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

NL part

Plant protection products

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

version 2.3; April 2018

ctgb

Board for the Authorisation of Plant protection products and Biocides

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

Category: Plant protection products

Important changes with the last version of the E.M.

Evaluation manual PPP NL part Chapter 6 Leaching			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014	§ 2.3.2, p. 5.	
		§ 2.3.3, p. 7.	
		§ 2.5, p.9	
2.1	October 2016	§ 2.3.2, p. 4.	Restrictions for the use of Tier 1 have been modified/clarified.
		§ 2.3.5., p. 7	Possibility of use-specific restriction for the use in groundwater protection areas.
		§ 2.3.6., p. 8	Section on the assessment of protected crops has been added.
		§ 2.3.7., p. 9	Section on the assessment of non-professional use has been added.
		§ 2.3.8., p.9	Section on uses which have specific requirements for the groundwater assessment.
		§ 2.5, p. 11	Section on developments has been updated.
2.2	January 2018	Paragraph 2.3.8, page 10	Instructions for modelling the exposure to groundwater after spreading champost to soil have been incorporated in the Evaluation Manual under Special cases.

2.3	April 2018	Paragraph 2.3.8, page 10	Instructions for modelling of the behaviour of substances applied in reed have been incorporated in the Evaluation Manual under Special cases.
		§ 2.3.8., p.10	Added instruction for those cases that a 90th percentile PECgw should be derived from multiple GeoPEARL runs with different soil properties.

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 its metabolites, degradation products and reaction products, 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 active substances, included in Commission Implementing Regulation (EU) No 540/2011.The plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree). The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 implementing Regulation (EC) No 1107/2009 (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 Member State.

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. This methodology is described in the report: 'The new decision tree for the evaluation of pesticide leaching from soils'.

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 with regards to groundwater leaching.

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

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

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 of the Bgb 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. A groundwater assessment needs to be performed for all components (active substance, metabolites, breakdown and reaction products) that were identified under point 7.1 (fate and behaviour in the soil) of part A of Commission Regulation (EU) No 283/2013 (see §1.3 of the EU part).

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 when going to higher tiers;
- 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 higher 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 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

Calculations with the model FOCUS_PEARL for the FOCUS Kremsmünster scenario are used in the 1st tier of the Dutch decision tree for leaching.

The following information from the dossier 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 half-life of the substance/metabolite, where necessary standardised

to reference conditions; i.e. DegT50[*](d), and the arithmetic/geometric mean[†] value for K_{om} (L/kg, obtained by dividing K_{oc} by 1.724) and the arithmetic mean value of the Freundlich exponent 1/n; the sorption constants for the neutral and the charged molecule are required for weak acids;

- The crop or the crops in which the substance will be used; If no direct crop selection is possible, select a comparable crop and provide argumentation for the comparability. If no comparable crop is available in FOCUS_PEARL, winter cereals is used. For all substances/metabolites the default value for the Transpiration Stream Concentration Factor (TSCF) is 0;
- The method of application, the dose level and the proposed application scheme (time of application, frequency). This information is derived from the GAP of the plant protection product. The maximum number of applications and highest rates of application, at the shortest time interval should be used. For spring applications (March 1st until September 1st) and autumn applications (September 1st until March 1st) a default date of May 25th and November 1st should be used respectively. When this default date does not fall within the range in the time of application specified in the GAP, the date closest to the default date that is possible according to the GAP should be selected.
- Interception value as relevant to the crop and crop stage or derived from appendix 3 & 4 of the EU part of 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 Degradation Kinetics.The derived $DT50_f$ needs to be normalised to reference conditions to be used as input.

The procedures as described in FOCUS Groundwater and Generic Guidance for Tier 1 FOCUS Ground Water Assessments 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[§]) and is injected or incorporated into the soil;
2. K_{om} depends on soil properties (other soil properties may include pH, clay content, organic matter);
3. DT50 depends on soil properties other than moisture, temperature or soil depth (other soil properties may include pH, clay content, organic matter)
4. the geometric mean DegT50 under reference conditions is shorter than 10 days and the arithmetic/geometric mean[**] K_{om} is lower than 10 L/kg;

---

* DT50 derived fromt laboratory studies called DegT50 conform the rapport of the FOCUS workgroup degradation kinetics. After the finalisation of the FOCUS kinetics workgroup report, the EFSA developed guidance on the estimation of degradation rates (DegT50matrix) from field experiments from historical field dissipation study designs (so called legacy studies) and for the design of new studies where the impact of surface processes and leaching are minimised.

† The same statistic as listed in the List of Endpoints of the active substance should be used in the assessment (see also §1.5 of the EU part).

‡ 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

§ This is the trigger defined in the FOCUS Air Guidance above which volatilisation from soil can become a significant process.

** The same statistic as listed in the List of Endpoints of the active substance should be used in the assessment (see also §1.5 of the EU part).

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.

In case point 2 and or 3 is met, leaching for the Kremsmünster scenario is calculated according to the FOCUS procedures, using conservative estimates of Kom and/or DT50. For example if sorption is dependent on pH, a Kom value can be taken at pH (CaCl2) of the soil of 7.5 or, alternatively the Kom,base can be used.
In Tier-2 calculations with GeoPEARL it is possible to include dependencies of the sorption coefficient to other soil properties than organic matter and dependencies of the DegT50 to soil properties. Guidance on this procedure is described in section 3.6 and 3.7 of a separate report: Leaching of plant protection products and their transformation products (Boesten et al., 2015).

For substances that come under point 4, 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 FOCUS_PEARL for the Kremsmünster scenario. These substances are for this reason directly evaluated according to the 2nd tier.

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 (Cornelese et al., 2003).

The procedure in tier 2 starts with GeoPEARL 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 shows to what extent the leaching behaviour of a substance can be simulated with FOCUS_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 procedure for evaluation of field and lysimeter experiments is described in a separate report (Verschoor et al., 2001).

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.

In case all criteria laid down in the mentioned report (Cornelese et al., 2003) are met, the results obtained by means of FOCUS_PEARL or GeoPEARL calculations are overruled by the

monitoring data.

2.3.3. Calculation of concentration to be expected at 10 m depth

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 FOCUS_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.

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 > 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.

2.3.4. Metabolites

Metabolites for which FOCUS calculations or other higher tier data show that the concentration exceeds 0.1 µg/l can be evaluated for their relevance according to the Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (see § 1.3.4 of the EU part).

2.3.5. Groundwater protection areas

GeoPEARL calculations show that groundwater protection areas are more vulnerable to leaching (Kruijne et al. 2003). 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. In a separate study it was investigated whether an assessment for the total potential area of use sufficiently protects the groundwater in groundwater protection areas (Kruijne et al., 2004). It was concluded that the spatial 90th percentile of the leaching concentration for groundwater protection areas as a whole can be up to five times higher than for the total potential area of use. Therefore a safety factor of 10 was introduced for groundwater protection areas where the calculated leaching concentration at the target depth of 1 m, in either a tier 1 calculation using FOCUS PEARL or a tier 2 calculation using GeoPEARL, must be ≤ 0.01 µg/L. In cases where the predicted leaching concentration 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. Please note that for metabolites an alternative option is to submit a non-relevance assessment as described in § 1.3.4 EU part.

As of August 1st 2016, it is possible to apply for a restriction on the use in groundwater protection areas which is only targeted at the use/uses of the product that leads/lead to an exceedance of the threshold of 0.01 µg/L (based on either a tier 1 calculation using FOCUS PEARL or a tier 2 calculation using GeoPEARL). The claim that a restriction on the use in groundwater protection areas can be use-specific must be demonstrated by the groundwater assessment submitted by the applicant. This may require additional groundwater modelling compared to the risk envelope approach used in the core assessment of a zonal application.

2.3.6. Protected crops

The EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments came into force in the Netherlands on the 1st of March 2016. Leaching to groundwater from protected crop systems may occur, depending on environmental conditions, the construction technology of the system and the substance properties. For all protection structures mentioned in Table 1 of the Guidance, except walk-in tunnels and greenhouses, it is proposed to use current open-field approaches for exposure of groundwater described in § 2.3.2 - 2.3.3. For walk-in tunnels and greenhouses, the procedure to develop appropriate scenarios is described in the Guidance.

The Dutch government installed two working groups to develop new exposure assessment scenarios for soil-less and soil-bound greenhouse crops. For soil-less cultivation systems leaching to groundwater can be considered not relevant. One exposure assessment scenario was derived for all soil-bound greenhouse crops, based on the model crop: chrysanthemum. The development of the scenario is described in a separate report (Wipfler et al., 2015). Please note that this is the same scenario of which the surface water assessment is included in Appendix B of the Guidance. This soil-bound greenhouse scenario has been implemented in the Greenhouse Emission Model (GEM). The model is available at the website http://www.pesticidemodels.eu/gem/home including a manual and a hands-on training.

The most important substance-related input parameters of the GEM model for the soil-bound scenario are:

- Geometric mean DT50 for degradation rate in soil at 20°C (days).
    - *Please note that in the scenario report it is recommended to adjust the DT50 values obtained using open field soils by a default factor of 10 in the absence of a thorough dataset to account for the presumably slower degradation in greenhouse soils. The Dutch ministries have decided that this adjustment factor will not be used until more experience has been gained with the model.*)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for suspended organic matter (L/kg) (if not available use K_{om} soil)
- Arithmetic/geometric mean[††] K_{om} and corresponding arithmetic mean 1/n for sediment (L/kg) (if not available use K_{om} soil)

[††] The same statistic as listed in the List of Endpoints of the active substance should be used in the assessment (see also §1.5 of the EU part).

- Saturated vapour pressure (Pa) usually available at 20 or 25 °C
- Solubility in water (mg/L) usually available at 20 or 25 °C
- Molecular mass (g/mol)

The use of GEM for a groundwater assessment for soil-bound greenhouse crops is considered as a second tier. For a first tier assessment, the first tier for open-field cultivation can be used (see § 2.3.2).

No separate scenario for walk-in tunnels was developed for the Netherlands. For walk-in tunnels, also the first tier assessment procedure for open-field cultivation can be used as a first tier (see § 1.3.5 EU part). When this assessment is not sufficient to demonstrate a safe use than a Tier 2 assessment needs to be performed using a scenario developed according to the EFSA GD on protected crops.

2.3.7. Non-professional use

Currently there is no EU Guidance on the assessment on non-professional use of plant protection products. However, for the national groundwater assessment, the dose rate in kg a.s./ha is corrected to match a maximum acreage of 500 m^2 for non-professional uses.

2.3.8. Special cases

Flower bulbs:

As in FOCUS_PEARL there is no comparable crop available for flower bulbs, winter cereals should be used as surrogate crop in Tier 1. From experiences in risk assessment for groundwater it is known that the 1st Tier results are not always higher than the predicted concentration in the 2nd Tier using GeoPEARL. In GeoPEARL flower bulbs are a defined crop and a more detailed calculation is possible. If for a Tier 1 assessment of a use in flower bulbs (all application methods), the predicted leaching concentration is not clearly below 0.001 µg/L, than a 2nd Tier calculation using GeoPEARL is required to confirm the results from Tier 1.

In the groundwater assessment of dipped flower bulbs, “injection” should be used as application method in either FOCUS_PEARL or GeoPEARL in combination with a planting depth of 5 cm .

Potatoes:

In the groundwater assessment of treated potato tubers or the in-furrow treatment of tubers, “injection” should be used as application method in either FOCUS_PEARL or GeoPEARL in combination with a planting depth of 10 cm.

Mushroom cultivation

Indoor mushroom cultivation can be among the proposed uses of a plant protection product. No EU agreed exposure assessment methodology for indoor uses exists. In Regulation 1107/2009 it is stated: For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses. It cannot be excluded that direct or indirect emissions to various compartments will occur. In the absence of an agreed methodology Ctgb makes use of the following approach. The exposure route to groundwater (after spreading the champost to soil) is deemed relevant.

The calculated corrected dose rate (guidance how to derive this corrected dose rate can be found in the Evaluation Manual 2.2., EU part, Chapter 6 Persistence, §1.3.6) can be applied in regular PEARL modelling, and used for GeoPEARL calculations when a higher tier assessment is triggered.

Settings in (Geo)PEARL

- ✓ Within the application scheme in (Geo)PEARL, Application type Incorporation should be chosen, at 20 cm depth.
- ✓ Date of application should be the date of spreading the champost to the soil.

Reed

The structure of the soil where commercial reed production takes place (peatlands) regards in the upper layers a wet, marshy complex, but solid enough to stand on. In some case, below this a non-consistent layer of mud occurs. On the ridges, it is more solid (permanent soil). The composition and structure of peatlands is different from that in 'standard' agricultural soils, which (also) influences the organic carbon content, depth of groundwater table and pH.
In the risk assessment, the deviant pH of peatlands should be taken care of with regard to the sorption values present in the LoEP of the active substance. Regarding the organic carbon content of the peatland soils, the Kremsmünster scenario will give PECgw results that are deemed protective enough. Regarding the predicted environmental concentrations in groundwater, a 'standard run' (concentration at 1 m depth) with the Kremsmünster scenario should be provided. Additional results should be reported for the concentration in the liquid phase (PEARL result) at 10, 20 and 40 cm. For these calculations, the organic matter content of the scenario may be adapted to a realistic value for peatlands.

Special uses:

In the final report of the working group that evaluated the Dutch decision tree for leaching (Boesten et al., 2015; see also § 2.5) it was noted that the decision tree was developed for normal uses on arable crops, permanent crops and grassland. Therefore the decision tree is not applicable for special uses; for example:

- on hard surfaces;
- artificial lawns;
- in public green;
- in mushrooms grown inside;
- on railway tracks;
- under crash barriers or road signs.

For special uses of plant protection products a realistic worst case leaching assessment needs to be submitted. This assessment could make use of the leaching models included in the decision tree.

Overall 90th percentile for multiple GeoPEARL runs (e.g. for varying substance properties).

In some cases, the substance properties may depend on the soil properties, such as pH or organic matter. GeoPEARL has the possibility to include a boundary of soil properties in the plot selection (e.g. one run with only plots with pH minimum - pH7 and one run with only plots with pH7 to maximum). In case this possibility is used and multiple runs –with subsequent results- are available, a 90^{th} percentile over all plots should be calculated. In order to do so, the results of the (250) plots of all runs should be combined and ranked, and a 90^{th} percentile of all plots can be calculated. This is the final PEC_{gw} value to be used in the risk assessment.

2.4. Approval

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

2.4.1. Criteria and trigger values

The approval criteria for active substances and plant protection products in the EU are described in § 1.4 of the EU part. For the national criteria and trigger values as applied in the evaluation of leaching to groundwater reference is made to the Bgb.
Article 8e of the 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.

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, taking into account the stipulations stated in the Bgb (Plant protection products and Biocides Decree), is described in this section.

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 FOCUS_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, equal to or 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 equal or to 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 equal to or 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 equal to or lower than 0.1 μg/l. This applies both to within and outside groundwater protection areas.

2.5. Developments

In 2005 a scientific working group was initiated to evaluate the Dutch decision tree for leaching of plant protection products. In 2015 the final report of the working group was published: Leaching of plant protection products and their transformation products (Boesten et al., 2015). The background was that the Dutch association for drinking-water producing companies (VEWIN) at the moment of the introduction of the decision tree expressed their doubts whether this new tree would provide enough protection of individual drinking-water abstractions. These doubts were based on groundwater monitoring data collected by companies that were part of VEWIN, that showed detections of active substances above 0.1 μg/l. The original intention of the study was to evaluate the Dutch decision tree on leaching by applying the tree to these three substances. However, while working on this evaluation it appeared that parts of the existing guidance (both at NL and EU level) were not clear or complete enough or not state-of-the-art scientifically. Therefore guidance proposals were developed to revise these parts. Most of the proposals concern issues that need to be incorporated in the EU framework. However, the procedure described in section 3.6 and 3.7 can be used for a Tier 2 GeoPEARL calculation for weak acids with pH dependent sorption and substances whose sorption depends on other soil properties than pH or organic matter.

The core of Tier 2 of the current decision tree is the leaching simulations with GeoPEARL. It has been noted that the organic matter map contained in the current GeoPEARL package may overestimate organic matter contents in arable soils and underestimate these in grassland soils, in certain areas in the Netherlands. This discrepancy is caused by the way the soil profiles were generated. In the estimation of the properties for the arable soils also properties from grassland soil profiles were included. In 2013 a working group was initiated to develop a new version of GeoPEARL based on a new organic matter map. The aim is to release an interim version in 2017 in which a new organic map has been incorporated. A final

‡‡ 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.

version will be released incorporating several other developments with regard to underlying (map) information and model development.

According to the Uniform Principles (Commission Regulation (EU) No 546/2011) Ctgb has to consider in its groundwater assessment “where relevant, monitoring data on the presence or absence of the active substance and relevant metabolites, degradation or reaction products in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues”. In The Netherlands several parties monitor the quality of groundwater regularly. Also active substances of plant protection products and their residues are monitored. However, currently no tools are available to easily gain access to these data. In 2015 a project was initiated as part of the policy supporting research for the Ministry of Economic Affairs with the goal to develop a tool to make relevant monitoring data accessible so that it can be used by Ctgb in the authorisation of plant protection products. The first release of the tool is planned in January 2017. This release will contain monitoring data from provinces that are part of the reports on groundwater quality that are required by the Water Framework Directive. In addition, data from observation wells of drinking water companies are included. In the first release, general statistics on the data will be available, as well as spatial and temporal presentation of the data.

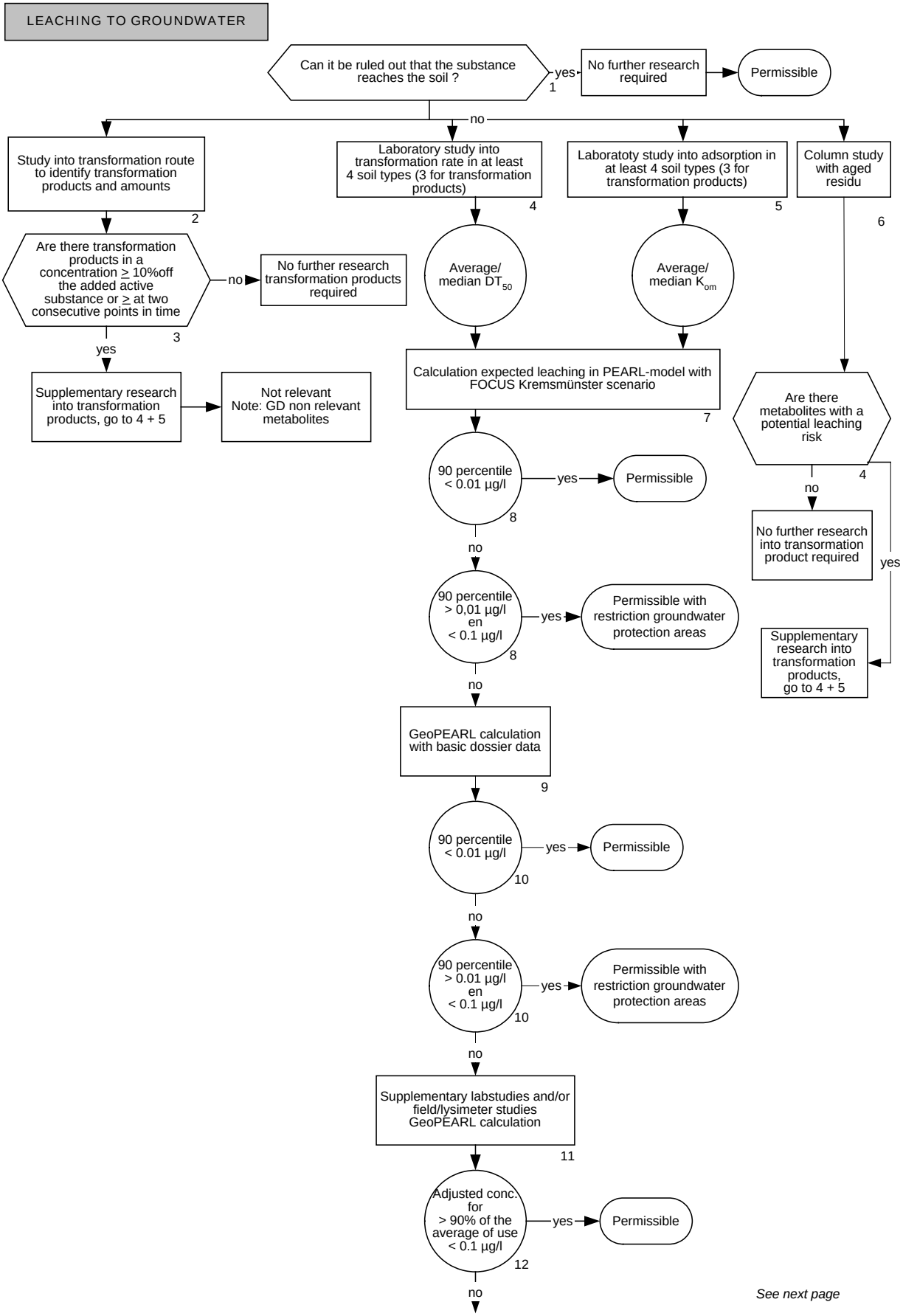
Developments in the EU procedure for evaluation of the risk for leaching to groundwater are described in §1.5 of the EU part.

3. APPENDICES

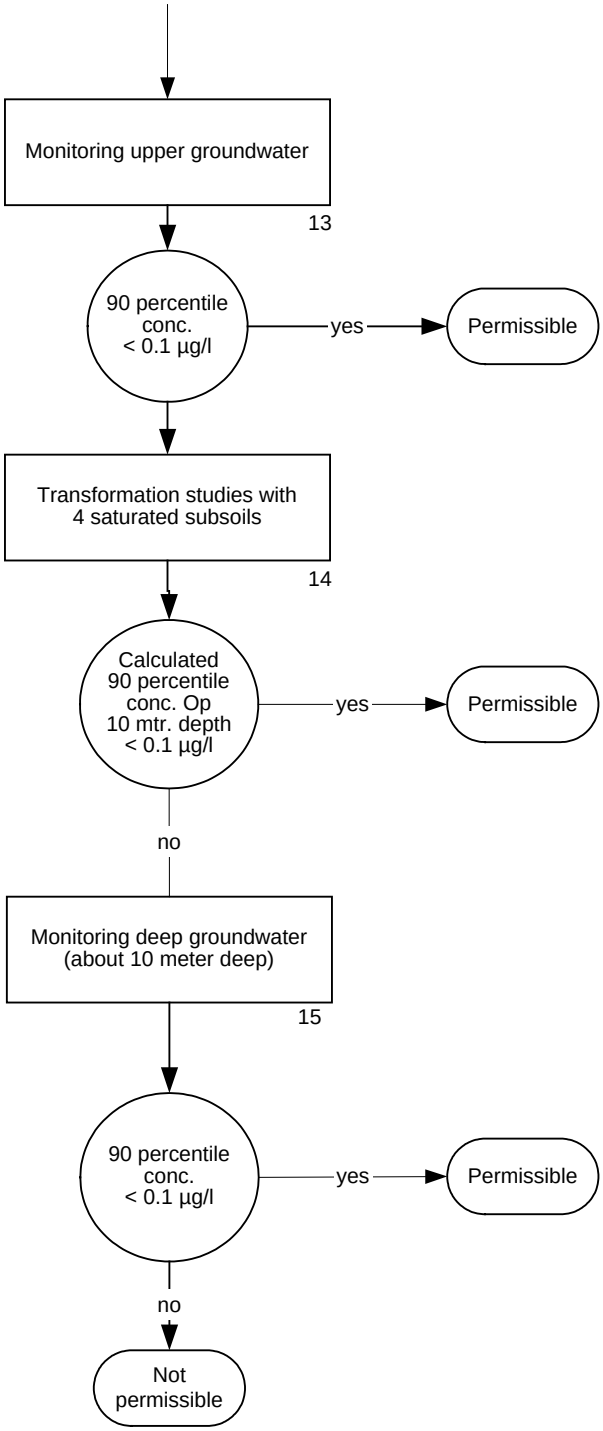
Appendix 1 Explanatory notes on the decision tree for leaching to groundwater

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
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).
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. The number of studies as described in Van der Linden et al., 2004 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 ('Evaluation of the behaviour of pesticides in the saturated zone of the soil', 1999). 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, 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.


LEACHING TO GROUNDWATER
Can it be ruled out that the substance reaches the soil ?
1
yes
No further research required
Permissible
no
Study into transformation route to identify transformation products and amounts
2
Laboratory study into transformation rate in at least 4 soil types (3 for transformation products)
4
Laboratoty study into adsorption in at least 4 soil types (3 for transformation products)
5
Column study with aged residu
6
Are there transformation products in a concentration ≥ 10%off the added active substance or ≥ at two consecutive points in time
3
no
No further research transformation products required
yes
Supplementary research into transformation products, go to 4 + 5
Not relevant
Note: GD non relevant metabolites
Average/ median DT_{50}
Average/ median K_{om}
Calculation expected leaching in PEARL-model with FOCUS Kremsmünster scenario
7
90 percentile < 0.01 µg/l
8
yes
Permissible
no
90 percentile > 0,01 µg/l en < 0.1 µg/l
8
yes
Permissible with restriction groundwater protection areas
no
GeoPEARL calculation with basic dossier data
9
90 percentile < 0.01 µg/l
10
yes
Permissible
no
90 percentile > 0.01 µg/l en < 0.1 µg/l
10
yes
Permissible with restriction groundwater protection areas
no
Supplementary labstudies and/or field/lysimeter studies GeoPEARL calculation
11
Adjusted conc. for > 90% of the average of use < 0.1 µg/l
12
yes
Permissible
no
Are there metabolites with a potential leaching risk
4
no
No further research into transormation product required
yes
Supplementary research into transformation products, go to 4 + 5
See next page

continuation



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.

<u>Dipping treatment</u>
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	winter cereals
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.