National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

The Dutch decision tree for the evaluation of the leaching of plant protection products

Revised 2022 version

RIVM report 2022-0048

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DOI 10.21945/RIVM-2022-0048

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This investigation was performed by order and for the account of the Ministry of Infrastructure and Water Management (project Evaluation of Plant Protection Products, M/260108) and the Ministry of Agriculture, Nature and Food Quality (project Leaching to the groundwater, BO-43-102.01-004).

Published by:
National Institute for Public Health and the Environment, RIVM
P.O. Box 1 | 3720 BA Bilthoven
The Netherlands
www.rivm.nl/en

Synopsis

The Dutch decision tree for the evaluation of the leaching of plant protection products
Revised 2022 version

Plant protection products can leach into the groundwater and cause problems for the abstraction of drinking water. Leaching into the groundwater is therefore one of the aspects included in the evaluation procedure that precedes the authorization of plant protection products for the Dutch market. In 2005, a decision tree was introduced for performing this evaluation. This decision tree has now been revised based on the latest insights and data.

The most important reason for the revision of the decision tree is the insight that the organic matter content of the soil was being overestimated. As a result, the predicted concentration of plant protection products in the groundwater was two to 10 times too low. This is undesirable because this could lead to the unwarranted authorization of a plant protection product. Applicants who want to have a plant protection product authorized in the Netherlands must therefore use the revised decision tree.

This decision tree follows a tiered approach, which means that an applicant can start with a simple and conservative calculation procedure. If a plant protection product can be used safely according to this simple calculation procedure, an authorization can be granted without requiring additional work.

If an authorization cannot be granted based on this simple calculation procedure, the applicant can provide additional and more precise studies. In the second tier, the applicant can demonstrate a safe use by calculating the leaching in the area in which a plant protection product is planned to be used in the Netherlands. Should the second tier not demonstrate a safe use, the applicant can use groundwater monitoring to show that the product can be safely used in the Netherlands. If groundwater monitoring does not show a safe use as well, the product cannot be authorized for use on the Dutch market.

Keywords: plant protection products, leaching, tiered approaches, GeoPEARL, authorization, calibration factor, Kremsmünster scenario

Publiekssamenvatting

De Nederlandse beslisboom voor de evaluatie van de uitspoeling van gewasbeschermingsmiddelen
Herziene versie van 2022

Gewasbeschermingsmiddelen kunnen in het grondwater terechtkomen (‘uitspoelen’) en daar problemen voor de drinkwaterwinning veroorzaken. Daarom wordt de kans dat een middel uitspoelt beoordeeld voordat een gewasbeschermingsmiddel wordt toegelaten op de Nederlandse markt. Nederland gebruikt sinds 2005 voor deze beoordeling de zogeheten beslisboom uitspoeling. Deze beslisboom is aangepast op basis van de nieuwste inzichten en data.

De belangrijkste aanleiding voor de aanpassing van de beslisboom is het inzicht dat de hoeveelheid organische stof in de bodem te hoog was ingeschat. Hierdoor was de berekende concentratie van gewasbeschermingsmiddelen 2 tot 5 keer lager dan volgens de nieuwe inzichten het geval is. Dit is ongewenst omdat hierdoor een gewasbeschermingsmiddel onterecht zou kunnen worden toegelaten. Fabrikanten die een gewasbeschermingsmiddel in Nederland toegelaten willen hebben, moeten daarom de aangepaste beslisboom gebruiken.

De beslisboom uitspoeling bestaat uit drie stappen. In de eerste stap voert de aanvrager een eenvoudige maar strenge berekening uit. Als het gebruik van het middel volgens deze stap als veilig wordt beschouwd, kan het middel zonder vervolgstappen worden toegelaten op de Nederlandse markt.

Als het gebruik volgens deze stap niet veilig is, is de volgende stap van de beslisboom nodig. In deze tweede stap wordt de uitgespoelde hoeveelheid van het middel preciezer bepaald, namelijk voor de gewassen waarvoor de aanvrager het product wil gebruiken. Mocht de tweede stap ook niet veilig zijn, dan kan de aanvrager in een derde stap met meetgegevens aantonen dat het middel veilig kan worden gebruikt. Als het gebruik ook volgens deze stap niet veilig is, kan het middel niet worden toegelaten op de Nederlandse markt.

Kernwoorden: gewasbeschermingsmiddelen, uitspoeling, GeoPEARL, getrapte benadering, grondwater, kalibratiefactor, toelating, Kremsmünster-scenario

Contents

Preface

In 2021, the Ministry of Agriculture, Nature and Food Quality and the Ministry of Infrastructure and Water Management requested an updated description of the Dutch decision tree on leaching into groundwater. The reason is that the existing decision tree became inconsistent after the introduction of a new version of GeoPEARL. The revised decision tree is described in this report. This report is based on an earlier RIVM-report called *The new decision tree for the evaluation of pesticide leaching from soils* by Ton van der Linden, Jos Boesten, Adi Cornelese, Roel Kruijne, Minze Leistra, Jan Linders, Werner Pol, Aaldrik Tiktak and Anja Verschoor. Although many parts of the report have been rewritten to reflect the current state of knowledge and regulation, the structure of the previous report is still visible. The authors of the present report wish to thank the authors of the previous report for their work. The authors further wish to thank Mark Montforts and Joost Lahr for reviewing an advanced version of this report.

Summary

The Dutch decision tree on leaching into groundwater
In 2005, a decision tree for evaluating the leaching of plant protection products into groundwater was introduced in the Netherlands. The decision tree follows a tiered approach. The concept of tiered approaches is to start with a simple conservative assessment and to do additional and more complex work only if necessary. The first tier of the Dutch decision tree is based on calculations using the FOCUS Kremsmünster scenario. This will reduce the workload for regulators and industry at the national level, because these calculations need to be included by the applicant for the core assessment of a plant protection product and are evaluated by the zonal Rapporteur Member State. The second tier involves simulations using the spatially distributed model GeoPEARL. This enables the explicit evaluation of the leaching potential in the area in which a plant protection product is planned to be used in the Netherlands. The tiered approach also considers higher-tier lysimeter and monitoring studies.

A new map of organic matter
The GeoPEARL model used at Tier 2 uses geographical data, such as climate data and soil data. The organic matter content is the most important spatially distributed parameter affecting pesticide leaching. In 2010, it was noted that the soil organic matter map in the database of GeoPEARL contained higher values for the organic matter content in the top layer of arable soils in the Netherlands than those measured in arable top soils. For this reason, a new map of organic matter content was created, which was then incorporated into the GeoPEARL model in 2017. Simulations using this new model version revealed that the predicted leaching concentration increased by a factor of 2 to 10. The increase of the simulated leaching concentration using GeoPEARL led to an inconsistency in the tiered approach of the Dutch decision tree on leaching. In many cases, the GeoPEARL model used at Tier 2 simulates higher concentrations than the FOCUSPEARL model for Kremsmünster at Tier 1. This inconsistency could lead to the unwarranted authorization of a plant protection product if only Tier 1 were to be evaluated.

Introduction of a calibration factor at Tier 1
It became clear that the introduction of the new version of GeoPEARL is not possible without a revision of the Dutch decision tree on leaching. A working group consisting of researchers from RIVM, WEnR and Ctgb reviewed the 2004 decision tree and concluded that, with the introduction of a calibration factor of 5 to 10 at Tier 1, the consistency of the tiered approach could be restored. In a few cases, the working group recommends skipping Tier 1 and moving on directly to Tier 2. The first exception applies to volatile substances that are injected or incorporated into the soil. The second exception applies to substances that have a ratio $K_{om}/DegT50$ between 3.5 and 4.5, and that are applied in the period September 1 to February 29. Other exceptions, which were included in the 2004 decision tree, are no longer applicable.

Parameter refinement options
The working group considers it appropriate to use refined substance parameters at Tier 1 and Tier 2. However, the use of new data on substance parameters in product authorizations is restricted by a European Guidance document.[1] The use of new data is only allowed in cases in which a safe use can only be demonstrated by using this new data. An important refinement is the option to use aged sorption, for which guidance has recently been accepted in the European Union. If substance properties depend on soil properties, Tier 1 can be used, provided that the substance parameters are set to conservative values. This can be refined at Tier 2, because GeoPEARL has the option to simulate the dependence of substance parameters on soil characteristics.

Groundwater protection areas
At Tier 1 and Tier 2, the Dutch decision tree considers a safety factor of 10 for groundwater protection areas. This means that a product cannot be used in these areas if the leaching concentration is above 0.01 μg/L. The safety factor is based on simulations done with an earlier version of GeoPEARL using the old organic matter content map. In the old organic matter map, organic matter content in groundwater abstraction areas was lower than organic matter content in Dutch agricultural soils as a whole. In the new organic matter content map, these differences are significantly smaller. The working group therefore recommends investigating whether the factor of 10 that is currently used for groundwater protection areas is always needed. This can be done by systematically comparing the predicted leaching concentration in groundwater abstraction areas with that in Dutch agriculture as a whole.

Crop data in GeoPEARL
The crop data used in GeoPEARL originates from 2004. This data is, however, subject to considerable change. In 2021, the Central Bureau of Statistics saw a decrease of the arable crop cultivation area by 17%, relative to 2000. Because the cropping area is considered to be a proxy for the potential area in which a plant protection product is intended to be used, we recommend updating the cropping database in GeoPEARL on a regular basis, for example every five years.

Higher-tier lysimeter studies and groundwater monitoring
The decision tree also considers higher-tier lysimeter studies and groundwater monitoring. These studies have not been reviewed by the working group for the present update, so existing guidance described in Verschoor et al. (2001) and Cornelese et al. (2003) is still applicable. However, the working group considers an update of these guidance documents necessary as soon as EFSA finalizes its review of the paper by Gimsing et al. (2019) on groundwater monitoring studies.

[1] Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9)

1 Introduction

1.1 Background

Leaching into groundwater is a possible side effect of using plant protection products. This endangers the use of groundwater as a source of drinking water. European policy laid out in the European Groundwater Directive[2] aims to protect the groundwater from becoming contaminated. Leaching is therefore one of the aspects included in the evaluation procedure preceding the authorization of plant protection products.

Legislative framework

In the European Union, placing a plant protection product on the market is regulated by Regulation (EC) No. 1107/2009[3] and its associated implementing Regulations (i.e. 546/2011[4] on uniform principles, plus 283/2013[5] and 284/2013[6] on data requirements). Regulation 284/2013 requires estimating the concentration of the active substances and their metabolites in groundwater. The decision-making in the uniform principles states that no authorization shall be granted if the substance or any of its relevant metabolites has a calculated or measured concentration in the groundwater of more than 0.1 μg/L or more than 0.1 times the Acceptable Daily Intake (ADI) in μg/kg bodyweight. In the vast majority of cases, the ADI is more than 10 times higher than 0.1 μg/L, so in practice the maximum permissible concentration of active substances and its relevant metabolites in groundwater is 0.1 μg/L. A metabolite is considered 'relevant' if its toxicological properties lead to certain classifications according to Regulation (EC) No 1272/2008.13. The value of 0.1 μg/L is based on the precautionary principle, hence not on a toxicological threshold of concern, nor mixtures thereof.

These criteria are incorporated in Dutch legislation. In the Netherlands, the leaching criterion has been set for the upper groundwater.[7] To protect the groundwater as a source of drinking water, there must be reasonable certainty that the concentration of the substance or its relevant metabolites in the groundwater at 10 m depth does not exceed 0.1 μg/L. The criterion of 10 m depth is the Dutch elaboration of the European standard described for groundwater that is intended to be used for drinking water.

Current evaluation procedures

Evaluation of the possible authorization of a plant protection product at the member state level can only be considered if the active substance of the plant protection product has been approved under Regulation (EC) No. 1107/2009. This means that it occurs on the list of approved active substances (Commission Implementing Regulation (EU) No 540/2011), for which safe use in areas of the EU is possible. With regard to leaching, the possible safe use of a substance can be demonstrated

[2] http://data.europa.eu/eli/dir/2006/118/2014-07-11
[3] https://eur-lex.europa.eu/eli/reg/2009/1107
[4] https://eur-lex.europa.eu/eli/reg/2011/546
[5] https://eur-lex.europa.eu/eli/reg/2013/283
[6] https://eur-lex.europa.eu/eli/reg/2013/284
[7] Besluit gewasbeschermingsmiddelen en biociden

using the procedures laid down in the final report of the groundwater working group of FOCUS (EC, 2014). The procedures in this report follow a tiered scheme, in which the first tier is quick, simple and cheap to conduct and allows substances that clearly do not cause any concern to be passed. The higher tiers are more complex and expensive, but should provide a more realistic and less conservative result.

In the Netherlands, a tiered approach has been operational since 1989. A central role was given to the so-called Dutch standard scenario (Van der Linden and Boesten, 1989; Boesten and Van der Linden, 1991). This standard scenario represented realistic worst-case conditions and was constructed using a great deal of expert judgement.

In 2005, a new decision tree on leaching was introduced (Van der Linden et al., 2004). The main reason for the development of the new decision tree was the need to harmonize the national authorization of plant protection products with the European procedure for the approval of the active substances in and the authorization of plant protection products. In addition, the availability of spatially distributed data made it possible to explicitly test the vulnerability objectives of the decision tree (see Section 2.1). In the first tier, the FOCUS Kremsmünster scenario is used, according to the European groundwater assessment procedure for the approval of active substances (EC, 2014). In the second tier, a spatially distributed leaching model (GeoPEARL) is used to obtain the leaching concentration in the area in which a plant protection product is intended to be used in the Netherlands. The third tier involves behaviour in the saturated zone and groundwater monitoring.

Shortcomings in the 2004 decision tree on leaching

In 2010, it was noted that the soil organic matter map in the database of GeoPEARL contained higher values for the organic matter content in the top layer of arable soils in the Netherlands than those actually measured in arable top soils reported by Reijneveld et al. (2009). The reason for this is that the organic matter map of the first version of GeoPEARL was generated using soil profile information from both arable and grassland soils. When using values for the organic matter content that are too high, the leaching to groundwater will be underestimated. For this reason, and because organic matter is the most important spatially distributed parameter affecting pesticide leaching (Heuvelink et al. 2010; Van den Berg et al., 2012), the Ministry of Economic Affairs[8] requested an update of the soil organic matter map and asked that this map be incorporated into the GeoPEARL model.[9] GeoPEARL simulations using the revised organic matter content map showed that the leaching concentration to be used in the risk assessment increased by a factor of 2 to 10 (Van den Berg et al. (2017). The increase of the simulated leaching concentration using the new GeoPEARL version led to an inconsistency in the tiered approach of the Dutch decision tree on leaching. In many cases, the GeoPEARL model used at Tier 2 simulates higher concentrations than the FOCUSPEARL model for Kremsmünster at Tier 1. Van den Berg et al. (2017) showed that this inconsistency can be repaired by introducing a calibration factor at Tier 1.

[8] Now the Ministry of Agriculture, Nature and Food Quality
[9] The new organic matter content map is available in GeoPEARL 4.4.4 and later versions (Van den Berg et al. 2018).

A review of the 2004 decision tree on leaching showed other shortcomings in the decision tree (Van der Linden et al. 2015; Boesten et al. 2015). Many of these shortcomings concerned the procedure for evaluating the leaching potential of substances whose properties depend on soil properties such as texture and pH.

1.2 Objective and outline of this report

This report describes an update of the Dutch decision tree on leaching. The main reason for this update is the introduction of GeoPEARL 4.4.4, which contains an improved description of the organic matter content in Dutch arable soils. Because the legislative framework has also changed since 2004, these sections have been updated as well. The report has been published at the request of the Ministry of Agriculture, Nature and Food Quality and the Ministry of Infrastructure and Water Management. The work was done by a working group consisting of independent researchers from the National Institute for Public Health and the Environment (RIVM), Wageningen University & Research (WUR) and the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

Chapter 2 first describes the Dutch groundwater protection goal. After this, an overview of the revised decision tree on leaching is given, including a flowchart. Then, Chapter 3 gives a detailed description of the individual tiers of the decision tree. In Chapter 4, a number of example calculations are provided. Finally, in Chapter 5 the overall conclusions and recommendations for future improvements of the decision tree are presented.

2 The 2022 Dutch decision tree on the leaching of plant protection products into groundwater

This chapter gives an overview of the 2022 Dutch decision tree on leaching. EFSA PPR Panel (2010) indicated that to design an appropriate risk assessment scheme, first a clear definition of the specific protection goal is needed. Such a specific protection goal describes which groundwater must be protected, when it should be protected and to what level. This chapter therefore starts with a description of the Dutch specific protection goal for leaching into groundwater (Section 2.1). Then Section 2.2 provides an overview of the Dutch decision tree on leaching, including a flowchart to guide the user through the decision tree.

2.1 The Dutch national protection goal for the leaching of plant protection products into groundwater

In this section, the national specific protection goal for leaching into groundwater is inferred from the current legislation. In the Netherlands, approximately 60% of drinking water is abstracted from groundwater. The need to protect this source is described in general terms in the Groundwater Directive of the European Union[10]: 'Groundwater in bodies of water used for the abstraction of drinking water or intended for such future use must be protected in such a way that deterioration in the quality of such bodies of water is avoided in order to reduce the level of purification treatment required in the production of drinking water.' The ambition to protect both groundwater abstraction areas and possible future sources is also included in the Dutch Water Act.[11]

2.1.1 Specific protection goal for leaching into groundwater

The above-mentioned protection goal for groundwater gives only a very general ambition to protect groundwater. It does not describe explicitly how much groundwater needs to be protected, when it should be protected and at what level. A protection goal can only form the basis for a decision tree when it is worked out in quantitative terms. Such a worked-out protection goal is called a specific protection goal and should be the same for all tiers in a decision tree. The Dutch protection goal for leaching into groundwater is described in the 'Besluit Gewasbeschermingsmiddelen en biociden'[12].

The EU has chosen to base decisions with respect to leaching on realistic worst-case conditions.[13] FOCUS (1995) specified the reasonable worst case as the situation indicating the 90th percentile in vulnerability. FOCUS (2000) attributes vulnerability to soil and climatic conditions in equal shares and not to crop, the properties of the plant protection product or management practice. When considering these five aspects of a scenario, we agree with FOCUS that substance properties, crop and management practice should not be a part of the vulnerability definition. Crop and management should not be a part because an authorization is

[10] https://eur-lex.europa.eu/eli/dir/2006/118
[11] https://www.helpdeskwater.nl/publish/pages/130656/wateract_total.pdf
[12] Besluit gewasbeschermingsmiddelen en biociden
[13] https://eur-lex.europa.eu/eli/reg/2009/1107

given for an application in one or more specific crops. Ignoring the uncertainty in substance properties may cause an underestimation of the leaching concentration (Vanderborght et al. 2011; Van den Berg et al. 2012). However, we consider it acceptable not to include substance properties in the vulnerability definition, because there is usually little information available about, for example, uncertainty in *DegT50* and K_{om} (the dossier contains usually some four degradation and sorption studies which does not result in robust estimates of the standard deviations of these properties).

With respect to groundwater quality and the function of groundwater being a source for drinking water, we consider it better to protect a larger area from exceeding the threshold value, on average, than to protect a smaller area against peaks. Following this line of thinking, the 90th percentile in vulnerability is determined by the area of use for which the average concentration in time should not exceed the threshold value. From this, Van der Linden et al. (2004) derived the following **specific protection goal** (see Van den Berg et al. 2017 for additional considerations):

The concentration in groundwater at 10 m depth should be less than or equal to 0.1 µg/L under at least 90% of the potential area of application for at least 50% of the time.

As mentioned in Section 1.1, the value of 0.1 µg/L should be replaced by the value of 0.1 times the ADI in µg/kg bodyweight if this value is smaller than 0.1 µg/L. Notice that the potential area of application applies to each combination of application and crop individually. If, for example, an applicant requests an authorization for use in maize and potatoes, an assessment must be done for both crops separately and the decision is based on the 90th-percentile concentration in each of these two crops.

Figure 2.1 gives a simplified graphical representation of the criterion for a substance just meeting the criterion. The figure indicates that, in this situation, the average concentration beneath 90% of the area is below 0.1 µg/L and beneath 10% of the area is 0.1 µg/L or above.

2.1.2 *Safety factor for groundwater protection areas*

Simulations using an earlier version of GeoPEARL revealed that groundwater abstraction areas are, on average, more vulnerable to pesticide leaching than other agricultural areas (Kruijne et al., 2004). Therefore, a safety factor of 10 is applicable for the use of plant protection products in **groundwater protection areas**, which means that a plant protection product cannot be used in groundwater protection areas if the calculated target concentration[14] for the area of use is greater than 0.01 µg/L. Notice that the calculated target concentration is a conservative estimate for the concentration in the specific protection goal described in Section 2.1.1.

[14] The target concentration for Tier-1 is the 80th percentile of the annual average leaching concentration at 1 m depth, multiplied by a calibration factor of 5 to 10, depending on the time of application (Section 3.1). The target concentration for Tier-2 is the 90th spatial percentile of the median leaching concentration at 1 m depth in the potential area of use of a substance (Section 3.2).

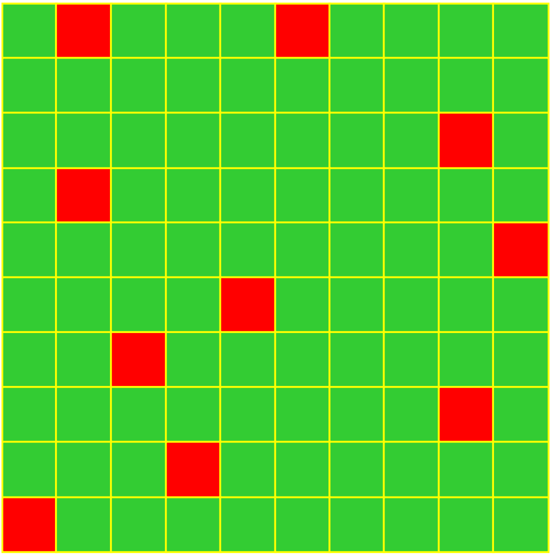


Figure 2.1 Graphical representation of the leaching criterion. Green grid cells indicate a concentration below 0.1 μg/L, red grid cells indicate a value at or above 0.1 μg/L

Additional information on the behaviour in groundwater protection areas might demonstrate the possible safe use and overrule the safety factor. Notice that the restriction for the use of plant protection products applies to groundwater protection areas and not to groundwater abstraction areas as mentioned in Kruijne et al. (2004). The reason is that groundwater protection areas are protected by law, which is not the case for groundwater abstraction areas. This also means that a restriction based on groundwater protection areas can be better enforced.

As mentioned above, the safety factor of 10 is based on simulations using an earlier version of GeoPEARL (Kruijne et al. 2004). This was mainly because organic matter in groundwater abstraction areas was lower than organic matter in Dutch agriculture as a whole. In GeoPEARL 4.4.4., a new organic matter map is introduced. Van den Berg et al. (2017) showed that differences between the organic matter content of groundwater abstraction areas and the Dutch agricultural areas as a whole are smaller for GeoPEARL 4.4.4 than for earlier versions. Therefore, Van den Berg et al. (2017) recommended reassessing the safety factor (Section 5.2). Until this reassessment has been carried out, the safety factor of 10 has to be applied as a precautionary measure.

2.1.3 *Domain of applicability of the decision tree*

As described by Boesten (2015), the decision tree was developed for normal uses on arable crops, permanent crops and grassland. The decision tree is not applicable to uses on hard surfaces, on artificial lawns, in public greens, on covered crops (see EFSA (2010) for a definition of covered crops), on mushrooms grown inside, on railway tracks and under crash barriers or road signs. Please refer to the EFSA Guidance on protected crops (EFSA, 2014) for a description of the procedures and models to be used for these crops. A description of the national tiered exposure assessment scheme for soil-bound crops in permanent greenhouses is presented in Wipfler et al (2014). The most recent national scenarios for these crops are described in Van den Berg et al. (2022).

2.2 Overview of the Dutch decision tree on leaching to groundwater

The decision tree follows a tiered approach, like most of the decision trees. In the following sections, the decision tree is summarized; a more detailed description is given in Chapter 3. Notice that the decision tree described in this report does not apply to soil-bound protected crops (see Section 2.1.3).

2.2.1 Exposure assessment goal used at Tier 1 and Tier 2

An important characteristic of tiered approaches is that the exposure assessment should aim at the same specific protection goal in all tiers (EFSA, 2012; EFSA PPR Panel, 2010). Furthermore, higher tiers must be more realistic and less conservative. As described in Section 2.1.2, the Dutch decision tree aims to protect the groundwater at a depth of 10 m. The models used at Tier 1 and Tier 2, however, simulate the leaching concentration at 1 m depth. We consider this appropriate, because it is likely that the groundwater concentration will be lower at deeper depths due to dispersion and/or dissipation/degradation processes. So, the exposure assessment goal at Tier 1 and Tier 2 can be considered a conservative surrogate for the groundwater concentration monitored at Tier 3 (see also Tiktak et al. 2020). It has indeed been demonstrated that the concentration at 10-m depth is generally lower than the concentration at 1-m depth (Tiktak et al. 2005).

2.2.2 Flowchart and outline of the tiered approach

Figure 2.2 gives a flowchart of the new Dutch decision tree on leaching. Notice that it is not needed to perform all steps of the decision tree, so applicants can move to a higher tier without performing earlier tiers (notice however that, in line with EU-practices, Tier 1 (FOCUS Kremsmünster) is always needed).

The **first tier** involves a simple calculation procedure for the FOCUS Kremsmünster scenario. The procedure entirely follows the procedures as recommended by EC (2014), although a calculation with FOCUSPEARL (Tiktak et al., 2000; Leistra et al., 2001; Van den Berg et al. 2016) is required. The substance parameters at Tier 1 are based on the agreed EU list of endpoints (LoEP). Refinement of substance parameters is acceptable at this stage, as long as these are agreed upon in the core assessment. To guarantee the consistency of the tiered approach, simulation results must be multiplied by a calibration factor of 5 to 10, depending on the time of application (see Section 3.1).

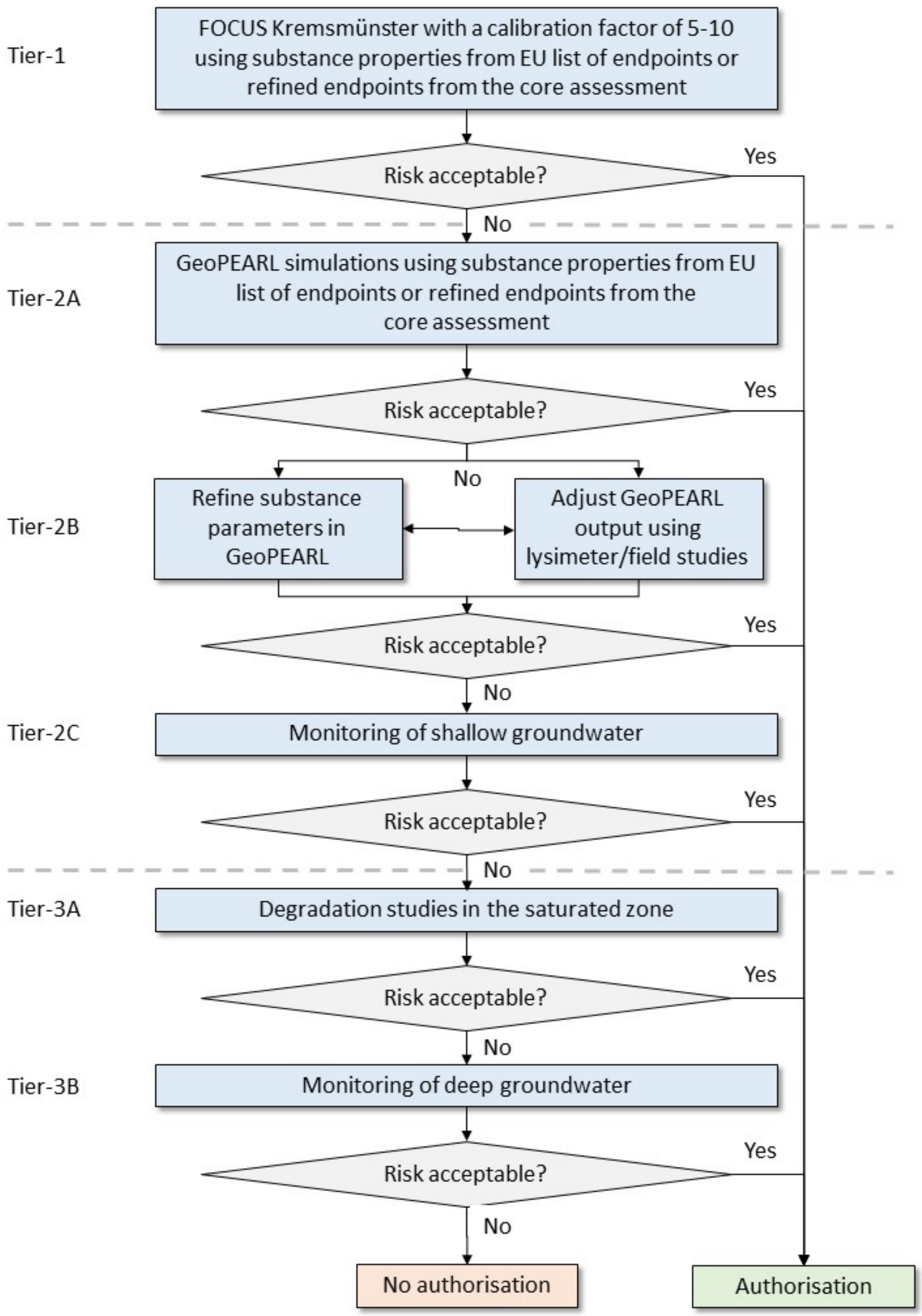


Figure 2.2 Overview of the Dutch decision tree on leaching

The **second tier** involves calculations using the GeoPEARL software package[15], which calculates the potential of a substance to reach the uppermost groundwater under the area of use. If the information from the core assessment is not sufficient to demonstrate an acceptable leaching potential, the applicant may use information from laboratory, lysimeter and/or field studies, which should be representative for the area of use of the plant protection product. Finally, at the end of the

[15] GeoPEARL 4.4.4 or later is required.

second tier, the applicant might perform a monitoring study in shallow groundwater in order to demonstrate that the leaching potential is acceptable.

The **third tier** evaluates the behaviour of the substance in the saturated zone of the soil to a depth of 10 m below soil surface. The applicant might demonstrate that transformation in the saturated zone is such that the concentration at 10 m below soil surface meets the requirements (see Van der Linden et al*.* (1999) for more details). The final stage of the third tier, at the same time the final stage of the decision tree, uses data from monitoring studies with samples taken around the target depth of 10 m below soil surface. If these data show that the leaching potential is acceptable, the plant protection product can be authorized. If these data fail to show an acceptable leaching potential, authorization of the product will not be possible, unless the applicant proposes suitable mitigation measures, which demonstrate a safe use.

3 Detailed description of the 2022 decision tree on leaching

This chapter provides a detailed description of the individual tiers of the Dutch decision tree on leaching. The Dutch decision tree on leaching follows a tiered approach. General principles of tiered approaches are (EFSA PPR Panel 2010):

- earlier tiers are more conservative than higher tiers to avoid unwarranted authorization of the product;
- the information used for taking decisions increases when going to higher tiers (i.e. studies are more complex, but also more realistic);
- going to higher tiers requires greater efforts from both the applicant and the assessor;
- all tiers aim at the same specific protection goal.

The advantage of this set-up is that it is not necessary to perform all tiers of the decision tree.

3.1 Tier 1: the FOCUS Kremsmünster scenario

Tier 1 is the first step of the Dutch decision tree on leaching. To benefit from existing leaching assessments in the core assessment, Tier 1 is based on one of the FOCUS groundwater scenarios (EC, 2014). This implies that the evaluation at Tier 1 does not consider the area in which plant protection products are intended to be used in the Netherlands. The scenario selected is the FOCUS Kremsmünster scenario. Results from simulations with the FOCUSPEARL model[16] must be submitted. This scenario has been chosen, because in this scenario the groundwater level is fluctuating within the boundaries of the soil profile. This situation is thought to be representative for most of the soil profiles occurring in the Netherlands (Van der Linden et al., 2004).

Calibration factor

Calculations with GeoPEARL 4.4.4 (Van den Berg et al., 2017) revealed that the FOCUS Kremsmünster scenario does not always give higher leaching concentrations than the GeoPEARL calculations at Tier 2. Because this would lead to inconsistencies in the tiered approach, a calibration factor must be applied to the results of the Kremsmünster simulations. This calibration factor is 5 when the substance is applied in the period from March 1 to August 31, and 10 when the substance is applied from September 1 to February 29 (please refer to Van den Berg et al. (2017) for the justification of these calibration factors).

Target concentration at Tier 1

The target concentration for Tier 1 is the 80th percentile of the annual average leaching concentration at 1 m depth, multiplied by a calibration factor of 5 to 10 depending on the time of application. A substance can be authorized if the target concentration is equal to or lower than 0.1 μg/L. An additional safety factor of 10 is applied for groundwater protection areas; the use of a plant protection product will therefore not be allowed in these areas if the target concentration is higher than 0.01 μg/L.

[16] FOCUSPEARL 5.5.5 or later is needed.

Exceptions
Tier 1 cannot be used in the following situations:
- the vapour pressure of the substance at 20 °C is higher than 10^{-4} Pa and it is injected or incorporated into the soil. In this case, the substance is considered to have some potential to reach the groundwater by vapour diffusion. These substances must be evaluated at the second or third tier, because a single scenario is considered insufficient to evaluate downward movement of relatively volatile substances through the soil;
- the ratio $K_{om}/DegT50$ is between 3.5 and 4.5, and products containing the substance are applied in the period September 1 to February 29. As shown in Van den Berg et al. (2017), Tier 1 may not be conservative enough in these cases.

Notice that the consistency of the tiered approach has not been checked for substances with a Freundlich exponent ($1/n$) smaller than 0.9 and for soil metabolites (see Section 5.2).

Input parameters for the simulations
The substance parameters at Tier 1 are based on the agreed EU list of endpoints (LoEP). According to Section 8 of the Working document of the Central Zone, refinement of substance properties is possible, but this should be agreed upon in the core assessment. The use of new data on substance parameters in product authorizations is restricted by a European Guidance document.[17] The use of new data is only allowed in cases in which a safe use can only be demonstrated by using this new data. An option would be to include long-term sorption kinetics in the soil system (see EC, 2021) for guidance on the assessment of these kinetic parameters).

The following information from the core dossier must be used in the simulations:
- physical-chemical properties of the substance/metabolite; for example, molecular mass, water-solubility, vapour pressure and, for dissociating substances, pKa;
- the *DegT50* of the substance/metabolite, where necessary standardized to reference conditions; i.e. *DegT50* (d), and the K_{om} (L/kg, obtained by dividing K_{oc} by 1.724) and the Freundlich exponent $1/n$. The sorption constants for the neutral and the charged molecule are required for weak acids. The substance properties should be averaged according to EU-agreed guidelines;
- 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 FOCUSPEARL, winter cereals are to be used (see Van den Berg et al. (2017) for argumentation). 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);

[17] Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9)

- interception value as relevant to the crop and crop stage.

In cases in which substance properties depend on other soil properties, the following conditions apply:
- use a conservative estimate of the Kom in the Tier 1 calculations if the Kom does depend on other soil properties (other soil properties include pH, sand, silt or clay content, and sesqui-oxide content);
- use a conservative estimate of the DegT50 in the Tier 1 calculations if the DegT50 does depend on soil properties other than moisture, temperature or soil depth (other soil properties may include pH, clay content, organic matter).

More detailed information on the input parameters and model concepts are presented in Van den Berg et al. (2016).

3.2 Tier 2: GeoPEARL and monitoring of uppermost groundwater

The second tier of the decision tree evaluates in greater detail whether a substance, which according to the conservative evaluation in the first tier has potential to leach into the groundwater, indeed has a potential to leach into groundwater above the threshold level. The target concentration is the 90th spatial percentile of the median leaching concentration at 1 m depth in the potential area in which a substance is intended to be used. A substance can be authorized if the target concentration is equal to or lower than 0.1 μg/L. An additional safety factor of 10 is applied for groundwater protection areas; the use of a plant protection product will therefore not be authorized in these areas if the target concentration is higher than 0.01 μg/L. Notice that this safety factor for groundwater protection areas applies to all steps in Tier 2, including the monitoring studies at Tier 2C.[18]

The second tier can be subdivided into three steps:
- step 2A using GeoPEARL in combination with substance data from the core assessment;
- step 2B using GeoPEARL in combination with additional information (additional laboratory and/or field studies, or lysimeter studies);
- step 2C in which monitoring data of the uppermost groundwater is considered.

3.2.1 Tier 2A: GeoPEARL simulations using substance data from the core assessment

The evaluation at Tier 2 starts with GeoPEARL simulations using substance and application data that are available in the core assessment. In practice, this means that the same substance parameters are used as those used at Tier 1. However, for substances showing sorption dependent on pH or soil properties other than organic matter, it is not necessary to provide a conservative estimate. Instead, the user may specify the parameters describing this dependency. See Sections 3.6 and 3.7 in Boesten et al. (2015) for guidance on the parameterization of the sorption coefficient in GeoPEARL.

[18] Only in certain cases, the safety factor is not needed at Tier 2C, see further paragraph 3.2.4.

As mentioned earlier, **GeoPEARL 4.4.4** or later versions that are fully consistent with version 4.4.4 are needed.[19] A detailed description of the concepts of GeoPEARL and how to use this software tool is given elsewhere; see Tiktak et al. (2003; 2004) for the theoretical background and Van den Berg et al. (2018) for the user manual. The procedure is partly similar to the procedure for the first tier, when using FOCUSPEARL. The most important difference is that the GeoPEARL software package is used instead of the FOCUSPEARL model. GeoPEARL is a spatially distributed model, which runs for up to 6,405 unique combinations of soil types, climate, etc. The most important output of GeoPEARL is the 90th percentile of the median leaching concentration in the area in which a plant protection product is intended to be used.

If the substance is to be used on more than one crop, GeoPEARL performs simulations for each of the crops independently and gives results for the individual crops, as well as for the combination of these crops. For regulatory submissions, only results for individual crops should be used. If, for example, an applicant requests an authorization for use in maize and potatoes, an assessment must be done for both crops separately and the decision is based on the 90th percentile concentration in each of these two crops.

Running the model for all 6,405 unique combinations would require a very long run time. For this reason, GeoPEARL is possible to run for fewer than 6,405 unique combinations. However, running the model with fewer unique combinations introduces an error. Analyses have shown that this error remains acceptable as long as the number of unique combinations is more than or equal to 250 (see Tiktak et al., 2004). Although it is possible to run GeoPEARL for fewer than 250 plots, an assessment with fewer than 250 plots will not be acceptable for registration purposes. On the other hand, a GeoPEARL assessment with more than 250 plots will be accepted because runs with more plots are considered more accurate.

3.2.2 *Tier 2B: GeoPEARL simulations using additional laboratory studies*

If the GeoPEARL run, using substance data from Tier 1, does not result in an acceptable leaching potential, i.e. the target concentration is above 0.1 µg/L, then the applicant may introduce information from additional laboratory experiments relevant to the area in which the plant protection product is planned to be used. In most cases, this additional information will already be required for a refined Tier 1 assessment in the core assessment. If agreed upon in the core assessment, these refined substance properties can also be included in a Tier 2A GeoPEARL simulation. In exceptional cases, refined substance properties based on additional information are only required for the national authorization of a product in the Netherlands. In this case, these refined endpoints can be used in a Tier 2B GeoPEARL simulation. The use of new data should be in accordance with agreed EU guidance. Currently, the use of new data is only allowed in cases in which a safe use can only be demonstrated by using this new data (see Section 3.1).

[19] A fully consistent version is a version that gives the same output as GeoPEARL 4.4.4. Examples are versions that are released to fix technical issues, e.g., problems with running on a certain platform.

Additional laboratory studies are accepted in the following situations:

- the average transformation rate for soils representative of the area in which the substance is to be used differs from the average transformation rate in the core assessment. An approach might be to check whether these averages are statistically significant (t-test, 95% confidence level). In this case, the data from the core assessment may be disregarded and the average transformation rate for the representative soils can be used as input; i.e. the DegT50 is calculated for the relevant soils only;
- the additional information reveals that the degradation of the substance is dependent on (correlated to) one or several soil parameters. The dependency is tested for statistical significance (R2 of the regression line better than 0.8 or F-test with significance level of 0.1). The data from the core assessment are included in this procedure, unless insufficient information is present in the dossier or it is demonstrated statistically that these data should be considered as outliers (Grubb's test, with significance level $\alpha = 0.05$).

In the second case, the GeoPEARL simulations should be performed with *DegT50,* dependent on soil-properties. The degradation rate may depend on the organic matter content in soil, soil clay content and / or soil pH. An example is given in Chapter 4; see Tiktak et al. (2003) for more details.

Chapter 4.4 in Boesten et al. (2015) provides additional guidance for the parameterization of the *DegT50* in GeoPEARL. At the moment there is, however, hardly any experience in deciding on the representativeness of sorption and transformation data. It is therefore recommended that the suggestions given above be used in combination with expert judgement.

3.2.3 *Tier 2B: Using field and lysimeter experiments to adjust the target concentration*

Interpretation of field and lysimeter experiments may show that the leaching of the substance cannot be simulated well using the PEARL model. The ratio of calculated leaching and measured leaching, the so-called simulation error (Verschoor et al., 2001), is then used to adjust the target concentration of the GeoPEARL calculations (the target concentration of GeoPEARL is the 90th percentile concentration in the area of use). The adjusted result, c_{adj}, is used for the decision:

$$c_{adj} = c_{target,\ GeoPEARL} \, / \, f_{adj} \qquad (1)$$

whereby c_{adj} is the adjusted concentration (µg/L) to be used for decision making, $c_{target,\ GeoPEARL}$ is the target concentration (µg/L) of the GeoPEARL calculations, and f_{adj} is the adjustment factor (-).

The adjustment factor is defined as the lower limit of the 75% confidence interval for the average simulation error, obtained via the procedure as described in Appendix 1.

3.2.4 *Tier 2C: Monitoring of the uppermost groundwater*

The third part of Tier 2 concerns data obtained from monitoring studies regarding the uppermost groundwater; i.e. the groundwater layer ranging from 0 to 1 m below the groundwater level, immediately beneath fields treated with the substance. Tier 2 evaluates whether the 90th percentile monitoring concentration in the uppermost groundwater is convincingly below the limit value. Two possible approaches exist:

- monitoring of the uppermost groundwater under a relatively small number of vulnerable soils, and
- monitoring of the uppermost groundwater under a large number of soils, collectively representative of the area in which the substance is to be used.

This tier is described in detail in Cornelese et al. (2003). Provided that all conditions in this report are fulfilled, the monitoring results overrule results obtained via calculations using FOCUSPEARL or GeoPEARL. Notice that the safety factor for use in groundwater protection areas is still applicable, unless the monitoring data concerns data within groundwater abstraction areas and is adequate to evaluate the 90th percentile monitoring concentration in the potential area of use in groundwater protection areas.

3.3 Tier 3: behaviour in the water-saturated zone

Tier 3 considers the behaviour of the substance in the water-saturated zone of the soil, i.e. the zone between 1 and 10 m below soil surface. A substance enters Tier 3 when the target concentration, as calculated using GeoPEARL at the end of Tier 2, was above 0.1 μg/L or when monitoring in the uppermost groundwater showed a concentration above 0.1 μg/L. Tier 3 is divided into two major parts: a part which considers behaviour studies with soil materials from the water-saturated zone and a part which considers monitoring data obtained from a depth of 10 m or more below soil surface.

3.3.1 Tier 3A: Degradation and sorption studies in the saturated zone

The applicant can perform degradation and sorption studies in materials obtained from the saturated zone at a depth between 1 and 10 m and show that under all chemical conditions, oxic to methanogenic, degradation is fast enough to reduce the concentration to below the level of 0.1 μg/L at a depth of 10 m. The calculation procedure is described in Appendix 2, backgrounds are given in Van der Linden et al. (1999). The materials gathered from the water-saturated zone should be representative of the subsurface conditions of the area in which the substance is intended to be used.

The concentration expected after 4 years of transport time at 10 m below the soil surface is calculated with the degradation rate in the saturated zone. At least two oxic soils and two anoxic soils must be tested (Van der Linden et al. 1999). 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 a depth of 10 m is then calculated on the basis of the 90th percentile concentration from GeoPEARL as the initial concentration, c_0. When this is ≤ 0.1 μg/L for each of the 4 calculations, the product can be authorized as far as leaching is concerned; when the concentration is > 0.1 μg/L for one or more of the calculations, the product cannot be authorized unless follow-up studies at

Tier 3B yield different results. Notice that the safety factor for use in groundwater protection areas is applicable for Tier 3A calculations.

3.3.2 *Tier-3B: Groundwater monitoring*

Finally, the applicant may show through monitoring that the concentration at a depth of 10 m will remain below 0.1 µg/L. Concentration measurements at a depth of 10 m below soil surface will seldom be available. Especially for new substances, it will take a long time before relevant monitoring results at this depth can be obtained; it may take more than 30 years before this substance arrives at this depth. The procedure for the monitoring and the interpretation of the results is described in more detail in Cornelese et al. (2003). The interpretation of the data does not include further statistical examination of the data. As the monitoring results will usually be obtained via sampling of existing (observation) wells, statistical boundary conditions will usually not be met. The reason for this is that these monitoring networks are not designed to reflect the area in which a particular plant protection product is to be used. The interpretation of the results therefore requires a great deal of expert judgement. Gimsing et al. (2019) provides additional recommendations for performing groundwater monitoring studies.

The safety factor for groundwater protection areas does not need to be applied at Tier 3B. This safety factor was added because the organic matter content in groundwater protection areas was, on average, lower than it was in the agricultural use area as a whole. This argument is not relevant for Tier 3B studies, because these studies deliver the measured groundwater concentration at a depth of 10 metres directly.

4 Example calculations

This chapter illustrates the use of Tier 1 and Tier 2 of the new decision tree by evaluating a few hypothetical examples:

A. substance D15K50, having a $DegT_{50}$ of 15 days (standard conditions) and a K_{om} of 50 L/kg, applied in maize;
B. substance D20K50, having a $DegT_{50}$ of 20 days (standard conditions) and a K_{om} of 50 L/kg, applied in maize;
C. substance D20KpH, having a $DegT_{50}$ of 20 days (standard conditions) and pH-dependent sorption: pK_a = 4.5, $K_{om,acid}$ is 500 l/kg^{-1} and $K_{om,base}$ is 25 L/kg. Two different situations are considered: use in maize and use in potatoes;
D. substance DsKs, having $DegT_{50}$ and K_{om} dependent on soil characteristics. The substance is applied in maize.

The use of monitoring data in Tier 2 and Tier 3, as a whole, will not be demonstrated. The use of monitoring data is explained in a separate report (Cornelese *et al.*, 2003). The part on transformation in the water-saturated zone has not changed. If a substance fails to pass Tier 2, the applicant has to demonstrate that the concentration for the 90th percentile of the use area, obtained by the GeoPEARL calculations or by the monitoring of the uppermost groundwater, declines below the limit value due to chemical or biochemical reactions under all kinds of redox conditions. The procedure has hardly changed, as only the initial concentration c_0 is obtained via a different procedure: a PEARL or monitoring result in the old situation versus a GeoPEARL or monitoring result in the new procedure.

4.1 Example A: substance D15K50

The substance is defined in FOCUSPEARL and the physico-chemical properties, the $DegT_{50}$ and the K_{om}, are entered into the database.[20] An application scheme is created – in this case a dosage of 1 kg ha^{-1} of active substance applied to the soil surface – one day before emergence of the crop (maize). With the help of the FOCUS wizard in FOCUSPEARL, a run is created in which Kremsmünster is chosen as the scenario, maize as the crop and the substance is applied each year, according to the created application scheme. Then FOCUSPEARL is run for a period of 26 years, including 6 warm-up years. Results for this case are shown in Figure 4.1. The 80th percentile leaching concentration for the Kremsmünster scenario is 0.005092 μg/L. Because the substance is applied in the spring, this concentration must be multiplied by a calibration factor of 5. The target concentration to be evaluated is therefore 0.02546 μg/L. This value is below the limit of 0.1 μg/L, which implies that the substance fulfils the criterion and can be authorized with respect to leaching. The use in groundwater protection areas, however, will be not be allowed as the calculated concentration is between 0.01 and 0.1μg/L.

[20] Up to FOCUSPEARL 4.4.4, substance data were defined and stored in the FOCUSPEARL database. FOCUSPEARL 5.5.5 uses a separate software application called SPIN (van Kraalingen et al. 2020) to create, edit and store substance data. The SPIN application is automatically called from FOCUSPEARL and GeoPEARL. This reduces the workload for regulators and industry, because substance data are available in both applications.

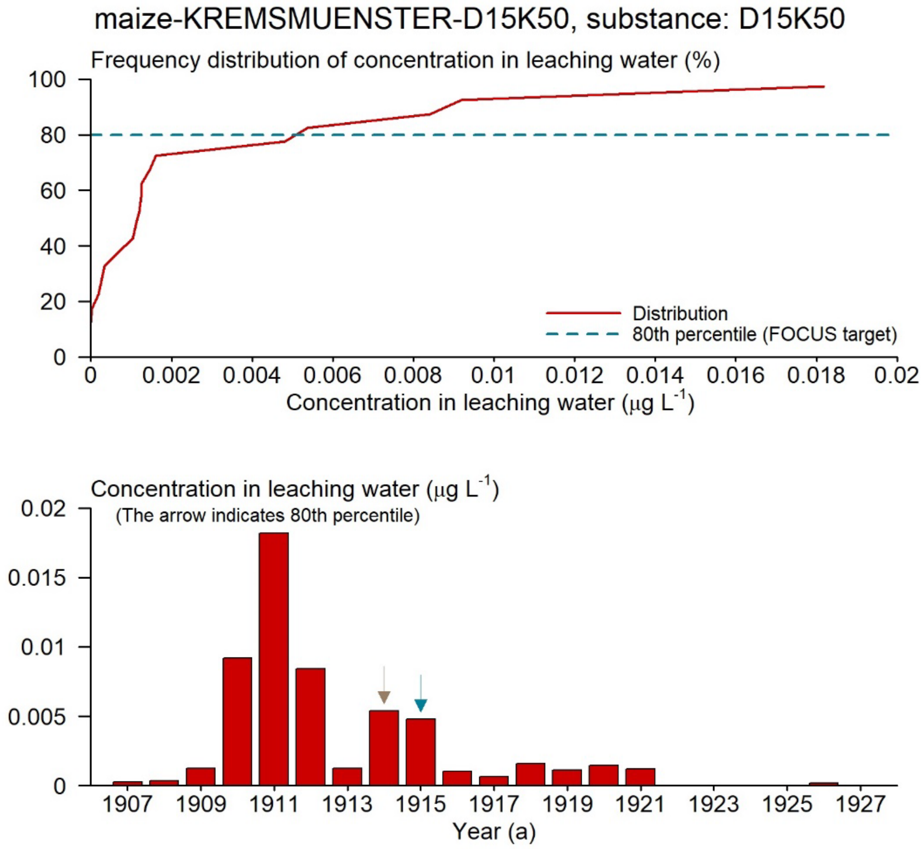
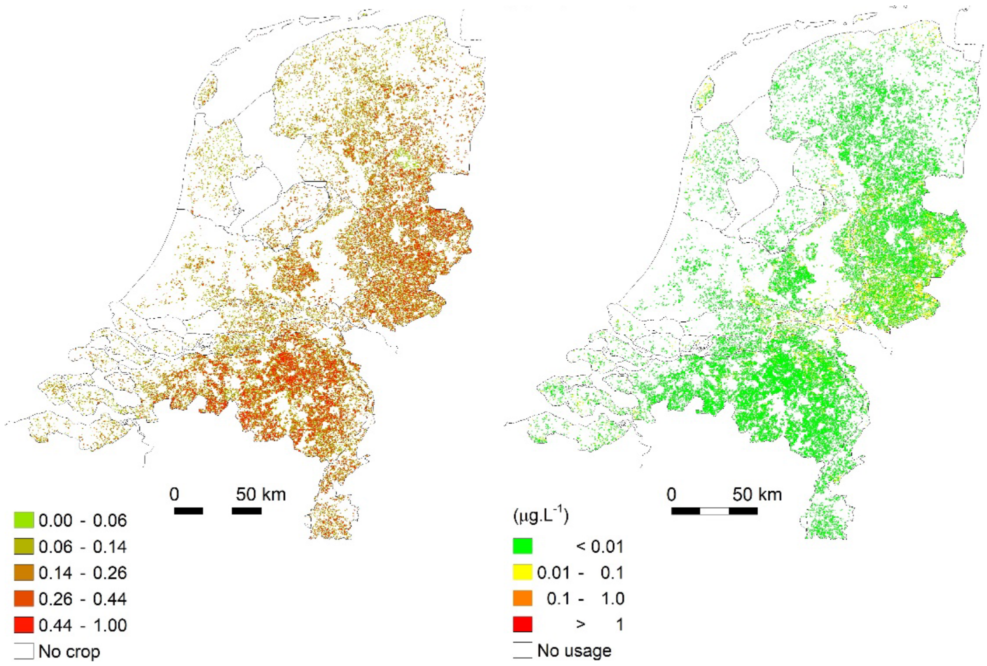


Figure 4.1 Summary graph of the FOCUSPEARL run for substance D15K50. Notice that the 80th percentile leaching concentration must be multiplied by a calibration factor of 5. The arrows denote the years around the 50th percentile

4.2 Example B: substance D20K50

The substance is applied to the soil surface one day before crop emergence (maize). The dosage is 1 kg ha^{-1} and the substance is applied each year. A standard run with FOCUSPEARL gives an 80th percentile leaching concentration of 0.065942 µg/L. This concentration must be multiplied by a calibration factor of 5, so the concentration to be evaluated at Tier 1 is 0.32971 µg/L. This is above the criterion and therefore a higher tier assessment is needed. A GeoPEARL run using the same substance data as that used at Tier 1 has to be performed. Figure 4.2 shows maps of the area in which the substance is to be used, together with the simulated leaching concentration.



Figue 4.2 Relative area (ha ha^{-1}) grown with maize (left) and the median value of the leaching concentration (µg/L) in the area in which the substance D20K50 (right) is used. The area of use is the same as the area grown with maize

The model calculates the 90th percentile leaching concentration from the cumulative frequency distribution of the leaching concentration in the area in which maize is used (Figure 4.3). This concentration is 0.014576 µg/L, which is well below the criterion of 0.1 µg/L. The substance can be authorized, but because the calculated concentration is above 0.01 µg/L, the use in groundwater protection areas will not be allowed. Note that only a calculation with GeoPEARL, with information from the core assessment, is necessary to reach the conclusion.

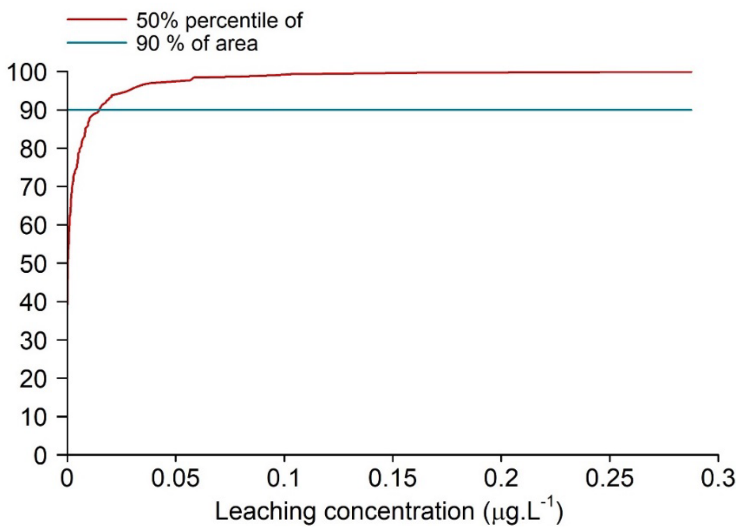
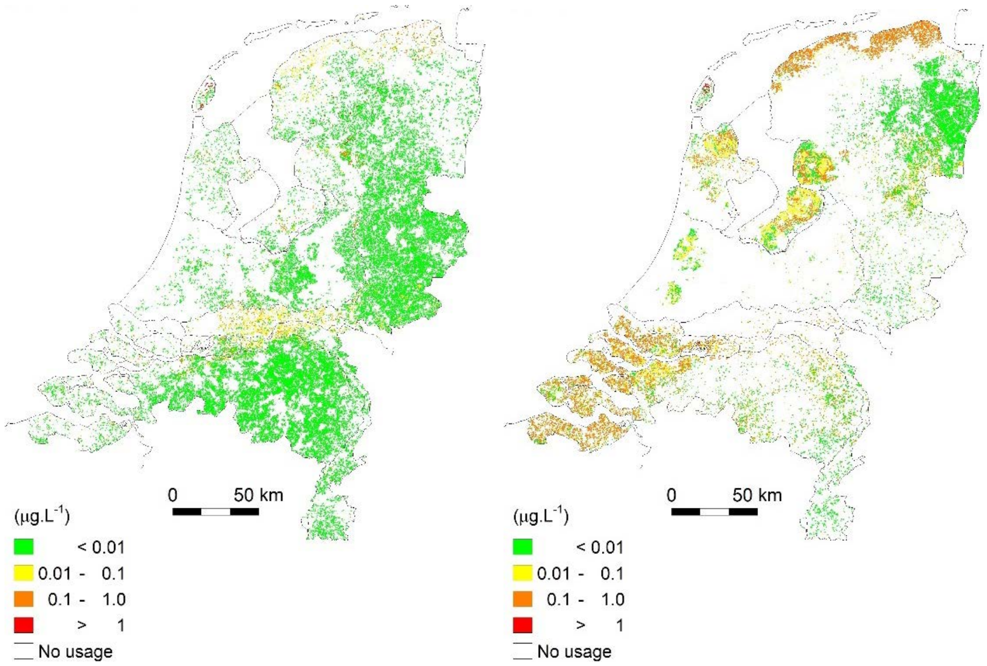


Figure 4.3 Cumulative frequency distribution of the median leaching concentration in the area in which substance D20K50 is used. The target concentration is the 90th percentile of the leaching concentration

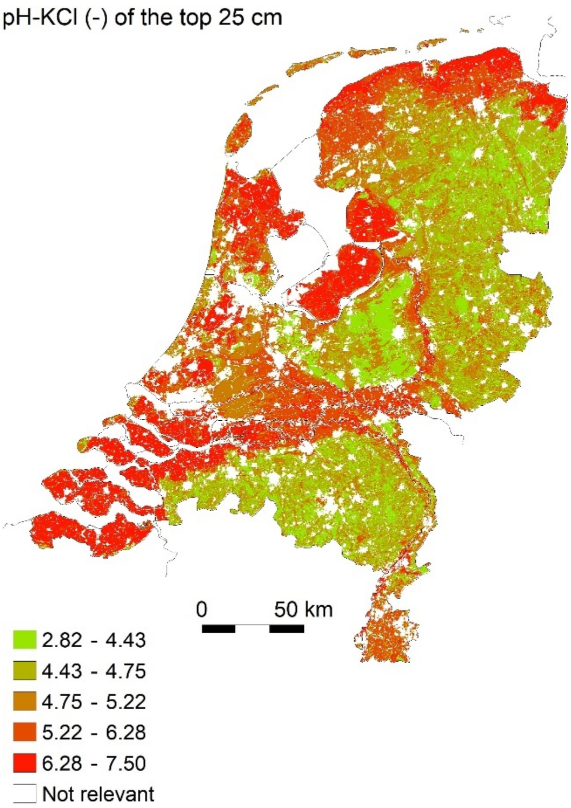
4.3 Example C: substance D20KpH

The substance shows pH-dependent sorption with a pKa-value of 4.5. At Tier 1, conservative values of K_{om} must be used, so the applicant must enter the $K_{om, base}$ of the substance, which is 25 L/kg. Two runs are performed with FOCUSPEARL, i.e. one run using maize and one run using potatoes. The dosage is 1 kg/ha and the substances are applied on May 26. The run for maize with $DegT_{50}$ = 20 days, K_{om} = 25 L/kg gives a calculated leaching concentration of 1.524 µg/L. This concentration must be multiplied by a calibration factor of 5, so the target concentration at Tier 1 is well above the limit of 0.1 µg/L. The run with potatoes gives a target concentration far above the limit as well. A higher tier assessment is therefore needed. Calculations using GeoPEARL take pH-dependent sorption into account, so the apparent sorption constant varies. A large difference can be observed between the leaching concentration of the substance in the two areas of use (Figure 4.4). The 90th percentile concentration for maize is 0.0001 µg/L, the corresponding concentration for potatoes is 0.322 µg/L. This means that the product could be authorized for use in maize. Authorization for use in potatoes, however, would not be possible.

The explanation for the different results is that potatoes are grown mainly on neutral to alkalic soils, whereas maize is primarily grown on soils with lower pH (see Figure 4.5 for the map showing the pH-value of the top 25 cm). The substance is less mobile in acidic soils and therefore the leaching potential is lower in these soils.



Figue 4.4 The median value of the leaching concentration of substance D20KpH (µg/L) in maize (left) and potatoes (right)



Figue 4.5 Map showing the pH-value of the top 25 cm of Dutch soils

4.4 Example D: substance DsKs

Substance DsKs shows both pH-dependent sorption, and pH-dependent degradation. Table 4.1 gives the most important properties of this substance. The substance is applied to the soil surface for maize one day before crop emergence. The dosage is 0.5 kg ha^{-1}.

Table 4.1 Overview of the most important properties# of substance DsKs

Property	**Description**	**Value**
M (g mol^{-1})	molar mass	350
$P_{v,s}$ (Pa)	saturated vapour pressure	0
S_w (mg L^{-1})	solubility in water	160
pKa	-log(dissociation constant)	3.0
$K_{om,ac}$ (L/kg)	equilibrium sorption	2000
$K_{om,ba}$ (L/kg)	equilibrium sorption	25
$DegT_{50,r}$ (d)	half-life	40 (20 °C, pH 4)
$DegT_{50,min}$ (d)	minimum half-life	2 (20 °C)
$DegT_{50,max}$ (d)	maximum half-life	50 (20 °C)
f_{pH} (d)	Factor for the effect of pH	-10

parameters not given, were set to default values (Tiktak *et al.*, 2000).

At Tier 1, worst-case substance properties must be input into the model. So a $DegT_{50}$ of 40 days and a K_{om} of 25 L/kg is input in FOCUSPEARL. The resulting 80th percentile concentration in time for the Kremsmünster scenario (maize) is 6.79 µg/L, which is far above the criterion. A higher tier assessment using GeoPEARL is therefore needed. A calculation with GeoPEARL using the same substance properties as those used at Tier 1 gives a 90th percentile leaching concentration of 5.03 µg/L, which is also above the criterion. The notifier, however, provided additional laboratory studies, which showed that *DegT50* is negatively correlated with pH. These studies show that for each unit increase in pH, DegT50 decreases by 10 days. This information can be considered at Tier 2B. Please refer to equation 62 in Tiktak et al. (2004) how to parameterize this pH-dependent degradation. When using this information in GeoPEARL, the 90th percentile leaching concentration decreases to 0.068 µg/L. This means that the product can be authorized for use in the Netherlands; however, there will still be a restriction for use in groundwater protection areas. Figure 4.6 gives the calculated leaching concentration. From this figure it becomes clear that the substance can be authorized for use in maize. In this specific case, the half-life is longer in acidic soils. For these soils, a higher sorption coefficient is also calculated. In neutral and alkalic soils, a low sorption coefficient is found, in combination with a short half-life. In most parts of the map, a relatively favourable ratio of $DegT_{50}$ to K_{om} is calculated, with relatively low leaching levels as a consequence.

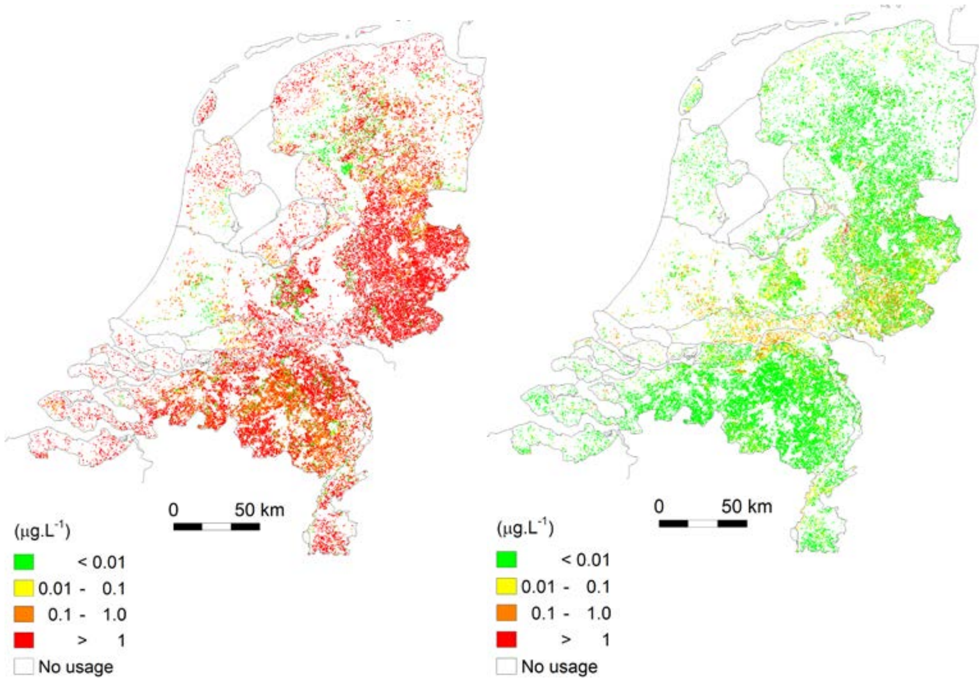


Figure 4.6 The median value of the leaching concentration of substance DsKs at 1 metre depth in the maize area of the Netherlands. Left: using conservative values of the substance properties. Right: using pH-dependent sorption and degradation as indicated in Table 4.1

5 Conclusions and recommendations

5.1 Conclusions

In 2004, a decision tree for evaluating the leaching of plant protection products into groundwater was introduced in the Netherlands (Van der Linden et al., 2004). A central role was given to the spatially distributed pesticide leaching model GeoPEARL (Tiktak et al. 2003; 2004). This model is used at Tier 2, preceded by a simple calculation using the FOCUS Kremsmünster scenario at Tier 1. With the introduction of GeoPEARL, explicit evaluation of the leaching potential in the area in which a plant protection product is to be used became possible. The tiered approach also considered higher-tier lysimeter and monitoring studies. Notice that the decision tree described in this report does not apply to covered crops.

A new organic matter map

In 2010, it was noted that the soil organic matter map in the database of GeoPEARL contained higher values for the organic matter content in the top layer of arable soils in the Netherlands than those measured in arable topsoils reported by Reijneveld et al. (2009). For this reason, a new map of organic matter content was created, which was incorporated into the GeoPEARL model in 2017. Simulations with this new model version revealed that the predicted leaching concentration increased by a factor up to 10 (Van den Berg et al. 2017). The increase of the simulated leaching concentration with the new version of GeoPEARL led to an inconsistency in the tiered approach of the Dutch decision tree on leaching. In many cases, the updated GeoPEARL model used at Tier 2 simulated higher concentrations than the FOCUSPEARL model (version 4.4.4) for Kremsmünster at Tier 1.[21]

Introduction of a calibration factor at Tier 1

It became clear that the introduction of the new version of GeoPEARL is not possible without a revision of the Dutch decision tree on leaching. The Dutch working group on groundwater leaching reviewed the 2004 decision tree and concluded that, with the introduction of a calibration factor of 5 to 10 at Tier 1, the consistency of the tiered approach could be restored. In a few cases, the working group recommends skipping Tier 1 and moving directly on to Tier 2. The first exception applies to volatile substances that are injected or incorporated into the soil. This exception was adopted in the 2004 decision tree. The second exception applies to substances that have a ratio $K_{om}/DegT50$ between 3.5 and 4.5, and that are applied in the period September 1 to February 29. Other exceptions mentioned in Van der Linden et al. (2004) are no longer applicable.

Substances whose properties depend on soil characteristics

A review conducted by Van der Linden et al. (2015) and Boesten et al. (2015) showed some other shortcomings in the description of the tiered

[21] The comparison in van den Berg et al. (2017) has been performed with FOCUSPEARL version 4.4.4. The more recent version of FOCUSPEARL, i.e. version 5.5.5, calculates groundwater concentrations that are fully consistent with those simulated by FOCUSPEARL version 4.4.4.

approach. Most of these shortcomings were related to substances whose properties depend on soil characteristics such as pH and clay content. In the updated description of the decision tree, it is made clear that Tier 1 can be used with such substances if the substance properties are set to conservative values. The updated description of the tiered approach now also makes a better distinction between the refinement of substance parameters and the possibility to submit additional laboratory and field studies for the area in which a plant protection product is intended to be used. Refinement of substance parameters can already be done in the core assessment. An important refinement is the option to account for aged sorption (EC, 2021). These refined parameters can also be introduced at Tier 1 and Tier 2 of the Dutch decision tree. The option to provide additional laboratory studies should only be used if the substance data in the core assessment is not relevant for the area of use in the Netherlands or if additional information shows that substance properties are dependent on soil properties such as pH and clay content.

Higher-tier lysimeter and monitoring studies

The decision tree also considers higher-tier lysimeter studies and groundwater monitoring. These studies have not been reviewed by the working group, so existing guidance described in Verschoor et al. (2001) and Cornelese et al. (2003) is still applicable. However, the working group considers an update of these guidance documents necessary as soon as EFSA finalizes its review of the paper by Gimsing et al. (2019) on groundwater monitoring studies.

5.2 Recommendations

Check the Tier 1 calibration factor for additional substances

The proposed calibration factors at Tier 1 in the Dutch decision tree are based on calculations for a Freundlich exponent of 0.9. Checks for two substances showed that these calibration factors might not be conservative enough for a Freundlich exponent of 0.8, which is usually the lowest value found in dossiers. To make the tiered approach consistent for all possible substances, we recommend also estimating the calibration factor for substances with a Freundlich exponent of 0.8. The consistency of the tiered approach has furthermore not been checked for soil metabolites. It is therefore recommended that this should also be checked.

Check the safety factor for groundwater protection areas

As mentioned in Section 2.1, the safety factor of 10 for groundwater protection areas is based on simulations using an earlier version of GeoPEARL (Kruijne et al. 2004). This was mainly because organic matter in groundwater abstraction areas was lower than organic matter in Dutch agricultural soils as a whole. In GeoPEARL 4.4.4., a new soil organic matter map was implemented. Van den Berg et al. (2017) showed that differences between the organic matter content of groundwater abstraction areas and Dutch agricultural areas as a whole are smaller in GeoPEARL 4.4.4 than in the earlier version. The working group therefore recommends investigating whether the factor of 10 that is currently used for groundwater protection areas is always needed. This can be done by systematically comparing the predicted leaching concentration in groundwater abstraction areas with those in Dutch agriculture as a whole.

Consider regular updates of the crop data in GeoPEARL
The GeoPEARL model in the Dutch decision tree on leaching uses geographical data that are subject to change. This is particularly the case for the cropping area. In 2021, the Central Bureau of Statistics reported a decrease of the arable crop cultivation area by 17% relative to 2000.[22] There were, however, large differences between crops. The area cultivated with seed onions doubled, for example, while the area grown with barley almost halved. Note that seed onions and barley are crops that cannot be selected in GeoPEARL. These crops are assigned to the crop groups 'onions' and 'cereals', respectively. Because the cropping area is considered to be a proxy for the potential area in which a plant protection product is to be used (Section 2.1), we recommend updating the cropping database in GeoPEARL. This should preferably be done on a regular basis; for example every five years.

Reconsider the number of crops used at Tier 2
Additional analysis showed that the average organic matter content showed only small differences between crops (Van den Berg et al., 2017). Given these small differences and the uncertainty in predicting organic matter for smaller areas, it may be questioned whether assessments for smaller crops, as done in Tier 2, will produce leaching concentrations that are statistically significant. We therefore recommend quantifying the uncertainty of model predictions for these smaller crops, with the aim of investigating if it is possible to simplify the second tier of the decision tree. Actualization of the cultivation area, as recommended in the previous paragraph, would benefit from this simplification because it would be easier to create an automated procedure.

Create a protocol to keep the decision tree up to date
The Tier 1 calibration factors and the safety factor for groundwater protection areas might be affected if a new version of FOCUSPEARL or GeoPEARL becomes available. We therefore recommend creating a protocol for keeping the decision tree up to date.

Update the description of Tier 3 assessments
The guidance for conducting monitoring studies referred to in the decision tree originated in 2003. At that time, there was hardly any experience with the combination of spatially distributed modelling and monitoring. The interpretation of the results, therefore, requires a great deal of expert judgement. Monitoring studies are now submitted as higher tier studies, in which spatially distributed models, such as GeoPEARL, are used to set monitoring in a wider spatial context. Experience with such studies has resulted in general recommendations for conducting groundwater monitoring studies (Gimsing et al. 2019). EFSA has been tasked by the European Commission to review this document. It is recommended that the recommendations in Gimsing et al. (2019) be considered once this review is done.

[22] https://www.cbs.nl/en-gb/news/2021/26/arable-crop-area-slightly-larger-in-2021

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Glossary

Property	**Description**
ADI	Acceptable Daily Intake
Ctgb	Dutch Board for the authorisation of plant protection products and biocides
Decision tree	Scheme to assist in decision making
DegT50	Time required for reducing the concentration by 50% by degradation processes.
EFSA	European Food Safety Authority
FOCUS	FOrum for the Co-ordination of pesticide fate models and their USe
FOCUSPEARL	The version of PEARL used for the approval of active substances at the European level
GeoPEARL	Spatially distributed model, based on a link between the PEARL model and a Geographical Information System, used to calculate leaching of a substance in the second tier of the decision tree in the Netherlands.
GIS	Geographical Information System
Groundwater	Water below the groundwater level; the level at which the soil water pressure is zero (in comparison with air pressure)
Kom	Equilibrium constant for the sorption of a substance on organic matter.
Leaching	Process by which a substance moves downward through a soil profile.
LoEP	List of Endpoints
PEARL	Pesticide Emission Assessment at Regional and Local scales. Software package used to simulate leaching of substances from the soil.
Potential area of use	The area in which a plant protection product is potentially applied. In GeoPEARL, this area is approximated by the area of an individual crop. Notice that if an applicant requests an authorization for use in multiple crops, the evaluation is done for each crop type individually.
PPP	Plant Protection Product. In this text PPP is used for the substance for which the possible registration is assessed.
Scenario	A combination of agricultural, climate, crop and soil parameters to be used in the evaluation process (FOCUS, 1995). The term 'scenario' is generally used to refer to a given set of input parameters to be used in model calculations. This given set of input parameters is considered representative for the Netherlands or part of the Netherlands.
SPIN	Substance Plug IN tool.
Substance	Term used to indicate the substance under investigation; the word is used to indicate the active ingredient of a plant protection product or any of its metabolites.

Appendix 1 Derivation of the simulation error in Tier 2B

At Tier 2B, field or lysimeter studies are simulated using PEARL. The ratio between the calculated and the measured concentration is called the simulation error (see Verschoor et al., 2001). The simulation error is used to correct the 90th percentile of the leaching concentration obtained by the GeoPEARL simulations. For one substance in different situations, the simulation error can differ by an order of magnitude. Considering this large variation in simulation errors for one substance, a decision based on one simulation error is highly uncertain. For this reason, the lower limit of the confidence interval of the average simulation error is used as the adjustment factor.

The simulation error is likely to be log-normally distributed because it can increase without bound, but is confined to a finite value at the lower limit (=0). Therefore, the procedure starts with a log-transformation of the observed simulation errors (we will use natural logarithms here). The natural logarithm of the simulation error probability distribution will yield a normal distribution curve. In practice, the number of simulation errors will be limited, so a *t*-distribution will apply. After transformation, the arithmetic mean and the standard deviation of the transformed data are calculated. The lower limit of the confidence interval for the transformed data is now determined according to:

$$SE_{tr,ll} = \overline{SE_{tr}} - t_{prob} \cdot \frac{SD_{tr}}{\sqrt{n}} \qquad \text{A1.1}$$

whereby $SE_{tr,ll}$ is the lower limit of the confidence interval of the transformed simulation errors, SE_{tr} is the arithmetic mean of the transformed simulation errors, t_{prob} is the *t*-distribution probability factor, SD_{tr} is the standard deviation of the transformed simulation errors, and n is the number of experiments (the number of degrees of freedom is n minus one).

As we are concerned about over-correction, only the lower limit of the confidence interval is of interest. Therefore, we can apply single-sided statistics. Up till now, there is little experience in using the adjustment factor and thus in choosing the probability factor. For the moment, it seems reasonable to use a 75% confidence limit (α = 0.25). The adjustment factor is obtained through back-transformation:

$$f_{adj} = \exp\left(SE_{tr.ll}\right) \qquad \text{A1.2}$$

The procedure described above can be followed if more than one field or lysimeter experiment is performed. If there is only one experiment, there are no degrees of freedom left and the adjustment factor cannot be determined according to the formula. If only one experiment is available, the adjustment factor is calculated using essentially the equations above, assuming a variation coefficient of 75% for the population of transformed simulation errors. This procedure might be updated after having gained more experience with the procedure.

Example

Suppose we have 3 lysimeter experiments with simulation errors of respectively 2, 7 and 20 (geometric mean = 6.55). Following the procedure, we obtain: ln (*SE*)=0.69, 1.94 and 3.00; mean=1.88 and standard deviation=1.15. As we have two degrees of freedom, the single sided *t*-probability factor (α = 0.25) is 0.816. The lower limit of the confidence interval $SE_{tr,\ ll}$ = 1.88 – 0.816*1.15/(√3) = 1.34, and the adjustment factor f_{adj} = exp(1.34) = 3.81

Table A1 t-values (one-sided, α=0.25)

Degrees of freedom	***t*-probability**
1	1.000
2	0.816
3	0.765
4	0.741
5	0.727
6	0.718
7	0.711
8	0.706
9	0.703
10	0.700

Appendix 2 Calculation procedure for Tier 3A

As mentioned in Section 3.3.1, the applicant can perform degradation and sorption studies in materials obtained from the saturated zone at between 1 and 10 m depth and show that under all chemical conditions, oxic to methanogenic, degradation is fast enough to reduce the concentration to below the level of 0.1 μg/L at a depth of 10 m. This appendix describes the calculation procedure, further backgrounds are described in Van der Linden et al. (1999).

In the calculation procedure, first-order degradation kinetics is assumed. This implies that the concentration at time *t* can be calculated from the initial concentration as follows:

$$c_t = c_0 \, e^{-kt} \qquad \text{(A2.1)}$$

in which c_t is the concentration of the substance (kg m^{-3}) at time t, c_0 is the concentration of the substance at $t = 0$, t (d) is the time and k (d^{-1}) is the first-order degradation coefficient. The degradation half-life of the substance can be calculated from k as follows:

$$DegT50 = \ln(2)/k \qquad \text{(A2.2)}$$

whereby *DegT50* (d) is the degradation half-life time of the substance. The half-life must be obtained using soil from the saturated zone at between 1 and 10 m depth. The soil must be relevant for the intended area of use of the substance and be done for all relevant chemical conditions from oxic to methanogenic. At least four degradation studies must be performed.

The initial concentration c_0 in equation A2.1 must be set to the 90th percentile of the leaching concentration at a depth of 1 m, as obtained at Tier 2. The time in equation A2.1 must be set to 1,460 days (4 years). This corresponds to the average travel time of water to a depth of 10 m, assuming an average precipitation surplus of 250 mm per year. The travel time t may be multiplied by a retardation coefficient R (-) if the application shows evidence of sorption in the saturated zone:

$$R = (\theta_s + \rho_b K_s)/\theta_s \qquad \text{(A2.3)}$$

whereby θ_s (m^3 m^{-3}) is the volume fraction of water at saturation, ρ_b (g dm^{-3}) is the dry bulk-density of the soil and K_s (dm^{-3} g^{-1}) is the sorption coefficient. The sorption coefficient must be obtained using sorption studies in the same material as was used for the degradation studies. The volume fraction of water and the bulk-density of the soil should be derived from the same soils as well.

The calculations must be done for each of the four soils studied. The worst-case of the four studies is taken, which means that authorization of the product is possible if each of the four concentrations is equal to or lower than 0.1 μg/L, unless follow-up monitoring studies at Tier 3B yield different results.

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