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

EU part

Plant protection products

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

version 2.3; January 2020

ctgb

Board for the Authorisation of plant protection products and biocides

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

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 6 Persistence			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014	Throughout the document	Data requirement for the active substance: full text taken from Commission Regulation (EU) No 283/2013
2.1	October 2016	Throughout the document	Full text taken from Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 was removed.
		Paragraph 1.3.4, page 9.	PEC soil calculations in case of spot treatment and/or non-professional use.
		Paragraph 1.3.5, page 9.	PEC soil calculations in case of seed treatment, flowerbulbs, potatoes.
2.2	January 2017	Paragraph 1.3.6, page 11	Instructions for modelling the exposure to soil of mushroom cultivation have been incorporated in the Evaluation Manual
		Appendix 5	PECsoil calculations for potatoes
		Appendix 5	Interception usage for grassland added from NL Part Evaluation Manual version 2.0 persistence; these were not included in version 2.1
2.3	January 2020	1.	Sentence included on the administrative EFSA guidance

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of persistence in soil of a plant protection product and its active substance and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009. The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal and interzonal (seed treatment and greenhouse) applications for the authorization of plant protection products (i.e. core registration reports).

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of an active substance is referred to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) Regulation (EU) No 540/2011.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

1.1. Introduction

Persistence in soil is included in the risk assessment when it cannot be ruled out that the plant protection product / the active substance reaches the soil (see Appendix 1). Furthermore the use of plant protection products may lead to accumulation of active substances and/or its metabolites in soil.

The questions in §1.2.1 (data requirements for the active substance) and §1.2.2 (data requirement for the product) of this chapter are relevant for the persistence (residence time) and accumulation of the plant protection product in soil. Data concerning the nature of the metabolites and the degradation rates of the active substance and relevant metabolites are considered. The proposed dose rate as mentioned according to good agricultural practices will be used for the risk assessment, taking into account the amount of product that will not reach the soil due to plant interception (see Appendix 3 and/or Appendix 4). These data are also used in evaluating the risk of leaching to shallow groundwater. For that aspect see chapter Fate and behaviour in the environment; behaviour in soil; leaching to groundwater.

Ecotoxicological data as described for the data requirements of other aspects than persistence are used in the higher tier persistence evaluation, when they are compared with the predicted accumulated soil concentrations ($PIEC_{soil}$ + $PEC_{soil,plateau}$) (see §1.3.2). This concerns all data, when available, for soil dwelling organisms (i.e. soil dwelling arthropods, earthworms, soil micro-organisms, other soil macro-organisms (see Chapters 7 Ecotoxicology; terrestrial; soil organisms and non targets)).

The calculation method for the concentration in the soil (PEC_{soil}) is also included in this chapter. This PEC_{soil} is also used in the risk assessment for soil dwelling organisms (i.e. soil dwelling arthropods, earthworms, soil micro-organisms, other soil macro-organisms) and birds and mammals (secondary poisoning).

Guidelines for evaluation of the aspect persistence are described in the Guidance Document on Persistence in Soil (9188/VI/97 rev. 8 12.07.2000) FOCUS Generic Guidance for

estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration (version 1.1, 18 December 2014) and the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

The relevant decision tree from the Guidance Document on Persistence in Soil is included in Appendix 2. Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the following paragraphs.

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communications 2013/C 95/01 (for active substances) and Commission Communications 2013/C 95/02 (for plant protection products).

When according to the applicant a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table, see Appendix A to Chapter 6.

1.2.1. Data requirements for the active substance

The data requirements for the active substance have been taken from Commission Regulation (EU) No 283/2013, section 7. - fate and behaviour in the environment. For the complete text please consult the text from Commission Regulation (EU) No 283/2013 itself. Any relevant results of the study are given.

The data requirements regarding persistence of the active substance in the soil are described in part A of (Commission Regulation (EU) No 284/2013, point 7.1 (fate and behaviour in the soil) and 7.5 (monitoring data).

1.2.2. Data requirements for the product

The data requirements for the product in the grey frames below have been taken from Commission Regulation (EU) No 284/2013, section 9. – fate and behaviour in the environment.

The data requirements regarding persistence of the plant protection product in the soil are described in part A of Commission Regulation (EU) No 284/2013, point 9.1 (fate and behaviour in the soil).

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communications 2013/C 95/02.

1.3. Risk assessment

Each study (see §1.2.1 and §1.2.2) must be summarised and evaluated separately.
The final conclusion and the endpoint per aspect (such as $DT50_{lab}$) are presented in a list of endpoints. The risks are assessed with use of these endpoints.

1.3.1. First tier assessment

The first tier risk assessment for persistence has in EU context been elaborated in the Guidance Document on Persistence in Soil. Persistence is defined as the residence time of an active substance in a defined compartment of the environment. Furthermore this document provides elaborations on how to assess accumulation levels. Soil persistence is related to the DT_{50} and DT_{90} values from field dissipation studies. Evaluation starts, however, earlier – with consideration of laboratory soil degradation studies.

The first tier assessment involves testing of the behavioural triggers (DT_{50} and soil-bound residues and mineralization) under controlled circumstances (in a laboratory). Generally, field studies have to be conducted in those cases where the DT_{50lab} determined in the laboratory at 20°C and at a moisture content of the soil related to a pF value of -10 to -32 kPa (suction pressure) is greater than 60 days.

If the field trigger values of DT_{50} of 3 months and DT_{90} of one year in the field or non-extractable residues greater than 70% with a mineralization rate of less than 5% in 100 days are not met, no authorisation shall be granted. However, this provision is not intended to set a cut-off point to the evaluation process, because its “unless” clause allows further consideration (see Appendix 2).

1.3.2. Higher tier assessment

In the Guidance Document on Persistence in Soil the higher tier risk assessment (unless clause) consists of weighing the measured, calculated or otherwise established plateau concentration of the active substance in the soil against an unacceptable impact on the environment (See Appendix 2).

Over the years this has evolved into using the $PIEC_{soil}$ plus $PEC_{plateau}$ in the higher tier risk assessment. This is common practice in the EU-dossiers.

Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) contains a tiered approach for substances with a $DT_{90field}$ >100 days for the risk assessment for soil non-target organisms. However, over the years this tiered approach has proven to have some shortcomings, especially concerning the final step that is based on the litterbag test. This test is not sensitive and at this moment there seems to be general consensus amongst most of the EU member states that this test is not sufficient to fulfill the highest tier step of the persistency risk assessment. Generally speaking, a ‘structural’ approach (based on species specific endpoints) is preferred compared to the ‘process’ based approach (endpoints based on soil processes, such as decomposition). In addition, it should be noted that in the data requirements under Regulation (EC) No. 1107/2009 (Commission Regulation (EU) No 283/2013 and Commision Regulation (EU) No 284/2013 the litterbag test is no longer included.

Another shortcoming of the decision tree in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) is the $DT_{90field}$ trigger (i.e. $DT_{90field}$ > 100d): this trigger does not match with the higher tier decision criterium for persistency in soil (DT_{90} > 1 year or DT_{50} > 90 days; see 1.4.2 below).

Based on the above, Ctgb uses the following approach for the higher tier persistency risk assessment, which is loosely based on the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) , and on the current EU risk assessment practice such as it has evolved over the recent years.

- If the first tier criteria for persistence in soil are not met, an ecotoxicological risk

assessment is performed based on the $PIEC_{soil}$+$PEC_{plateau,soil}$.
- The $PIEC_{soil}$+$PEC_{plateau,soil}$ is tested against all endpoints for soil organisms that are available in the dossier. I.e.: soil-dwelling arthropods (tested in soil), earthworms, soil micro-organisms, other soil macro-organisms.
- For a persistent substance, a test with either *Folsomia candida* or *Hypoaspis aculeifer* is in principle preferred by Ctgb. However, if in the EU-dossier for Annex I listing for the substance of concern it is explicitly decided that these tests are not necessary based on the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final), and the dossier did not have to comply with the data requirements under Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, Ctgb will follow that approach. It should be noted that the data requirements for *Folsomia candida* and *Hypoaspis aculeifer are changed* under Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. [a]
- In the risk assessment for secondary poisoning of birds and mammals (via earthworms), the $PEC_{soil,twa\ 21\ d}$ + $PEC_{plateau,soil}$ is used.
- If a litterbag is available, it is taken into account in the risk assessment. It can be used to draw conclusions on the effects on organic matter decomposition. However, the litterbag cannot be used as a final higher tier step that overrules risk identified with the species specific endpoints.
- There are two routes for further higher tier: via higher tier fate studies, showing that the a.s. meets the persistency criteria, or via higher tier ecotox testing (e.g. soil community field tests).

For (interzonal) greenhouse uses for which the EFSA GD on protected crops[b] applies, a risk assessment for soil is also performed for persistent active substances and, if applicable, their persistent metabolites.

The protected crops risk assessment for persistence in soil is based on a long term time scale, for which a change in land use cannot be excluded. Furthermore, it is assumed that soil beneath greenhouses might become available again for other destinations on the long term. For changed land use no additional use of plant protection producs is assumed, therefore the endpoints are tested against the $PEC_{plateau,soil}$ (i.e. without summing up the $PIEC_{soil}$). For persistent metabolites case-by-case justifications can be provided to waive additional data.

The approach above is used until the revised FOCUS Document 'Soil persistence models and EU registration' and Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final)(see also par.1.5 Developments) become final.

1.3.3. Calculation concentration active substance and metabolites in the soil

This section describes how the concentration in the soil must be calculated in accordance with EU guidance. The concentration in soil is relevant in the higher tier risk assessment for persistence. The concentration in soil is also used in the risk assessment for earthworms, birds and mammals (secondary poisoning) and soil micro-organisms (see Chapters 7 Ecotoxicology; terrestrial; soil organisms and birds and mammals).

The concentration active substance in the soil is calculated on the basis of the FOCUS

[a] Note that the data requirement for Folsomia and Hypoaspis in Commision Regulations (EU) 283/2013 and 284/2013 leaves room for interpretation, which is described in Chapter 7 Ecotoxicology: terrestrial soil organisms – EU-part.

[b] 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. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

Document 'Soil persistence models and EU registration'. The concepts of FOCUS Degradation Kinetics (version 1.1, 18 December 2014) and the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) are applied. The equations below for calculating concentrations in soil can be used for the active substance as well as for metabolites, where the dose (D) of the metabolite is determined by multiplying the dose level of the active substance by the maximum observed percentage and relative molecule mass of the metabolite in question.

Predicted Environmental Concentrations in Soil (PEC_S) for active substance
[1] PEC_{soil} immediately after a single application ($PEC_{S,\ initial}$) was calculated using the following equation:

$$PEC_{S,\ initial}\ [mg/kg] = \frac{A[g/ha] \times (1 - F)}{100 \times d\ [cm] \times \rho\ [g/cm^3]}$$

Where:
A = Application rate
F = Fraction intercepted by crop
d = Depth of field soil layer (5 cm)
ρ = Dry bulk density (1.5 g/cm3)

This PEC value is used as the basis for the short and long term PEC calculations (after multiple applications). The $PEC_{S,\ initial}$ should not be confused with the actual PEC ($PEC_{s,actual}$, also expressed as PIEC), which is often used to describe the highest concentration. When only a single application takes place, the $PEC_{S,\ initial}$ is similar to the $PEC_{S,actual}$.

Assuming SFO degradation kinetics
[2] For multiple applications the initial PEC_S immediately after the n^{th} application was calculated as follows:

$$PEC_{S,actual}\ (n)\ [mg/kg] = \frac{PEC_{S,\ initial} \times (1 - e^{-nki})}{(1 - e^{-ki})}$$

Where:
n = number of applications
i = interval in days between applications
k = first order degradation/dissipation rate constant (ln(2)/half-life)

When the application pattern follows a constant pattern with similar application rates and intervals between applications, the PEC after the final application is the maximum PEC ($PEC_{s,actual,max}$).

When different application rates and intervals are applied, the maximum PEC ($PEC_{s,actual,max}$) will not always immediately occur after the last application. In that case the $PEC_{S,actual}$ has to be calculated for each application, where the $PEC_{S,\ initial}$ in the formula above is replaced by the PEC at the previous application.

[3] The maximum ('moving window') time weighted average (TWA) PEC values are found by calculating a set of TWA PECs over a time window that is moved along the time axis. The average PEC within a day is calculated by:

$$\text{Average PEC over a day [mg/kg]} = \frac{PEC_{S,\ initial} \times (1\text{-}e^{-kt})}{kt}$$

Where:
t = days after application
k = first order degradation/dissipation rate constant (ln(2)/half-life)
The maximum TWA over the moving window is calculated from the $PEC_{S,\ actual,max}$:

$$PEC_{twa,max}\ [mg/kg] = \frac{PEC_{S,\ actual,max} \times (1-e^{-kt})}{kt}$$

[4] The plateau concentration ($PEC_{S,plateau}$), i.e. the minimum concentration in soil before the first annual application, is calculated as:

$$PEC_{S,plateau}\ [mg/kg] = PEC_{S,\ actual,max\ /}\ (1 - e^{(-365-((n-1)i)k)})$$

Where:
$PEC_{S,\ actual,max}$ = $PEC_{S,\ actual,max}$ calculated for 5 cm soil depth [mg/kg]
n = number of applications (-)
i = interval period between applications (days)

The plateau concentration in soil resulting from long-term use is calculated for a worst-case soil depth of 5 cm assuming that ploughing can be excluded (i.e. for perennials) and for a soil depth of 20 cm when soil incorporation by ploughing between application schemes could be expected. The latter option allows the $PEC_{S,plateau}$ (5 cm) to be divided by 4 after which the $PEC_{S,plateau}$ for 20 cm is presented.

The peak accumulated PEC_S ($PEC_{S,peak\ accum}$) is calculated as the sum of the plateau concentration before the first annual application and the maximum actual PEC_S (calculated for 5 cm soil depth):

$$PEC_{S,peak\ accum}\ [mg/kg] = PEC_{S,plateau} + PEC_{S,actual,max}$$

<u>Assuming FOMC degradation kinetics</u>
FOMC uses formula [1] to determine the $PEC_{S,\ initial}$.

[5] For multiple applications the initial PEC_S immediately after the n^{th} application was calculated as follows:

$$PEC_{S,actual}\ (n)\ [mg/kg] = \frac{PEC_{S,\ initial}}{(t\ /\ ß\ +1)^{(\alpha)}}$$

Where:
t = days after application
α = 1st fitting parameter
ß = 2nd fitting parameter

When the application pattern follows a constant pattern with similar application rates and intervals between applications, the PEC after the final application is the maximum PEC ($PEC_{s,actual,max}$).

When different application rates and intervals are applied, the maximum PEC ($PEC_{s,actual,max}$) will not always immediately occur after the last application. In that case the $PEC_{S,actual}$ has to be calculated for each application, where the $PEC_{S,\ initial}$ in the formula above is replaced by the PEC at the previous application.

The TWA over the moving window is calculated manually by averaging the PEC values within a timeframe, by multiplying the PEC ($PEC_{S,actual}$) values with their corresponding

period length in days (=weight) and subsequently dividing the PEC x weight by the numbers of days within the timeframe.

The $PEC_{S,plateau}$ is also calculated manually by running the simulation for 20 years (20 application periods) and selecting the $PEC_{S,actual}$ at day 364, the day right before a new application.

Assuming DFOP degradation kinetics
DFOP uses formula [1] to determine the $PEC_{S, initial}$.

[6] For multiple applications the initial PEC_S immediately after the n^{th} application was calculated as follows:

$$PEC_{S,actual}\ (n)\ [mg/kg] = PEC_{S,\ initial} \times (g \times e^{(-k_1 t)} + ((1-g) \times e^{(-k_2 t)}))$$

Where:
t = days after application
g = fraction of the pesticide applied to the first compartment
k_1 = rate constant in the first compartment (d^{-1})
k_2 = rate constant in the second compartment (d^{-1})

Predicted Environmental Concentrations in Soil (PEC_S) for Relevant Metabolites

IIIA 9.5.1 Initial PEC_S values
[7] Metabolite PEC calculations were based on the $PEC_{S,initial,metabolite}$, based on the parent substance according to the equation given below.

$$PEC_{s,initial,\ metabolite}\ [mg/kg] = PEC_{initial,parent} \frac{\text{maximum metabolite observed (\%)}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

Where:
$PEC_{initial,parent}$ = initial parent concentration ($PEC_{S,\ initial}$) [mg/kg]
Maximum metabolite amount observed = maximum percentage observed in the corresponding compartment
MM_{parent} = molecular mass of parent
$MM_{metabolite}$ = molecular mass of metabolite

The functions as described for the parent also apply for the metabolite PEC calculations, where the $PEC_{S,initial,parent}$ should be replaced by the $PEC_{S,initial,metabolite}$.

1.3.4. PEC calculations in case of spot treatment and/or non-professional use
Please note that in case of spot treatment and/or professional use, the full dose rate as mentioned according to good agricultural practices will be used since the full dose rate will reach the soil organisms.

1.3.5. PEC calculations in case of seed treatment
Guidance on treated seeds is currently under development (SANCO/10553/2012 version January 2014). A new commenting round by the Member States of the document is expected in 2017 (take note date and entry into force date yet unknown).

Currently there is no European method for PECsoil calculations for seed dressings or treated propagation material. The calculation method presented in Appendix 5 to this chapter is

therefore proposed as further elaboration. The method is briefly summarised below.

A *homogeneous distribution* of the active substance in spherical spheres of influence around the seed is assumed. Analogous to the distribution depth for a spray formulation, it is assumed that the radius of the *sphere of influence* is 5 cm. For drilling/planting of larger seeds at ≥ 5 cm depth, e.g., pilled beet seed or seed potatoes, the sphere of influence has the form of a full spheroid. A maximum volume of 500 m^3 per ha is assumed as maximum volume of the sphere of influence of the seeds.

The calculation method has been elaborated in Appendix 5 to this chapter.

Seed treatment (excluding flower bulbs) mostly takes place indoor. In that case no exposure is expected from the treatment itself. However, when treated seeds are transferred to the field or soil bound greenhouse, exposure of soil organisms becomes likely. The effective application rate of the active substance is highly influenced by seed radius, amount of seeds per ton and the sowing density. Please calculate the PECsphere assuming a homogenous distribution over 5 cm. Please use the formula or the PECsphere calculation sheet as mentioned in chapter 1.3.5.

Flowerbulbs
PECsphere is not relevant for treated flower bulbs (bulb dipping) since the bulbs are almost completely and equally distributed over the topsoil. PECsoil calculations PEC_{INI} and PEC_{TWA} are calculated according to the normal PEC_{soil} acute calculation for a homogenous distribution. For the calculations a soil layer of 10 cm (5 cm cover soil and 5 cm soil below) is used instead of 5 cm.

Potatoes
For proposed uses in potatoes for both *tuber treatment* and *in furrow treatment*, a planting depth of 10 cm is taken into account for the calculation of the Predicted Environmental Concentrations (PEC).

Tuber treatment:
PECsoil calculations for the active substances are performed for two scenario's:

- $PECsoil_{(PIEC)}$ and PEC_{TWA} are calculated according to the normal PECsoil acute calculation for a homogenous distribution over 10 cm (corresponding to a plant depth of 5 cm).
- $PECsphere_{(PIEC)}$ calculations according to the PECsphere formula:

$$PECsphere = \frac{1000 * D}{1500 * n * \frac{S}{1000} * 4/3*pi*((0.05+r)^3 - r^3)}$$

Where
D = dose (g/ha)
S = seeds per ton
n = sowing density (kg/ha)
r = radius of 1 seed (m)

Please refer to the PECsphere sheet in the PECsoil spreadsheet available at the Ctgb website: http://ctgb.nl/gewasbescherming/toetsingskader/handleidingen/methodieken.

Please note that PEC_{TWA} values for the parent, and PIEC and PEC_{TWA} values for metabolites can

be calculated according to the normal PECsoil acute calculation for a homogenous distribution over 10 cm

In furrow treatment:
Calculate PECsoil $_{(PIEC)}$ and PEC_{TWA} in line with the normal PECsoil acute calculation for a homogenous distribution over 10 cm.

PECsoil and PECplateau
Please refer to 1.3.3

1.3.6. PEC calculations in case of indoor 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 of spreading the champost to soil is deemed relevant.

Below a methodology is described to achieve modified input dose rates for input in PECsoil spreadsheets (correction of dose rate/ha indoor to dose rate/ha outdoor).

Assumptions

- ✓ Default agricultural soil weight and soil density (1500 kg/m3) has been used for PECs calculations, as the relative contribution of mushroom compost (with different soil weight and soil density (550 kg/m3 according to Kennisakker.nl)) to the soil layer is very limited (based on the assumption of 11111 kg spent mushroom compost (champost) applied per hectare of agricultural soil; this value was calculated via the phosphate threshold of 50 kg P2O5/ha (2015-2017) and a concentration of 0.45% P2O5 in spent mushroom compost (Source: Productschap Akkerbouw)).
- ✓ The concentration of a.s. in champost is calculated using values for production settings. Mushroom compost, as used in production facilities, has a minimum of 85 kg/m2 and is on average of 90 kg/m2 (efficacy expert judgement).

Calculation

- ✓ Dose rate in production facility [x] kg(a.s.)/ha * [n] applications = Total quantity active substance used at production facility (kg / hectare) [A]
- ✓ [A] / [Minimum weight champost/ hectare] of 850000 (kg/ha) = Total quantity active substance at production facility (kg / kg) champost [B]
- ✓ [B] * [Quantity champost per hectare agricultural soil] of 11111 (kg/ha) = Corrected dose rate applicable for PECs calculations after use of champost as bodemverbeteraar/mest [C]

NB: The above calculated corrected dose, as applied to agricultural soil [C], is distributed over the top 20 cm of the soil in the case of champost. The standard calculations for PIECsoil and $PECsoil_{TWA21d}$ are for the top 5 cm, therefore the application dose for PIECsoil and $PECsoil_{TWA21d}$ needs to be divided by 4.

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant

protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1. Approval of the active substance

Regulation (EC) No 1107/2009 Chapter II provides the procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II of Regulation (EC) No 1107/2009.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011.

1.4.3. Decision making for plant protection products

The principles for decision-making as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011.

1.5. Developments

1. EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. The current methodology considers annual field crops including field crops grown on ridges and permanent crops. A commenting round was held in September 2016. Take note date and entry into force date yet unknown.
2. New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). Until the revision of these guidance documents is finished, the methods as described in 1.3.2 are used for the higher tier persistency risk assessment.
3. Furthermore a new Guidance document on treated seed is currently under development, Draft “Authorization of plant protection products for seed treatment” (SANCO/10553/2012). A new commenting round by the Member States of the document is expected in 2017 (take note date and entry into force date yet unknown).

2. APPENDICES

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

To answer the above question it is important whether the substance comes into contact with the soil, either during or after the application according with good agricultural practice .

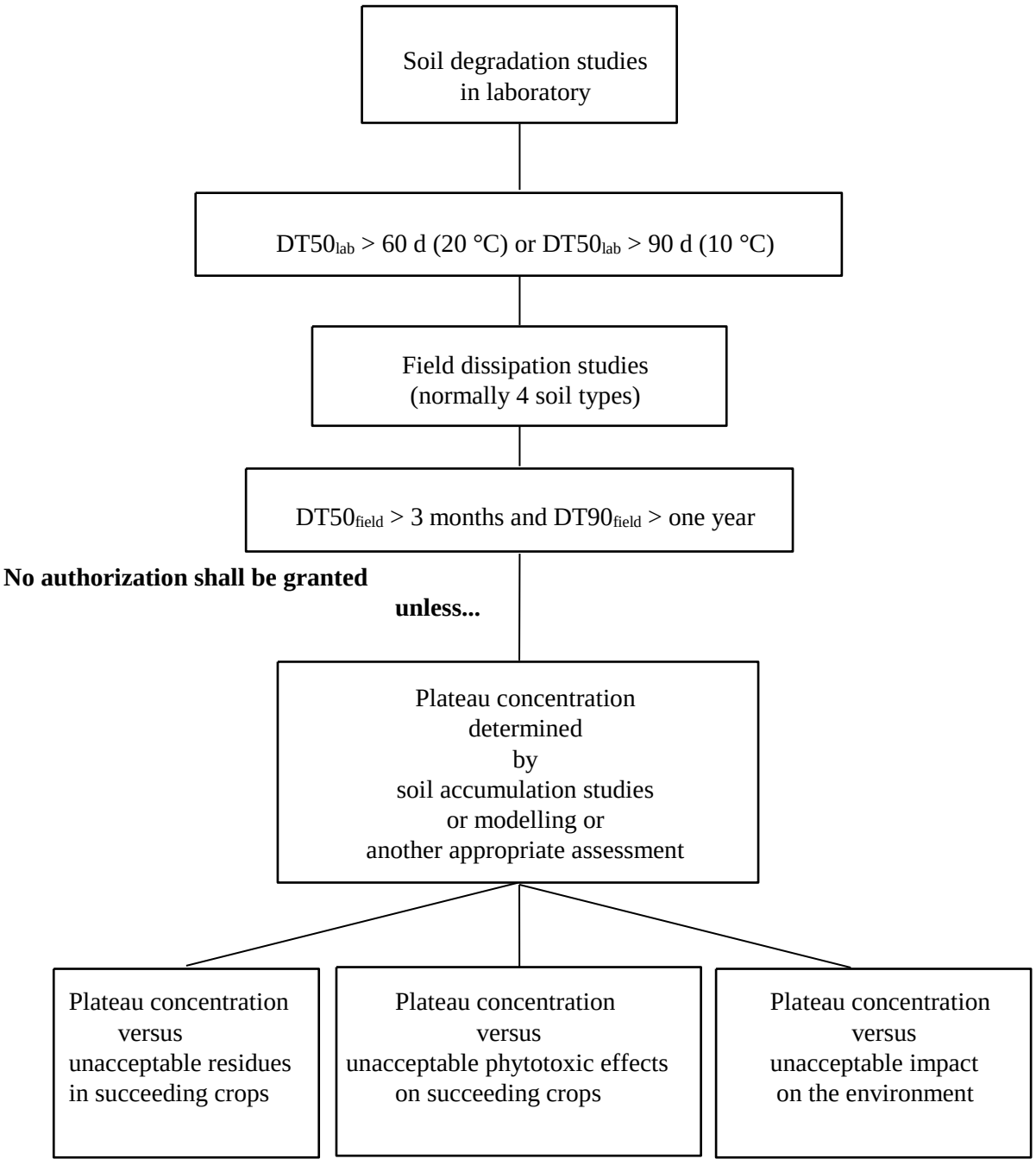
The first criterion is whether the application takes place in the open, or in enclosed spaces (greenhouses (cultures on substrate), barns, bee hives etc., please refer to EFSA GD on protected crops). During applications in enclosed spaces, it is not ruled out *a priori* that the product reaches the soil. This can only be ruled out if the applied water is collected for re-use, or is discharged to a sewage treatment plant in a controlled manner. In the some cases of treatment in enclosed spaces, persistence is relevant.

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

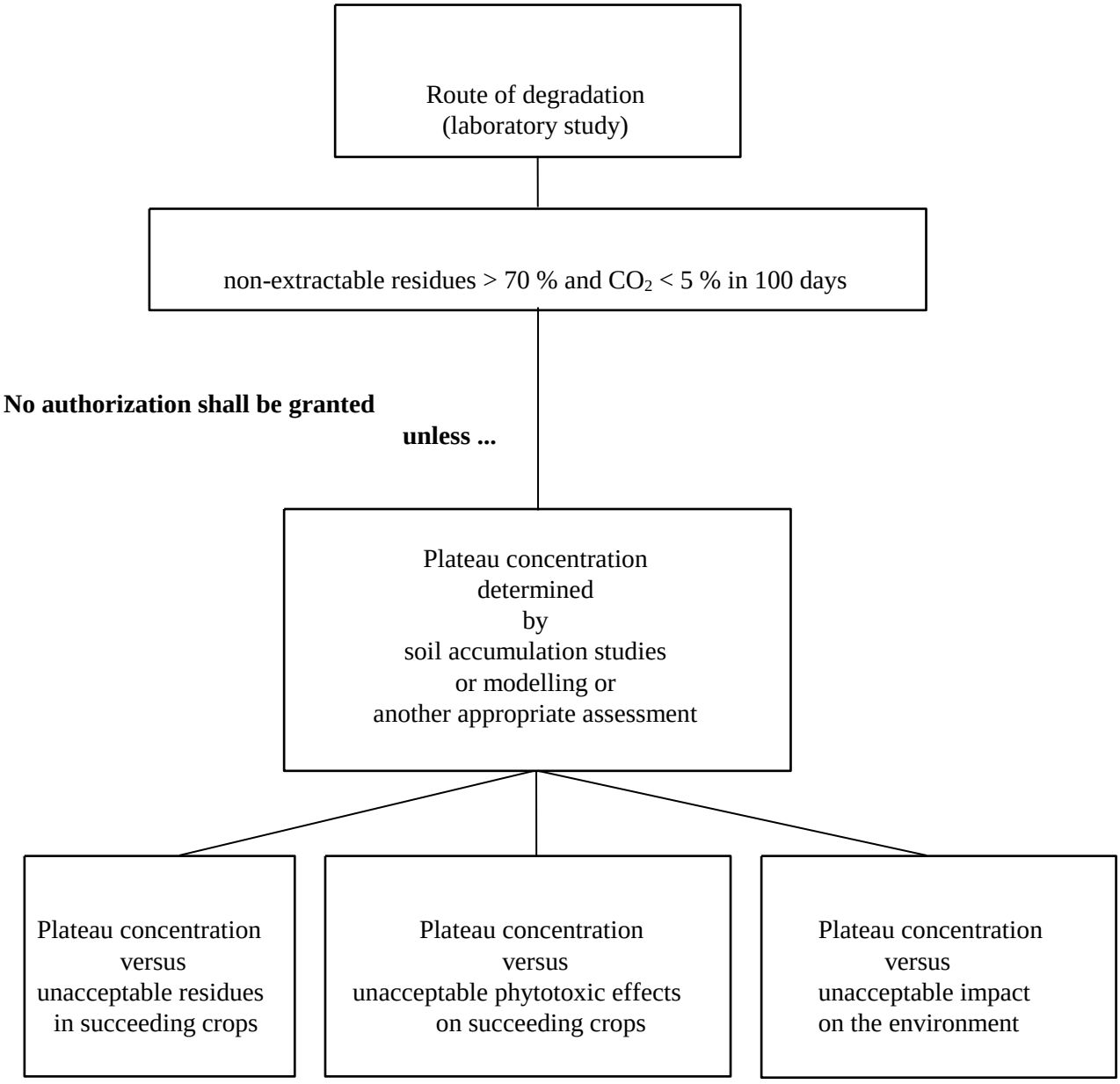
There are uses where the actual use of the plant protection product takes place at a different location than the crop cultivation (seed treatment, treatment of propagation material, tray treatment etc.). In those cases, the situation of the actual crop cultivation should serve as a basis. This means that, in the case of treated seed or other propagation material, it is not ruled out that the substance reaches the soil.

Appendix 2 Desicion tree for persistent sustances (taken from Guidance Document on Persistence)

Decision-making schemeaccording to Regulation 1107/2009 2.5.1.Fate and distribution in the environment 2.5.1.1 Soil (Part I)



Decision-making scheme according to Uniform Principles 2.5.1.Fate and distribution in the environment Soil (Part II)



Appendix 3 Focus interception tables

The following Tables 1.4 and 1.5 from Generic Guidance for Tier 1 FOCUS Groundwater Assessments are used for determination of the fraction intercepted by the crop (f_{int}).

Tables 1.4 and 1.5 give interception data for separate growth stages of different crops. Note that the interception data in Tables 1.4 and 1.5 are only valid for applications made directly to the crop. Examples where these data do not apply include herbicide applications made beneath orchard crops and vines, and direct application on bare soil. For such applications zero interception should be assumed.

The updated crop interception values mentioned in Tables 1.4 an 1.5 apply for submissions made from May 1st 2015 and onwards.

Table 1.4 Interception (%) by apples, bushberries, citrus and vines dependent on growth stage.

Crop	**stage**				
	BBCH# 0-9	BBCH# 10-69	BBCH# 71-75	BBCH# 76-89	
Apples	without leaves 50	flowering 60	Early fruit development 65	full canopy 65	
	BBCH# 0-9	BBCH# 10-69	BBCH# 71-75	BBCH# 76-89	
Bushberries	without leaves 40	flowering 60	Flowering 60	full foliage 75	
Citrus	all stages 80				
Vines	BBCH# 0-9	BBCH# 11-13	BBCH# 14-19	BBCH# 53-69	BBCH# 71–89
	without leaves 40	first leaves 50	leaf development 60	flowering 60	ripening 75

The BBCH code is indicative (Meier, 2001)

Table 1.5 Interception (%) by other crops dependent on growth stage.

Crop	Bare – emergence	Leaf development	Stem elongation		Flowering		Senescence Ripening
	BBCH[#]						
	00 - 09	10 - 19	20 – 39		40 - 89		90 - 99
Beans (field + vegetable)	0	25	40		70		80
Cabbage	0	25	40		70		90
Carrots	0	25	60		80		80
Cotton	0	30	60		75		90
Grass[##]	0	40	60		90		90
Linseed	0	30	60		70		90
Maize	0	25	50		75		90
Oil seed rape (summer)	0	40	80		80		90
Oil seed rape (winter)	0	40	80		80		90
Onions	0	10	25		40		60
Peas	0	35	55		85		85
Potatoes	0	15	60		85		50
Soybean	0	35	55		85		65
Spring cereals	0	0	BBCH 20-29	BBCH 30-39	BBCH 40-69	BBCH 70-89	80
			20	80	90	80	
Strawberries	0	30	50		60		60
Sugar beets	0	20	70 (rosette)		90		90
Sunflower	0	20	50		75		90
Tobacco	0	50	70		90		90
Tomatoes	0	50	70		80		50
Winter cereals	0	0	BBCH 20-29*	BBCH 30-39*	BBCH 40-69	BBCH 70-89	80
			20	80	90	80	

The BBCH code is indicative (Meier, 2001).
A value of 90 is used for applications to established turf
* BBCH code of 20-29 for tillering and 30-39 for elongation

Appendix 4 Link between DTG crops and the FOCUS Interception Tables

The following Table can be used to extrapolate interception values for crops from the DTG list that are not listed in the FOCUS Interception Tables (Appendix 4).

Please take note of the fact that this Table is not harmonised within the EU.

x	not relevant for downward directed spraying

DTG crop code	DTG crop	FOCUS crop
1	Arable crops	
1.1	Potatoes	
1.1.1	-	
1.1.1.1	Seed potatoes	Potatoes
1.1.1.2	Ware potatoes	Potatoes
1.1.1.3	Starch potatoes	Potatoes
1.2	Beetroot	
1.2.1	-	
1.2.1.1	Sugar beets	Sugar beets
1.2.1.2	Fodder beets	Sugar beets
1.3	Cereals	
1.3.1	Winter cereals	
1.3.1.1	Winter wheat	Cereals
1.3.1.2	Winter barley	Cereals
1.3.1.3	Winter rye	Cereals
1.3.1.4	Triticale	Cereals
1.3.1.5	Spelt	Cereals
1.3.1.6	Canary grass	Cereals
1.3.2	Spring cereals	
1.3.2.1	Spring wheat	Cereals
1.3.2.2	Spring barley	Cereals
1.3.2.3	Spring rye	Cereals
1.3.2.4	Oats	Cereals
1.3.2.5	Teff	Cereals
1.3.3	Other cereals	
1.4	Maize	
1.4.1	-	
1.4.1.1	Silage maize	Maize
1.4.1.2	Seed maize	Maize
1.4.1.3	Corn cob mix	Maize
1.4.1.4	Corn cob silage	Maize
1.5	Pulses	
1.5.1	Dry-harvested peas	
1.5.1.1	Marrowfat peas	Peas
1.5.1.2	Yellow peas	Peas
1.5.1.3	Grey peas	Peas
1.5.1.4	Green peas	Peas
1.5.1.5	Lentils	Peas
1.5.1.6	Maple peas	Peas
1.5.1.7	Brown marrowfat	Peas
1.5.1.8	Sugar snaps	Peas

1.5.1.9	Chickpeas	Peas
1.5.2	Dry-harvested beans	
1.5.2.1	Brown bean	Beans (field+vegetable)
1.5.2.2	Yellow bean	Beans (field+vegetable)
1.5.2.3	Pinto bean	Beans (field+vegetable)
1.5.2.4	White bean (haricot)	Beans (field+vegetable)
1.5.2.5	Soya bean	Beans (field+vegetable)
1.6	Grass seed crops	
1.6.1	Ryegrass	
1.6.1.1	English ryegrass	Grass
1.6.1.2	Italian ryegrass	Grass
1.6.1.3	French ryegrass	Grass
1.6.1.4	Westerwold ryegrass	Grass
1.6.1.5	Hybrid ryegrass	Grass
1.6.1.6	Other ryegrasses	Grass
1.6.2	Fescue	
1.6.2.1	Red Fescue	Grass
1.6.2.2	Sheep's Fescue	Grass
1.6.2.3	Tall Fescue	Grass
1.6.2.4	Other fescues	Grass
1.6.3	Bluegrass	
1.6.3.1	Kentucky bluegrass	Grass
1.6.3.2	Fowl bluegrass	Grass
1.6.3.3	Wood bluegrass	Grass
1.6.3.4	Meadow fescue	Grass
1.6.3.5	Other bluegrasses	Grass
1.6.4	Other grasses	
1.6.4.1	Timothy-grass	Grass
1.6.4.2	Cock's-foot	Grass
1.6.4.3	Colonial bent	Grass
1.6.4.4	Crested dog's-tail	Grass
1.6.4.5	Tufted hair-grass	Grass
1.6.4.6	Junegrass	Grass
1.6.4.7	Other grass seed crops	Grass
1.7	Oil-bearing seeds	
1.7.1	-	
1.7.1.1	Poppy seed	Linseed
1.7.1.2	Caraway	Linseed
1.7.1.3	Linseed	Linseed
1.7.1.4	Mustard seed	Oilseed rape
1.7.1.5	Winter Rapeseed	Oilseed rape
1.7.1.6	Summer Rapeseed	Oilseed rape
1.7.1.7	Evening primrose	Linseed
1.7.1.8	Sunflower	Sunflower
1.7.1.9	Camelina	Linseed
1.7.1.10	Crambe	Linseed
1.7.1.11	Other oil-bearing seeds	Linseed
1.8	Fibre crops	
1.8.1	-	
1.8.1.1	Hemp	Sunflower
1.8.1.2	Flaxseed	Linseed
1.8.1.3	Nettle	Sunflower
1.8.1.4	Other fibre crops	Sunflower

1.9	Green fertiliser crops	
1.9.1	Leguminous green fertilisers	
1.9.1.1	Clover	Linseed
1.9.1.2	Lupin	Linseed
1.9.1.3	Serradella	Linseed
1.9.1.4	Common vetch	Linseed
1.9.1.5	Sanfoin	Linseed
1.9.1.6	Field beans	Beans (field+vegetable)
1.9.1.7	Other leguminous green fertilisers	Beans (field+vegetable)
1.9.2	Grass family green fertilisers	
1.9.2.1	Rye	Grass
1.9.2.2	Ryegrass	Grass
1.9.3	Brassicaceae green fertilisers	Oilseed rape
1.9.3.1	Oil radish	Oilseed rape
1.9.3.2	Rapeseed	Oilseed rape
1.9.3.3	Yellow mustard seed	Oilseed rape
1.9.3.4	Rape kale	Oilseed rape
1.9.3.5	Marrow-stem kale	Oilseed rape
1.9.4	Other green fertilisers	
1.9.4.1	Phacelia	Grass
1.9.4.2	Corn spurrey	Grass
1.9.4.3	Marigold (Tagetes)	Grass
1.9.4.4	Sticky nightshade	Grass
1.9.4.5	Sudan grass	Grass
1.10	Fodder crops	
1.10.1	Leguminous fodder crops	
1.10.1.1	Clover	Linseed
1.10.1.2	Alfalfa	Linseed
1.10.1.3	Common vetch	Linseed
1.10.1.4	Sanfoin	Linseed
1.10.1.5	Field beans (for silaging)	Beans (field+vegetable)
1.10.1.6	Field mustard	Sugar beets
1.10.2	Other fodder crops.	Sugar beets
1.11	Other arable crops	Sugar beets
1.11.1	-	
1.11.1.1	Chicory (roots)	Sugar beets
1.11.1.2	Wild chicory	Sugar beets
1.11.1.3	Buckwheat	Cereals
1.11.1.4	Hops	X
1.11.1.5	Common madder	Sugar beets
1.11.1.6	Elephant grass	Grass
2	Cultivated grassland	
2.1	Fodder grassland	
2.1.1	-	
2.1.1.1	Pastureland	x
2.1.1.2	Mowing grassland	x
2.2	Grass sod	x
3	Fruit crops Only refers to production of unharvested fruits	
3.1	Large fruits	
3.1.1	Pomes	x
3.1.1.1	Apples	x
3.1.1.2	Pears	x

3.1.1.3	Quince	x
3.1.1.4	Medlar	x
3.1.1.5	Other pomes	x
3.1.2	Drupes	
3.1.2.1	Cherries	x
3.1.2.2	Plum	x
3.1.2.3	Apricot	x
3.1.2.4	Peach	x
3.1.2.5	Other drupes	x
3.2	Small fruits	
3.2.1	Strawberries	Strawberries
3.2.2	Berries	
3.2.2.1	Currant (red, white and black)	X
3.2.2.2	Gooseberry	X
3.2.2.3	Blueberry	X
3.2.2.4	Cranberry	Strawberries
3.2.2.5	Mulberry	X
3.2.2.6	Rose hips	X
3.2.2.7	Kiwiberry	X
3.2.2.8	Elderberry, Chokeberry, Sea-buckthorn	X
3.2.2.9	Other berries	X
3.2.3	Grapes	X
3.2.3.1	Table grape	X
3.2.3.2	Wine grape	X
3.2.4	‘Blackberry and raspberry family (Rubus spp.)’	X
3.2.4.1	Blackberry	X
3.2.4.2	Raspberry	X
3.2.4.3	Dewberries	X
3.3	Nuts	X
3.3.1	-	-
3.3.1.1	Hazelnut	X
3.3.1.2	Chestnut	X
3.3.1.3	Walnut	X
3.4	Other fruits	X
3.4.1	-	
3.4.1.1	Fig	X
3.4.1.2	Kiwi	X
4	Vegetable crops	
4.1	Leafy vegetables	
4.1.1	Lettuce; *Lactuca* spp	Beans (field+vegetable)
4.1.2	Endive	Beans (field+vegetable)
4.1.3	Spinach family	
4.1.3.1	Spinach	Beans (field+vegetable)
4.1.3.2	Chard	Sugar beets
4.1.3.3	Orache	Beans (field+vegetable)
4.1.3.4	Purslane	Beans (field+vegetable)
4.1.4	Other leafy vegetables	
4.1.4.1	Chicory	Sugar beets
4.1.4.2	Garden cress	Beans (field+vegetable)
4.1.4.3	Watercress	Beans (field+vegetable)
4.1.4.4	Lamb's lettuce	Beans (field+vegetable)
4.1.4.5	Rocket	Beans (field+vegetable)

4.1.4.6	Sea lavender	Beans (field+vegetable)
4.2	Pulses	
4.2.1	Bean with pod	
4.2.1.1	Bush green beans	Beans (field+vegetable)
4.2.1.2	Bush common bean	Beans (field+vegetable)
4.2.1.3	Waxpod bean	Beans (field+vegetable)
4.2.1.4	Climbing green beans	Beans (field+vegetable)
4.2.1.5	Climbing common bean	Beans (field+vegetable)
4.2.1.6	Snap bean	Beans (field+vegetable)
4.2.1.7	Runner bean	Beans (field+vegetable)
4.2.1.8	Yardlong bean	Beans (field+vegetable)
4.2.2	Podless beans	
4.2.2.1	Broad bean	Beans (field+vegetable)
4.2.2.2	Lima bean	Beans (field+vegetable)
4.2.2.3	Flageolet bean	Beans (field+vegetable)
4.2.3	Pea with pod	
4.2.3.1	Legume/pod	Peas
4.2.3.2	Asparagus pea	Peas
4.2.3.3	Sugar snap	Peas
4.2.4	Pea without pod	
4.2.4.1	Green pea/garden pea	Peas
4.2.4.2	Marrowfat pea	Peas
4.2.5	Vegetable sprouts	
4.2.5.1	Bean sprouts	x
4.2.5.2	Alfalfa	x
4.2.5.3	Other vegetable sprouts	x
4.3	Fruiting vegetables	-
4.3.1	Fruiting vegetables of *Cucurbitaceae* with, edible skin	-
4.3.1.1	Gherkin	potatoes
4.3.1.2	Courgette	potatoes
4.3.1.3	Cucumbers	x
4.3.2	Fruiting vegetables of *Cucurbitaceae* with, non-edible skin	-
4.3.2.1	Pumpkin family	potatoes
4.3.2.2	Melon	x
4.3.2.3	Watermelon	x
4.3.3	Fruiting vegetables of *Solanaceae*	
4.3.3.1	Aubergines	x
4.3.3.2	Tomato	x
4.3.3.3	Sweet pepper	x
4.3.4	Fruiting vegetables of *Malvaceae*	
4.3.4.1	Okra	x
4.4	Cabbages	
4.4.1	Heading cabbages	
4.4.1.1	Heading cabbage	Cabbage
4.4.1.2	Sprouts	Cabbage
4.4.2	Cauliflower family	
4.4.2.1	Cauliflower	Cabbage
4.4.2.2	Broccoli	Cabbage
4.4.3	Loose leaf cabbage family	
4.4.3.1	Chinese cabbage	Cabbage
4.4.3.2	Kale	Cabbage

4.4.4	Stalk cabbage	
4.4.4.1	Kohlrabi	Cabbage
4.5	Root vegetables and tubers	
4.5.1	Radish family	
4.5.1.1	Cultivated radish	Sugar beets
4.5.1.2	Black/white radish	Sugar beets
4.5.2	Root vegetables (Umbelliferae)	
4.5.2.1	Carrots	Carrots
4.5.2.2	Skirret	Carrots
4.5.2.3	Hamburg root parsley	Carrots
4.5.2.4	Parsnips	Carrots
4.5.3	Other root vegetables and tubers	
4.5.3.1	Turnip	Sugar beets
4.5.3.2	Swede	Sugar beets
4.5.3.3	Jerusalem artichoke	Sugar beets
4.5.3.4	Chinese artichoke	Sugar beets
4.5.3.5	Sweet potato	Sugar beets
4.5.3.6	Beetroot	Sugar beets
4.5.3.7	Celeriac	Sugar beets
4.5.3.8	Salsify	Sugar beets
4.5.3.9	Horseradish	Sugar beets
4.5.3.10	Yam	Sugar beets
4.6	Onion family	
4.6.1.	Onions	
4.6.1.1	Seed onions	Onions
4.6.1.2	First year bulb onion	Onions
4.6.1.3	Second year bulb onion	Onions
4.6.1.4	Silverskin	Onions
4.6.1.5	Picklers	Onions
4.6.2	Shallots	
4.6.2.1	Seed shallot	Onions
4.6.2.2	Bulb shallot	Onions
4.6.3.1	Scallion	Onions
4.6.4	Garlic	Onions
4.7	Stalk vegetables	
4.7.1	-	
4.7.1.1	Asparagus	Beans (field+vegetable)
4.7.1.2	Stalk celery	Beans (field+vegetable)
4.7.1.3	Cardoon	Beans (field+vegetable)
4.7.1.4	Rhubarb	Beans (field+vegetable)
4.7.1.5	Florence fennel	Sugar beets
4.7.1.6	Leek	Beans (field+vegetable)
4.7.1.7	Artichoke	Beans (field+vegetable)
4.7.1.8	Sea kale	Beans (field+vegetable)
4.8	Other vegetable crops	
4.8.1	-	
4.8.1.1	Sweet corn	Maize
5	Herb crops (fresh and dried herbs) Herb crops (fresh and dried herbs)	Beans (field+vegetable)
5.1	Aromatic herbs	
5.1.1	-	
5.1.1.1	Basil	Beans (field+vegetable)

5.1.1.2	Chives	Beans (field+vegetable)
5.1.1.3	Savoury	Beans (field+vegetable)
5.1.1.4	Lemon balm	Beans (field+vegetable)
5.1.1.5	Dill	Beans (field+vegetable)
5.1.1.6	Tarragon	Beans (field+vegetable)
5.1.1.7	Hyssop	Beans (field+vegetable)
5.1.1.8	Chervil	Beans (field+vegetable)
5.1.1.9	Coriander	Beans (field+vegetable)
5.1.1.10	Parsley	Beans (field+vegetable)
5.1.1.11	Lovage	Beans (field+vegetable)
5.1.1.12	Marjoram	Beans (field+vegetable)
5.1.1.13	Oregano	Beans (field+vegetable)
5.1.1.14	Mint	Beans (field+vegetable)
5.1.1.15	Burnet	Beans (field+vegetable)
5.1.1.16	Rosemary	Beans (field+vegetable)
5.1.1.17	Sage	Beans (field+vegetable)
5.1.1.18	Thyme	Beans (field+vegetable)
5.1.1.19	Fennel	Beans (field+vegetable)
5.1.1.20	Leaf Celery	Beans (field+vegetable)
5.1.1.21	Sorrel	Beans (field+vegetable)
5.1.1.22	Other aromatic garden herbs	Beans (field+vegetable)
5.2	Aromatic root crops	
5.2.1	-	
5.2.1.1	Lovage root	Beans (field+vegetable)
5.2.1.2	Angelica	Beans (field+vegetable)
5.2.1.3	Burnet Saxifrage root	Beans (field+vegetable)
5.2.1.4	Hamburg root parsley	Beans (field+vegetable)
5.2.1.5	Other aromatic root crops	Beans (field+vegetable)
5.3	Medicinal herbs	
5.3.1	-	
5.3.1.1	Indian tobacco	Beans (field+vegetable)
5.3.1.2	Woolly foxglove	Beans (field+vegetable)
5.3.1.3	Heartsease	Beans (field+vegetable)
5.3.1.4	German chamomile	Beans (field+vegetable)
5.3.1.5	Purple coneflower	Beans (field+vegetable)
5.3.1.6	Pot marigold	Beans (field+vegetable)
5.3.1.7	Other medicinal herbs	Beans (field+vegetable)
5.4	Medicinal root crops	
5.4.1	-	
5.4.1.1	Valerian	Beans (field+vegetable)
5.4.1.2	Ginseng	Beans (field+vegetable)
5.4.1.3	Purple coneflower root	Beans (field+vegetable)
5.4.1.4	Other medicinal root crops	Beans (field+vegetable)
5.5	Seed herbs	
5.5.1	-	
5.5.1.1	Caraway	Oilseed rape
5.5.1.2	Poppy seed	Oilseed rape

5.5.1.3	Other seed herbs	Oilseed rape
6	Mushroom crops	
6.1	Edible mushrooms	
6.1.1	-	
6.1.1.1	Champignon mushroom	x
6.1.1.2	Oyster mushroom	x
6.1.1.3	Other mushrooms	x
7	Ornamental crops	
7.1	Flower bulb and Flower corm crops	
7.1.1	-	
7.1.1.1	Winter Flower bulbs and Flower corms cultivation for reproduction	Onions
7.1.1.2	Summer Flower bulbs and Flower corms cultivation for reproduction	Onions
7.1.1.3	Winter Bulb flower and Corm flower forced cultivation	Onions
7.1.1.4	Summer Bulb flower and Corm flower forced cultivation	Onions
7.2	Floriculture crops	
7.2.1	-	
7.2.1.1	Pot plants	Beans (field+vegetable)
7.2.1.2	Cut flowers	Beans (field+vegetable)
7.2.1.3	Forced shrubs	Beans (field+vegetable)
7.2.1.4	Cut green	Beans (field+vegetable)
7.3	Tree nursery crops	
7.3.1	-	
7.3.1.1	Spindle trees	x
7.3.1.2	Transplanted trees	x
7.3.1.3	High Avenue trees	x
7.3.1.4	Climbing plants	Cabbage
7.3.1.5	Roses	Cabbage
7.3.1.6	Conifers	Cabbage
7.3.1.7	Ornamental shrubs	Cabbage
7.3.1.8	Christmas trees	Cabbage
7.3.1.9	Heather	Cabbage
7.3.1.10	Forest trees and hedging plants	Cabbage
7.3.1.11	Fruit trees and shrubs	Cabbage
7.4	Perennial crops	Potatoes
7.5	Flower seed crops	Potatoes
7.6	Marsh and Water plants	x
7.7	Plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops.	x
8	Public green spaces	
8.1	Grass vegetation	
8.1.1	-	
8.1.1.1	Lawn (including grass sods)	x
8.1.1.2	Playing field (including grass sods)	x
8.1.1.3	Sports field including golf courses and grass sods	x

8.1.1.4	Grassy verges	x
8.2	Woody plantings	
8.2.1	-	
8.2.1.1	Avenue and border trees	x
8.2.1.2	Shelter belts, windbreaks and protective hedgerows	x
8.2.1.3	Other woody plantings (forest trees and verge plantings)	x
8.2.1.4	Grassy verges	x
8.3	Herbaceous plantings	x
9	Forestry	
9.1	Deciduous trees	x
9.2	Coniferous trees	x
10	Uncultivated land	
10.1	Temporarily uncultivated terrain	
10.1.1	-	
10.1.1.1	Deforestation area	x
10.1.1.2	Temporarily uncultivated land	x
10.1.1.3	Buffer areas of fields	x
10.2	Permanently uncultivated land	
10.2.1	-	
10.2.1.1	Closed surfaces	x
10.2.1.2	Half-open surfaces	x
10.2.1.3	Open surfaces	x
10.2.1.4	Unmetalled	x
11	Water courses	
11.1	Bank (dry or otherwise)	x
11.2	Dry ditches	x
11.3	Water courses carrying water	x
11.4	Maintenance paths for water courses	x
11.5	Ponds	x
12	Reed and osier crops	
12.1	-	
12.1.1	-	
12.1.1.1	Osier	x
12.1.1.2	Reed	x
13	Refuse heaps	x
14	In and around the house, private home environment	
14.1	Ornamental garden	x
14.2	Vegetable gardens	x
14.3	House plants and container plants	x
14.4	Container plants	x
14.5	Lawns and pastures	x
14.6	Pastures	x
14.7	Open surfaces	x
14.8	Half-open surfaces	x
14.9	Closed surfaces	x
14.10	Unmettaled terrain	x
15	Disinfectants	
15.1	-	
15.1.1	-	

15.1.1.1	Agricultural and horticultural equipment, tools and materials	x

Jan van de Zande & Mechteld ter Horst, in prep., PRI report 420, Wageningen, The Netherlands

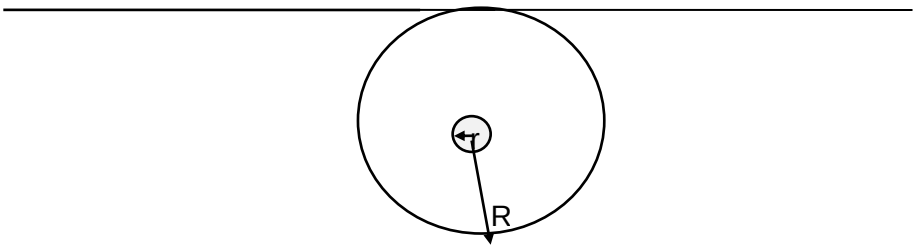
Appendix 5 Calculation $PIEC_{s,sphere}$ seed dressings and some NL exceptions

Summary
A method for calculating the PIEC of seed dressings is proposed in this note. Drilling/planting of larger treated seeds at ≥ 5 cm depth, e.g., pilled beet seed, maize, potatoes or bulbs is assumed to have large influence on local exposure concentration in soil. A *homogeneous distribution* of the active substance in spherical spheres of influence around a seed is assumed for the calculation. Analogous to the distribution depth for a spray formulation it is assumed that the radius of the *sphere of influence is 5 cm*. The sphere of influence has the form of a full spheroid. For both scenarios a maximum volume of 500 m^3 is assumed.

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

The proposed calculation method for seed dressings of seeds with a diameter > 0.5 cm sown at 5 cm or larger depth is presented below (figure 1).

Figure 1. Sphere of influence of seeds > 0.5 cm sown at 5 cm depth.



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

Scenario
The sphere of influence of seeds with a diameter > 0.5 cm sown at 5 cm depth or deeper has the shape of a full **spheroid** (see figure 2). Because the size of the seed is not

negligible, the volume of the seed must be deducted from the volume of the spheroid. The model parameters are described in Table 1.

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

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

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

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

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

$$R = r + 0.05 \qquad -7-$$

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

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

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

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

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

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

Table 1. Description of the parameters.

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

Conclusions

The calculation of $PIEC_s$ via sphere of influence does in a three-dimensional way take into account which soil is/is not burdened with the active substance. The proposed method is based on the same starting points as those for the evaluation of spray formulations. Comparison with the classical method (homogeneous distribution over 5 cm soil) highlights that there are equal outcomes at high seed densities but that the PIEC values are higher for low seed densities.

$PEC_{s,sphere}$ for potatoes

A product applied as tuber treatment can be dosed indoor or outdoor (attached to the sowing machine). Therefore, the spherical distribution model (see above) applies for this assessment. For potatoes, the PIEC (mg/kg) for a tuber treatment is calculated as:

$$\text{PECsphere soil initial} = \frac{\text{mg active substance/kg seed potato} \times \text{kg seed potato/ha}}{\text{volume sum of sphere of influence per hectare } (m^3)}$$

The following default values are used in these calculations:

parameter	value for seed potatoes planted to produce seed potatoes	value for seed potatoes planted to produce ware/starch potatoes
kg seed potato/ha	5200 kg/ha	2700 kg/ha
volume sum of sphere of influence per hectare (m^3)	121 m^3	63 m^3
These values are based on the underlying parameters given below:		
radius tuber	2.5 cm	2.5 cm
density tuber	1.12 kg/l	1.12 kg/l
density soil	1.5 kg/l	

The default value for the radius of a potato tuber is a conservative value based on the 4 – 6 cm size class (diameter) for seed potatoes.

The default value for the density of potato tubers is based on Commission Regulation (EC) No 1949/95 of 7 August 1995, laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards the minimum price and compensatory payment to be paid to potato producers. The underwater weight of 5050 grams of potatoes given in this regulation ranges from 352 to 545 gram. This translates to densities of 1.07 to 1.12 kg/l potatoes.

$PEC_{s,\ sphere}$ for potatoes can also be calculated using the Ctgb PECsoil sheet available on the Ctgb website ('Excel rekensheet PECsoil').

Interception usage for grassland

If the proposed label does not explicitly exclude the application on first year grass, than two scenarios should be assessed: one scenario for first year grassland, where an interception value is used as presented in the table above for grass corresponding to the BBCH code specified in the GAP; one scenario for established grass using an interception value of 90%.