations (Rgb), the Board applies the 90 percentile when testing monitoring data.
When this value is used a maximum of 10% of the monitoring data exceeds the 90-percentile value.

Determination MPC_{soil} and risk assessment
The TGD contains different methods to derive a PNEC for the soil. The different $PNECs_{soil}$ are compared to determine the MPC_{soil}. Different $PNECs_{soil}$ may, e.g., be chronic data on soil organisms and an assessment factor, equilibrium partitioning from aquatic toxicity data, a HC5 or an endpoint from a field study. Unbound values are not allowed in the MPC determination. INS also indicates that secondary poisoning and human risk should be taken into account in establishing the MPC_{soil}. For secondary poisoning this means that a concentration in the soil is calculated from the BCF value for worms and the chronic endpoint for birds and mammals, with the corresponding assessment factor of 5 (PEC_{soil} = chronic criterion / BCF_{worm}). The human –toxicological limit is calculated from the ADI, using models as described in the TGD.
The above means that three different types of MPC_{soil} may have been derived: an MPC for species, secondary poisoning and human health. The final MPC_{soil} is chosen on the basis of a comparison between these three MPCs.

The risk is assessed by comparing the MPC_{soil} with the calculated concentration in the soil (PEC_{soil}). Guidance in the TGD about the $PECs_{soil}$ to be used is not applicable in this context. Comparison with the concentration (mg kg^{-1}) of a single substance (active substance or metabolite) two years after the last (tenth) application in the plough layer of the soil (within a parcel) ($G_{p,10}$) is therefore chosen.

2.4. Approval

The assessment of the risk of persistence in the soil has been laid down in regulations. The Wgb (Plant protection products and Biocides Act) 2006 [1] stipulates in Art. 28 (1) (b4 and b5): “a pesticide may only be authorised where this has no unacceptable effect on 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 Plant Protection Products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

2.4.1. Criteria and trigger values

For the criteria and trigger values for persistence used in the national authorisation reference is made to the Plant Protection Products and Biocides Regulations (Rgb). Article 2.8 (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant Protection Products and Biocides Regulations (Rgb) describes the authorisation criterion persistence. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC-INS[12] method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM[13]-report 601782001/2007[14].

The texts specifically referring to the aspect persistence in the soil are given below (in Dutch):

§ 4. Bepalingen inzake het milieutoxicologische risico van chemische gewasbeschermingsmiddelen

Artikel 2.8. Persistentie

1. Het college komt bij de toepassing van het uniforme beginsel bedoeld in bijlage VI, deel I, onderdeel C, punt 2.5.1.1, bij richtlijn 91/414/EEG tot het oordeel dat een gewasbeschermingsmiddel geen voor het milieu onaanvaardbaar effect heeft als bedoeld in artikel 28, eerste lid, onderdeel 5, van de wet, indien bij de toepassing van de tweede alinea van voornoemd beginsel wordt aangetoond dat de concentratie van die werkzame stof, dan wel een relevant reactie- of afbraakproduct in de bodem van het perceel, twee jaar na de laatste toepassing van het gewasbeschermingsmiddel het MTR voor bodem niet overschrijdt.
2. Het college berekent het MTR, bedoeld in het eerste lid aan de hand van de methode INS.

Artikel 2.10b. 90-percentiel [Treedt in werking per 01-01-2010]

Het college toetst met behulp van een 90-percentiel de blootstelling aan een gewasbeschermingsmiddel van:

a. de bodem, het grondwater, het oppervlaktewater en het sediment, bedoeld in de artikelen 2.8, 2.9 en 2.10, en
b. innamepunten van drinkwater uit oppervlaktewater, bedoeld in bijlage VI, deel I, onderdeel C, punt 2.5.1.3, bij richtlijn 91/414/EEG.

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[12] INS: international and national quality standards for substances in the Netherlands.
[13] RIVM: National institute of public health and the environment.
[14] 601782001/2007: P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'.

Artikel 10.3. Beoordeling van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

2.4.2. Decision making

Decision making for approval regarding persistence for national authorisations follows the Plant Protection Products and Biocides Regulations (Rgb). Article 2.8 (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant Protection Products and Biocides Regulations (Rgb) describes the authorisation criterion persistence. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC-INS method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM-report 601782001/2007.

2.5. Developments

A working party, commissioned by the Ministries of VROM (Housing, Regional Planning and the Environment) and LNV (Agriculture, Nature and Food Quality), has been working on a new NL decision tree for the aspect persistence in the soil.
The working group have finalised a proposal for the risk assessment of persistence of Plant Protection Products in soil [9]. This methodology is also evaluated based on data of five substances. A final report of this evaluation report is available [10].
Based on this evaluation process the working group has finalised a revised proposal [11].
After EFSA has finalised the new persistence guidance based on the IRIS workshop the Ministries will reconsider if the new EU procedure will be implemented in The Netherlands or the Dutch revised proposal for the risk assessment of persistence of Plant Protection Products in soil will be applicable.

3. APPENDICES

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Appendix 1 Can it be ruled out that the substance reaches the soil?

To answer the above question it is important whether the substance during or after the application in a not entirely closed system consistent with good agricultural practice, comes into contact with the soil or not.

The first thing that matters is whether the application takes place in the open, or in enclosed spaces (greenhouses (substrate cultivation), sheds, bee hives etc.). During applications in enclosed spaces, it is not *a priori* ruled out that the product reaches the soil. This can only be ruled out if the applied water is collected for re-use, or is discharged to a sewage treatment plant in a controlled manner. In the other cases of applications in enclosed spaces, persistence is relevant.

During outdoor use, the aspect persistence is relevant for nearly all applications. Only for a number of specific application techniques (treatment of wounds by pasting, injection of trees etc.), and applications whereby the water is collected for re-use or is discharged to a sewer, can it be ruled out that the product reaches the soil.

There are applications where the actual use of the Plant Protection Product takes place at another location, other than the crop cultivation itself (seed treatment, treatment of propagation material, tray treatment etc.). In those cases, the situation of the crop cultivation itself should serve as a basis. This means that in the case of treated seed or other propagation material, it can be assumed that the substance reaches the soil.

Appendix 2 Explanatory notes for the decision tree persistence in the soil

1. For each active substance, data must be submitted on the behaviour in soil, unless it is demonstrated that it can be ruled out that the substance reaches the soil during good (agricultural) use of the product, consistent with the WG/GA (Statutory Use Instructions/Directions For Use). See Appendix 1 for answering this question.

2. The aerobic transformation route (A7.1.1.1.1a) and transformation rate (A7.1.1.2.1b) must always be determined. The aerobic transformation route must be determined in a laboratory study with at least one soil type. During this study, the metabolites must be identified, and the amount of soil-bound residues and the rate of mineralisation determined. The aerobic transformation rate must be determined in laboratory studies in three different soil types. In this way, the DT_{50} and DT_{90} values of the active substance and major metabolites are determined (metabolites > 10%; see ‘4’ below).
The laboratory studies must meet the criteria of the UP, Annex II.
The soils used are preferably chosen from soil types 1, 2 and 3 in Appendix A7.1a of the supplementary instruction of the Application Form; this Appendix is also included as Appendix 3 of this chapter.

3. The anaerobic transformation route (A7.1.1.1.2b) and transformation rate (A7.1.1.2.1c) must be determined, unless it can be justified that it is unlikely that the Plant Protection Product will be exposed to anaerobic conditions. The anaerobic transformation route must be determined in a laboratory study with at least one soil type. The anaerobic transformation rate must be determined in laboratory studies in three soils. The soils used are preferably chosen from soil types 1, 2 and 3 in Appendix A7.1a of the supplementary instruction of the Application Form; this Appendix is also included as Appendix 3 of this chapter. See also under ‘2’.

4. DT50 values must be determined in three soil types for metabolites of which in the laboratory studies into the (an)aerobic transformation route of the active substance at any point in time the amount is higher than or equal to 10% of the added amount of active substance.
The decision tree should for such metabolites be followed as for the active substance.

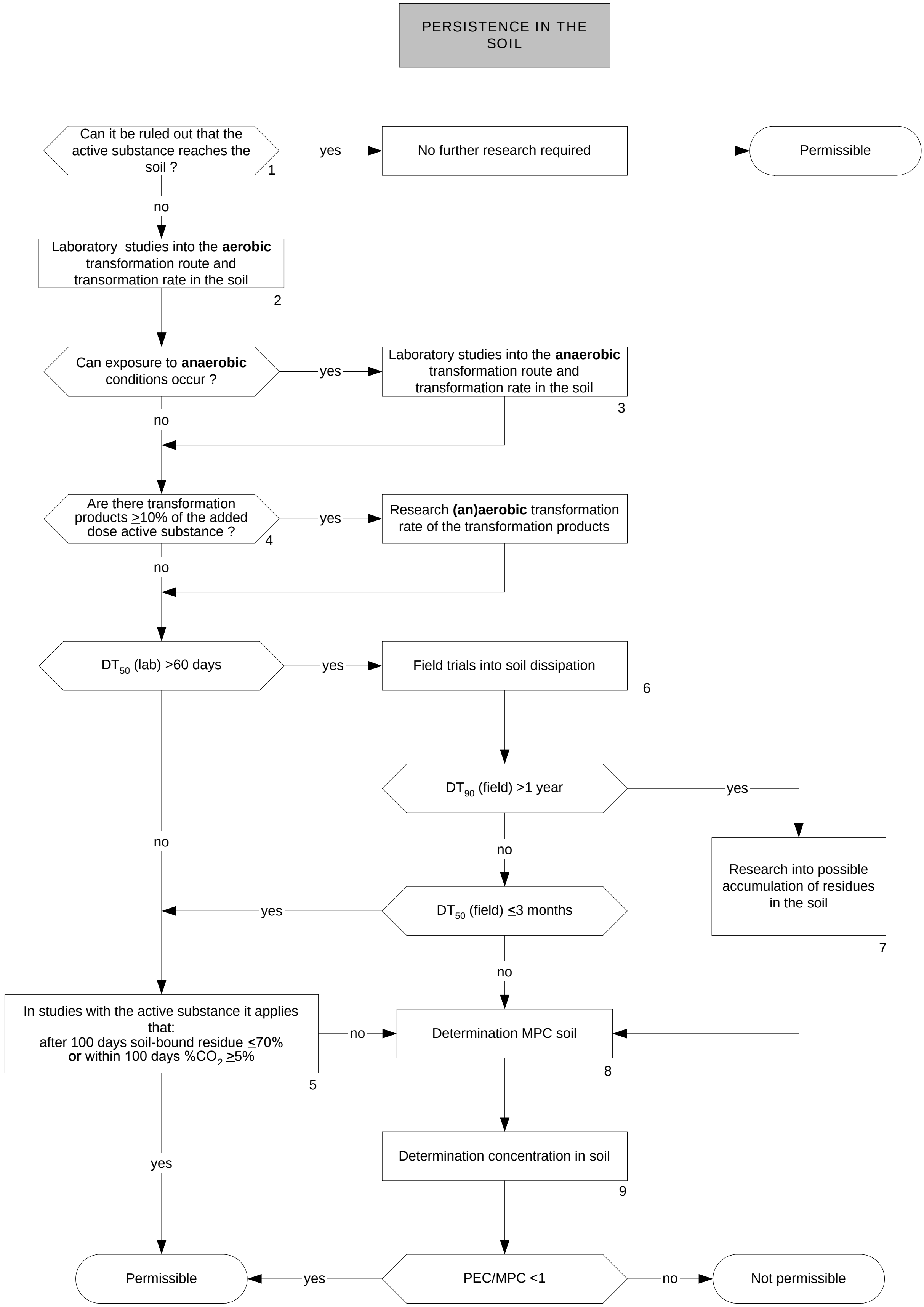
5. In order to meet the criterion for persistence in soil (UP) the following requirements apply for active substance and metabolites:
   - DT_{50} (field) is ≤ 3 months
   - after 100 days, in laboratory studies the percentage active substance or metabolites in the soil-bound residue is ≤ 70% of the initial dose, <u>or</u> the mineralisation rate ≥ 5%. Where the criteria above are not met, supplementary studies are required.

6. As regards the half life value a field study is required if the DT50 (lab, 20 ^{o}C) is > 60 days (or, for application in a cold climate, if the DT50 (lab, 10 ^{o}C) is > 90 days. During the field dissipation studies (A7.1.1.2.2b), the rate of disappearance of the active substance and its relevant degradation products from the soil is determined.
The study is performed under climatological and soil conditions comparable to the NL conditions. Information on Dutch soil conditions can be found in GeoPEARL [3], [4].
The suitability of the field studies as regards other aspects is based on expert judgement. The field studies yield values for DT50 (field) and DT90 (field)

7. If field soil-dissipation studies show that the DT_{90} (field) is > 1 year, and repeated use during the same growing season or in successive years is envisaged, (field) studies into the possibility of accumulation of residues in the soil and into the level at which the plateau value is reached must be conducted (A7.1.1.2.2d). Long-term studies, in which the substance is applied several times, must be conducted with two relevant soils.

8. Determination of the MPC_{soil} is based on the Technical Guidance Document (TGD) [**Fout! Bladwijzer niet gedefinieerd.**]. The MPC_{soil} is derived by means of assessment factors or by means of statistical extrapolation (SSD method). For the SSD method at least 10 NOECs of different species from at least 8 different taxonomic groups are required. However, unbound values cannot be used. . If no suitable soil toxicity data is available, equilibrium partitioning from aquatic toxicity data should take place. Secondary poisoning and the risk to human health must also be taken into account in determining the MPC_{soil}. For secondary poisoning this means that a concentration in the soil is calculated from the BCF value for worms and the chronic endpoint for birds and mammals, with the corresponding assessment factor of 5 (PEC_{soil} = chronic criterion / BCF_{worm}). The human –toxicological limit is calculated from the ADI, using models as described in the TGD.
   The above means that three different types of MPC_{soil} may be derived: an MPC for species, secondary poisoning and human health. The final MPC_{soil} is chosen on the basis of a comparison of these three values. See §2.3.2 for further clarification.

9. The soil concentration of active substance and/or metabolites against which the MPC_{soil} is tested is the time-weighted average plateau concentration in the top 20 cm of the soil (plateau PEC_{soil}) over several years of application.
   Where the DT90 (field) > 1 year, the plateau concentration determined by means of field studies (see point 7) must be used.


PERSISTENCE IN THE SOIL
Can it be ruled out that the active substance reaches the soil ? 1
yes
No further research required
Permissible
no
Laboratory studies into the **aerobic** transformation route and transormation rate in the soil
2
Can exposure to **anaerobic** conditions occur ?
yes
Laboratory studies into the **anaerobic** transformation route and transformation rate in the soil
3
no
Are there transformation products ≥10% of the added dose active substance ? 4
yes
Research **(an)aerobic** transformation rate of the transformation products
no
DT_{50} (lab) >60 days
yes
Field trials into soil dissipation
6
DT_{90} (field) >1 year
yes
Research into possible accumulation of residues in the soil
7
no
no
yes
DT_{50} (field) ≤3 months
no
In studies with the active substance it applies that:
after 100 days soil-bound residue ≤70%
or within 100 days %CO_2 ≥5%
5
no
Determination MPC soil
8
Determination concentration in soil
9
yes
Permissible
yes
PEC/MPC <1
no
Not permissible

Appendix 3 Overview of soil types to be used in the studies; pre-treatment of the soil

A brief description of the five soil types most relevant for the Netherlands is given below. The margins for the different properties were chosen in such a way that there is a large degree of overlap with the soil requirements laid down in the BBA Merkblätter.

Data from experiments carried out outside the Netherlands with soil types prescribed in the country in which the experiments were carried out will generally be acceptable, unless the selected soils differ on essential points from the specifications given below.

1. humous sandy soil with:
Clay (particles < 2 µm) content < 8%; organic matter content 4-8%; < 25% silt (2-50 µm); pH-KCl 4.5-6.0. (Partial overlap with BBA 2 = 'Sand').

2. loam, moderately low in humus with:
Clay content 12-25%; organic matter content 2-3%; pH-KCl 6.5-7.5.

(Partial overlap with BBA 3 = 'Sandiger Lehm' and 'Sandy Loam' and 'Silt Loam').

3. sandy soil, low in humus with:
Clay content < 8%; silt content < 50%, organic matter content < 2%; pH-KCl 4.5-7.0.
(Partial overlap with BBA 1 = 'Sand' and 'Agricultural Sand').

4. heavy clay soil, with low or moderate humus content with:
Clay content > 35%; organic matter content 2.0-4.5% (for arable land); pH-KCl 6.0-7.5.
(Partial overlap with 'Clay' or 'Clay loam').

5. peaty soil or peat soil with:
Minimum organic matter content dependent on clay content, viz., > 15% organic matter if the mineral fraction consists of particles > 2 µm only, or > 30% organic matter if the mineral fraction consists of clay only. Intermediate values to be interpolated according to clay content; pH-KCl 4.5-5.5. (Overlap with 'Muck Soil'.)

Description of the history of the soil, e.g. on last application of the Plant protection products is required; obviously for metabolism research soil should be used on which the chemical or structural analogues have not been applied for at least 5 years in order to avoid disturbing side-effects in the experiments. For soil fumigants a period of at least one year before sampling applies. Apart from that, no organic manure may have been applied to the soil during at least one year. The soil may, after fresh collection from the field, be stored for a maximum of 3 months at 4 ^{o}C. Storage at higher temperatures leads to shortening of the permitted storage periods (50 days at 10 ^{o}C, 30 days at 15 ^{o}C, and 20 days at 20 ^{o}C). Data on history, storage and pre-incubation should be included in the reports of the experiments. Soils may in no way be activated or manipulated, unless for studying a specific aspect.
For laboratory research the soil is preferably freshly collected from the field, or otherwise from a well-drained temporary storage in the open air (maximum layer thickness 30 cm). Before use, the soil is rubbed through a sieve (2 mm), brought (and maintained) at a moisture content corresponding to a pF value of about 2.5, and stored for about 2 weeks under aerobic conditions (e.g. in plastic oxygen-pervious bags) at the temperature at which the measurements are to be carried out.

Appendix 4 Calculation $PIEC_{soil}$ seed dressings

Summary

A method for calculating the PIEC of seed dressings is proposed in this note.
A *homogeneous distribution* of the active substance in spherical spheres of influence around a seed is assumed for the calculation. Analogous to the distribution depth for a spray formulation it is assumed that the radius of the *sphere of influence is 5 cm*. Two scenarios are proposed. Superficially drilling of small seeds with a radius < 0.5 cm such as cereals, carrots or radish is assumed in the first scenario. The sphere of influence then has the form of a half spheroid. Drilling/planting of larger seeds at ≥ 5 cm depth, e.g., beet, maize, potatoes or bulbs is assumed in the second scenario. The sphere of influence has the form of a full spheroid. For both scenarios a maximum volume of 500 m^3 is assumed.

Introduction

In striving for a reduction in the use of Plant Protection Products seed treatment is increasingly chosen instead of overall field treatment. Seed treatment can contribute to achieve the objectives of the MJPG (MeerjarenPlan GewasBescherming; Multi Year Crop Protection Plan) through:

- a reduction in the amount of required pesticide (reduction usually > 90%)
- reduced emission to the compartments groundwater, surface water and air.

The evaluation procedures are lagging behind in this development (except the risk evaluation for birds). Questions that arise at the moment in particular are:

1) What is the effect on the transformation of the substance?
2) What is the effect on emissions, in particular to groundwater?
3) What is the effect on the exposure of soil organisms?

Extensive research is required to answer these questions. The gaps in knowledge regarding 1 and 2 have been notified to the Stuurgroep Gewasbescherming (Crop Protection Steering Group); point 3 is elaborated here.

General calculation method

Starting point in the evaluation of spray formulations is the homogeneous distribution of the active substance in the top 5 cm layer of the soil. For the calculation of the PIEC, spraying losses and interception are taken into account but disappearance routes such as evaporation, photochemical transformation and microbial degradation are not. The volume of soil with a layer thickness of 5 cm of a hectare is 500 m^3, and the mass of the soil is $750*10^3$ kg (at a bulk density of 1500 kg/m^3). The dose of active substance divided by the mass of the soil then yields a measure for the acute exposure of soil organisms (= PIEC).

The proposed calculation method for seed dressings consists of two parts:
Scenario A. seeds with a diameter < 0.5 cm superficially sown (figure 1).
Scenario B. seeds with a diameter > 0.5 cm sown at 5 cm or larger depth (figure 2).

Figure 1. Sphere of influence of seeds < 0.5 cm sown at the surface. Scenario A.

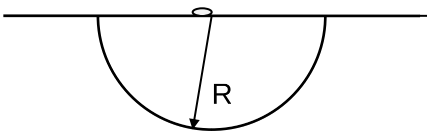
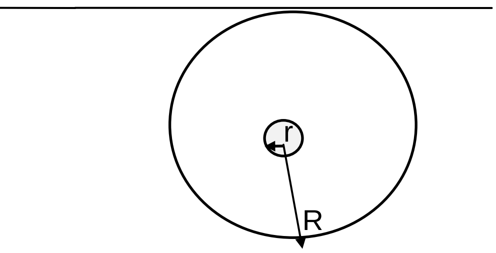


Figure 2. Sphere of influence of seeds > 0.5 cm sown at 5 cm depth. Scenario B.



<u>Assumptions</u>:

- Analogous to the depth (5 cm) that is applied in the calculation of a PIEC for a spray formulation, for seed dressings a sphere of influence of 5 cm around the seed is proposed.
- The seed dressing is fully released into the soil.
- A maximum size of the sphere of influence of 500 m^3. Because at a higher seed density the spheres of influence will be overlapping, in that case a homogeneous distribution through the top 5 cm of the soil is assumed.

Scenario A

Seeds with a diameter < 0.5 cm sown on the soil surface are considered as point sources. The diameter of the seed is negligibly small in comparison with the sphere of influence. The model parameters are described in Table 1.

As the seed is sown on the surface, the sphere of influence with radius R has the shape of a **half spheroid** (see figure 1) with volume (v):

$$v = {}^{2}/_{3}\,\pi R^3 \qquad \text{-1-}$$

Volume and mass of the soil within the sphere of influence of n seeds per m^2 are calculated. The total volume of the sphere of influence on one hectare of soil is bound to a maximum of 500 m^3/ha and is calculated as follows:

$$V = \min[n \cdot v, 500] \qquad \text{-2-}$$

The total mass of soil for a hectare within the sphere of influence of the seeds is then

$$M = \rho \cdot V \qquad \text{-3-}$$

The dose of the seed dressing is then divided by the mass of soil within the sphere of influence of the seeds, which results in the PIEC at:

$$PIEC = 10^6\, D / M \qquad \text{-4-}$$

Scenario B

The sphere of influence of seeds with a diameter > 0.5 cm sown at 5 cm depth or deeper has the shape of a full **spheroid** (see figure 2). Because the size of the seed is not negligible, the volume of the seed must be deducted from the volume of the spheroid.
The model parameters are described in Table 1.

The volume of a **round** seed is:

$v_{seed} = {}^{4}/_{3}\ \pi\ r^3$ -5-

The volume of the sphere of influence of a seed is calculated as follows:

$v = {}^{4}/_{3}\ \pi\ (R^3 - r^3)$ -6-

where for R the radius of the seed is added to radius of the sphere of influence, thus

$R = r + 0.05$ -7-

Volume and mass of the soil within the sphere of influence of n seeds per m^2 are then calculated. The total volume of the sphere of influence on one hectare of soil is bound to a maximum of 500 m^3/ha and is calculated as follows:

$V = \min[n \cdot v, 500]$ -8-

The total mass of soil at a hectare within the sphere of influence of the seeds is then

$M = \rho \cdot V$ -9-

The dose of the seed dressing is then divided by the mass of soil within the sphere of influence of the seeds, which results in the PIEC at:

$PIEC = 10^6\ D\ /\ M$ -10-

Table 1. Description of the parameters.

Input		
R	radius of the sphere of influence of the seed	m
r	radius seed	m
n	sowing density	ha^{-1}
D	dose	kg a.s.· ha^{-1}
ρ	dry bulk density of the soil	kg· m^{-3}
Intermediates		
v	volume of the sphere of influence of a seed	m^3
v_{seed}	volume of a seed	m^3
V	total volume of soil within the sphere of influence of the seeds on one hectare soil	m^3· ha^{-1}
M	total mass of soil within the sphere of influence of the seeds on one hectare soil	kg· ha^{-1}
Output		
PIEC	Predicted Initial Environmental Concentration	mg a.s./ kg soil

Conclusions

The calculation of PIECs via spheres of influence does in a three-dimensional way take into account which soil is/is not burdened with the active substance. The proposed method is based on the same starting points as those for the evaluation of spray formulations.
Comparison with the classical method (homogeneous distribution over 5 cm soil) highlights that there are equal outcomes at high seed densities but that the PIEC values are higher for low seed densities.
The proposed method yields lower PIEC values than the calculation based on a “spread-out” seed surface. This is the result of the two-dimensional approach of that method.

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