Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009

NL part

Plant protection products

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

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Board
for the Authorisation
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Chapter 6 Fate and behaviour in the environment; behaviour in soil; leaching

Category: Plant protection products

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the potential leaching to groundwater of an active substance of a plant protection product and/or its metabolites/reaction products, and how reference values are derived in the NL framework (§2 - §2.5).

Substances that are approved under Regulation (EC) No 1107/2009 [1] and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included in Commission Implementing Regulation (EU) No 540/2011 [3] 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 plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (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 which are specific for the Netherlands.

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.

2.1. Introduction

This chapter describes the data for leaching to groundwater 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.

There is a deviation from the EU evaluation methodology as regards the interpretation of the aspect leaching to groundwater, for which a NL-specific method is followed according to the the Bgb (Plant protection products and Biocides Decree) [4].
This methodology is described in the report: 'The new decision tree for the evaluation of pesticide leaching from soils' [7].
The deviation is because the Netherlands is a delta with relatively high groundwater tables in combination with intensive soil use. In the Netherlands about 60% of the drinking water is abstracted from groundwater; a number of these abstractions is relatively shallow.
The combination of high groundwater tables and intensive soil use means that the Netherlands is vulnerable as regards groundwater leaching.

The other points in this chapter concern further elaborations of the EU procedure.

For the chemical parameters of a substance that are required as model input data reference is made to Chapter 2 Physical-chemical properties.

A decision tree with corresponding clarification is presented in Appendix 1. This decision tree shows the approval framework for groundwater leaching.

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).
NL-specific data requirements and further interpretations of the EU data requirements are given in the text below.

2.3. Risk assessment

The evaluation methodologies for chemical crop protection products comply with the description under EU framework (see §1.3 of the EU part).
Article 8e (new and existing substances) of the Plant protection products and Biocides Decree (Bgb) [4] describes the authorisation criterion leaching to groundwater.
NL-specific evaluation methodologies and further elaborations of the EU procedure are presented in the text below.

2.3.1. General

In view of the quality of the groundwater and the fact that groundwater serves as source for drinking water production it is assumed that a larger area needs to be protected against the average exceedance rather than a smaller area against peak exceedance. Along these lines it is posed that the 90 percentile in vulnerability is determined by the soil where the average concentration may not exceed the criterion. Evaluation is required for active substances and for metabolites of which the concentration in the soil at any point in time is 10% or more, or at 2 subsequent points in time 5% or more of the amount of added active substance or where the maximum formation percentage has not yet been reached at the end of the study.

The risk of leaching is determined by means of a tiered approach. The principle of a tiered approach is that:

- Earlier tiers are more stringent to be able to rule out unlawful authorisation of a substance.
- The required information increases with increasing progress.
- Higher tiers in the evaluation mean more efforts for the authorisation holder and for the evaluation.
- The final criterion is the same as the legal requirements to be met by a substance.
- Jumping to later tiers in the decision tree is permitted.

2.3.2. Calculation of leaching to the upper metre of groundwater

Tier 1

This is the fist step in the evaluation. This step distinguishes substances/metabolites with a low or negligible leaching risk leaching on the basis of the minimally required dossier information and with a minimal effort of the evaluator.
The potential acreage of use is not taken into account in this step

The model FOCUSPEARL [Pesticide Emission Assessment at Regional and Local scales] [8, 9] with the FOCUS Kremsmünster scenario is used to calculate the leaching risk in the 1st tier of the Dutch decision tree for leaching.

The following information from the dossier/ the monograph is used for the calculations:

- Physical-chemical properties of the substance/metabolite; e.g. molecular mass, water-solubility, vapour pressure and, for dissociating substances, pK_a;
- The geometric mean/median value for transformation of the substance/metabolite, where necessary standardised to reference conditions; i.e. DegT50* (d), and the arithmetic mean/median value for K_{om} (L/kg, obtained by dividing K_{oc} by 1.724) and the arithmetic mean/median value of the Freundlich exponent 1/n; the sorption constants for the neutral and the charged molecule are required for acid-forming substances;
- The crop or the crops in which the substance will be used; If no comparable crop is available in PEARL winter cereals is used. For all simulations the crop uptake is set to 0 as default. For systemic substances a default of 0.5 is chosen.
- The method of application, the dose level and the proposed application scheme (time, frequency).
- Interception value as relevant to the crop and crop stage or derived from Appendix 3 to chapter Chapter 6 Fate and behaviour in the environment: behaviour in soil; persistence

The DegT50 value that is to be entered may originate from field studies ($DT50_f$ [†]) where the field experiment meets the requirements as phrased in Chapter 9.1 of FOCUS Kinetics [10].The derived $DT50_f$ needs to be normalised to reference conditions to be used as input.

The procedures as described in FOCUS groundwater [11 and xx] are followed for 1st tier calculations except substances that come under the following exceptional criteria:

1. the substance is volatile (vapour pressure at 20ºC >10^{-4} Pa [12]) and is injected or incorporated into the soil;
2. the substance is not dissociating or the pK_a of the substance is ≥ 8;
3. the average $DT50^3$ under reference conditions is shorter than 10 days and the average K_{om} is lower than 10 L/kg.
4. DT50 depends on soil properties

In case point 2 is met, leaching for the Kremsmünster scenario is calculated according to the FOCUS procedures, where a K_{om} value is entered which corresponds with a pH ($CaCl_2$) of the soil of 7.5. The $K_{om,base}$ can be used as alternative. The same approach can be used in tier 1 for substances that show pH dependent sorption.
For further assessment in the 2nd tier, if required, data on the sorption constants for the

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* DT50 derived fromt laboratory studies called DegT50 conform the rapport of the FOCUS workgroup degradation kinetics.

† DT50 obtained from field studies becomes $DT50_f$ when $DT50_f$ is of the same quality as the DegT50 (lab studies). If this is true the value can be used as model input after normalization to reference conditions

neutral and the charged molecule are required.

Where the 1st point is met, it is assumed that the possibility exists that the substance reaches the groundwater through gas diffusion besides leaching.
These substances are always directly evaluated in tier 2 of the decision tree.

For substances that come under point 3, the time of application has a great effect on the calculated leaching concentration. This means that the concentration calculated with GeoPEARL (tier 2) does not necessarily need to be lower than the 80 percentile of the concentration calculated with Kremsmünster scenario. These substances are for this reason directly evaluated according to the 2e tier.

For a use applied for in flower bulbs, calculation results not clearly below 0.001 µg/L should be confirmed by performing a 2nd Tier calculation using GeoPEARL. As in PEARL there is no comparable crop available, winter cereals is used. From experiences in risk assessment for groundwater is appears the 1st Tier is not always conservative enough in this way. In GeoPEARL flower bulbs are a defined crop and more detailed calculation is possible.

For the use of Q10 in the NL risk assessment the Q10 that has been used in the latest EU evaluation (DAR/LoEP) for the active substance. If in the European dossier a Q10 of 2.2 was used, we use this value also (an 54000 J/mol as activation energy). If in the latest EU evaluation a Q10 of 2.58 is applied than we use this value also for the NL assessment (and 65400 J/mol as activation energy). In general we can say that for existing substance mostly a Q10 of 2.2 is applied and for new active substances (read more recently approved) a Q10 van 2.58. The same applies for metabolites.

Metabolites
Metabolites are modelled using the transformation scheme of the model input. If degradation studies are available where the metabolite was dosed, the formation fraction will be 1 for this studies by default. For other studies the kinetic formation fraction or the maximum observed formation is used for calculation.
The plant uptake factor for metabolites is set to 0 by default.
Metabolites for which the FOCUS calculation or different data show that the expected concentration in groundwater exceeds 0.1 µg/l need to be evaluated for their relevance according to the Guidance Document on the assessment of the relevance of metabolites in groundwater [7].

Tier 2
Substances which according to the 1st tier have a leaching potential need more detailed evaluation in the 2nd tier of the Dutch decision tree to establish whether a risk of leaching does indeed exist. The 2nd tier can be divided into 2 parts: one part in which GeoPEARL is used and a part in which higher tier data like e.g. monitoring data of the upper groundwater can be considered. Details regarding the use of monitoring in shallow groundwater are described in a separate report [13].
The procedure in tier 2 starts with GeoPEARL [14, 15] calculations with the data from the basic dossier as input parameters but additional information can be used directly to refine the evaluation. When the GeoPEARL run with the data from the basic dossier does not lead to an acceptable risk of leaching, i.e., the target concentration is higher than 0.1 µg/l, the applicant can submit additional information (extra laboratory studies and/or field or lysimeter studies). The results of extra laboratory studies lead to different input values for GeoPEARL. Lysimeter and field studies can lead to new input values as well as to a correction factor for the outcome of the GeoPEARL calculation. Interpretation of field and lysimeter experiments [16] shows to what extent the leaching behaviour of a substance can be simulated with PEARL. The ratio

between calculated leaching and leaching measured in the experiment, the so-called simulation error, is then used to adjust the target concentration calculated with GeoPEARL.
The 2nd part of tier 2 considers results obtained from monitoring studies of the upper groundwater, i.e., the groundwater present between 0 and 1 metre below the groundwater table underneath fields that have been treated with the substance.
Two approaches are possible:

a) monitoring of the upper groundwater underneath a restricted number of fields with a vulnerable soil type, and
b) monitoring of the upper groundwater underneath a large number of fields with various soil types that are together representative of the total acreage of use of the substance [13].

In case all criteria laid down in the mentioned report [13] are met, the results obtained by means of PEARL or GeoPEARL calculations are overruled by the monitoring data.

Tier 3

Tier 3 considers the behaviour of a substance in the water-saturated zone of the soil, i.e., the zone between 1 and 10 metres below the soil surface. A substance is evaluated in tier 3 where the target concentration as calculated with PEARL or GeoPEARL at the end of tier 2 exceeds 0.1 μg/l and/or monitoring of the upper groundwater does not yield a different result.
Tier 3 can also be divided into 2 parts; a part in which studies into the behaviour of a substance in the subsoil are considered and a part that takes monitoring data at a depth of 10 metres into consideration.
The applicant may conduct transformation and sorption studies with soil material that has been obtained from the saturated zone between 1 and 10 metres deep and demonstrate that under all redox conditions, from oxic to methanogenic, transformation (hydrolysis and/or biological transformation processes) takes place to such an extent that the concentration decreases to <0.1 μg/l. The studied subsoil material must be representative of the subsoil conditions in the potential acreage of use. Guidelines for experimental setup and calculations are given in the report of Van der Linden *et al.* 'Evaluation of the behaviour of pesticides in the saturated zone of the soil', 1999 [17].
The concentration expected after 4 years transport time at 10 m below the soil surface is calculated with the degradation rate in the saturated zone. Four soils must be tested.
The transformation rate and – where appropriate – a sorption constant is determined for each of these four soils.
For each of these values the concentration to be expected at 10 m depth is then calculated on the basis of the 90 percentile concentration from GeoPEARL as C_0. Where this is $<$ 0.1 µg/l for each of the 4 calculations, the product can be authorised as far as leaching is concerned; where the concentration is $\geq$ 0,1 µg/l, the product can not be authorised unless follow-up studies yield different results.
Finally, the applicant can demonstrate by means of monitoring that the concentration in the groundwater at 10 m depth remains <0.1 μg/l. The procedure and the interpretation of monitoring at larger depth is described in more detail by Cornelese *et al.*, 2003 [13].

2.3.3. Groundwater protection areas

GeoPEARL calculations show [18] that groundwater protection areas are more vulnerable to leaching. This is probably a result of the fact that the organic-matter concentration of the soils in these areas is usually lower than in the average agricultural area. This means that the calculated 90 percentile of the acreage within the groundwater protection areas <0.1 μg/l gives insufficient protection for groundwater protection areas. An extra safety factor of is 10 used for groundwater protection zones where the calculated concentration for the 90 percentile of the area must be <0.01 μg/l.
Where the 90 percentile for groundwater protection areas is >0.01 μg/l but <0.1 μg/l it should be indicated on the label of the product that application in groundwater protection areas is

prohibited. Supplementary data can be submitted which show that in practice the 90 percentile is <0.1 μg/l in groundwater protection areas. Where sufficient reliable data are available about this, authorisation can be granted without this restriction.

2.4. Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3] or new substances has been laid down Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection products and Biocides Decree (Bgb) [4].

2.4.1. Criteria and trigger values

For the criteria and trigger values as applied in the evaluation of leaching to groundwater reference is made to the Plant protection products and Biocides Decree (Bgb) [4].
Article 8e of the Plant protection products and Biocides Decree (Bgb) describes the authorisation criterion leaching to groundwater.

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

§ 1. Beoordeling van aanvragen inzake gewasbeschermingsmiddelen

Artikel 8e. Uitspoeling

1. Het college komt bij de toepassing van het uniforme beginsel, in uitvoeringsverordening (EU) 546/2011, bijlage, deel I, onderdeel C Besluitvorming, punt 2.5.1.2, tot het oordeel dat een gewasbeschermingsmiddel geen onaanvaardbaar effect op het milieu heeft als bedoeld in artikel 4, derde lid, onderdeel e, van verordening (EG) 1107/2009 indien bij de toepassing van dit beginsel wordt aangetoond dat:
   a. de concentratie van een werkzame stof, een relevant reactieproduct of een relevant afbraakproduct in het grondwater gelijk is aan of lager is dan 0,1 µg/liter bij toepassing van één van de volgende methoden van beoordelen van het gewasbeschermingsmiddel:
      1° een berekening met het model PEARL voor het FOCUS Kremsmünster scenario, bedoeld in bijlage 1 onder 12.
      2° een berekening met het model GeoPEARL, bedoeld in bijlage 1 onder 12
      3°. een toetsing aan metingen van concentraties in het bovenste grondwater,
      4° een berekening voor de verzadigde zone, bepaald volgens een rekenvoorschrift waarbij wordt uitgegaan van een afbraaksnelheid volgens de eerste orde kinetiek na 4 jaar op 10 meter diepte,
      5°. een toetsing aan metingen van concentraties in het diepere grondwater op minimaal 10 meter beneden het maaiveld, of
   b. bij het gebruik van een gewasbeschermingsmiddel in een grondwaterbeschermingsgebied de maximaal toelaatbare concentratie van een werkzame stof, een relevant reactieproduct of een relevant afbraakproduct van 0,01 µg/liter gebaseerd op een berekening of toetsing als bedoeld in onderdeel a, onder 1 tot en met 3 niet wordt overschreden, tenzij met nadere gegevens aan de hand van een berekening of toetsing als bedoeld in onderdeel a, onder 3, 4 of 5, wordt aangetoond dat in grondwaterbeschermingsgebieden de waarde van 0,1 µg/liter niet wordt overschreden.

Please note that for non-professional use the dose rate in kg/ha is corrected to match a maximum acreage of 500 m2.

2.4.2. Decision making

The way in which the Ctgb judges the leaching of an active substance from a plant protection product and/or its metabolites/reaction products, to groundwater against the criteria of Regulation (EC) No 1107/2009 [1], taking into account the stipulations stated in the Bgb (Plant protection products and Biocides Decree) [4].
Decision-making around leaching against the applicable criteria follows a tiered approach according to the decision tree for leaching (Appendix 1). Decisions are taken after each evaluation in each tier. The decisions at the end of the 1st and at the end of the 2nd tier can be overruled by data from higher tier experiments or analyses.

The decisions that are taken in the different tiers are as follows:
Tier 1: is the calculated 80 percentile concentration [‡] that is obtained with PEARL and the Kremsmünster scenario when using input data from the basic dossier <0.1 μg/l, or <0.01 μg/l for groundwater protection areas;
Tier 2: is the calculated concentration obtained with GeoPEARL and input data from the basic dossier or supplementary input data, lower than 0.1 μg/l for 90% of the potential acreage of use or <0.01 μg/l for groundwater protection areas. Or is the 90 percentile concentration from upper groundwater monitoring lower than 0.1 μg/l or <0.01 μg/l for groundwater protection areas.
Tier 3: is the transformation in the saturated zone under redox conditions that are relevant for the authorisation such that the 90 percentile concentration in the groundwater at 10 m depth is lower than 0.1 μg/l. Or do monitoring results of samples originating from groundwater at about 10 m depth show that the 90 percentile concentration at 10 m depth is lower than 0.1 μg/l. This applies both to within and outside groundwater protection areas.

2.5. Developments

- The current decision tree is in a validation process. In 2011 a first report on results became available (Boesten, J.J.T., A.M.A. van der Linden, W.H. Beltman and J.W. Pol. Leaching of plant protection products and transformation products; Proposals for improving the assessment of leaching to groundwater in the Netherlands. Alterra report 2264.
- EU guidance for deriving DegT50 values from lab and field studies is currently under development (Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (EFSA Journal 2014;12(5):3662).
- Guidance Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU (Version 3 of 10 October 2014. EC Document Reference Sanco/13144/2010).

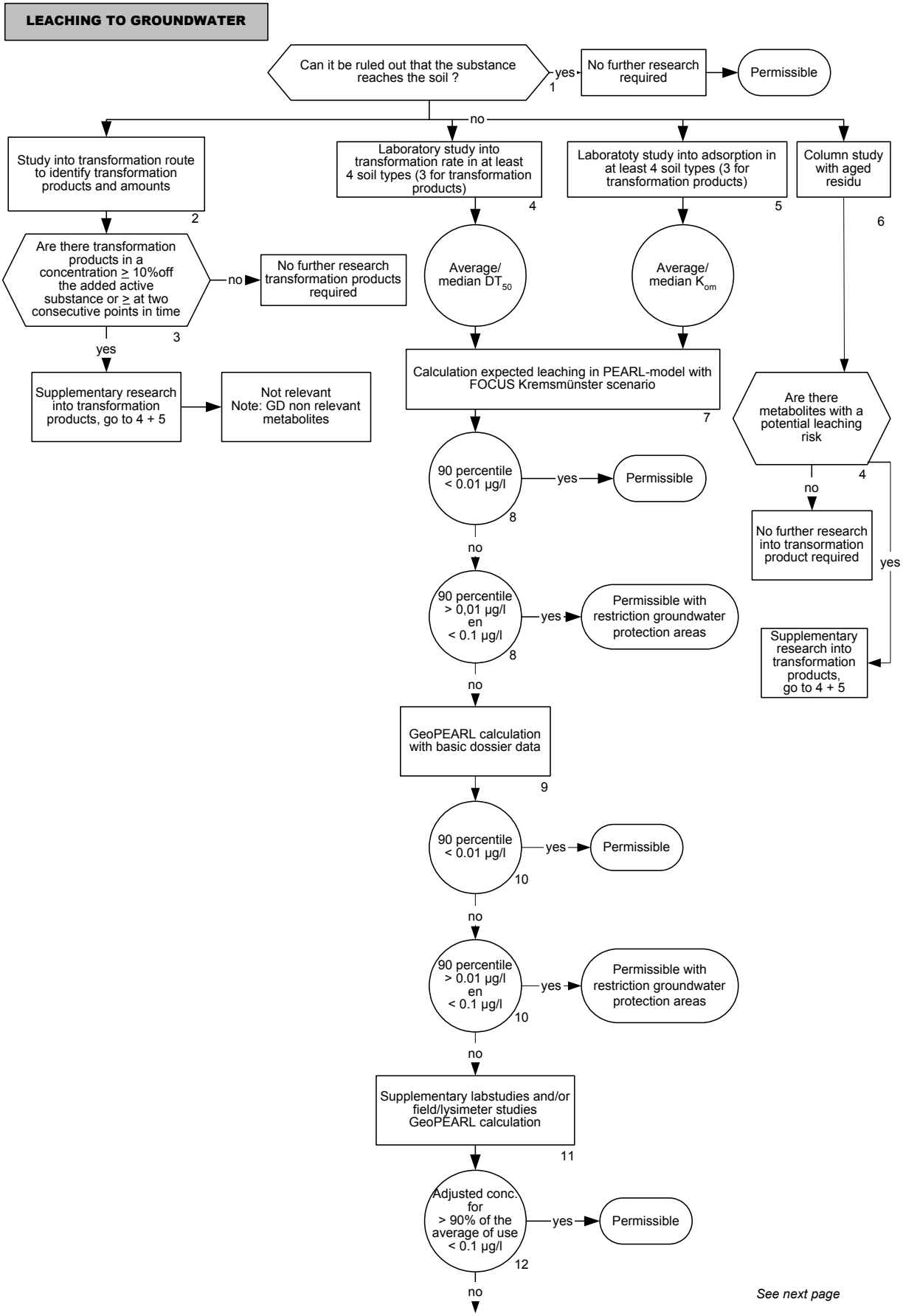
‡ Starting point within each scenario is an 80% sensitive soil and an 80% sensitive weather situation. The 80-percentile year-averaged concentration is a ‘reasonable worst case’ concentration and represents the 90-percentile.

3. APPENDICES

Appendix 1 Explanatory notes on the decision tree for leaching to groundwater

1) For each active substance data on the behaviour in the soil are required unless it is demonstrated that it is impossible that the substance reaches the soil under proper (agricultural) use of the product in compliance with the WG/GA (Statutory Use Instructions/Directions for Use).
2) The study into the transformation route according to OECD 307 or comparable method is necessary because besides active substances also metabolites must be evaluated for their risk of leaching to the shallow groundwater. The study (A7.1.1.1.1a) gives insight into which products are formed in which amounts during the transformation of the active substance in at least 1 soil type (choice from soil types 1, 2 and 3 from Appendix 3 to the chapter Behaviour in soil; persistence). The degradation rate of the substance and significant metabolites is determined according to the Guidance document FOCUS Kinetics [10]
3) Important metabolites are metabolites of which in the laboratory study into the aerobic transformation route the concentration in the soil is at any point in time higher than or equal to 10% or at 2 subsequent points in time higher than or equal to 5% of the amount of added active substance, or the maximum has not yet been reached at the end of the study.
4) Metabolites of which the applicant demonstrates that these are not relevant are not tested for the risk of leaching to groundwater;.see the “Guidance Document on non-relevant metabolites”. The option that these are not relevant can also be used for metabolites that form a potential risk of leaching on the basis of, e.g., the column study with aged residue and a lysimeter. The DT_{50} value of the active substance and its transformation products (A7.1.1.2.1b) should have been determined in transformation rate studies in three soils (preferably soil types 1, 2 and 3 from Annex 3 of the chapter Behaviour in soil; persistence)
   The geometric mean/median value is used as input in the leaching model PEARL (Pesticide Emission Assessment at Regional and Local scales) [8,9].
5) The shaking experiment is carried out in compliance with OECD guideline 106. Mobility should be determined in at least 4 different soil types, resulting in at least 4 values for the sorption constant (K_{OM}) for the active substance. K_{OM} values determined in 3 soil types are required for metabolites. The arithmetic mean/median value is used as input in the leaching model PEARL.
6) A column study with aged residue provides insight in the risk of leaching of the transformation products to shallow groundwater. This research is not required in case for each transformation product with at any point in time a formation percentage of 10% or more of the amount of active substance, research has been carried out in compliance with A7.1.1.2.1b and A7.1.2a.
7) The PEARL model together with the FOCUS Kremsmünster scenario are used to calculate the expected leaching to groundwater. Leaching is calculated with the highest requested dose of the WG/GA (Statutory Use Instructions/Directions for Use) and the corresponding application times unless a different application is estimated as more worst-case. Interception of the crop is determined using table xxx. If relevant, for metabolites the transformation scheme available in the PEARL model will be used to estimate the risk for leaching of metabolites. All relevant substance properties available for metabolites are included. Where no values are provided parent values are used. For metabolites, preferable, arithmetic mean fitted formation fractions are used with corresponding DT_{50} values. If these are not derived maximum formation percentages are used together with the geometric mean DT_{50}. For studies on degradation where the metabolite is applied to soil a default formation fraction of 1 is chosen.

8) In case the 90 percentile of the concentration A.< 0.1 µg/l for agricultural areas and B. <0.01 µg/L for groundwater abstraction areas, a low risk is expected, and the product can be authorised.
9) GeoPEARL calculation of the expected concentration in the upper groundwater for the acreage of the requested fields of use with the basic dossier data. If relevant,.for metabolites the transformation scheme available in the PEARL model will be used to estimate the risk for leaching of metabolites. All relevant substance propoerties available for metabolites are included. Where no values are provided parent values are used. For metabolites, preferable, arithmetic mean fitted formation fractions are used with corresponding DT_{50} values. If these are not derived maximum formation percentages are used together with the geometric mean DT_{50}.
10) In case 90% of the acreage of use has a concentration A. <0.1 µg/L for agricultural areas and B. <0.01 µg/L for groundwater abstraction areas, a low risk is expected, and the product can be authorised.
11) Field or lysimeter research or supplementary laboratory studies can be used to adjust the expected concentration. Supplementary laboratory studies give cause to adjust the input values in GeoPEARL and to run a new calculation. The results are interpreted according to Verschoor et al., 2001 [16]. The number of studies as described in Van der Linden et al. [7] are taken into account with the determination and use of the so-called adjustment factor, f_{adj}. After standardisation this results in an adjusted concentration from GeoPEARL. For metabolites, methods to interpret and analyse lysimeter and field studies are still lacking. It has neither been laid down how many soils need to be tested.
12) In case the adjusted concentration for more than 90% of the acreage of use is <0.1 µg/L, the product can be authorised as far as the leaching criterion is concerned. In case the concentration, however, is ≥ 0.1 µg/l, supplementary research must be carried out.
13) Post registration monitoring of the upper metre of the groundwater on a number of fields on which the product is used, as described in Cornelese et al., 2003, leads to a measured 90 percentile concentration in the upper groundwater. If this 90 percentile concentration is <0.1 µg/L, the product can be authorised. If the concentration, however, is ≥ 0,1 µg/l, supplementary research must be carried out.
14) The concentration expected after 4 years transport time at 10 m below the surface level is calculated with the degradation rate in the saturated zone (Van der Linden *et al.* 'Beoordeling van het gedrag van bestrijdingsmiddelen in de verzadigde zone van de bodem' (Evaluation of the behaviour of pesticides in the saturated zone of the soil), 1999) [17]. Four soils need to be tested. The transformation rate and, if applicable, a sorption constant is determined for each of these 4 soils. The expected concentration at 10 m depth is then calculated with each of these values, based on the 90 percentile concentration from GeoPEARL as C_0. In case this is < 0.1 µg/l for each of the 4 calculations, the product can be authorised in case the concentration is ≥ 0.1 µg/l, the product cannot be authorised unless supplementary research yields different results.
15) Monitoring of groundwater at or around 10 m depth as described in Cornelese et al., 2003 [13], leads to a measured 90 percentile concentration in the groundwater at 10 m depth. In case this is < 0.1 µg/l the product can be authorised in as far as leaching is concerned; in case the concentration is ≥ 0.1 µg/l, the product cannot be authorised.



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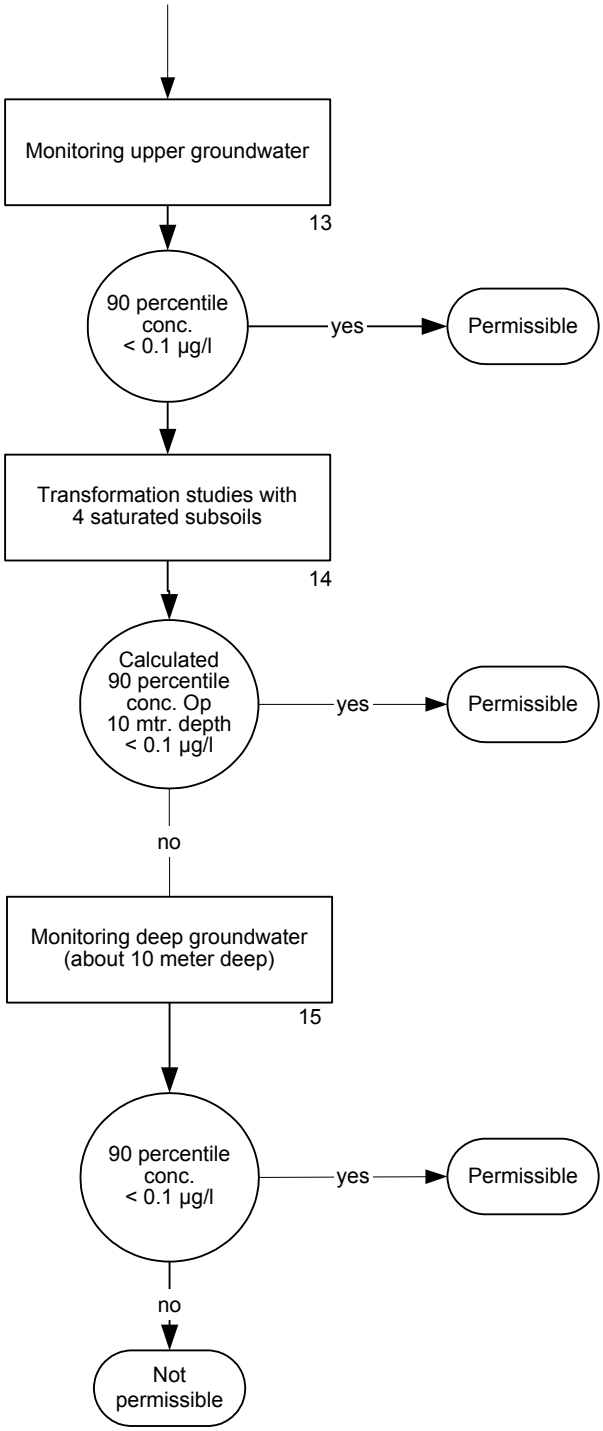

Appendix 2 Can it be ruled out that the substance reaches the soil?

For answering this question it is important whether the substance does, during or after application in compliance with good agricultural practice in a not fully closed system, get into contact with the soil.

The first important question is whether application takes place outside or inside closed spaces (greenhouses (substrate culture), sheds, bee hives etc). For applications in closed spaces (warehouses etc) it can be presumed that the product does not get into the soil. However, when greenhouse culture is included in the WG/GA, without explicitly stating that substrate culture is concerned, soil-bound culture is assessed as a conservative approach for the aspect leaching to groundwater.
In case application on bare soil is not precluded: calculate for leaching to groundwater; in case of application on shelves/tables: do not calculate. Concentration in the (potting) soil is only relevant when the pots are planted in open soil or when the potting soil is brought on open soil. The PECs in pots are not relevant. The following data are relevant for:

- applications on tables: Fsoil = 0.
- pots placed on concrete or covered soil, no leaching assessment
- in case of doubt about underground: Fsoil = 0.9-Fcrop (in case of drenching Fsoil = 1) (for Fcrop: see interception percentages in Appendix 5 to chapter Persistence)
- density potting soil default for soil: 1500 kg/m3
- 500 m3 potting soil per ha (default)
- 90 pots per m2 (default)
- 0.5 l potting soil per pot (default)
- convert Kom for 30% o.m.

In case the label allows for different interpretations, the worst case situation is assumed (exposure soil not precluded: leaching calculations).

For outdoor use, the aspect persistence/leaching to groundwater is relevant for almost all fields of use. It can only be ruled out that the product gets into the soil for a number of specific application techniques (wound treatment by smearing, injection of trees etc) and applications where the water is collected for re-use or discharge on a sewage system.

There are applications where the actual use of the crop protection product takes place at a different location than the culture itself (seed treatment, treatment of planting stock, tray treatment, etc). In those cases the situation of the culture should be used. This means that in case treated seed or planting stock is brought into the soil it cannot precluded that the substance gets into the soil and therefore is subject to leaching.

Dipping treatment
According to information from DLV (Advisory Service) in Lisse, planting of bulbs results in about 600-700 l/ha dipping liquid getting onto the land with the dipping liquid that adheres to the bulbs.

Appendix 3: Crop table comparison GeoPEARL/FOCUS

Selection of crops in the Tier 1 leaching evaluation for the Netherlands

The new NL decision tree leaching prescribes the use of FOCUSPEARL and the FOCUS Kremsmünster scenario in Tier 1 evaluation and the use GeoPEARL in Tier 2 evaluations. Unfortunately, the number of defined crops in GeoPEARL differs from the number of crops defined for the FOCUS Kremsmünster scenario. Some crops of the FOCUS Kremsmünster scenario are not present in the GeoPEARL database. The number of crops / crop groups defined in the GeoPEARL database is 24 whereas for the FOCUS Kremsmünster scenario only 14 crops have been defined. The FOCUS Kremsmünster crops are in the table below linked to the GeoPEARL crops. The choice of the interception value in the model is not linked to this table; see Appendix 5 of the chapter Fate and behaviour in the environment, part persistence for further details.

Table 1 Link between GeoPEARL crops and FOCUS Kremsmünster crops

GeoPEARL crop	FOCUS Kremsmünster crop
potatoes	potatoes
strawberries	strawberries
asparagus	potatoes
sugar beets	sugar beets
leaf vegetables	cabbage
plants for commercial purposes	winter cereals
floriculture	winter cereals
flower bulbs	onions
tree nursery	winter cereals
fallow	no crop
fruit culture	apples
cereals	winter cereals
grass	grass
grass seed	grass
green manuring	oil seed rape winter
vegetables	Carrots
cannabis	winter cereals
silviculture	winter cereals
cabbage	Cabbage
maize	Maize
remaining agricultural crops	winter cereals
legumes	Beans
leek	Onions
onions	Onions

In general the links were established according to the following hierarchical criteria:
1. use the same crop;
2. use a crop which resembles the crop in appearance and / or management practices
3. use winter cereals

The third option is included from a conservative point of view.

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