GUIDANCE OF EFSA

EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil[1]

European Food Safety Authority[2,3]

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ABSTRACT

This EFSA guidance document provides guidance for the exposure assessment of soil organisms to plant protection products (PPPs) and their transformation products in accordance with Regulation (EC) No 1107/2009[4] of the European Parliament and the Council. This guidance was produced by EFSA in response to a question posed by the European Commission according to Article 31 of Regulation (EC) No 178/2002[5] of the European Parliament and of the Council. Guidance is provided for all types of concentrations that are potentially needed for assessing ecotoxicological effects, i.e. the concentration in total soil and the concentration in pore water, both averaged over various depths and time windows. The current guidance considers both permanent crops and annual field crops. The recommended exposure assessment procedure consists of four tiers. To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools have been developed. In higher tiers of the exposure assessment, crop interception and subsequent dissipation at the crop canopy may be included. The models that simulate these processes were harmonised. In addition, an easy-to-use table for the fraction of the dose reaching the soil has been developed, which should be used in combination with the simple analytical model. With respect to substance-specific model inputs, this guidance generally follows earlier documents; however, new guidance is included for some specific substance parameters.

KEY WORDS

exposure assessment, soil organisms, exposure scenarios, tiered approaches, guidance, crop interception, fraction reaching soil

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[4] EC (European Commission), 2009. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309/1, 24.11.2009, p. 1-50.

5 EC (European Commission), 2002. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-22

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SUMMARY

This European Food Safety Authority (EFSA) guidance document provides guidance for the exposure assessment of soil organisms to plant protection products (PPPs) and their transformation products in accordance with Regulation EC No 1107/2009 of the European Parliament and the Council.[6] This guidance was produced by EFSA in response to a question posed by the European Commission according to Art. 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.[7] The recommended methodology was developed for the assessment of active substances and metabolites in the context of approval at the European Union (EU) level, and it is expected to be used for the assessment of products at the zonal level as well. This guidance document, together with the EFSA Guidance Document on how to obtain *DegT50* values (EFSA, 2014a) and the Forum for Co-ordination of Pesticide Fate Models and their Use (FOCUS) Degradation kinetics report (FOCUS, 2006), is intended to replace the current Directorate-General for Health and Consumer Affairs (DG SANCO) Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000) (EC, 2000).

The draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil was subject to public consultation from 10 July 2014 to 4 September 2014. A technical report has been produced containing the stakeholder comments received during the public consultation and how these comments have been taken into account (EFSA, 2015a).

This guidance document is based on the EFSA opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of PPPs in soil (EFSA PPR Panel, 2012a). The goal is to assess the 90th percentile concentration considering all agricultural fields within a regulatory zone (North–Central–South) where a PPP is intended to be used. The guidance considers all types of concentrations that are potentially needed for assessing the ecotoxicological effects, i.e. the concentration in total soil (mg kg^{-1}) and the concentration in pore water (mg l^{-1}), both averaged over various depths and time windows. The guidance also describes how to use older soil ecotoxicological studies in which exposure is expressed in terms of the applied rate (in kg ha^{-1}). The current methodology considers annual field crops including field crops grown on ridges and permanent crops.

The recommended exposure assessment procedure consists of four tiers. To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools have been developed for the first three tiers. This includes the new software tool PERSAM (Persistence in Soil Analytical Model) and new versions of the pesticide fate models PEARL (Pesticide Emission At Regional and Local Scales) and PELMO (Pesticide Leaching Model). The software tools generate reports that can be submitted for regulatory purposes. Users of this guidance are advised to use these software tools when performing the exposure assessment. Models other than PEARL or PELMO are currently not supported unless the process descriptions in such numerical models have a similar or higher level of detail than those in PELMO and PEARL (EFSA PPR Panel, 2012a). Furthermore, it should be demonstrated that the models give similar results to PEARL and PELMO. This is necessary to guarantee consistency of the tiered approach. If a numerical model is to be used, applicants and rapporteurs are advised to report simulations with at least two numerical models (e.g. PEARL and PELMO) and provide the highest Predicted Environmental Concentration (PEC) for regulatory submissions (this procedure is in line with EC (2014)).

[6] EC (European Commission), 2009. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309/1, 24.11.2009, p. 1–50.

[7] EC (European Commission), 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–22.

This guidance has changed the tiered assessment scheme given in EFSA PPR Panel (2012a) with the goal of simplifying the exposure assessment for regulatory purposes. The exposure assessment starts with simulations for one predefined scenario per regulatory zone, North–Central–South. At this tier, simulations are carried out with the simple analytical model PERSAM. PERSAM has the advantage that the required number of inputs is very limited and thus the documentation also requires little effort.

Based on discussions with stakeholders, it was a boundary condition that the exposure assessment can be applied by taking median or average substance properties from the dossiers. Such substance properties are uncertain and inclusion of this uncertainty leads to probability density distributions that show greater spread. As a consequence, this boundary condition led to the need to base the exposure assessment procedure on the spatial 95th percentile concentration instead of the spatial 90th percentile concentration.

Two sets of predefined scenarios have been developed, i.e. one set for annual field crops and one set for permanent crops. The predefined scenarios for annual crops in Tier-1are based on the total area of annual crops in a regulatory zone and the predefined scenarios for permanent crops are based on the total area of permanent crops. However, the exposure assessment goal is based on the agricultural area where a PPP is intended to be used. The applicant may therefore wish to perform an exposure assessment for a particular crop. For this purpose, Tier-2 is provided. At this tier, a spatially distributed version of PERSAM is used and the target percentile is directly calculated from the concentration distribution within the area of a given crop. Should the assessment at Tier-2 still indicate an unacceptable risk to soil organisms, the applicant has the option to move to Tier-3. Tier-3 is also based on the area of a given crop, but uses numerical models (PEARL and PELMO). Tier-3A requires slightly more effort; however, this tier has the advantage that more realistic modelling approaches are used and therefore this tier will deliver less conservative values. At Tier-3A the same crop-specific and substance-specific scenarios as selected at Tier-2 are used. Tier-1 is based on the assumption that crop interception of the substance does not occur. In all other tiers this can be included. Interception and subsequent dissipation at the crop canopy may be based on simulations with the numerical models. To facilitate harmonisation of the regulatory process, canopy processes in PEARL and PELMO were harmonised. This guidance further introduces a table for the default fraction of the dose reaching the soil surface that was created based on simulations with PEARL and PELMO. This table should be used at Tier-2.

The predefined scenarios used at Tier-1 are based on the 95th spatial percentile considering the total area of annual crops or permanent crops in each regulatory zone. However, the purpose of the exposure assessment is to consider the total area of the crop where the PPP is intended to be applied. Since the 95th spatial percentile of a given crop may be higher, scenario adjustment factors (named crop extrapolation factors in EFSA PPR Panel, 2012a) have been included at Tier-1 to ensure that these tiers are more conservative than Tiers-2, 3A and 3B.

The simple analytical model PERSAM is used in lower tiers. Since it cannot be *a priori* guaranteed that the simple analytical model is more conservative than the more realistic numerical models used in Tiers-3A and 3B, model adjustment factors have been included in all tiers where the analytical model is used. The model adjustment factors proposed in EFSA PPR Panel (2012a) have been reassessed for this guidance document and the number of factors has been reduced to ease their use in the regulatory process.

With respect to substance-specific model inputs, this guidance document generally follows recommendations given in the FOCUS Degradation kinetics report (FOCUS, 2006), the generic guidance for Tier-1 FOCUS groundwater assessments (Anonymous, 2014) and the EFSA Guidance Document on how to obtain *DegT50* values (EFSA, 2014a). New guidance is included for (i) the calculation of the rapidly dissipating fraction at the soil surface, (ii) the sorption coefficient in air-dry soil and (iii) the *DegT50* or K_{om} of substances whose properties depend on soil properties such as pH or clay content.

BACKGROUND AS PROVIDED BY EFSA

During a general consultation of Member States on needs for updating existing guidance documents and developing new ones, a number of EU Member States (MSs) requested a revision of the SANCO Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000). The consultation was conducted through the Standing Committee on the Food Chain and Animal Health.

Based on the Member State responses and the Opinion prepared by the PPR Panel (EFSA PPR Panel, 2012a) the Commission tasked EFSA to prepare a Guidance of EFSA for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil in a letter of 31 July 2012. EFSA accepted this task in a letter to the Commission dated 9 October 2012. The Commission requests this scientific and technical assistance from EFSA according to Article 31 of Regulation (EC) no 178/2002 of the European Parliament and of the Council.

Following public consultations on the Opinion (EFSA PPR Panel, 2012a), Member States and other stakeholders requested "an *easy to use Guidance Document*" to facilitate the use of the proposed guidance and methodology for the evaluation of PPPs according to Regulation (EC) No 1107/2009.

Once this Guidance Document is delivered, the Commission will initiate the process for the formal use of the Guidance Documents within an appropriate time frame for applicants and evaluators. It may be noted that guidance on the circumstance under which each individual exposure estimate should be used is still under development.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA, and in particular the Pesticides Unit, is asked by the Commission (DG SANCO) to draft an EFSA Guidance Document entitled "EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil". The EFSA Guidance Document should respect the science proposed and methodology developed in the adopted PPR opinion mentioned in this document (EFSA PPR Panel, 2012a).

EFSA proposed to the Commission (DG Santé) to include also guidance for permanent crops, crops grown on ridges and annual crops where no tillage is applied into the updated Guidance Document. The Commission also accepted an extension of the deadline for finalisation of the guidance till end of 2017.

EFSA was requested to organise public consultations on the draft Guidance Document, to ensure the full involvement of Member States and other stakeholders. To support the use of the new guidance, EFSA is requested to organise training of Member State experts, applicants and other relevant stakeholders.

CONTEXT OF THE SCIENTIFIC OUTPUT

The purpose is to address the Terms of References as provided by the European Commission.

ASSESSMENT

1. Introduction

1.1. Aim of this guidance document

This document provides guidance for the exposure assessment of soil organisms to plant protection products (PPPs) in the three regulatory zones in accordance with Regulation EC No 1107/2009 of the European Parliament and the Council (Figure 1). The recommended methodology was developed for the assessment of active substances and metabolites in the context of approval at the European Union (EU) level, and it is expected to be used also for the assessment of products at the zonal level.

The draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil was subject to public consultation from 10 July 2014 to 4 September 2014. A technical report has been produced containing the stakeholder comments received during the public consultation and how these comments have been taken into account (EFSA, 2015a).

This guidance document presents a brief overview of the recommended procedure and provides the guidance necessary to enable users to carry out the exposure assessment. A comprehensive description of the methodology and the science behind this methodology can be found in European Food Safety Authority (EFSA) Plant Protection Products and their Residues (PPR) Panel (2010a, d, 2012a, b) and in Beulke et al. (2015). Some further scientific developments have taken place after the publication of these scientific reports with the goal to facilitate and further harmonise the exposure assessment. These scientific developments are described in the appendices to this guidance document.

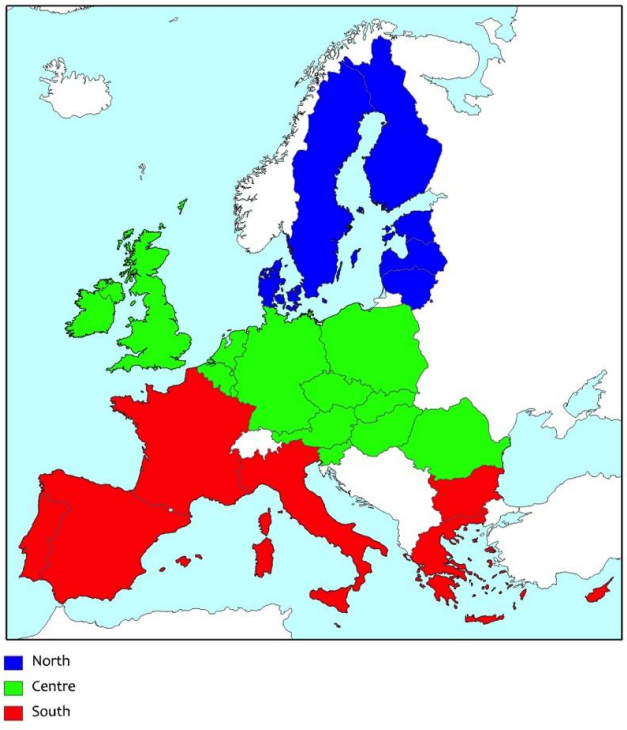

Figure 1: Map of the three regulatory zones according to Regulation EC No 1107/2009 of the European Parliament and the Council.

The recommended procedure consists of four tiers (Chapter 2). The lower tiers are explained in detail. This guidance document will also provide brief guidance on spatially distributed modelling with numerical models and post-registration monitoring. The scenarios in this guidance document were selected using a procedure that works well for both parent substances and soil metabolites and started

with the compilation of a coherent database, which is available for free at the European Soil Data Centre (Panagos et al., 2012).

Until this guidance has been taken note of by the Standing Committee of Plant Animal Food and Feed (SCoPAFF), and a date for implementation has been set, old methods still apply.

1.2. The exposure assessment goal

As described in EFSA PPR Panel (2012a), the methodology is based on the goal to assess the 90th percentile concentration considering all agricultural fields within a regulatory zone (North–Central–South) where the particular PPP is intended to be used. The agricultural area of use is represented by the crop in which the pesticide is intended to be used, e.g. for a pesticide that is to be applied in maize, the area is defined as all fields growing maize in a regulatory zone. By defining the total area as the regulatory zones within the EU, considerably fewer scenarios were distinguished here than in earlier guidance, which used climatic and pedological data to identify scenarios (e.g. Forum for Co-ordination of Pesticide Fate Models and their Use (FOCUS) Groundwater reports of 2000 and 2014, in which nine scenarios were distinguished). This was implemented to keep the regulatory process as simple as possible. In general, exposure estimates for all three zones should be evaluated for review of substances at the EU level. For zonal evaluations of PPPs it would be sufficient to consider only the exposure estimates for the particular zone in question.

The exposure assessment is part of the terrestrial effect assessment. This guidance document therefore considers all types of concentrations that are potentially needed for assessing the ecotoxicological effects. Please note that guidance on the circumstance under which each individual exposure estimate should be used still needs to be developed. EFSA (2009) indicated that the following types of concentrations are needed:

- The concentration in total soil (mg kg^{-1}) averaged over the top 1, 2.5, 5 or 20 cm of soil for various time windows: peak and time-weighted averages (TWAs) for 7–56 days.
- The concentration in pore water (mg l^{-1}) averaged over the top 1, 2.5, 5 or 20 cm of soil for the same time windows.

As indicated in EFSA PPR Panel (2012a), the peak concentration is approximated by the maximum concentration of time series of 20 years (application each year), 40 years (application every 2 years) or 60 years (application every 3 years). The TWA concentrations are calculated for periods over a maximum of 56 days following after the occurrence of the peak concentration.

Older soil ecotoxicological studies sometimes expressed exposure in terms of only the applied rate (in kg ha^{-1}). This guidance document therefore also briefly describes how to express exposure in kg ha^{-1}.

Presently, pore water concentrations are not used in standard risk assessments for soil organisms; however, the pore water concentrations were included in the methodology in case the standard approach would be revised in the future (as recommended by EFSA (2009) and EFSA PPR Panel draft scientific opinion (In preparation)).

Based on discussions with stakeholders, it was a boundary condition that the exposure assessment methodology can be applied by taking median or average substance properties from the dossiers (so no high or low percentile values of substance properties should be used). Such substance properties are uncertain and inclusion of this uncertainty leads to probability density functions that show greater spread. As a consequence, this boundary condition led to the need to base the exposure assessment procedure on the spatial 95th percentile concentration instead of the 90th percentile spatial concentration (see Section 4.2.5 of EFSA PPR Panel (2012a) for details). Together with the 100th percentile in time and the median or average substance properties, the overall goal (90th percentile concentration) is considered to be reached.

1.3. Cropping and applications systems covered by this guidance

The methodology covers a wide range of different cropping and application systems (Figure 2). The exposure assessment for annual crops differs from that for permanent crops because the distribution of organic matter with depth in permanent crops differs from that in annual crops. For this reason, the exposure assessment scheme makes a distinction between annual crops (lef-hand side of Figure 2) and permanent crops right-hand side of Figure 2).

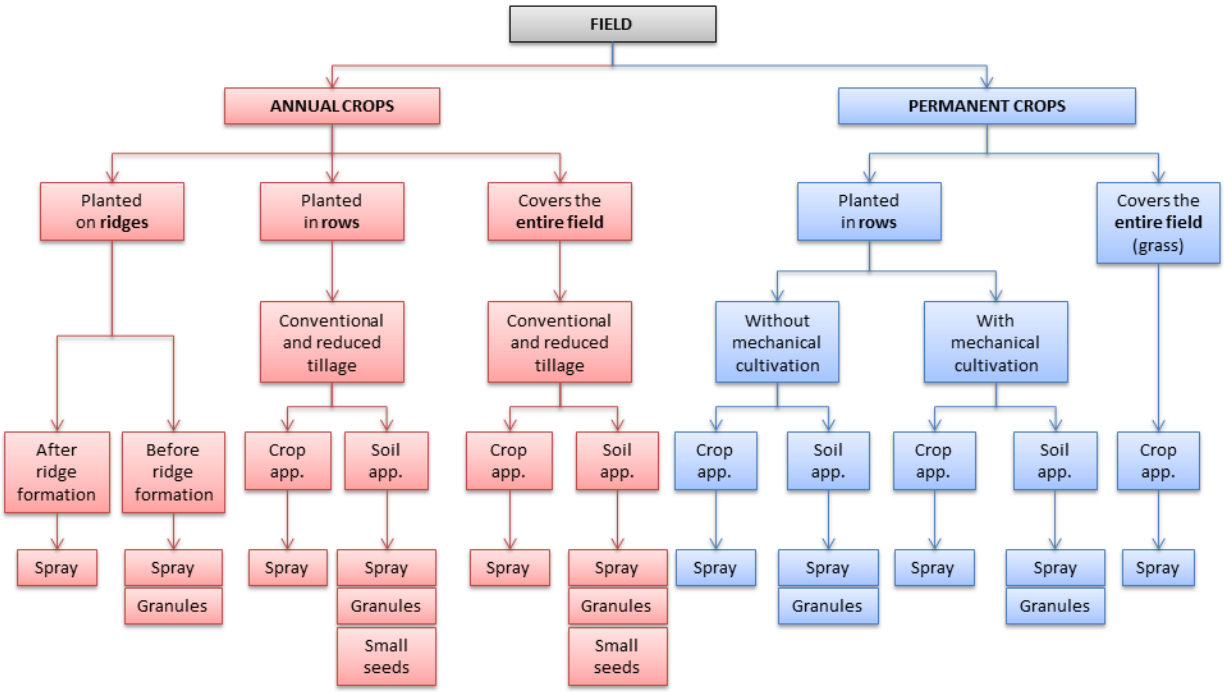

Figure 2: Cropping and application systems covered by this guidance.

The guidance does not cover all cropping and application systems. For uses that are not covered by this guidance, the applicant should describe how the guidance document is implemented and justify its applicability.

Off-crop exposure (e.g. as a result of spray drift deposition or as a result of storage or disposal of growing media used in horticultural production) is not covered by this EFSA guidance because the current methodology does not describe emissons from the treated field and subsequent deposition of the emitted amounts onto the off-field surface. EFSA PPR Panel draft scientific opinion (in prepartion) provides some considerations; however, appropriate off-crop exposure scenarios that apply to a given percentile of the concentration distribution still need to be developed.

1.3.1. Annual crops

The exposure assessment was originally developed for spray applications in annual crops covering the entire field (EFSA PPR Panel, 2010d). However, additional work revealed that with small modifications the methodology can also be used for crops grown in rows (row treatments) and to crops grown on ridges (second row in Figure 2).

It was further proposed to make a distinction between conventional/reduced tillage sytems and no-tillage systems (EFSA PPR Panel, 2010d) because annual ploughing has a large diluting effect on the concentration in the topsoil which does not occur in no-tillage systems. However, the GAP-tables included in regulatory submissions do not include information whether the substance is applied in no-tillage systems. Furthermore, the area of soil with no-tillage is relatively small in many EU-countries. For these reasons, no specific guidance was developed for no-tillage systems (See Section 2.8 for

additional considerations). Until guidance for no-tillage systems is developed, it is recommended to use the guidance for tilled systems for annual crops.

This guidance covers spray applications, applications of granular products (to the soil surface or incorporated) and treated small seeds. Guidance for spray applications is given in Chapter 3. For granules and small seeds the same guidance is to be used; however, the additional considerations in Chapter 4 should be taken into account. This guidance does not cover large treated seeds; please refer to SANCO draft guidance on seed treatment (in preparation) for guidance on large treated seeds.

1.3.2. Permanent crops

Also in the case of permanent crops, a distinction is made between crops grown in rows (e.g. fruit, vines and olives) and crops that cover the entire field (mainly permanent grassland). In permanent crops grown in rows, mechanical cultivation can be carried out in or between the crop rows. Based on Beulke et al. (2015) mechanical cultivation is assumed between the rows in citrus, vines, olives and hops. In olives, mechanical cultivation is also assumed in the crop rows. In all other permanent crop situations, no mechanical cultivation is assumed. Where mechanical cultivation is carried out, the mixing depth is assumed to be 5 cm. The mixing depth of 5 cm is consistent with the depth distribution of organic matter in situations with mechanical mixing (see Section 2.2.2). Notice that the mixing depth in permanent crops is considerably less than the tillage depth in annual crops (20 cm).

In permanent crops grown in rows pesticides can be applied to the crop canopy (air blast applications) or to the soil (ground spray applications, granular applications and incorporation into the soil) (Figure 3). Application to the soil can be in the crop row ("in-row treatment") or between the crop rows ("between-row treatment"). In the case of air-blast applications, exposure of soil organisms will occur both in and between the crop rows. In the case of in-row soil treatments, exposure is considered relevant in-row only and in the case of between-row soil treatments, exposure is considered between the rows only. The same set of predefined scenarios is used for all combinations; however, the calculation procedure differs between the various application types.

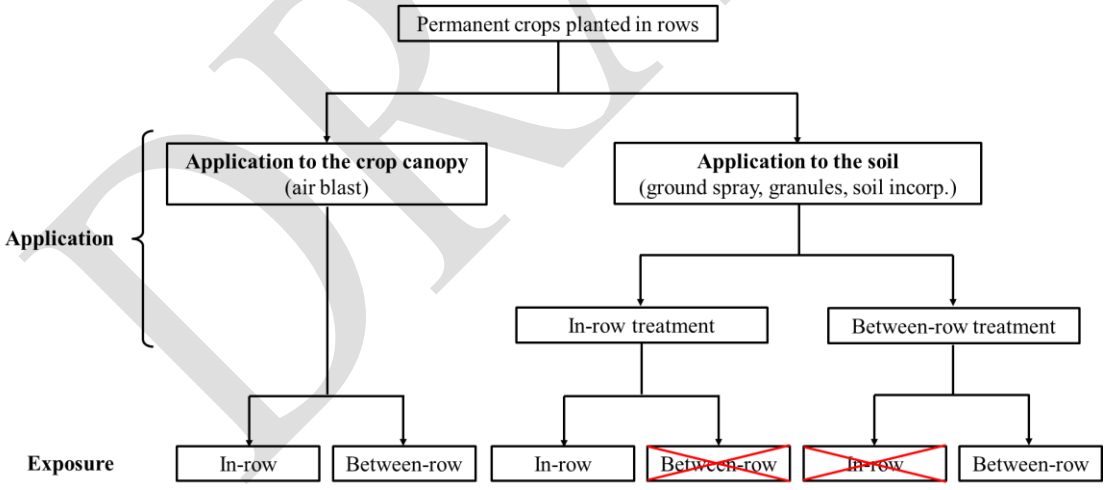

Figure 3: Application systems in permanent crops grown in rows covered by this guidance.

1.3.3. Protected crops

When the uses being assessed includes a crop that can be grown under protection (greenhouses and crops grown under cover) and soil has not been precluded as being a possible growing substrate, soil exposure calculations for these uses have to be calculated following the procedures outlined in this guidance (see section 3.2 of EFSA, 2014b for details). The only exception, is when the applicant specifies that they wish use to be restricted to high technology greenhouses that are permanent structures, the changes to the soil parameters and the soil organism community can be considered such that a risk assessment for soil organisms is not relevant (EFSA, 2014). However, for persistent

substances (DegT90 > 1 year; Uniform principles (Regulation (EU No 546/2011)) an assessment as it is for open field is required with regard to their residues, to account for possible change of destination of the soil within the structure in the longer term (e.g. if the soil is removed and used outside and/or the structure is removed).

1.4. Software tools

To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools have been developed. This includes the software tool PERSAM (Persistence in Soil Analytical Model) (Decorte et al., 2016a (in preparation); based on EFSA, 2015b) and Tiktak et al. (2013) and new versions of the pesticide fate models PEARL (Pesticide Emission At Regional and Local Scales) (Tiktak et al., 2000; Van den Berg et al., 2016) and PELMO (Pesticide Leaching Model) (Klein, 2011) that have been adapted to deliver the appropriate soil exposure concentrations. Applicants are advised to use these software tools when performing the exposure assessment. However, applicants might want to use the analytical model outside the PERSAM software (see the listing of the model in Appendix A). This must be performed in combination with the EFSA spatial dataset (version 1.1) as available at the Joint Research Centre (JRC) website. Applicants should demonstrate that their own software reproduces the same output as PERSAM, e.g. by comparison for the predefined scenarios.

For higher tier assessments, models other than PEARL or PELMO are not currently supported. The reason is that consistency of the tiered approach cannot be guaranteed when using different models. If applicants chose to use another model, other than PEARL or PELMO, they should demonstrate that their model produces the same output (see Section 3.1 for more details). If a numerical model is to be used, applicants and rapporteurs are advised to report simulations with at least two numerical models (e.g. PEARL and PELMO) and provide the highest Predicted Environmental Concentration (PEC) for regulatory submissions (this procedure is in line with EC (2014)).

The currently available version of the PERSAM model is not applicable to permanent crops for all evaluation depths because it assumes mixing of the top 20 cm of the soil before each application and ignores leaching from the evaluation layer. For these two reasons, a new version of PERSAM has been developed, which is described in Appendix A. For consistency reasons, this new version of the analytical model is also be used for annual crops. Notice that the software tools that are currently available are not in line with this guidance document. An update of the tools is, however, foreseen before the guidance will be adopted for use in regulatory submissions.

1.5. Structure of this guidance document

Chapter 2 gives an overview of the tiered approach and highlights some new developments that have taken place since the publication of the scientific opinion (EFSA PPR Panel, 2012a) on which this guidance document is based. Chapter 3 provides practical guidance on how to perform exposure assessments in soil for active substances of PPPs and for the metabolites of these active substances. Chapter 3 is applicable to spray applications in crops covering the entire field. The guidance also applies to crops grown on ridges and crops grown in rows; however, additional guidance in Chapter 4 needs to be considered. Chapter 4 also gives additional guidance for other application types (small seed treatments and granules). Chapter 5 briefly describes documentation requirements. Scientific backgrounds to the new developments, desirable future developments and practical examples are given in the Appendices.

Advice to the reader
This version of the guidance document has been produced for the public consultation. The exposure concentrations in this guidance document have been calculated using preliminary versions of the models. These concentrations can change slightly when the final model versions will be released. Although this is not expected to have a large effect on the final results, readers are advised to use these concentrations in this document with care.

2. Overview of the tiered approach and new developments

This section provides a general overview of the tiered approach and highlights some new developments that have taken place since the publication of the scientific opinion on which this guidance document is based.

2.1. General overview

EFSA PPR Panel (2012a) proposed a tiered assessment scheme for the exposure assessment of soil organisms in annual crops. This guidance has changed the tiered assessment scheme with the goal to simplify the exposure assessment for regulatory purposes. Moreover this guidance extends the use of the tiered assessment scheme to permanent crops and crops grown on ridges. The revised scheme can be found in Figure 4. The lower tiers are more conservative and less sophisticated than the higher tiers, but all tiers aim to address the same protection goal (i.e. the 90th percentile concentration within the area of intended use of a PPP). This principle allows the direct move to higher tiers without performing assessments for all lower tiers (an applicant may, for example, directly go to higher tiers without first performing a Tier-1 assessment).

The exposure assessment starts with simulations for one predefined scenario per regulatory zone, North–Central–South. Simulations are carried out with PERSAM at Tier-1. PERSAM has the advantage that the required number of inputs is very limited and thus also the documentation requires little effort. As mentioned in Section 1.4, a new version of PERSAM has been developed, which is also applicable to permanent crops (Appendix A).

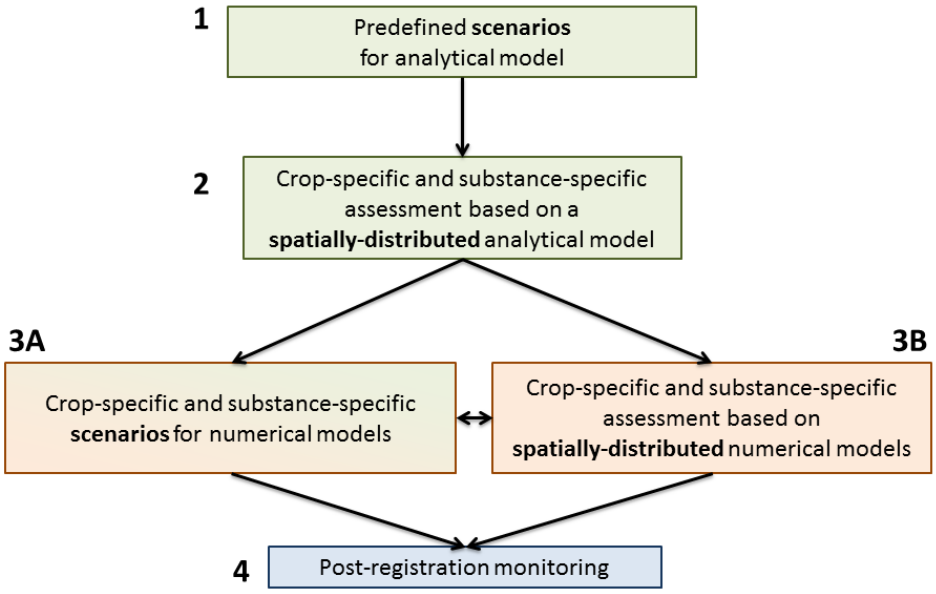

Figure 4: Tiered scheme for the exposure assessment of soil organisms in annual crops and in permanent crops. The scheme applies to both the concentration in total soil and the concentration in pore water. Tiers 1, 2 and 3 are all based on one PEC for each of the regulatory zones, North, Central and South, and allow for one or multiple applications every one, two or three years. At Tiers 1 and 2 the analytical model in the software tool PERSAM is used. At Tiers 3A and 3B modelling is carried out with numerical models.

The exposure assessment for annual crops differs from that for permanent crops (e.g. the distribution of organic matter with depth in permanent crops differs from that in annual crops). For this reason, two sets of predefined scenarios have been developed, i.e. one set for annual field crops and one set for permanent crops. The predefined scenarios for annual crops in Tier-1 are based on the total area of annual crops in a regulatory zone; the scenarios for permanent crops are based on the total area of

permanent crops in a regulatory zone. However, the exposure assessment goal is based on the agricultural area where a substance is intended to be used. The applicant may therefore want to perform an exposure assessment for a particular crop. For this purpose, Tier-2 is provided. At this tier, PERSAM is used to directly calculate the target percentile from the concentration distribution within the area of a given crop.

The predefined scenarios at Tier-1 are not designed for substances whose properties depend on soil properties such as pH. For such substances, the applicant should therefore go to Tier-2 or Tier-3 directly. These tiers offer the option to include relationships between substance properties (*DegT50* and K_{om} or K_{oc}) and soil properties such as pH.

Tier-1 is based on the assumption that crop interception of the substance does not occur. In all other tiers, crop interception and subsequent loss processes at the plant canopy can be included. This can be carried out by simulations with the numerical models at Tier-3A or 3B, or by using a table with default soil loads depending on crop development (Tables 11 and 12) at Tier-2. Refer to Section 2.5 for details on crop interception.

Should the assessment at Tier-2 still indicate an unacceptable risk to soil organisms, the applicant has the option to move to Tier-3A, which uses the same crop- and substance-specific scenarios as selected at Tier 2. Tier-3A is based on the numerical models and on the area of a given crop. In Tier-3A, the scenario is first identified in the PERSAM software. PERSAM then generates a file containing the geographical coordinates. This file is used by PEARL or PELMO to automatically generate the input files for the Tier-3A scenarios.

The scheme also contains a Tier-3B, which is a spatially distributed modelling approach based on calculations with the numerical models for many scenarios for each of the zones. Spatially distributed modelling with PEARL or PELMO has the advantage that the spatial 95th percentile of the PEC for all types of concentration of either the parent substance or any soil metabolite can be derived by statistical analysis of the output of the model runs. It can, however, not *a priori* be guaranteed that spatially distributed modelling delivers lower concentrations than Tier-3A. For this reason, spatially distributed modelling is not considered to be a higher tier than Tier-3A. Tier-3B has been made operational for permanent crops using the database, which is available at the European Soil Data Centre (Panagos et al., 2012). Using the same methodology, Tier-3B could also be made available for annual crops; guidance is given in Section 3.5.

Tier-4 is a post-registration monitoring approach, which is described in Section 3.6.

2.2. Properties of the predefined soil exposure scenarios

As described in the previous section, Tier-1 is based on one predefined scenario per regulatory zone (North–Central–South) for each of the two types of Ecotoxicological Relevant Concentration (ERC), namely the concentration in total soil and the concentration in pore water. Different scenarios have been derived for annual crops and for permanent crops. These scenarios are briefly described in the sections below; a comprehensive description of the scenarios is given in Appendix B.

2.2.1. Predefined scenarios for annual crops

The scenarios for annual crops are based on the total area of annual crops in a regulatory zone (EFSA PPR Panel, 2012). The properties of these scenarios are summarised in Tables 1 and 2 and their position is shown in Figure 5. Rainfall was not part of the scenario selection procedure and therefore the 10th percentile of rainfall in the entire area of annual crops was chosen to represent realistic worst-case conditions for leaching (Appendix B). Soil properties in Table 1 and Table 2 are averages over the top 30 cm. Annual crops are assumed to be tilled annually and therefore these averages apply to the entire soil layer.

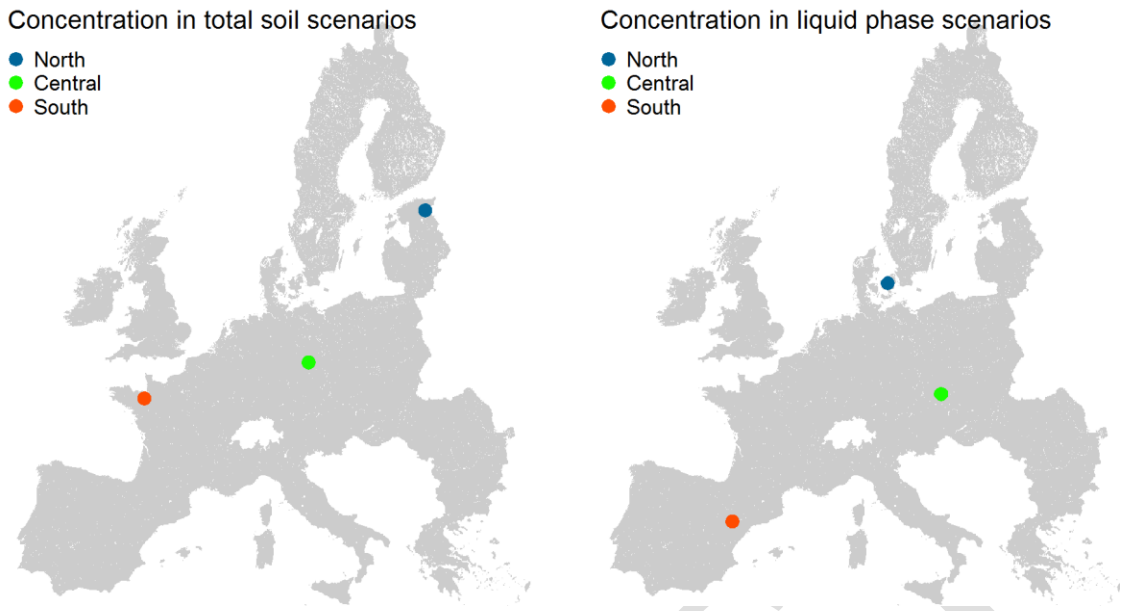

Figure 5: Position of the six predefined scenarios for carrying out Tier-1 soil exposure assessments. Left-hand panel: Scenarios for the concentration in total soil. Right-hand panel: Scenarios for the concentration in pore water.

Table 1: Properties of the predefined scenarios for annual crops used at Tier-1 for the concentration in total soil.

Zone	Code	Focus zone	T_{arit} (a) (°C)	T_{arr} (b) (°C)	P (c) (mm)	f_{om} (d) (–)	θ_{fc} (e) (m^3 m^{-3})	ρ (f) (kg dm^{-3})
North	ACTN	Jokioinen	4.7	7.0	568	0.118	0.244	0.95
Central	ACTC	Châteaudun	8.0	10.1	528	0.086	0.244	1.05
South	ACTS	Kremsmünster	11.0	12.3	445	0.048	0.385	1.22

(a): T_{arit} is the arithmetic mean annual temperature
(b): T_{arr} is the Arrhenius-weighted mean annual temperature (explained in EFSA PPR Panel, 2012a)
(c): P is the annual mean precipitation (mm)
(d): f_{om} (–) is the organic matter content averaged over the top 30 cm.
(e): θ_{fc} (m^3 m^{-3}) is the water content at field capacity
(f): ρ (kg dm^{-3}) is the dry bulk density of the soil.
Soil properties are those of the top 30 cm of the soil, for properties of the other soil layers refer to EFSA PPR Panel (2012b)

ACTC, scenario for the total concentration in the Central Zone; ACTN, scenario for the total concentration in the North Zone; ACTS, scenario for the total concentration in the South Zone.

Table 2: Properties of the selected predefined scenarios for annual crops used at Tier-1 for the concentration in pore water.

Zone	Code	Focus Zone	T_{arit} (a) (°C)	T_{arr} (b) (°C)	P(c) (mm)	f_{om} (d) (–)	θ_{fc} (e) (m^3 m^{-3})	ρ (f) (kg dm^{-3})
North	ACLN	Hamburg	8.2	9.8	568	0.023	0.347	1.39
Central	ACLC	Châteaudun	9.1	11.2	528	0.018	0.347	1.43
South	ACLS	Sevilla	12.8	14.7	445	0.011	0.347	1.51

(a): T_{arit} is the arithmetic mean annual temperature
(b): T_{arr} is the Arrhenius-weighted mean annual temperature (explained in EFSA PPR Panel, 2012a)
(c): P is the annual mean precipitation (mm)
(d): f_{om} (–) is the organic matter content averaged over the top 30 cm.
(e): θ_{fc} (m^3 m^{-3}) is the water content at field capacity
(f): ρ (kg dm^{-3}) is the dry bulk density of the soil.
Soil properties are those of the top 30 cm of the soil, for properties of the other soil layers refer to EFSA PPR Panel (2012b)

ACLC, scenario for the concentration in pore water for the Central Zone; ACLN, scenario for the concentration in pore water for the North Zone; ACLS, scenario for the concentration in pore water for the South Zone.

2.2.2. Predefined scenarios for permanent crops

The scenarios for permanent crops are based on the total area of permanent crops (including permanent grassland areas) and so their properties differ from those of the predefined scenarios for annual crops. Properties of the six scenarios for permanent crops are summarised in Tables 3 and 4 and their position is shown in Figure 6. The 10th percentile of rainfall in the entire area of permanent crops was chosen to repreent realistic worst-case conditions for leaching (Appendix B). Soil properties in Table 3 and Table 4 are averages over the top 30 cm. However, in permanent crops organic matter cannot be assumed to be uniformly distributed within this top 30 cm soil layer. Beulke et al. (2015) introduced correction factors for calculating the depth distribution of organic matter in the top 30 cm (Table 5). Notice that they made a distinction between situations with and situations without mechanical cultivation depending on the crop type. In situations without mechanical cultivation, it is assumed that organic matter decreases sharply with depth. In situations with mechanical cultivation (typically between the rows only), a depth gradient can still be observed, but less pronounced than in situations without mechanical cultivations. Averaged over the top 30 cm the organic matter content is the same for both situations.

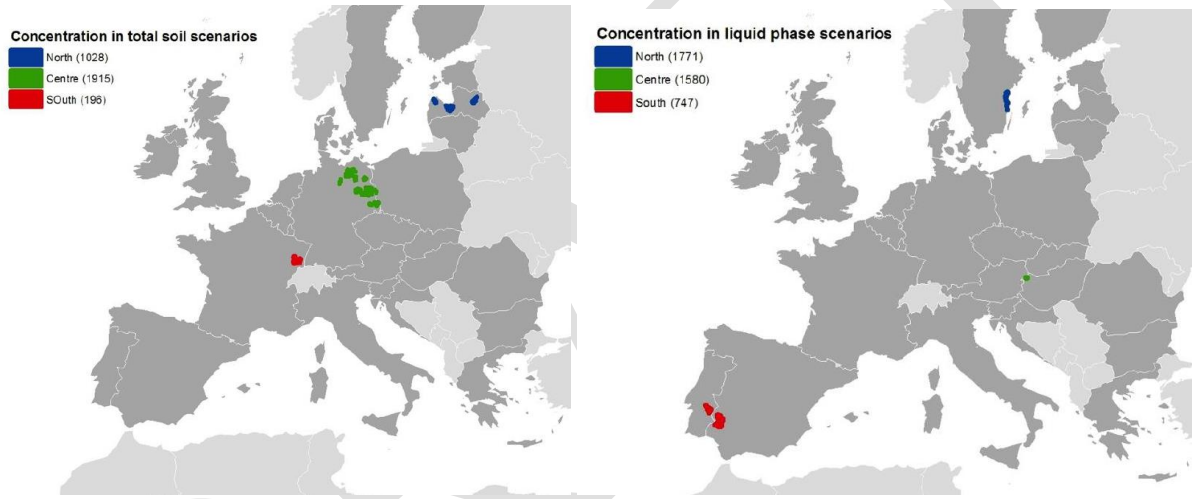

Figure 6: Position of the six predefined scenarios for permanent crops for carrying out Tier-1 soil exposure assessments. Left-hand panel: Scenarios for the concentration in total soil. Right-hand panel: Scenarios for the concentration in pore water.

Table 3: Properties of the predefined scenarios for permanent crops used at Tier-1 for the concentration in total soil.

Zone	Code	Focus Zone	T_{arit} [(a)] (°C)	T_{arr} [(b)] (°C)	P [(c)] (mm)	f_{om} [(d)] (–)	θ_{fc} [(e)] (m^3 m^{-3})	ρ [(f)] (kg dm^{-3})
North	PCTN	Hamburg	6.2	7.6	654	0.212	0.244	0.722
Central	PCTC	Châteaudun	8.9	10.5	564	0.176	0.347	0.797
South	PCTS	Kremsmünster	8.8	11.0	473	0.084	0.244	1.060

(a): T_{arit} is the arithmetic mean annual temperature
(b): T_{arr} is the Arrhenius-weighted mean annual temperature (explained in EFSA PPR Panel, 2012a)
(c): P is the annual mean precipitation (mm)
(d): f_{om} (–) is the organic matter content averaged over the top 30 cm.
(e): θ_{fc} (m^3 m^{-3}) is the water content at field capacity
(f): ρ (kg dm^{-3}) is the dry bulk density of the soil.
Soil properties are those of the top 30 cm of the soil, for properties of the other soil layers refer to EFSA PPR Panel (2012b)

PCTC, scenario for the total concentration in the Central Zone; PCTN, scenario for the total concentration in the North Zone; PCTS, scenario for the total concentration in the South Zone.

Table 4: Properties of the predefined scenarios for permanent crops used at Tier-1 for the concentration in pore water.

Zone	Code	Focus Zone	T_{arit} (a) (°C)	T_{arr} (b) (°C)	P (c) (mm)	f_{om} (d) (–)	θ_{fc} (e) (m^3 m^{-3})	ρ (f) (kg dm^{-3})
North	PCLN	Châteaudun	7.0	8.4	654	0.067	0.347	1.130
Central	PCLC	Châteaudun	10.1	11.8	564	0.043	0.347	1.250
South	PCLS	Thiva	15.5	17.2	473	0.014	0.347	1.473

(a): T_{arit} is the arithmetic mean annual temperature
(b): T_{arr} is the Arrhenius-weighted mean annual temperature (explained in EFSA PPR Panel, 2012a)
(c): P is the annual mean precipitation (mm)
(d): f_{om} (–) is the organic matter content averaged over the top 30 cm.
(e): θ_{fc} (m^3 m^{-3}) is the water content at field capacity
(f): ρ (kg dm^{-3}) is the dry bulk density of the soil.
Soil properties are those of the top 30 cm of the soil, for properties of the other soil layers refer to EFSA PPR Panel (2012b)

PCLC, scenario for the concentration in pore water in the Central Zone; PCLN, scenario for the concentration in pore water in the North Zone; PCLS, scenario for the concentration in pore water in the South Zone.

Table 5: Correction factors for estimating the distribution of organic matter within the top 30 cm of the soil in permanent crops. The organic matter content of a layer is calculated by multiplying the correction factor below with the organic matter content in Tables 3 and 4, respectively.

Depth (cm)	C.1. Correction factor (-) for situations without mechanical cultivation	C.2. Correction factor (-) for situations with mechanical cultivation
0 – 5	1.95	1.50
5 – 10	1.30	1.20
10 – 20	0.76	0.90
20 – 30	0.62	0.75

2.2.3. Dealing with litter in permanent crops

According to Beulke et al. (2015) data on the litter layer is scarce and it is suggested that no litter layer is present in the majority of the permanent crops. Furthermore, the current exposure models are not capable of simulating exposure in the litter layer. For these reasons, no litter layer is accounted for in the present guidance document. Litter might, however, become more important in the future as good soil-management practices are promoting the presence of organic matter on the soil, so there may be a shift to a more sustainable management of this litter layer (EFSA PPR Panel, in preparation). Should there be a need for estimating exposure in litter; a simple estimation of the peak concentration could be based on the current scenarios for permanent crops considering the application rate, the crop interception at the time of application, and a bulk density of litter assuming an organic matter content of 100% (i.e. 0.126 kg L^{-1}. Nevertheless, the development of more advanced computer models that also consider additional processes (e.g. the uptake of pesticide *via* the plant roots) would be necessary to describe this exposure completely.

2.3. Scenario adjustment factors

The scenarios in Tables 1 - 4 are based on the 95th spatial percentile considering the total area of annual or permanent crops in each regulatory zone. However, the purpose of the exposure assessment is to consider the total area of the crop where the PPP is intended to be applied. For any specific crop assessed, the spatial statistical distribution of the exposure concentrations would be different. Therefore, in Tier-1 default scenario adjustment factors are needed because the 95th percentile scenario for a specific crop could differ from the 95th percentile scenario for all arable land (see Table 6 for an overview of tiers where scenario adjustment factors are needed).

Table 6: Overview of inclusion of canopy processes, scenario adjustment factors and model adjustment factors in the different modelling tiers of Figure 4. "+" indicates that the process or factor is included, "–" indicates that it is not included.

Tier	Canopy processes	Scenario adjustment factors	Model adjustment factors
1	–	+	+
2	+	–	+
3A	+	–	–
3B	+	–	–

The default scenario adjustment factors are listed in Table 7. Notice that the scenario adjustment factors are different for annual crops than those for permanent crops. For substantial future changes to spatial datasets a revision of the scenarios and the adjustment factors might again be needed. However, this is not expected to happen very often.

Table 7: Default scenario adjustment factors (f_s) used when performing an assessment for one of the predefined scenarios at Tier-1 for the three regulatory zones and for the concentration in total soil and for the concentration in pore water. Refer to Appendix C and Beulke et al. (2015) for background information.

Zone	Default scenario adjustment factors to be used for the			
	Concentration in total soil		Concentration in pore water	
	Annual crops	Permanent crops	Annual crops	Permanent crops
North	3.0	1.0	1.5	1.5
Central	2.0	1.0	1.5	1.5
South	1.5	1.5	1.5	1.5

2.4. Crop selection at Tier-2, 3A and 3B

With the exception of Tier-1, an assessment is always performed for a specific crop. The starting point is the list of crops described in EC (2014), hereafter referred to as "FOCUS crops". These crops should be specified at Tier 2 (PERSAM), Tier 3A and 3B (numerical models). In case of annual crops one CAPRI crop or crop group was linked to the FOCUS crop (Table 8). As described in EFSA PPR Panel (2012a), PERSAM uses these so-called Common Agricultural Policy Regionalised Impact (CAPRI) crops or crop groups (Leip et al., 2008) as a proxy of the area of potential use of the PPP. EU crop maps for CAPRI crops are available at a scale of 1×1 km^2. Contrary, the area for permanent crops in PERSAM is based on the CORINE Land Cover database and EUROSTAT datasets (Beulke et al., 2015). Table 8 give the link between the FOCUS and the CAPRI crop lists for annual crops. As an example, if the user wants to carry out an assessment for the FOCUS crop "cabbage", the CAPRI crop "other fresh vegetables" is selected in PERSAM as an estimate of the "cabbage" cropping area. The link between the FOCUS crop and the crop in PERSAM for permanent crops is given in Table 9. Note that for permanent crops the user also has to specify the exposure type (in-row or between-row exposure) for which the assessment should be carried out.

If a crop is not specified in Table 8 and 9, the notifier should use the crop in PERSAM with the highest scenario adjusment factor (see Table C.2 and C.3 for their values) unless it can be justified that the crop under consideration should be assigned a different crop. Only if a well-documented crop map is available, it is acceptable to use Tier-2, Tier-3A or Tier-3B to calculate the 95th spatial percentile of the PEC using this crop map. Since the current version of the PERSAM tool does not provide the option to import other crop maps, the Tier-2 and Tier-3A assessments should be performed outside the software tool using, for example, the script in Appendix A. "Well-documented" implies that the methodology for deriving this crop map should be described preferably by referring to a scientific background report and/or paper. The methodology should be reproducible and be based on generally

accepted procedures. Further considerations on data quality are given in EFSA's scientific opinion on Good Modelling Practice (EFSA PPR Panel, 2014).

Table 8: Link between FOCUS and CAPRI crops for annual crops. The table further shows which FOCUS scenario is used to build the Tier-3A scenario.

FOCUS crop	CAPRI crop[(d)]	North	Centre	South
Beans[(c)]	Pulses	HA	HA	TH
Cabbage	Other fresh vegetables	HA	CH	SE
Carrots	Other fresh vegetables	HA	CH	TH
Cotton	Texture crops	–	TH	SE
Linseed	Texture crops	OK	OK	OK
Maize	Maize	HA	HA	HA
No crops (= fallow)	Fallow	HA	CH	SE
Oil seed rape (summer)	Oilseed rapes	OK	OK	OK
Oil seed rape (winter)	Oilseed rapes	HA	HA	HA
Onions[(a)]	Other fresh vegetables	HA	CH	TH
Peas	Pulses	HA	CH	HA
Potatoes	Potatoes	HA	HA	HA
Soybean	Soya beans	PI	PI	PI
Spring cereals	Cereals[(b)]	HA	CH	HA
Strawberries	Other fresh vegetables	HA	CH	SE
Sugar beets	Sugar beets	HA	HA	HA
Sunflower	Sunflowers	PI	PI	PI
Tobacco	Tobacco	–	PI	TH
Tomatoes	Other fresh vegetables	CH	CH	SE
Winter cereals	Cereals[(b)]	HA	CH	HA

(a): Also to be used for flower bulbs because there is no such crop in FOCUS

(b): Barley, common wheat, durum wheat, oats, rye and other cereals

(c): Field beans in North and Centre, vegetable beans in South

(d): Used as a proxy of the area of potential use of the PPP

CH, Châteaudun; HA, Hamburg; JO, Jokioinen; KR, Kremsmünster; OK, Okehampton; PI, Piacenza; PO, Porto; SE, Seville. See EC (2014) for further details.

The numerical models at Tier-3A not only need the crop type but also detailed information about crop development, weather and irrigation data. This information is derived from FOCUS groundwater input files (EC, 2014). Tables 8 and 9 show the FOCUS information that is used to build the Tier-3A scenario. This selection is based on the dominant FOCUS zone within each regulatory zone. (The dominant zone is the zone with the highest crop area within a regulatory zone; please refer to Appendix B for background information.)

673 **Table 9:** Link between FOCUS crops and permanent crops. The table further shows which FOCUS
674 scenario is used to build the Tier-3A scenario. Note that in permanent crops grown in rows there is a
675 distinction between in row and between-row exposure.

FOCUS crop	Permanent crop[(d)]	North[(e)]	Centre	South	Exposure type
Apples	Pome and stone fruit	HA	HA	SE	In-row (apples)
					Between-row (grass cover)
Bush berries[(a)]	Bush berries	HA	CH	SE	In-row (bush berries)
					Between-row (grass cover)
Citrus	Citrus	-	-	SE	In-row (citrus)
					Between-row (bare soil)
Permanent grass	Permanent grass	HA	HA	HA	Not relevant
Hops[(b)]	Hops	-	HA	HA	In-row (hops)
					Between-row (bare soil)
Olives[(c)]	Olives	-	-	SE	In-row (olives)
					Between-row (bare soil)
Vines	Vines	-	CH	SE	In-row (vines)
					Between-row (bare soil)

676 (a): Development stages set to those for FOCUS apples; all other crop parameters from FOCUS bush berries (Jokioinen
677 only; Beulke et al. 2015)
678 (b): Not a FOCUS GW crop; citrus crop parameter used; max. LAI set to 3 m m^{-3} (Beulke et al., 2015)
679 (c): Not a FOCUS GW crop; development stages, rooting depth and max. LAI taken from Beulke et al. (2015)
680 (d): Used as a proxy of the area of potential use of the PPP
681 (e) CH, Châteaudun; HA, Hamburg; JO, Jokioinen; KR, Kremsmünster; OK, Okehampton; PI, Piacenza; PO, Porto; SE,
682 Seville. See EC (2014) for further details.

683 ## 2.5. Model adjustment factors

684 The simple analytical model is used in lower tiers. Since it cannot be *a priori* guaranteed that the
685 simple analytical model is conservative enough when compared with the more realistic numerical
686 models used in Tier-3A and Tier-3B, model adjustment factors are needed in all the tiers that use the
687 analytical model (Table 6). The model adjustment factors proposed in EFSA (2010a) have been
688 reassessed to incorporate the effect of changing model parameters other than *DegT50* and K_{om}. Since
689 not all possible combinations of model parameters could be studied, the model adjustment factors
690 were rounded up for the sake of simplicity. The revised model adjustment factors are listed in
691 Table 10.

692 The model adjustment factors used in the tiered approach have been calculated using PEARL and
693 PELMO so consistency of the tiered approach cannot be guaranteed when using different models. The
694 use of models other than PEARL and PELMO is therefore not currently supported. However, EFSA
695 PPR Panel (2012a) encourages parameterising the scenarios for other numerical models, the only
696 requirement being that the process descriptions in such numerical models have a similar or higher
697 level of detail than those in PELMO and PEARL. Furthermore, applicants should demonstrate that
698 their own software reproduces the same output as PEARL and PELMO, e.g. by comparison for
699 scenarios in Appendix I (see Section 1.4).

Table 10: Model adjustment factors (f_M) used when performing an assessment with the analytical model. Refer to Appendix C for background information.

Zone	Model adjustment factors to be used for the	
	Concentration in total soil	Concentration in pore water
North	2.0	4.0
Central	2.0	4.0
South	2.0	4.0

2.6. Crop canopy processes

Tier-1 is based on the assumption that crop interception of the substance does not occur. In all other tiers this may be included (Table 6). Since the introduction of the FOCUS groundwater scenarios, it has been common practice to reduce the application rate by the fraction that is intercepted by the crop canopy and to apply this reduced fraction to the soil (Anonymous, 2014). As described by EFSA PPR Panel (2010d), this approach is not considered defensible because there is insufficient evidence that wash-off from the crop canopy can be ignored. So the effect of dissipation at the crop canopy and foliar wash-off should be included when the substance is applied to the crop canopy.

Crop canopy processes and foliar wash-off can be simulated by PEARL and PELMO in Tier-3A and Tier-3B. However, Reinken et al. (2013) identified serious differences between PEARL and PELMO with respect to the parameterisation of wash-off calculations. The working group concluded that these differences were primarily caused by differences in the calculation of the crop cover fraction and crop development. After harmonisation of crop development and the calculation of the crop cover fraction, differences between PEARL and PELMO were, generally, small (see Appendix D3 for details).

The analytical model used at Tier-2 cannot simulate plant processes. For this reason, a table of the default fraction of the dose reaching the soil depending on the crop development stage was created based on simulations with PELMO. This table should be used only when performing an assessment at Tier-2.

The fraction of the dose reaching the soil is defined as the sum of the fraction of the dose washed off and the fraction of the dose that directly reaches the soil (see also Figure 7):

$$f_{soil} = (1 - f_i) + f_i f_w \quad (1)$$

where f_{soil} is the fraction of the dose reaching the soil, f_i is the fraction of the dose intercepted and f_w is the fraction of the dose washed off from the canopy. The fraction of the dose intercepted was taken from EFSA (2014a). Further details on the development of the tables are given in Appendix D; the resulting calculations are summarised in Tables 11 and 12. Note that this guidance uses the average fraction washed-off (f_{soil}) instead of the maximum fraction washed-off ($F_{soil,max}$), which was used in EFSA PPR Panel (2012a). The background for this is that using the maximum value in the wash-off tables would lead to considerable overestimation of the exposure concentration, which is the result of assuming that the maximum wash-off occurs every year (Appendix D2).

Crop interception should not be included in calculations for row treatments and crops grown on ridges unless the spray is targeted on just the crop canopy or the crop canopy has closed between the rows or ridges. For these situations the normal procedure for calculating crop interception and wash-off should be used.

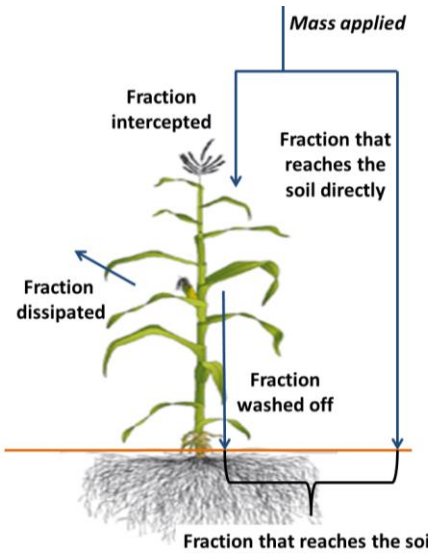

Figure 7: Schematic overview of the processes occurring at the crop canopy. The fraction of the dose reaching the soil is the sum of wash-off from the canopy and the fraction of the dose that reaches the soil directly.

Table 11: Default fraction of the dose reaching the soil (f_{soil}) in annual crops to be used at Tier-2 considering crop interception and canopy dissipation processes as a function of crop development stage.

	BBCH code[(a)(b)]				
Crop	**00–09**	**10–19**	**20–39**	**40–89**	**90–99**
Beans (vegetable and field)	1.00	0.95	0.95	0.85	0.45
Cabbage	1.00	0.90	0.95	0.60–1.00[(c)]	1.00[(c)]
Carrots	1.00	0.95	0.90	0.60–1.00[(c)]	1.00[(c)]
Cotton	1.00	0.95	0.85	0.75	0.50
Linseed	1.00	0.85	0.85	0.75	0.35
Maize	1.00	0.85	0.85	0.80	0.60
Onions	1.00	1.00	0.95	0.85–1.00[(c)]	1.00[(c)]
Peas	1.00	0.80	0.80	0.70	0.45
Potatoes	1.00	0.90	0.70	0.70	0.70
Oil seed rape (summer)	1.00	0.75	0.60	0.70	0.55
Oil seed rape (winter)	1.00	0.65	0.45	0.60	0.35
Sugar beets	1.00	0.90	0.75	0.65–1.00[(c)]	1.00[(c)]
Soybeans	1.00	0.85	0.85	0.80	0.60
Strawberries	1.00	0.90	0.85	0.90	0.70
Sunflowers	1.00	0.95	0.90	0.85	0.60
Tobacco	1.00	0.75	0.85	0.85	0.85
Tomatoes	1.00	0.80	0.85	0.80	0.70
Crop	**BBCH code[(d)]**				
	00–19	**20–29**	**30–39**	**40–69**	**70–99**
Spring cereals	1.00	0.90	0.60	0.65	0.70
Winter cereals	1.00	0.90	0.60	0.55	0.60

(a): The BBCH code is a decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001).
(b): BBCH 00–09: bare to emergence; BBCH 10–19: leaf development; BBCH 20–39: stem elongation; BBCH 40–89: flowering; BBCH 90–99: senescence and ripening.
(c): Since these crops are harvested at BBCH 50, the higher value of 1.00 should be used for BBCH code 50–99.
(d): BBCH 00–19: bare to leaf development; BBCH 20–29: tillering; BBCH 30–39: stem elongation; BBCH 40–69: flowering; BBCH 70–99: senescence and ripening.

BBCH, Biologische Bundesanstalt, Bundesortenamt und Chemische Industrie.

Table 12: Default fraction of the dose reaching the soil (f_{soil}) in permanent crops to be used at Tier-2 considering crop interception and canopy dissipation processes as a function of crop development stage or season.

	BBCH code[(a)]			
Crop	**00–09**	**10–69**	**71-75**	**76-89**
Apples (pome and stone fruit)	0.80	0.80	0.75	0.75

	BBCH code[(a)]		
	00–09	**10–69**	**71–89**
Bush berries	0.80	0.80	0.70
Hops	0.80	0.75	0.75

	BBCH code[(a)]				
	00–09	**11–13**	**14–19**	**53–69**	**71–89**
Vines	0.80	0.75	0.70	0.75	0.75

	Season			
	Jan-Mar	**Apr-Jun**	**Jul-Sep**	**Oct-Dec**
Citrus	0.60	0.45	0.35	0.60
Olives	0.60	0.45	0.35	0.60
Permanent grass	0.50	0.60	0.60	0.55
Grass between rows	0.50	0.60	0.60	0.55

For cultivations of protected crops it has been recommended to apply the same approaches as for open field crops (see EFSA, 2014b). However, crops grown under cover are generally drip irrigated and protected from rainfall and therefore wash-off from the canopy is not relevant. Therefore, for annual crops grown under cover we recommend using the crop interception tables published in Appendix C to EFSA (2014a). Please note that there is no wash-off for in-field drip irrigation or under-canopy spray applications either.

2.7. Applicability of the tiered assessment scheme for soil metabolites

The scenarios described in this guidance document can be considered appropriate for both parent compounds and metabolites. The reason is that the scenarios described here were selected using a version of the analytical model that includes leaching.

2.8. Exposure assessment based on the total amount in soil

If a robust Regulatory Acceptable Concentration (RAC) can be calculated in mg kg^{-1} it should be compared with the PEC in mg kg^{-1} in the appropriate soil layer. This requires knowledge of the distribution of the substance and the nature of the test media in the ecotoxicological effect study. However, older soil ecotoxicological studies sometimes expressed exposure in terms of only the applied rate (in kg ha^{-1}). If such studies have to be used in the risk assessment, it is proposed to perform the exposure assessment on the basis of the concentration in the top 20 cm of soil (i.e. to recalculate the PEC in total soil given in mg kg^{-1} into kg ha^{-1} exposure estimate to allow comparison with the ecotoxicological endpoint). The value of 20 cm should be used because this is the largest value for the ecotoxicological averaging depth. This is a conservative approach for estimating the total amount in soil (EFSA PPR Panel, 2012a) since the total amount increases as the thickness of the evaluation layer increases.

Only the scenarios for the concentration in total soil are relevant for such cases, and the total amount in the topsoil, Z (kg ha^{-1}), is calculated from the PEC in total soil (in mg kg^{-1}) for an ecotoxicological averaging depth (z_{eco}) of 20 cm and the dry bulk density ρ (in kg dm^{-3}) with:

$$Z = a\rho PEC \quad (2)$$

where a = 2 kg dm^3 ha^{-1} mg^{-1} (parameter a is needed to convert the concentration in the top 20 cm into the total amount in kg ha^{-1}). Therefore, if ρ = 1.05 kg dm^{-3} and the PEC is 1 mg kg^{-1} then $Z = 2 \times 1.05 \times 1 = 2.1$ kg ha^{-1}.

The procedure in this section may not be applied to Tier-1 because an inappropriate value of the bulk density would be applied. The applicant should therefore start at Tier-2 and apply Tier-3A when a risk is identified. The value of ρ should be obtained from the PERSAM output.

2.9. Exposure assessment for no-tillage systems in annual crops

The main difference between no-tillage and conventional or reduced tillage systems is that the latter are ploughed annually over 20 cm depth, which will usually lead to reduction of the concentration in the top centimetres of soil for substances that are not yet to a large extent degraded at the time of ploughing. This makes no difference for the types of concentration based on an ecotoxicological averaging depth (z_{eco}) of 20 cm as these types of concentrations are anyhow averaged over this 20-cm ploughing depth. However, the concentrations for z_{eco} < 20 cm (i.e. for z_{eco} of 1, 2.5, 5 or 10 cm) will be higher for no-tillage systems in case there is still a non-negligible fraction of the annual dose left at the time of ploughing. Thus, the exposure assessment for annual crops under conventional/reduced tillage is expected to underestimate concentrations of persistent substances for annual crops under no-tillage for z_{eco} < 20 cm.

Despite this, no specific guidance is provided for no-tillage systems in annual crops for the following reasons. First, the Good Agricultural Practice (GAP) tables included in regulatory submissions do not yet include information whether the substance is applied in systems with conventional tillage, reduced tillage or no-tillage. Second, no-tillage farming practices are not abundant in EU. The surface area of no-tillage farming systems for annual crops ranges between 0 and 7% of the arable land in 15 member states (EFSA PPR Panel, 2010c, Table 2; percentage is below 5% for 13 member states and 7% for Finland and Greece).

Until guidance for no-tillage systems is developed, the only option is to use the guidance for tilled systems for annual crops.

3. Exposure assessment in soil for spray applications

This section provides practical guidance on how to perform exposure assessments in soil for active substances of PPPs and for the metabolites of these active substances (See Figure 4 for an overview of the tiered approach). This chapter is applicable to spray applications in crops covering the entire field. The guidance also applies to crops grown on ridges and crops grown in rows; however, additional guidance in Chapter 4 needs to be considered. Chapter 4 also gives additional guidance for other application types (seed treatments and granules). This section starts with the tiers using the simple analytical model (Tier-1 and Tier-2) and then describes the tiers based on the numerical models (Tier-3A and Tier-3B) and post-registration monitoring (Tier-4).

3.1. Required software tools

To be able to perform the assessments in this section, the following versions of the software tools should be available:

- The PERSAM software tool, which can be downloaded from the website of the European Soil Data Centre: http://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool. Applicants might want to use the analytical model outside the PERSAM software. Applicants should demonstrate that their own software reproduces the same output as PERSAM, e.g. by comparison for the predefined scenarios (see Section 1.4).

- An appropriate version of the numerical models PEARL or PELMO[8]. These models can be downloaded from their website (respectively, www.pearl.pesticidemodels.eu and http://server.ime.fraunhofer.de/download/permanent/mk/EFSA/PELMO/).

Please refer to the manuals of the respective software tools for instructions on how to install the software.

3.2. Tier-1: Predefined scenarios using the PERSAM tool

As described earlier, Tier-1 is based on a simple analytical model and on one scenario per regulatory zone North–Central–South for each of the two types of PECs (i.e. the concentration in total soil and the concentration in the liquid phase). There are two sets of predefined scenarios, i.e. one set for annual crops and one set for permanent crops. The scenarios were selected based on the total area of annual or permanent crops. The scenarios at Tier-1 are not designed for substances whose properties depend on soil properties, such as pH. For such substances, the applicant should therefore go to Tier-2 or Tier-3A directly.

The Tier-1 scenarios for the annual crops were based on the properties given in Tables 1 and 2; topsoil properties for the Tier-1 scenarios for permanent crops are given in Tables 3 and 4. However, the top soil properties of the scenarios for permanent crops are different within the 0-30 cm layer (Table 5). Therefore, the Tier-1 scenarios for the permanent crops have top soil properties that depend on the ecotoxicological averaging depth, z_{eco}: for each z_{eco} value the average properties over this z_{eco} depth are taken. Also the water flux q for the calculation of the leaching term depends on the ecotoxicological relevant averaging depth; see Appendix B for details.

EFSA (2014a) provides guidance for the calculation of the rapidly dissipating fraction at the soil surface (F_{field}) from field dissipation studies. This correction should, however, be applied to only those tiers where the numerical models (PEARL or PELMO) are used. The reason is that the fraction of the dose reaching the soil surface depends on the crop development stage. Such a dependency cannot be introduced into the analytical model.

Tier-1 is implemented in the PERSAM software tool. Practical guidance on how to input the substance properties and how to perform the calculations is given in Decorte et al. (2016a, 2016b (both in preparation)). The PERSAM software can generate an output report in pdf format for use in regulatory submissions to competent authorities. The values given by the PERSAM software tool already include the model adjustment factor and the default scenario adjustment factor (Tables 7 and 10). The factors were added to ensure that Tier-1 delivers more conservative values than higher tiers.

Advice to the reader
This version of the updated PERSAM tool (v2.0.0) available during this public consultation has been updated with features proposed by stakeholders to the public consultation on EFSA Guidance Document (2015b). The features added to the PERSAM (v2.0.0) can be found in section 1.3 of the draft manual (Decorte et al, 2016b (in preparation)) on the JRC website. See link.

http://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool

The PERSAM tool will be aligned with this Guidance Document when finalised end of 2017.

[8] The model versions that are available at the time of the public consultation are not aligned with the guidance document and should therefore not be used in combination with this version of the guidance document.

At Tier-1, interception by the canopy is not considered and therefore the input for this analytical model is restricted to:

- the crop type. This is needed to select the appropriate set of scenarios (annual or permanent crops).
- the application scheme (i.e. the number of applications per year, the rate of each application (expressed as mass applied per surface area of field) (kg ha^{-1}) and the time (in days) between the individual applications;
- the application cycle (years);
- the organic matter/water distribution coefficient (K_{om}) or the organic carbon/water distribution coefficient K_{oc} (dm^3 kg^{-1}). Note that in PERSAM either of these two values can be input;
- the half-life for degradation (*DegT50*) in topsoil at 20 °C and a moisture content corresponding to field capacity (days);
- the Arrhenius activation energy (kJ mol^{-1});
- the molar mass of the molecule (g mol^{-1});
- in the case of a transformation product: the molar fraction of formation (–) of the metabolite as formed from its precursor.

3.2.1. Additional guidance for applications in row crops, crops grown on ridges and in permanent crops

In the case of annual row crops and crops grown on ridges, the procedure above can be used to calculate concentrations in the soil averaged over the entire field. However, in row crops and crops grown on ridges the concentration in and between the crop rows or ridges may need to be assessed. In those cases the procedure described in Section 4.2.1 must be followed. An important additional input parameter is the fraction of the field that is treated (f_{row}). Given the large variety of possible crops, a default value for this parameter is not given. The application must, however, justify the choice of this parameter.

Also in permanent row crops, both the exposure concentration in and between the crop rows may need to be assessed (Figure 3). In the case of spray applications, the dose will generally be targeted to the crop canopy, so the canopy will receive more than the intended dose (expressed in kg/ha) and the area between the rows will receive less than the intended dose. How to deal with this non-uniform distribution in permanent row crops is described in Section 4.3. In Tier-1 the default dose rate assessment factors should be used.

3.2.2. Guidance for substance-specific parameters

In general, the selection of substance-specific input values should follow recommendations given in FOCUS (2006) and in the generic guidance for Tier-1 FOCUS ground water assessments (Anonymous, 2014). This guidance document has further incorporated the following amendments (EFSA, 2007, 2014a; EFSA PPR Panel, 2012a):

- Guidance on deriving the degradation half-life in topsoil at reference conditions is given by EFSA (2014a). This guidance document prescribes using the geometric mean from laboratory and/or field experiments following normalisation to reference conditions (20 °C, pF 2).
- The default value for the molar activation energy is 65.4 kJ mol^{-1} (EFSA, 2007) and should be changed only when based on experimental evidence.
- The geomean K_{om} or K_{oc} of dossier values should be used since the geomean is the best estimator of the median value of a population (EFSA, 2014a).

- In the analytical model the formation fraction is based on molar fractions and is usually derived from kinetic fitting procedures in line with FOCUS (2006). Formation fractions should be derived following the stepped approach in the section below.

3.2.3. Guidance for the formation fraction of soil metabolites

For the assessment of the formation fraction of soil metabolites, a stepped approach may be followed in all tiers that involve exposure calculations (i.e. Tiers 1, 2 and 3):

- The first conservative step is to assume that the formation fraction is 1.0, unless more than one molecule of this metabolite can be formed from one parent molecule. In the latter case, the formation fraction should be set to the number of molecules of this metabolite that can be so formed (e.g. one dazomet molecule forms two molecules of methyl isothiocyanate, thus the formation fraction should be set to two).
- The second step is to take the maximum of all relevant formation fractions in the dossier.
- The third step is to take the arithmetic average of all relevant formation fractions in the dossier, thus also including zero values derived from relevant soil metabolism experiments in which this soil metabolite was not detected. Use of arithmetic means is consistent with the recommendations by FOCUS (2006, p. 235). "Relevant" in this context means that there are no indications that the soil metabolism study in the dossier is invalid for the soil of the selected scenario.

3.3. Tier-2: Spatially distributed modelling using PERSAM

Tier-2 provides the option of an exposure assessment with the simple analytical model for a particular crop and a particular substance. Tier-2 is based on a spatially distributed version of the analytical model described in Tier-1. This implies that the exposure concentration is known for every pixel and therefore the 95th spatial percentile can be directly obtained from the spatial frequency distribution of the exposure concentration. At Tier-2, the default scenario adjustment factors as listed in Table 7 are not applied; therefore, Tier-2 simulates less conservative values than Tier-1.

Tier-2 is implemented in the PERSAM software tool. Practical guidance on how to input the substance properties and how to perform the calculations is given in Decorte et al. (2016a, 2016b (both in preparation)). The PERSAM software can generate an output report in pdf format for use in regulatory submissions to competent authorities. Note that the values given by the PERSAM software tool include the model adjustment factor (Table 10). This factor was added to account for differences between PERSAM and the numerical models (EFSA PPR Panel, 2012a).

The PERSAM tool only provides the final outcome of the assessment in terms of the 95th percentile of the exposure concentration. Should the user wish to view the concentration distribution in the entire use-area, PERSAM has the option to export an ASCII GRID file. This file can be easily imported into most commonly used geographic information systems (GIS) programmes.

The user has to select a crop for which the exposure assessment will be carried out. The crop selected is linked to the FOCUS crops as listed in Tables 8 and 9.

Tier-2 offers the possibility of incorporating the effect of crop interception in the PEC calculation. In Tier-2, the effect of crop interception is lumped into a single parameter, i.e. the fraction of the dose reaching the soil (f_{soil}, see Section 2.5 for details). This parameter can be read from Table 11 for annual crops and from Table 12 for permanent crops and needs to be input in the PERSAM software. Tables 11 and 12 are based on simulations with PEARL and PELMO using a half-life for the decline of the dislodgeable residue of 10 days and a wash-off factor of 0.1 mm^{-1}. Should the applicant wish to refine these parameters, an assessment with the numerical models should be carried out at Tier-3A or Tier-3B.

The other model inputs are exactly the same as those in Tier-1 with the exception of substance properties that depend on soil properties such as pH. PERSAM basically provides two options for the relationship between soil properties and substance properties:

- The K_{om} or K_{oc} depends on the pH of the soil. In this case, the sigmoidal function for sorption of weak acids, as described by Van der Linden et al. (2009), may be applied (see Section 3.3.1).
- The K_{om} or *DegT50* depend on soil properties according to other mathematical rules. When this option is used, the applicant should provide statistical evidence that such a relationship exists.

3.3.1. pH-dependent sorption

For weak acids, the following equation may be used to calculate the coefficient for sorption on organic matter (Van der Linden et al., 2009):

$$K_{om} = \frac{K_{om,acid} + K_{om,anion}\frac{M_{anion}}{M_{acid}}10^{pH-pKa-\Delta pH}}{1+\frac{M_{anion}}{M_{acid}}10^{pH-pKa-\Delta pH}} \quad (3)$$

where $K_{om,acid}$ (m^3 kg^{-1}) is the coefficient for sorption on organic matter under acidic conditions, $K_{om,anion}$ (m^3 kg-1) is the coefficient for sorption on organic matter under basic conditions, M (kg mol^{-1}) is the molar mass, *p*Ka is the negative logarithm of the acid dissociation constant and ΔpH is a constant accounting for surface acidity.

According to the Organisation for Economic Co-operation and Development (OECD) Guideline 106, at least four sorption experiments should be submitted, which have been selected from a wide range of soils. More specifically, for ionisable substances, the selected soils should be selected so that it is possible to evaluate the adsorption of the substance in its ionised and unionised forms. Values in normal agricultural soils range between 4 and 8, so it is recommended to select soils covering this pH range. It should then be possible to fit the parameters of the equation as described by Van der Linden et al. (2009).

Section 3.6 in Boesten et al. (2012) provides additional guidance on estimating sorption coefficients for weak acids with pH-dependent sorption. The most essential item in this guidance is that Equation 3 can be fitted to experimental sorption data using any software package capable of fitting non-linear functions to data. However, because of the existence of at least three different pH-measuring methods, the pH values in the sorption experiments must first be brought in line with the type of pH data in the PERSAM dataset (i.e. pH_{H2O}). This is performed using the two equations below (Boesten et al., 2012):

$$pH_{H2O} = 0.982\,pH_{CaCl2} + 0.648 \quad (4a)$$

$$pH_{H2O} = 0.860\,pH_{KCl} + 1.482 \quad (4b)$$

where pH_{H2O} refers to the measurement of pH in water, pH_{CaCl2} is the pH measured in 0.01 M $CaCl_2$ and pH_{KCl} is the pH measured in 1 M KCl. Please note that these equations differ somewhat from the equations given in EC (2014). Since the equations in EC (2014) were based on preliminary figures, Equations 4a and 4b should be used instead of the equations in EC (2014. The parameters of the sigmoidal function should be fitted using the corrected pH values. Because this function has four parameters, at least four pH–K_{om} values are required for an adequate fit (see also requirements above). Furthermore, it should be checked that the surface acidity is in a plausible range (i.e. ΔpH should be between 0.5 and 2.5). For further details refer to Section 3.6 in Boesten et al. (2012).

3.4. Tier-3A: Crop- and substance-specific scenarios using the numerical models

Tier-3A offers the possibility of simulating exposure concentrations with numerical models for crop- and substance-specific scenarios focusing on only the type of concentration (pore water or total soil) that is required. As a consequence, neither a model adjustment factor nor a scenario adjustment factor is needed in Tier-3A.

Scenario development at Tier-3A consists of two steps, i.e. (i) selection of the pixel coordinates of the pixel that corresponds to the 95th percentile for the crop and substance under consideration and (ii) building the actual scenario. The first step is carried out in the PERSAM tool. The second step is automatically carried out in the shells of PEARL and PELMO. These model shells and documentation will be made available at the website of the respective models (see Section 3.1 for details and conditions). Guidance on performing these two steps is given in Sections 3.4.1 and 3.4.2; a full description of the applied procedure is given in Appendix B. Applicants and rapporteurs are advised to report simulations with at least two numerical models (e.g. PEARL and PELMO) and provide the highest PEC for regulatory submissions (this procedure is in line with EC (2014)).

To guarantee consistency in the tiered approach, substance-specific input values and application schedules that were used in Tier-2 should also be used in Tier-3A (see Section 3.2). However, the numerical models require some more substance-specific input values. The selection of these additional substance-specific input values should follow recommendations given in FOCUS (2006) and in the generic guidance for Tier-1 FOCUS ground water assessments (Anonymous, 2014). Section 3.4.3 gives somes amendments to these guidance documents.

3.4.1. Selection of the Tier-3A scenarios

The scenario can be selected by running Tier-3A in the PERSAM tool. The PERSAM tool will return the geographical coordinates (X and Y) and properties of the selected pixel but will not run the numerical models. Note that the pixel selected by PERSAM for Tier-3A is identical to the pixel used for the analytical model at TIER-2. PERSAM can write the geographical coordinates to a comma-separated value (csv) file. This file can be read by the PEARL and PELMO shells, which then use this information to automatically build the scenario. Please refer to the PERSAM manual for practical guidance on scenario selection at Tier-3A. As described in EFSA PPR Panel (2012a), the selected pixel is dependent on the selected substance, the selected evaluation depth (1, 2.5, 5 or 20 cm) and the selected type of concentration (pore water or concentration in total soil) and whether it is a parent or metabolite. For this reason, different Tier-3A scenarios are needed for each substance (parent and metabolites), for each evaluation depth and for each type of concentration. However, we consider it justified to base the scenario selection solely on the peak concentration, so it is not necessary to select different scenarios for each TWA window. In the case of permanent crops grown in rows it is needed to base the scenario selection on the crop map for the in-row crop.

3.4.2. Building and running the Tier-3A scenarios

In the next step, the applicant generates and runs the Tier-3A scenarios with the shells of the numerical models (PEARL or PELMO). The following steps must be carried out by the user:

- Specify the csv file generated by PERSAM to get the geographical coordinates of the Tier-3A scenarios.
- Specify the FOCUS crop, application schedule, application cycle and substances.
- Run the scenarios and generate reports.

All scenarios included in the csv file will be stored in one project. This will allow the user to generate a summary report for the regulatory submissions with one push on the button. Please refer to the manual of the models for details.

3.4.3. Model inputs

To run the models, the following inputs are needed:

- the FOCUS crop for which the simulations are carried out,
- the application cycle (one year, two years or three years),
- the application scheme of the PPP,
- properties of the active substance and its transformation products (when applicable).

Application scheme

In general the application scheme entered in the numerical models should reflect the application scheme used at Tier 2. However, application timing (according to Good Agricultural Practice) may be different in different regulatory zones and Member States. PPPs can be applied to the crop canopy, sprayed onto the soil surface or incorporated into the soil. For each application, the applicant must introduce the application date and the rate of application (kg ha^{-1}).

As mentioned in EFSA PPR Panel (2012a), the exposure assessment scheme has been developed for spray applications. It is proposed to apply the current exposure assessment scheme also to incorporated granules and treatments of small seeds (Section 4.4) that are uniformly distributed over the surface area of the field. When this option is used, the applicant should use the option "incorporation in the soil" and provide the appropriate incorporation depth. The exposure assessment scheme also covers row treatments and crops grown on ridges, refer to Sections 4.1 and 4.3 for additional guidance on application schemes for such treatments.

In permanent crops, both the exposure in the rows and between the rows may need to be assessed (Figure 3). In the case of spray applications, the dose will generally be targeted to the crop canopy, so the canopy will receive more than the intended dose (expressed in kg/ha) and the area between the rows will receive less than the intended dose. How to deal with this non-uniform distribution is described in Section 4.2.

Canopy processes

When PPPs are applied to the crop canopy, the numerical models will simulate canopy processes. In these simulations, crop interception should be based on EFSA (2014a). The most important properties affecting canopy processes are the half-life for the decline of the dislodgeable residue on plants and the wash-off factor. These properties are generally not available in the dossier and therefore EFSA PPR Panel (2012a) proposed to use as default values in the exposure assessment a wash-off factor of 0.1 mm^{-1} (100 m^{-1}) and a half-life for the dislodgeable foliar residue on plants of 10 days. It is considered acceptable to override these default values by experiments with the substance considered and plants under a range of relevant conditions. Refinements of the wash-off factor should be based on experiments with relevant formulated products and not with the active ingredient (EFSA PPR Panel, 2012a, p. 59). General recommendations on how to perform such experiments can be found in Olesen and Jensen (2013, p. 48).

The rapidly dissipating fraction at the soil surface (F_{field})

EFSA (2014a) provides guidance for the calculation of the rapidly dissipating fraction at the soil surface (F_{field}) from field dissipation studies. This correction should apply only to the fraction of the dose that directly reaches the soil surface (see Figure 7) since it is unlikely that fast dissipation processes play an important role for the fraction that is washed off from the canopy. The application rate to the soil surface can be calculated using the following equation:

$$A_{soil} = (1 - f_i)(1 - F_{field})A + f_i f_w A \quad (8)$$

where f_i is the fraction of the dose intercepted by the canopy, F_{field} (–) is the rapidly dissipating fraction and f_w is the fraction washed off from the canopy. Detailed guidance on the use of F_{field} in the

regulatory process is given in Appendix G. Equation 8 implies that F_{field} is an application-related parameter, i.e. a different value of F_{field} may be required for each application within a year.

Note that such a correction is only defensible when used in combination with an appropriately derived geometric mean $DegT50_{matrix}$ as described in EFSA (2014a). Thus, the geomean $DegT50_{matrix}$ may be based on a mixture of $DegT50_{matrix}$ values obtained from laboratory studies, tailored $DegT50_{matrix}$ field studies or legacy field studies. However, only experiments with surface application (legacy studies) can be used to derive the rapidly dissipating fraction provided that a clear biphasic decline is observed (see Equation 3 in EFSA (2014a)).

The sorption coefficient under air-dry conditions

As mentioned in EFSA PPR Panel (2012a), the all-time-high concentration in pore water in the top centimetre may occur when this top centimetre is very dry. This is, however, not realistic since the sorption of pesticide may increase by several orders of magnitude if the soil becomes very dry. In PEARL and PELMO a simple approach to describe this effect has therefore been included (see Van den Berg and Leistra, 2004). Application of this approach needs one additional parameter, i.e. the sorption coefficient for air-dry soil (in PELMO the ratio between the sorption coefficient at air-dry conditions and the sorption coefficient at reference conditions has to be specified). Petersen et al. (1995) and Hance (1977) found the sorption coefficient in air-dry soil to be roughly 100 times higher than the sorption coefficient measured under reference conditions. A maximum sorption coefficient that is 100 times the sorption coefficient measured under reference conditions is therefore implemented as a default in PEARL and PELMO. Please note that the sorption coefficient will not be affected when the soil is wetter than wilting point. Introduction of this additional parameter will therefore not affect leaching assessments.

3.4.4. Warming-up period

The Tier-3A scenarios are based on a time series of 20 years of daily meteorological information, such as rainfall and temperature. EC (2014) used a warming-up period of 6 years in the leaching simulations before starting the 20-year evaluation period. As described in EFSA PPR Panel (2012a), for persistent substances a longer warming-up period is needed to ensure that the plateau value of the exposure concentration is closely approximated before the evaluation starts. The length of the warming-up period was re-evaluated using PEARL and PELMO. It was concluded that the warming-up period ranges between 6 and 54 years, depending on the K_{om} and *DegT50* of the substance (Table 13). For ease of implementation it was decided to repeat the same time series of six years for this purpose (see Appendix B.2 for background information). The updated versions of PEARL and PELMO will automatically apply the appropriate warming-up period, based on the K_{om} and *DegT50* of the parent and transformation products so the user does not need to input the length of the warming-up period.

Table 13: Warming-up periods (years) needed to reach the plateau concentration as a function of *DegT50* (days) and K_{om} (l kg^{-1}). Please note that the half-life refers to the half-life at the average temperature of the scenario and not to the half-life at reference conditions.

DegT50	**K_{om} < 100**	**100 ≤ K_{om} < 500**	**K_{om} ≥ 500**
DegT50 < 100	6	6	6
100 ≤ *DegT50* < 200	12	12	12
200 ≤ *DegT50* < 500	12	24	30
500 ≤ *DegT50* < 1 000	18	30	30
DegT50 ≥ 1 000	24	30	54

3.5. Tier-3B: Spatially distributed modelling with the numerical models

A further tier may be considered (Tier-3B) which would consist of spatially distributed modelling with numerical models. Spatially distributed modelling has the advantage that the spatial 95th percentile of the PEC for all types of concentrations (pore water or concentration in total soil) of either the parent substance or any soil metabolite can be derived by statistical analysis of the output of the model runs, thus avoiding the need for simplifications in the scenario selection procedure.

Using the procedure described below, it is, in principle, possible to parameterise each 1 × 1 km^2 grid cell in the whole EU. In view of computation time, it is, however, not desirable to perform calculations with a numerical model for each individual grid cell of the whole EU. It is therefore necessary to reduce the number of grid cells for which calculations are performed by clustering them into groups of similar pedo-climatic properties. This process is called "schematisation". Therefore, simulation with spatially distributed models consists of the following three steps:

- creating a spatial schematisation;
- assigning scenarios to each individual cluster;
- calculating the 95th spatial percentile of the concentration distribution.

These three steps are briefly described in the sections below.

3.5.1. Setting up the spatial schematisation

A spatial schematisation may be obtained by overlaying maps with spatially distributed parameters. The maps available in EFSA spatial dataset version 1.1 (Hiederer, 2012) should be used for this purpose. Before creating the overlay, grid cells with land uses other than annual crops should be removed. It is advised to include the following maps in the spatial overlay:

- the map with EU regulatory zones;
- the map with FOCUS zones;
- the soil textural map of Europe;
- the map of topsoil organic matter;
- the map of topsoil pH;
- the map of mean annual temperature;
- the map of the mean annual precipitation.

Because the last four maps are continuous maps, the spatial overlay would result in a very large number of combinations. For this reason, these maps must be classified so that each category covers an equal area. Some 10 categories for each of these maps will generally be sufficient because this will result in a spatial schematisation consisting of some 10 000 unique combinations.

3.5.2. Parameterisation of the unique combinations

Once the schematisation is obtained, a scenario must be assigned to each individual unique combination. As a first step, average values of topsoil organic matter, pH, precipitation and temperature should be derived for each unique combination. This may be carried out by applying the so-called zonal mean function in a GIS package. Once the mean values of topsoil organic matter, temperature, precipitation and pH are known, the Tier-3A procedure for building the scenario can be applied to each individual unique combination (refer to Appendix B for details). However, in contrast to Tier-3A, it is advised to always use the weather- and crop conditions at the scenario location.

3.5.3. Calculation of the 95th spatial percentile of the concentration distribution

The 95th spatial percentile of the PEC within each regulatory zone should be based on a cumulative frequency distribution of the PEC in the area of one of the PERSAM crops. When constructing the cumulative frequency distributions, the crop area in each unique combination must be used as a weighting factor. Maps of the crop area are available in the EFSA spatial dataset (see Hiederer (2012) for file names).

Since at Tier-3B neither a model adjustment factor nor a scenario adjustment factor is needed, the PECs generated in this procedure do not need further processing.

3.6. Tier-4: Post-registration monitoring

The PPR Panel proposes to include post-registration monitoring as Tier-4 (EFSA PPR Panel, 2012a). As described in Section 2.1, one of the principles of tiered approaches is that all tiers aim to assess the same exposure assessment goal. In the context of the tiered approach of Figure 4, this means that all tiers aim to assess the spatial 90th percentile of the PEC_{SOIL} considering the spatial statistical population of agricultural fields (in one of the three regulatory zones) where the target crop is grown and in which this PPP is applied.

For Tier-4, this implies that this percentile has to be assessed via one of the following procedures:

- random sampling in combination with appropriate statistical assessment of the 90th percentile;
- some form of modelling combined with geostatistical analysis that enables a more targeted sampling strategy to assess this percentile (this also includes the use of existing data that are analysed afterwards).

It is to be expected that hundreds of samples will be needed to assess the 90th percentile with sufficient accuracy on the basis of measurements alone. The alternative would be to use one of the models to find the appropriate locations for monitoring studies. In this approach, monitoring studies should be carried out at locations that are identified by the analytical model to be at least 95th percentile worst-case locations and that are randomly selected from the population above the 95th spatial percentile. To demonstrate that this condition is met, the notifier must report for each monitoring site the substance properties, soil properties, climatic conditions, application procedures and crop management practices. Monitoring sites that do not meet these conditions should be excluded from the analysis. As described in EFSA PPR Panel (2012a), the scenario selection procedure is targeted mainly at applications of substances in crops where most of the substance penetrates into the soil. Thus, monitoring problems for substances that are dissipated to a large extent on plant or soil surfaces cannot be tackled using this alternative approach.

In line with the procedure that was used to simulate the overall 90th percentile of the PEC, the median value of the PEC at the individual monitoring sites should be used. Since the PECs at individual monitoring sites are expected to vary because of variation in K_{om} and *DegT50* (normalised by temperature), uncertainty on the calculated median PEC value should be considered. Using this information, it should be tested by statistical inference whether the derived PEC is significantly lower than the RAC.

Post-registration monitoring is likely to be meaningful only for PPPs that show accumulation of residues at a time scale of at least five years. Interpretation of post-registration monitoring studies needs to take into consideration the fraction of the treated target crop included in such monitoring. If the results of the post-registration monitoring are obtained for a fraction of, for example, 50 %, then the resulting 90th percentile concentration has to be corrected via some procedure to obtain the 90th percentile concentration corresponding to the spatial statistical population considering only fields treated with this active ingredient (because this was the target spatial statistical population as defined in Section 1.2).

4. Additional guidance for non-spray applications and for crops grown on ridges and in rows

As described in Section 1.3, it is assumed that for treatments of small seeds and applications of granular products (to the soil surface or incorporated), the procedure in Chapter 3 can be used as well. With small modifications, the procedure also covers, reasonably well, row treatments and treatments in crops grown on ridges. This chapter provides calculation procedures for row treatments in annual crops (Section 4.1), for treatments in crops grown on ridges (Section 4.2), for row treatments in permanent crops (Section 4.3) and for small seeds and granules (Section 4.4). These calculation procedures should be used in addition to the guidance in Chapter 3.

4.1. Additional guidance for spray applications in annual row crops

For row treatments, the part of the field to consider in risk assessment depends on the mobility of species groups for which the risk assessment has to be carried out. Further guidance on the appropriate spatial scale will be given in the guidance on in-soil risk assessment. There are at least three options for the spatial scale: (i) the concentrations in the soil averaged over the whole soil surface, (ii) the concentrations in the soil below the fraction of the soil surface that is treated (so below the treated rows) and (iii) both the concentrations in the soil below the treated rows and the concentrations in the soil below the untreated part of the soil surface. The exposure assessment in Chapter 3 will provide appropriate concentrations for option (i) provided that the dosage used in the exposure assessment is defined as mass of active ingredient applied per surface area of the field. If the dosage is defined as the mass of active ingredient per surface area of treated field (i.e. if the dosage per surface area of field would be divided by the fraction of soil that is treated) the methodology will also give conservative estimates for options (ii) and (iii). The latter is, however, a very conservative assumption because it implicitly implies that the crop rows are always at the same position.

In a more realistic exposure assessment procedure it is assumed that the location of the treated rows changes from year to year. In such a system the background concentration is calculated using the procedure for crops covering the entire field. However, because the peak concentration usually only occurs immediately or shortly after an application, the calculation of the peak concentration needs to take into account the fraction of the soil that is treated (f_{row}). This refined calculation procedure is available in PERSAM (see Appendix A) and the numerical models (Appendix F).

Note that the fraction of the soil surface treated is not necessarily the same as the fraction of cropped rows (Figure 8) because pesticides may be applied to either the crop rows or the intercrop rows, depending on the type of treatment. Selection of f_{row} should be justified and supported by a thorough description of the method and rate of application.

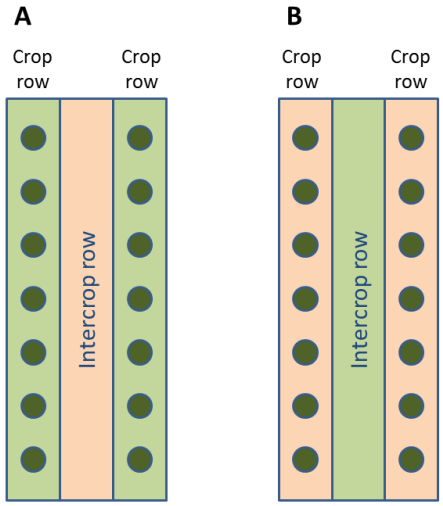

Figure 8: Graph showing the fraction of the soil surface treated (indicated in orange) and the fraction of the soil that is not treated (green). There are two possible situations. (A) The pesticide is applied to the intercrop row (usually herbicide treatments) so f_{row} equals the relative area of intercrop rows. (B) The pesticide is applied to the crop row (usually fungicide or insecticide treatments) so f_{row} equals the area of crop rows.

4.1.1. Crop interception

Crop interception should not be included in calculations for row treatments unless the spray is targeted on just the crop canopy or the crop canopy has closed between the rows. For these situations the normal procedure for calculating crop interception and wash-off should be used (see further Section 2.5).

4.2. Additional guidance for spray applications in crops grown on ridges

For spray applications onto the whole field after ridge-furrow formation it is recommended to use the exposure assessment methodology developed for spray applications to level surfaces (Chapter 3). This is justifiable because the initial concentrations in the top layer are expected to be the same for both tillage systems and because the long-term accumulation is also expected to be the same.

For spray application onto only the ridge or only the furrow, the guidance in Section 4.1 should be used additionally. For furrow applications, it should be assumed that there is no interception by the crop. The exposure assessment of row applications in Section 4.1 defines f_{row} as the fraction of the surface area of the field that was treated. So for ridge applications f_{row} = f_{ridge} and for furrow applications f_{row}= f_{furrow} where f_{ridge} (-) is the fraction of the surface area occupied by ridges and f_{frow} (-) is the fraction of the surface area occupied by furrows.

The 50th percentiles for potatoes of f_{ridge} for the three regulatory zones determined by Beulke et al. (2015) as given in Table 14 should be used. The same applies to f_{furrow}. Use of 50th percentiles is considered acceptable because the scenario selection procedure generates spatial 95th percentile cases for potatoes and there are no reasons to assume that the expected value of f_{ridge} or f_{furrow} differs from the 50th percentiles for these spatial 95th percentile cases. For other crops grown on ridges, it is recommended to use the same f_{ridge} values in the absence of better information.

Table 14: Values of f_{furrow} and f_{ridge} to be used for spray applications onto only the ridge or only the furrow.

Regulatory zone	f_{ridge} (-)	f_{furrow} (-)
North	0.55	0.45
Centre	0.72	0.28
South	0.62	0.38

4.2.1. Crop interception

Crop interception should not be included in calculations for ridge-furrow systems unless the spray is targeted on just the crop canopy or the crop canopy has closed between the rows. For these situations the normal procedure for calculating crop interception and wash-off should be used (see further Section 2.5).

4.3. Additional guidance for applications in permanent crops grown in rows

Air blast application in permanent crops usually leads to non-uniform distribution of pesticides depending on the application technique used. Non-uniform pesticide distribution in permenant crops should not be ignored because this may lead to underestimation of pesticide loads to areas directly under the crop canopy as well as neglecting exposure to off-target deposition loads in areas between the rows. Consequently, it is recommended to perform two separate soil exposure assessments in case of permanent crops: one for the in-row and one for the between-row situation, the latter typically with

bare soil or grass cover (Section 1.3.2). As pesticide application is targeted to the crop canopy, areas in the rows typically recieve higher amounts of pesticides than the intended application rate (expressed in kg ha^{-1}), whereas areas between the rows will typically receive less than intended.

The relationship between the intended and the actually received application rate for the in-row or between-row exposure may be expressed by a simple dose rate assessment factor, f_{dose}:

$$f_{dose} = \frac{A_{actual}}{A_{intended}} \quad (11)$$

where A_{actual} (kg ha^{-1}) is the actually received application rate and $A_{intended}$ (kg ha^{-1}) is the intended applications rate. In the case of a uniform pesticide distribution $f_{dose,in\text{-}row}$ equals $f_{dose,between\text{-}row}$. However, in practice $f_{dose,in\text{-}row}$ will typically be greater than one and $f_{dose,between\text{-}row}$ less than one. In the extreme case of no deposition in areas between the treated rows (e.g. using tunnel spray techniques), $f_{dose,in\text{-}row}$ equals f_{row} as defined in Section 4.1. Considering that there are no losses to areas outside the crop area, $f_{dose,in\text{-}row}$ and $f_{dose,between\text{-}row}$ are linked to each other depending on the row distance and the crop canopy width:

$$f_{dose,in-row} = 1 + \frac{(1 - f_{dose,between-row})(d_{row} - d_{crop})}{d_{crop}} \quad (12)$$

where d_{row} (m) is the distance between the rows and d_{crop} (m) is the width of the crop canopy (Figure 9). For both in-row and between-row applications, the application rate should be multiplied by the corresponding dose rate assessment factors.

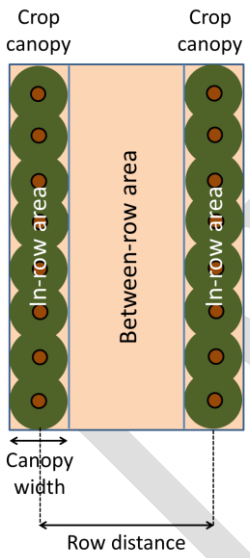

Figure 9: Graph showing the two soil exposure areas, i.e. the in-row and between-row area, in permanent crops depending on the row distance (d_{row}) and the canopy width (d_{crop}).

At present, there is no common agreement how to account for non-uniform distribution of spray deposition within the field. Therefore, the working group recommends further data collection to adequately address non-uniform distribution of pesticides in permanent crops. However, until more tailored data has become available, it is recommended to apply dose rate assessment factors on the basis of the FOCUS surface water drift curves (FOCUS, 2001) as described below.

On the basis of these spray drift curves, $f_{dose,between\text{-}row}$ values are between 0.2 and 0.8, depending on the distance to the crop wall (1 to 4 m), the crop and the crop development stage (for details refer to Appendix E). Assuming a standard width of the crown of 1.2 m and a standard row distance of 3.5 m in apple orchards (EPPO, 2012), $f_{dose,in\text{-}row}$ values will typically be between 1.8 and 2.2, depending on

the crop development stage (Table 15). In other words, assuming an intended application rate of 1 kg ha^{-1}, the crop canopy actually receives 1.8 – 2.2 kg ha^{-1}, whereas the between-row area receives 0.4 – 0.6 kg ha^{-1}. It is recommended to apply default dose rate assessment factors at all tiers in case of air blast application in permanent crops grown in rows. Note that these default dose rate assessment factors may be adopted for other combinations of row distances and canopy crop widths if considered justified (refer to Appendix E).

Table 15: Default dose rate assessment factors to be used at all tiers for the in-row and between-row exposure assessment in case of air blast application in permanent crops grown in rows (data based on FOCUS surface water drift curves (FOCUS 2001) assuming a crop canopy width of 1.2 m and a standard row distance of 3.5 m).

Dose rate assessment factor	Pome/stone fruit (early application)	Pome/stone fruit (late application), citrus, olives	Vines (early application)	Vines (late application)	Hops
$f_{dose,in\text{-}row}$	1.8	2.2	2.3	2.2	2.0
$f_{dose,between\text{-}row}$	0.6	0.4	0.3	0.4	0.5

4.4. Additional guidance for granules and seed treatments

4.4.1. Applications to crops on level surfaces

The current guidance document does not cover large treated seeds because for large treated seeds the exposure concentration cannot be assumed to be uniformely distributed in space. Guidance for large treated seeds is given in the DG SANCO guidance on treated seeds. The approach in Chapter 3 can be used for incorporated granules and treated small seeds (< 0.5 cm) [9] when the agricultural practice aims to result in even horizontal spatial distribution across the field. It does not cover annual crops where treated seed is drilled in widely spaced rows or when granules are placed within or between crop rows, as this will result in substance(s) having higher concentrations within the crop row in the year of drilling or treatment. An example of a crop with small seeds that can have this pattern of drilling in widely spaced rows is *Brassica* vegetables.

The definition of the ecotoxicologically relevant type of concentrations in this guidance is based on the concept that concentrations are averaged over the evaluation depth, z_{eco} (ranging between 1 and 20 cm). The consequence is that the procedure for calculations for incorporated granules and treated small seeds is identical to that for spray applications unless the incorporation depth is deeper than z_{eco}. If the incorporation depth is greater than 20 cm the increased concentration resulting from the last application has to be based on averaging over the incorporation depth and not on averaging over the evaluation depth (Appendix A4.1). Both the numerical models and PERSAM will account for this.

4.4.2. Granule applications in crops grown on ridges

Appendix A.4.2 describes a first-tier exposure assessment procedure for the following application method and subsequent tillage operation: (i) the granules are applied to a level soil surface at a dosage of *A* kg/ha, (ii) they are incorporated to a depth z_{inc}, (iii) thereafter the top layer with a thickness z_{rf} (ridge furrow) of this level soil system is transformed into a ridge-furrow system. It is assumed that the incorporation depth z_{inc} is larger than z_{rf}. This is commonly the case because this application method is usually used for nematicides in potatoes and protection of the potato roots against the nematodes is expected to be insufficient when z_{inc} is smaller than z_{rf}.

Developing a sophisticated higher-tier approach for these granule applications would be rather complicated in view of the two-dimensional structure of the tillage system. However, as a pragmatic

[9] Definition of small seeds is taken from draft SANCO guidance on seed treatments (SANCO/10553/2012). For this EFSA guidance it is proposed to handle maize seeds and pelleted seeds as small seeds.

solution, it is proposed using also a Tier-3A scenario assuming incorporation to the depth z_{inc} in the numerical models.

5. Documentation to be provided

This section briefly summarises the documentation requirements. The assumption is that the notifier uses one of the standardised tools as described in this guidance document (i.e. PERSAM for lower tier assessments and PEARL or PELMO for higher tier assessments). If this is not the case, the notifier should demonstrate that the scenarios used in the tiered approach are adequately parameterised and that the alternative models provide results comparable to existing software tools (see also EFSA PPR Panel (2014) for guidelines on model development and model documentation).

The substance properties and the application regime (i.e. application rate, type of application, frequency of application and fraction of the dose reaching the soil) determine the outcome of a regulatory assessment to a large extent and should therefore be well documented. Whenever possible, harmonised approaches, as described in this or earlier guidance, should be used. Justifications should be provided for using approaches, assumptions or inputs other than those recommended in this guidance.

As described in Section 2, the selected crop has a large effect on the outcome of the regulatory assessment. A justification for the selected crop should therefore be provided with specific attention to how the crop links to the area of the intended use of the PPP. If the notifier imports his own crop map, its suitability and reliability should be demonstrated.

As described in EFSA PPR Panel (2014), sufficient information should be provided so that the calculations can be reproduced. In practice this means that the following information must be provided to the regulator:

- The versions of the models that have been used in the regulatory assessment. If non-standard software tools have been used, a description of these models, including a justification of their applicability, should be provided (see first paragraph of this section).
- All relevant input values and results generated by PERSAM (Tier-1 and Tier-2) or the numerical models (Tier-3A and Tier-3B).
- A document describing all manual calculations done outside the model shells.

The applicant may move directly to higher tiers without performing assessments for lower tiers. Results from parallel tiers and lower tiers do not need to be submitted.

If a numerical model is to be used, applicants and rapporteurs are advised to report simulations with at least two numerical models (e.g. PEARL and PELMO) and provide the highest PEC for regulatory submissions (this procedure is in line with EC (2014)).

1383 ## CONCLUSIONS OR RECOMMENDATIONS

1384 ### RECOMMENDATIONS

1385 • This guidance has changed the tiered assessment scheme given in EFSA PPR Panel (2012a)
1386 with the goal to simplify the exposure assessment for regulatory purposes. Many of these
1387 changes could not yet be included in the user-friendly software tool PERSAM and in the
1388 numerical models PEARL and PELMO. It is recommended that the software tools be aligned
1389 with the current guidance document as soon as possible.

1390 • For regulatory purposes, applicants must use commonly agreed versions of the software tools.
1391 It is therefore recommended that a procedure for version control and updating the software
1392 tools be developed, including PERSAM, PEARL and PELMO.

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GLOSSARY AND ABBREVIATIONS

ACTC	scenario for the total concentration in the Central Zone (annual crops)
ACTN	scenario for the total concentration in the North Zone (annual crops)
ACTS	scenario for the total concentration in the South Zone (annual crops)
ACLC	scenario for the concentration in pore water for the Central Zone (annual crops)
ACLN	scenario for the concentration in pore water for the North Zone (annual crops)
ACLS	scenario for the concentration in pore water for the South Zone (annual crops)
application rate	see dose
BBCH code	Biologische Bundesanstalt, Bundesortenamt und Chemische Industrie code: decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001)
CAPRI	Common Agricultural Policy Regionalised Impact modelling system. An economic model developed to support EU policy
DOSE	the mass of substance applied per unit surface area of the field (kg ha^{-1}). Substances may be applied uniformly or be applied in rows. In both cases, the mass is expressed per surface area of the entire field (both treated and untreated)
$DOSE_{in\_rows}$	the mass of substance applied per unit surface area of treated rows (kg ha^{-1}). See further definition of f_{row}
EFSA	European Food Safety Authority
ERC	Ecotoxicological Relevant Concentration
f_{dose}	dose rate adjustment factor for the in-row and between-row exposure assessment to account for non-uniform spray drift in permanent crops
F_{field}	rapidly dissipating fraction that is not related to degradation in the soil matrix (EFSA PPR Panel, 2010c)
f_{ridge}	fraction of the surface area of the field that is occupied by the ridge (–).
f_{furrow}	fraction of the surface area of the field that is occupied by the furrow (–).
f_{row}	fraction of the surface area of the field that is occupied by the treated rows (–). This fraction may refer to the intercrop row or the crop row, depending on where the pesticide is applied
FOCUS	Forum for Co-ordination of Pesticide Fate Models and their Use
f_{soil}	fraction of the dose that reaches the soil
model adjustment factor (f_M)	a factor that accounts for differences between the simple analytical model used at lower tiers and the more realistic numerical models used at higher tiers. The model adjustment factor should ensure that lower tiers are more conservative than higher tiers
PCTC	scenario for the total concentration in the Central Zone (permanent crops)
PCTN	scenario for the total concentration in the North Zone (permanent crops)
PCTS	scenario for the total concentration in the South Zone (permanent crops)
PCLC	scenario for the concentration in pore water for the Central Zone (permanent crops)

PCLN	scenario for the concentration in pore water for the North Zone (permanent crops)
PCLS	scenario for the concentration in pore water for the South Zone (permanent crops)
PEARL	Pesticide Emission At Regional and Local Scales. A pesticide fate model intended for higher tier exposure and leaching assessments
PEC	Predicted Environmental Concentration
PELMO	Pesticide Leaching Model. A pesticide fate model intended for higher tier exposure and leaching assessments
PERSAM	Persistence in Soil Analytical Model. Software tool for performing lower tier soil exposure assessments
PPR	Plant Protection Products and their Residues
PPP	Plant Protection Product
RAC	Regulatory Acceptable Concentration
scenario adjustment factor (f_S)	a factor that accounts for the effect of using in lower tiers the total area of annual crops instead of the area of intended use. The scenario adjustment factor should ensure that lower tiers are more conservative than higher tiers
SCoPAFF	Standing Committee of Plant Animal Food and Feed
TWA	time-weighted average

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APPENDICES

Appendix A. Description of the PERsistance in Soil Analytical Model

Tier-1 and Tier-2 are based on a simple analytical model (Chapter 2) that is parameterised for the three zones (North/Centre/South). This model is also used to select the Tier-3A scenarios for the numerical models. So this analytical model plays a key role in the exposure-assessment procedure. This appendix gives a description of the model (first in terms of a conceptual model and thereafter mathematically). It starts with the model for spray applications in the whole field. Section A.2 and A.3 describe the model for spray applications in row crops and ridge-furrow systems and section A.4 gives the model for granular applications.

A.1. Spray applications in crops covering the whole field

The simple analytical model is based on the following conceptual model:

- the substance is applied to the soil surface as a single dose on the same date every year or every two or three years. This single dose may consist of multiple applications within a year. Between these applications, first-order degradation is assumed;
- at Tier-2 this dose may be corrected to account for crop interception and dissipation on plant surfaces based on other models or data;
- the only loss processes from the soil are degradation and leaching. The degradation rate is a function of only soil temperature and leaching is assumed to result from convective flow only;
- soil properties such as moisture content and temperature are constant in time;
- the model does not consider the time course of concentrations; instead the maximum of the exposure concentration after infinite time is considered;
- the effect of tillage or mechinal cultivation is accounted for by assuming complete mixing over the tillage depth at the moment of tillage. Tillage depth is assumed to be 20 cm for annual crops (EFSA, 2010a) and 5 cm for permanent crops (when applicable);
- adsorption is described by a linear isotherm using the concept of a sorption coefficient that is proportional to organic-matter content (K_{om});
- the average exposure concentration over a certain depth is calculated from the sum of the concentration just before the last application and the dose is divided by this depth;
- a flexible approach is taken for introducing relationships between *DegT50* or K_{om} and soil properties when used for Tier-2;
- concentrations of metabolites are based on the assumption that each metabolite is applied at the application time of the parent at a dose that is corrected for the kinetic formation fraction and the molar mass of the metabolite.

A.1.1. Parent substances

The mathematical description is as follows for parent substances. Firstly the initial concentration in total soil directly after application is calculated:

$$C_{T,ini} = \frac{A_{year}}{\rho z_{eco}} \quad \text{(A1)}$$

where $C_{T,ini}$ (mg kg^{-1}) is the initial concentration in total soil, A_{year} is the annual application rate (kg ha^{-1} or mg dm^{-2}), z_{eco} (dm) is the ecotoxicological averaging depth (i.e. 1, 2.5, 5 or 20 cm), and ρ is the dry

soil bulk density (kg dm^{-3}). In the second step, the background concentration ($C_{T,plateau}$ mg kg^{-1}), just before the next application after an infinite number of annual applications, is calculated:

$$C_{T,plateau} = \frac{z_{eco}}{z_{til}} C_{T,ini} \frac{X}{1-X} \quad \text{(A2)}$$

where z_{til} (dm) is the plough depth (fixed at 20 cm based on EFSA, 2010a) and X is defined as:

$$X = \exp(-t_{cycle}(f_T k_{ref} + k_{leach})) \quad \text{(A3)}$$

where t_{cycle} is the time between applications (365, 730 or 1095 d), f_T is a factor describing the effect of soil temperature on the degradation rate coefficient, k_{ref} (d^{-1}) is the first-order degradation rate coefficient at a reference temperature T_{ref} (i.e. 20 °C) and the soil moisture content at field capacity, and k_{leach} (d^{-1}) is a rate constant accounting for leaching. Although the soil temperature is constant in time, the factor f_T is needed because dossiers are based on degradation rate measurements at 20 °C and f_T converts this rate to the rate at the scenario temperature. As follows from the combination of Eqns A1 and A2, the background concentration does not depend on the ecotoxicologically relevant averaging depth but depends only on the plough depth.

The dimensionless factor f_T describing the effect of temperature on degradation is given by:

$$T > 0^o\text{C} \quad f_T = \exp\left(\frac{-E}{R}\left[\frac{1}{T+273.15} - \frac{1}{T_{ref}+273.15}\right]\right) \quad \text{(A4a)}$$

$$T \leq 0^oC \quad f_T = 0 \quad \text{(A4b)}$$

where E is the Arrhenius activation energy, (kJ mol^{-1}), R is the gas constant (0.008314 kJ mol^{-1} K^{-1}), T (°C) is the soil temperature, and T_{ref} (°C) is the temperature at reference conditions (20 °C). The coefficient k_{ref} is calculated from the degradation half-life by:

$$k_{ref} = \frac{\ln(2)}{DegT_{50}} \quad \text{(A5)}$$

where $DegT_{50}$ (d) is the degradation half-life in soil at the reference temperature.

The background concentration corresponds to the residue remaining immediately before the next application. So the maximum concentration in this model will occur directly after this next application and it can be calculated by:

$$C_{T,peak} = C_{T,ini} + C_{T,plateau} \quad \text{(A6)}$$

where $C_{T,peak}$ (mg kg^{-1}) is the maximum concentration in total soil.

The maximum concentration in the liquid phase is calculated from the maximum concentration in total soil assuming a linear sorption isotherm:

$$C_{L,peak} = \frac{C_{T,peak}}{\theta/\rho + f_{om}K_{om}} \quad \text{(A7)}$$

where $C_{L,peak}$ (mg L^{-1}) is the maximum concentration in the liquid phase, θ (m^3 m^{-3}) is the volume fraction of liquid in soil at field capacity, f_{om} (kg kg^{-1}) is the mass fraction of organic matter, and K_{om} (L kg^{-1}) is the coefficient for sorption on organic matter.

The model includes also calculation of *TWA* concentrations. Because it is assumed that the substance is degraded following first-order kinetics, the *TWA* concentration in total soil, $C_{T,TWA}$ can be calculated from:

$$C_{T,TWA} = \frac{C_{T,peak}}{t_{avg} f_T k_{ref}} \left[1 - \exp\left(- f_T k_{ref} t_{avg}\right)\right] \quad \text{(A8)}$$

The *TWA* concentration in the liquid phase, $C_{L,TWA}$, is calculated from an equation akin to Eqn A8 but with $C_{L,peak}$ instead of $C_{T,peak}$.

Leaching from the ecotoxicological mixing layer

The rate coefficient k_{leach}, which accounts for leaching from the ecotoxicological averaging layer, is calculated assuming only convective flow and perfect mixing. So the substance flux J (g dm^{-2} d^{-1}) at the bottom of the mixing layer is described by

$$J = qC_L \quad \text{(A9)}$$

where q (dm d^{-1}) is the mean annual downward water flow rate at the bottom of the layer. The conservation equation for the mixing layer can then be written as:

$$S\, z_{eco} \frac{dC_T}{dt} = S\, z_{eco}\left(- k_{ref}\, f_T C_T\right) - S\, J \quad \text{(A10)}$$

where S (dm^2) is the surface area considered. Assuming linear sorption, we get:

$$C_T = C_L\left(\theta + \rho\ f_{om}\ K_{om}\right) \quad \text{(A11)}$$

Combination of the above equations and rearranging gives:

$$\frac{dC_T}{dt} = -C_T\left(k_{ref}\, f_T + k_{leach}\right) \quad \text{(A12)}$$

where k_{leach} (d^{-1}) is

$$k_{leach} = \frac{q}{z_{eco}\left(\theta + \rho\, f_{om} K_{om}\right)} \quad \text{(A13)}$$

The analytical model is based on X, i.e. the remaining fraction at the moment of the next application, so equal to the C_T at this moment divided by the initial C_T. This is given by Eqn. A3.

Multiple applications in a year

In the original description of the simple analytical model (EFSA PPR Panel, 2012a) all applications within a year were summed to a single application. Because this is a very conservative assumption, the model has been extended so that degradation between individual applications can be considered. The equations below show how the annual application rate A_{year} in Eqn. A1 is calculated from multiple applications within a year:

$$i = 1 \quad R_1 = f_{soil,1} A_1 \quad \text{(A14a)}$$

$$i > 1 \quad R_i = f_{soil,i} A_i + R_{i-1} \exp\left(- f_T k_{ref} t_{app,i}\right) \quad \text{(A14b)}$$

where A_i (kg ha^{-1}) is the application rate of application i, n is the number of applications in a year, $f_{soil,i}$ is the fraction of the dose reaching the soil for application i (to be taken from Tables 11 and 12), and R_i (kg ha^{-1}) is the residue including residues remaining from the previous applications. The remaining residue is calculated assuming first-order degradation kinetics between two applications using f_T, k_{ref} and $t_{app,i}$ (d) with $t_{app,i}$ as is the time between application i and application i-1.

Please notice that this is a recursive algorithm. That means for example that for three applications within a year that first R_1 must be calculated, followed by R_2 (based on R_1) and finally R_3 (based on R_2) to get the annual application rate A_{year} (= R_3).

A.1.2. Metabolites

For soil metabolites, the calculation procedures are the same recursive procedure as described above for the active compound with one exception: the annual application rate A_{year} is replaced by the equivalent annual application rate of the metabolite (and of course using the *DegT50* and K_{om} of the metabolite instead of the parent). Considering multiple applications, for a soil metabolite formed from the parent, this equivalent rate is given by:

$$i=1 \quad R_1 = f_{soil,1} A_1 \frac{M_{met}}{M_{parent}} \sum_{j=1}^{n} \left(F_{f,p,j} \; F_{f,s,j} \right) \tag{A15a}$$

$$i>1 \quad R_i = f_{soil,i} A_i \frac{M_{met}}{M_{parent}} \sum_{j=1}^{n} \left(F_{f,p,j} \; F_{f,s,j} \right) + R_{i-1} \exp\left(- f_T k_{ref} t_{app,i} \right) \tag{A15b}$$

where $F_{f,p,j}$ and $F_{f,s,j}$ (-) are formation fractions of the metabolite (i.e. the stoichiometric coefficient of the formation of this metabolite from its precursor, kinetically determined). $F_{f,p,j}$ is the formation fraction for the primary metabolite j which is formed directly by the parent whereas $F_{f,s,j}$ is the formation fraction for the secondary metabolite which is formed by primary metabolite j. n is the number of primary metabolites that are transformed into the secondary metabolite. When primary metabolites are calculated the sum of the formation fractions $F_{f,p,j}$ x $F_{f,s,j}$ over n can be replaced by the single formation fraction $F_{f,p,j}$.

Similar as in equation (A9) and (A10) A_i (kg ha^{-1}) is the application rate of application i, $f_{soil,i}$ is the fraction of the dose reaching the soil for application i (to be taken from Tables 11 and 12), and R_i (kg ha^{-1}) is the current residue including residues remaining from the previous application. Finally, M_{met} (g mol^{-1}) is the molar mass of the metabolite, M_{parent} (g mol^{-1}) is the molar mass of the parent substanc.

As for parent compounds the remaining residue is calculated assuming first-order degradation kinetics between two applications using f_T, k_{ref} and $t_{app,i}$ (d) with $t_{app,i}$ as is the time between application i and application i-1.

A.2. Spray applications in row crops

As described in Section 4.2, three types of concentrations may be relevant, i.e. the concentration averaged over the entire field, the concentration between the treated rows and the concentration in the treated rows. For the concentration averaged over the entire field, the model in Section A.1 can be used. For the other two types of concentrations, a simple conservative approach is given in Section 4.2. This approach is based on the assumption that the crop rows are always at the same position. A more realistic procedure would assume that the rows are at different locations in the different application years and that this, in the long term, leads to a plateau concentration that is constant across the surface area of the field. This approach is described below.

The simple analytical model considers the situation of an application after a steady-state plateau concentration has been reached. Based on the foregoing assumptions, it seems justifiable to assume that in the area between the treated rows the maximum concentration is equal to this steady-state plateau concentration. So the maximum concentration between the rows can be calculated with an equation akin to Eqn. A2:

$$C_{T,between\_rows} = \frac{z_{eco}}{z_{til}} C_{T,ini} \frac{X}{1-X} \tag{A17}$$

where $C_{T,between\_rows}$ (mg kg^{-1}) is the concentration between the treated rows.

The maximum concentration in the treated rows (C_{T,in_rows} mg kg^{-1}) will be highest after the last application and is the sum of plateau concentration (which is the same as the concentration between the rows) and the concentration generated by this last application:

$$C_{T,in\_rows} = \frac{A_{year}}{f_{row} \rho z_{eco}} + C_{T,between\_rows} \quad \text{(A18)}$$

Notice that the only difference between Eqn. A6 and Eqn. A18 is the incorporation of the factor f_{row} in the first term.

The concentration in pore water is calculated by an equation akin to Eqn. A7 where $C_{T,peak}$ is replaced by $C_{T,between\_rows}$ and C_{T,in_rows}, respectively.

A.3. Spray applications in ridge – furrow systems

The exposure of soil organisms in ridge-furrow systems may depend strongly on the type of application. Many different application techniques in ridge-furrow tillage systems exist at Member State level (e.g. Boesten at al., 2015) but these are not all relevant for the soil exposure assessment at EU level everywhere in Europe. This section only describes the following applications:

- full overspray after the ridge-furrow formation
- spraying of only the ridge or only the furrow

We define f_{ridge} as the fraction of the surface area of the field occupied by the ridges and f_{furrow} as the fraction of the surface area of the field occupied by the furrows. So

$$f_{ridge} + f_{furrow} = 1 \quad \text{(A19)}$$

Spraying over the full surface area of field after ridge-formation

For spray applications onto the whole field after the ridge-furrow formation it is recommended to use the model for spray applications to level surfaces, so the model described in Section A.1. This is justifiable because the initial concentrations in the top layer are expected to be the same for both tillage systems and because the long-term accumulation is also expected to be the same.

Spraying of only the ridge or only the furrow

Spraying onto only the ridge or only the furrow can be handled in the same way as the exposure for row applications in annual crops grown on level surfaces as described in Section A.2. This exposure assessment of row applications defines f_{row} as the fraction of the surface area of the field that was treated. So for ridge applications $f_{row} = f_{ridge}$ and for furrow applications $f_{row} = f_{furrow}$.

A.4. Granular applications

A.4.1. Granular applications in level soils

As described in Section 4.1, the analytical model in Section A.1 may be used for granular applications with an incorporation depth less than 20 cm. For depths greater than 20 cm this needs to be slightly changed. The reason is that the increase of the concentration has to be based on averaging over the incorporation depth instead of averaging over z_{eco}. So Eqn. A2 needs to be replaced by Eqn. A20a and Eqn. A6 needs to be replaced by Eqn. A20b:

$$C_{T,plateau} = \frac{z_{eco}}{z_{inc}} C_{T,ini} \frac{X}{1-X} \quad \text{(A20a)}$$

$$C_{T,peak} = \frac{A_{year}}{\rho z_{inc}} + C_{T,plateau} \quad \text{(A20b)}$$

where z_{inc} (dm) is the incorporation depth.

A.4.2. Granular applications in ridge-furrow system

The procedure in Section A.4.1 is also valid for the combination of the following application method and subsequent tillage operation in ridge-furrow systems: (i) the granules are applied to a level soil surface at a dosage of A_{year} kg ha^{-1}, (ii) they are incorporated to a depth z_{inc}, (iii) thereafter the top layer with a thickness z_{rf} (ridge furrow) of this level soil system is transformed into a ridge-furrow system. It is assumed that the incorporation depth z_{inc} is larger than z_{rf}. This is commonly the case because this application method is usually used for nematicides in potatoes and protection of the potato roots against the nematodes is expected to be insufficient when z_{inc} is smaller than z_{rf}.

For this system, the calculation procedure as described in Section A.4.1 can be used. It is assumed that z_{inc} is equal to or larger than the ecotoxicological averaging depth, z_{eco}. If, however, the incorporation depth z_{inc} is smaller than the ecotoxicological averaging depth, z_{eco}, in the calculation procedure of Section A4.1 z_{inc} has to be replaced by z_{eco}. The reason is that then use of z_{eco} leads to more dilution.

A.5. Comparison of PERSAM and PEARL

A.5.1 PERSAM version with leaching

Results of PERSAM and PEARL were compared for some 2000 different scenarios for permanent crops obtained using the Tier-3B procedure described in Section 3.6.2. Simulations were done for five substances, i.e. P1 (*DegT50* = 10 days, K_{om} = 10 days), P4 (*DegT50* = 31 days, K_{om} = 31 days), P8 (*DegT50* = 100 days, K_{om} = 100 days), P13 (*DegT50* = 316 days, K_{om} = 316 days) and P19 (*DegT50* = 1000 days, K_{om} = 1000 days). Simulations were done for annual crops assuming tillage to 20 cm and for permanent crops assuming no mixing. Application was in spring (1 kg ha^{-1} to the soil surface at May 1). In the annual crop simulations, soil properties were uniform to a depth of 30 cm whereas in the permanent crops soil properties were adjusted according to Table 5.

Results for spring applications (Figures A.1 and A.2) show an excellent correlation between PERSAM results and PEARL results for both annual crops and for permanent crops. The absolute level is, however, different which implies that a model adjustment factor is still necessary to ensure that results based on PERSAM are more conservative than results based on the numerical models (Appendix C).

Simulations have also been done for summer applications (application at July 1) and for autumn applications (application at October 1). Results for summer applications in annual crops (Figure A.3) show that results are comparable to that of the spring applications; however a number of different trend lines can be distinghuished for the concentration in pore water in this case. Further investigation revealed that each of these trend lines corresponds to a FOCUS scenario. Apparently different seasonal patterns of the FOCUS scenarios cause different soil moisture conditions at the time that the maximum concentration is reached. Results for the other application times are comparable and therefore not shown.

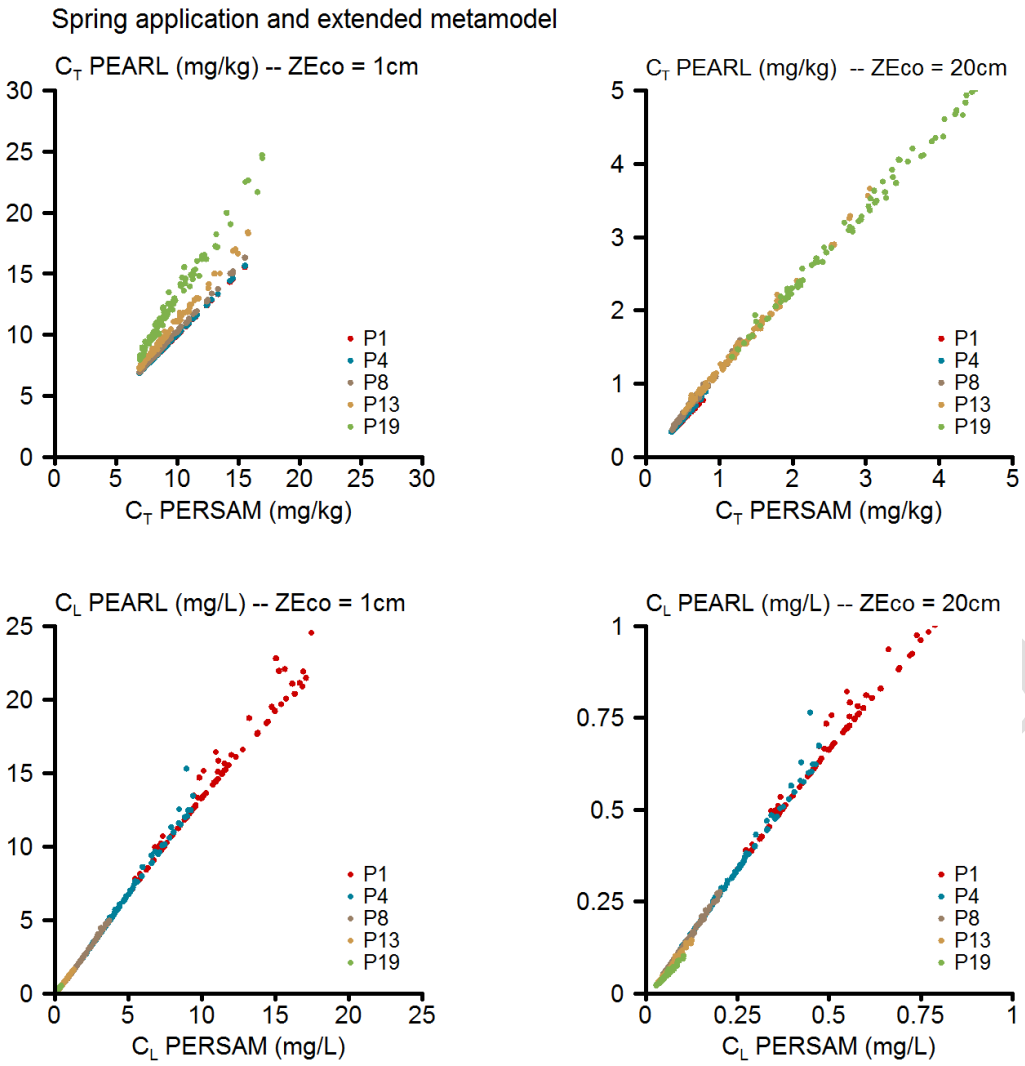

Figure A.1: Comparison of PERSAM and PEARL results for some 2000 scenarios in annual crops derived using the Tier-3B procedure. Application was in spring (May 1) with a dose of 1 kg ha^{-1} (see further text).

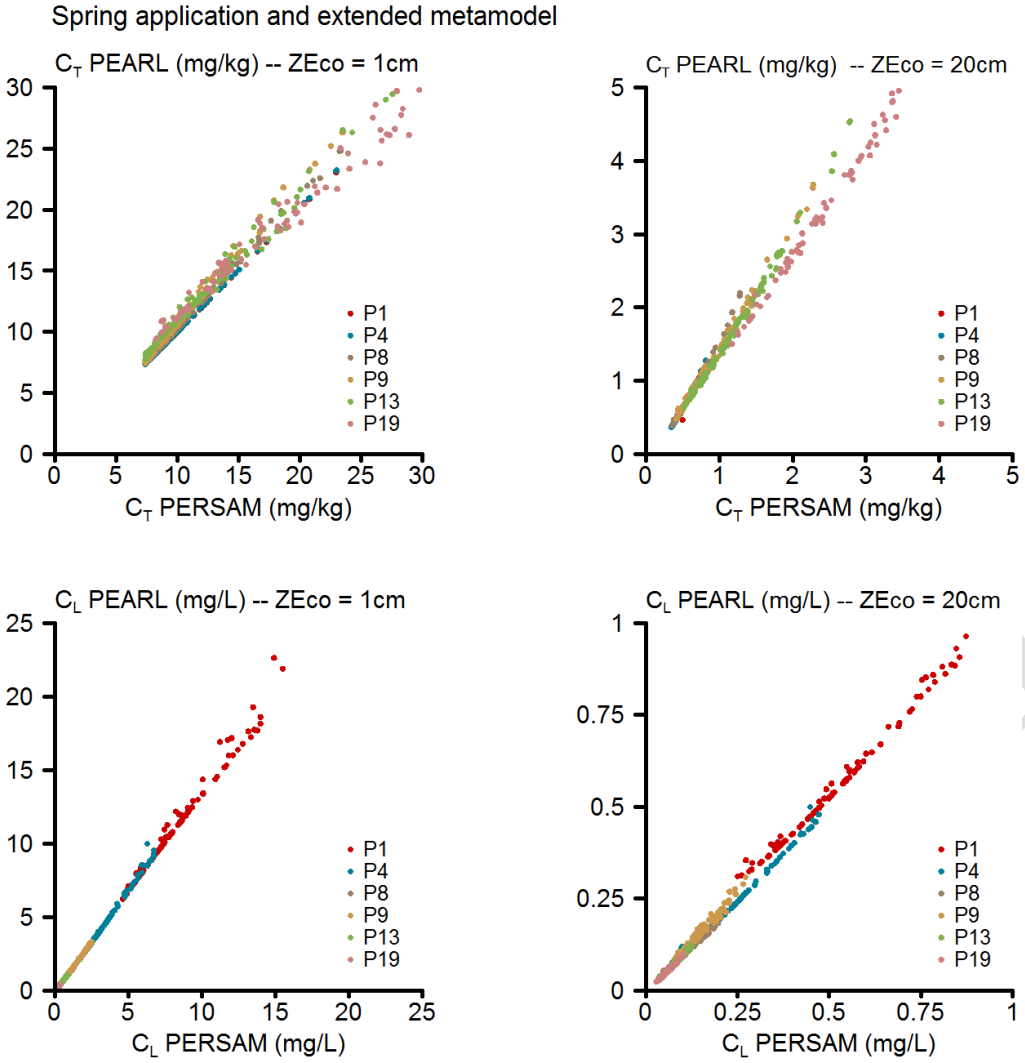

Figure A.2: Comparison of PERSAM and PEARL results for some 2000 scenarios in permanent crops derived using the Tier-3B procedure. Application was in spring (May 1) with a dose of 1 kg ha^{-1} (see further text).

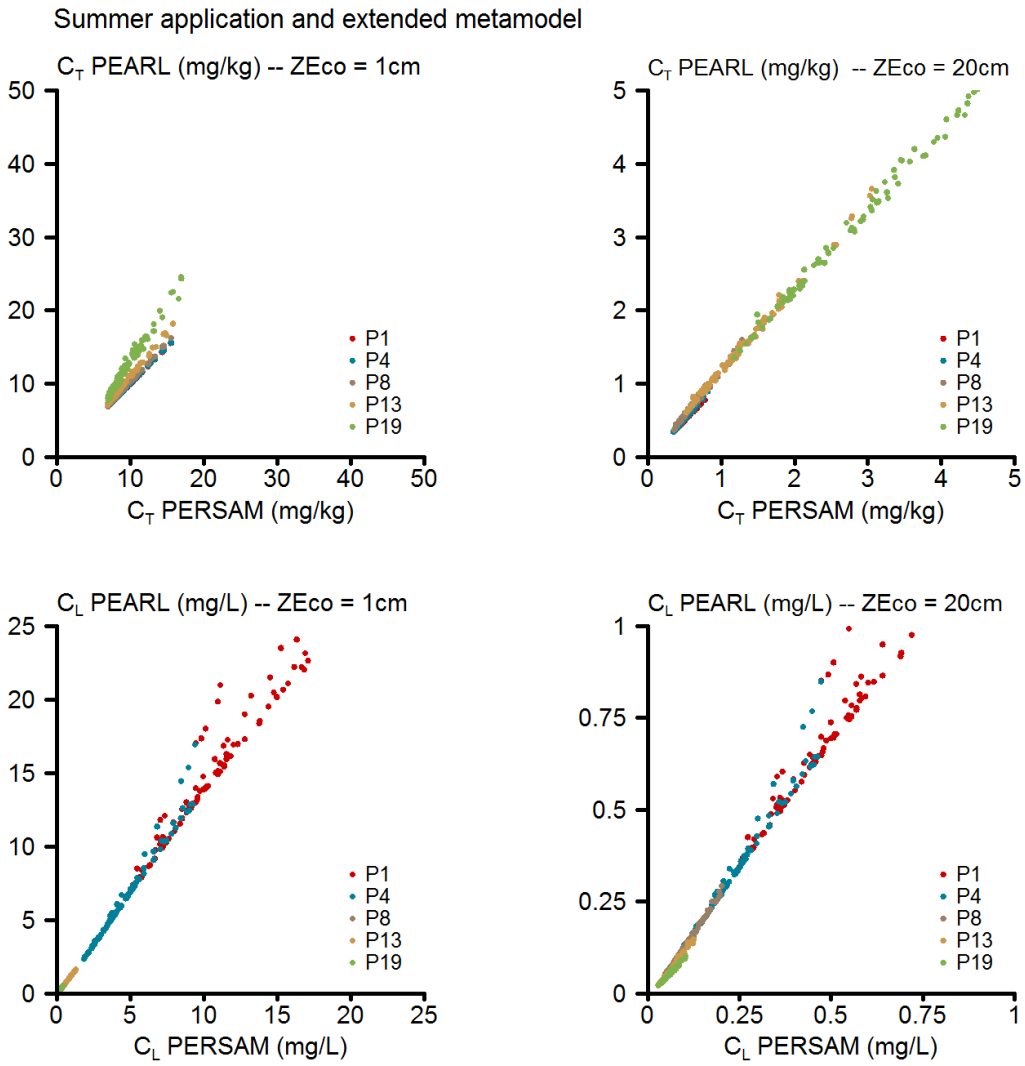

Figure A.3: Comparison of PERSAM and PEARL results for some 2000 scenarios in annual crops derived using the Tier-3B procedure. Application was in summer (July 1) with a dose of 1 kg ha^{-1} (see further text).

A.5.2 PERSAM version without leaching

We performed exactly the same comparison using the PERSAM version described in EFSA (2012), i.e. the version that does not include the leaching term. The agreement between both models is still reasonable good for annual crops (Figure A.4). However, in the case of permanent crops the agreement between the two models is worse (Figure A.5). So the addition of the leaching term is essential for creating a suitable model for scenario selection.

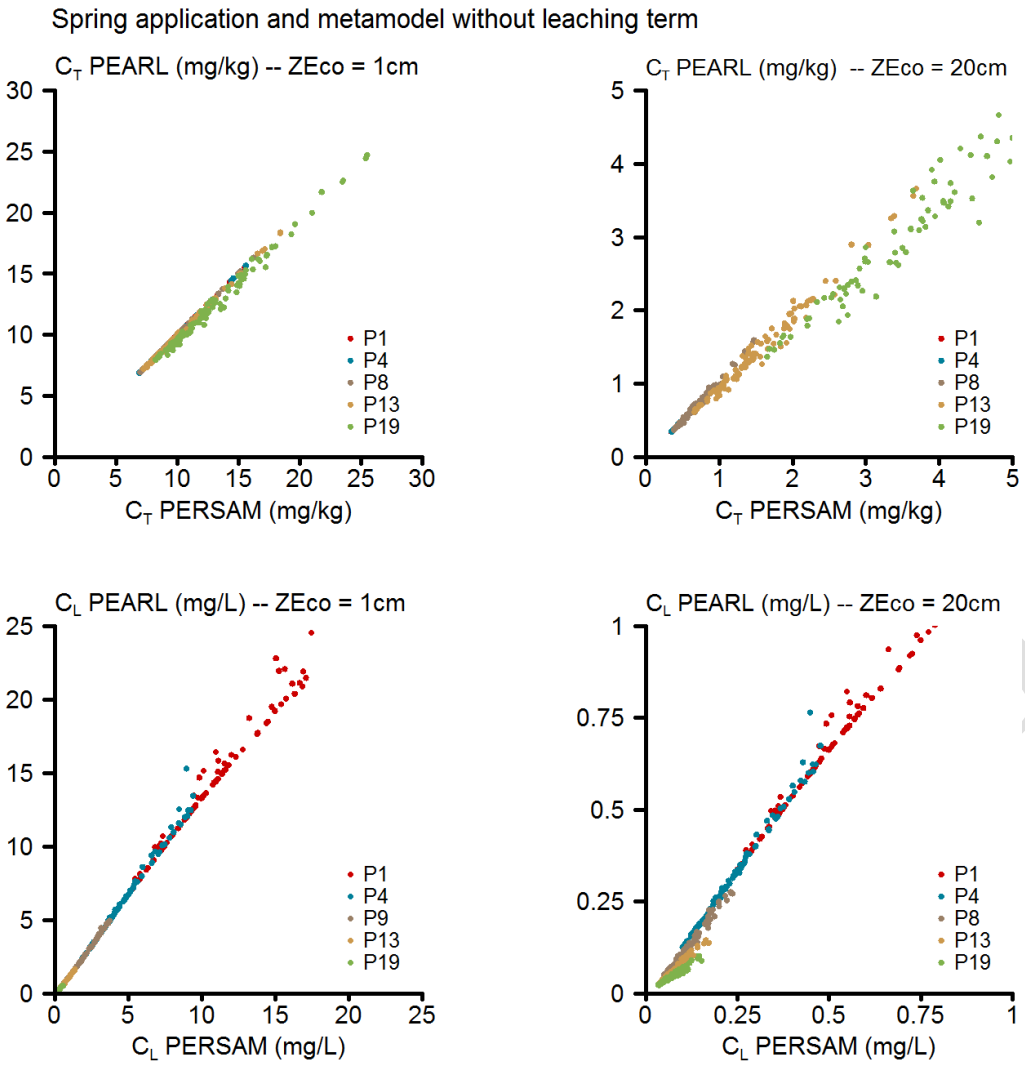

Figure A.4: Comparison of PERSAM and PEARL results for some 2000 scenarios in annual crops derived using the Tier-3B procedure. Application was in spring (May 1) with a dose of 1 kg ha^{-1} (see further text).

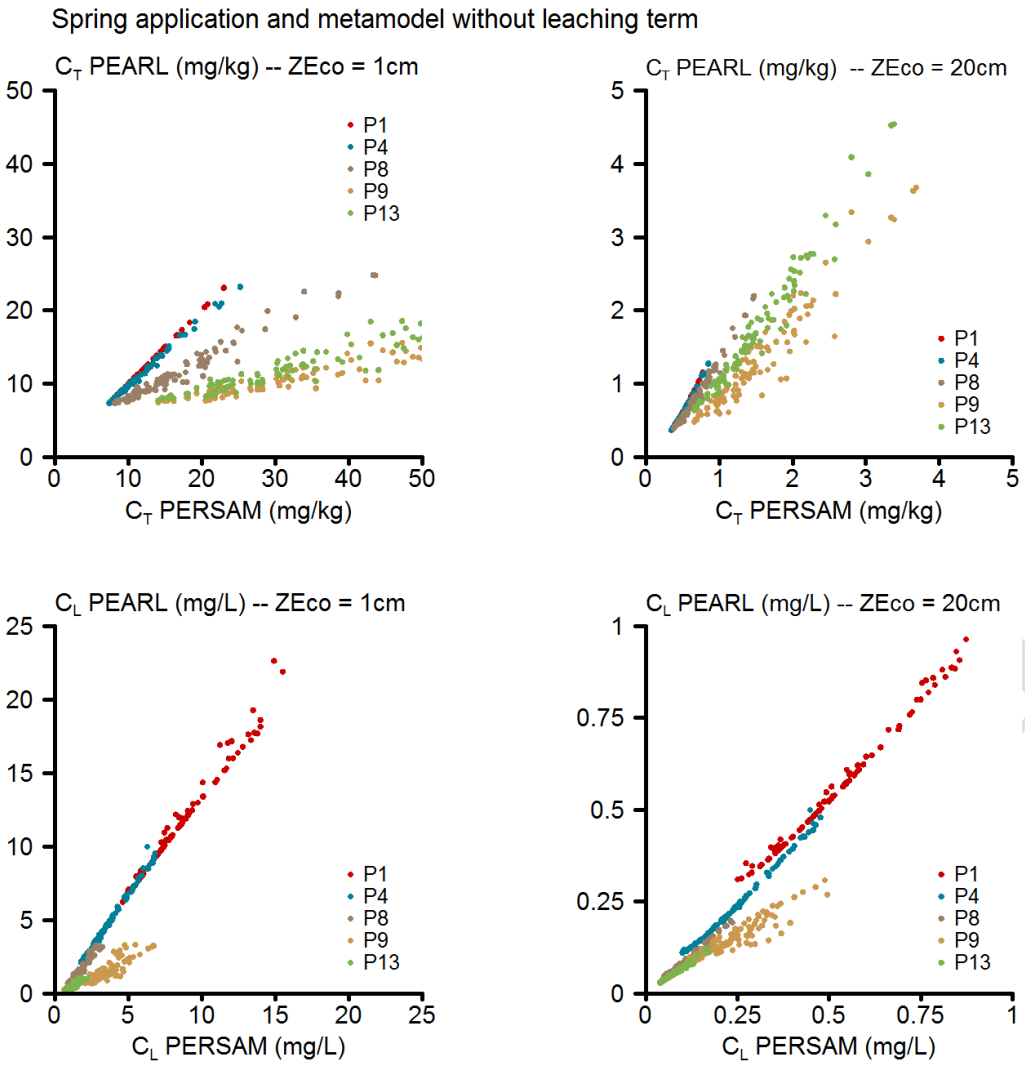

Figure A.5: Comparison of PERSAM and PEARL results for some 2000 scenarios in permanent crops derived using the Tier-3B procedure. Application was in spring (May 1) with a dose of 1 kg ha^{-1} (see further text).

A.6. Listing of the analytical model including the leaching term

The text below shows the source code of the simple analytical model programmed in awk (https://en.wikipedia.org/wiki/AWK) but can of course be programmed in any other programming language. This code has been used to calculate the examples in Section A.5 and is provided as an example.

```
# Listing of the extended PERSAM model including leaching from the evaluation layer
# See Appendix A of EFSA (2016)

BEGIN {

   # User settings (substance and application parameters)
   c = 1;                 # Substance number
   DegT50 = 10;           # Degradation half-life (d)
   Kom = 10;              # Sorption coefficient on organic matter (kg/L)
   ZEco = 0.2;            # Evaluation depth (dm)
   Ztil = 0.2;            # Tillage depth (dm)
   DOSE = 1;              # Application rate (kg/ha or mg/dm2)
   tcycle = 365;          # Application cycle (d)
   kref = 0.6931/DegT50; # Eqn. A4: Degradation constant (d-1)
}
```

```
{
   # Plot specific input, the $ sign refers to the column in the input file
   ID = $1;              # Plot ID
   Zone = $2;            # Focus Zone
   fom = $3;             # Organic matter (kg.kg-1)
   Rho = $4;             # Bulk density (kg.dm-3)
   Teff = $5;            # Mean annual effective temperature (deg C)
   ThetaFC = $6;         # Water content at field capacity (kg.kg-1)
   WFC = ThetaFC/Rho;    # Water content at field capacity (dm3.kg-1)
   Flux = $7;            # Mean daily water flux at the bottom (dm.d-1)

   # Eqn. A1: Concentration after application (mg.kg-1)
   CTini = DOSE/(ZEco*Rho);

   # Eqn. A4: ft
   ft = exp(-7866*(1/(Teff+273.15)-1/293.15));

   # Exponent X: Eqn. A15 (includes the leaching term)
   X = exp(-tcycle*(kref*ft+Flux/(ZEco*(ThetaFC+Rho*fom*Kom))));

   # Eqn. A2: Plateau concentration (mg/kg)
   CTplat = (ZEco/Ztil)*CTini*X/(1-X);

   # Eqn. A5: Peak concentration in total soil (mg/kg)
   CTpeak = CTplat + CTini;

   # Eqn. A6: Peak concentration in the liquid phase (mg/l)
   CLpeak = CTpeak/(WFC+fom*Kom);

   # Output
   printf ("%14s %5d %5d %5d %5d %14.7f %14.7f\n",
   ID,c,10*ZEco,DegT50,Kom,CTpeak,CLpeak);
}
```

Appendix B. Parameterisation of the exposure scenarios

This appendix gives a description of the parameterisation of the exposure scenarios for annual crops and for permanent crops. A comprehensive description of the procedure can be found in EFSA (2010ab), EFSA PPR Panel (2012), and Beulke et al. (20125); the data is described in Hiederer (2012). Because the procedures have slightly changed for the sake of harmonisation, a short summary of the final procedure is given here.

B.1. Scenarios for the analytical model

This section first describes in general how the site specific input data for the simple analytical model was derived from the EFSA spatial dataset. Then specific considerations are given for Tier-1 and Tier-2.

B.1.1 General considerations

The simple analytical model as implemented in the PERSAM software tool requires the following five site specific parameters:

- Arrhenius weighted mean annual temperature (°C)
- Mass fraction of organic matter in the top 30 cm (kg kg^{-1})
- Top soil bulk density (kg L^{-1})
- Top soil water content at field capacity (m^3 m^{-3})
- The mean annual water flux at the lower boundary of the ecotoxicological averaging depth (dm d^{-1})

All basic data to derive these input data is available in the EFSA spatial dataset (version 1.1), which is available at the address http://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool.

Soil data

Organic matter was obtainted by applying a conversion factor of 1.72 to the topsoil organic carbon map as described by Jones et al. (2005). Soil bulk density was calculated from organic matter using a continuous pedotransfer function (Tiktak et al., 2002):

$$\rho = 1800 + 1236 f_{om} - 2910\sqrt{f_{om}} \quad \text{(B1)}$$

where ρ (kg m^{-3}) is the dry bulk density of the soil and f_{om} (kg kg^{-1}) is the organic matter content. The volume fraction of water at field capacity was derived from the soil textural class in the Soil Geographical Database of Europe, using the HYPRES pedotransfer rule (Wösten *et al.*, 1999). Notice that only six different classes are available in the HYPRES database, i.e. course, medium, medium fine, fine, very fine, and non-mineral. The Arrhenius weighted long-term average temperature was derived from the WorldClim database (Hijmans et al., 2005) using the procedure in Appendix A3 of EFSA (2010). The mean annual precipitation, necessary to calculate the water flux at the lowerboundary of the ecotoxicological averaging depth, was also derived from this database.

The soil properties in the EFSA spatial dataset refer to the top 30 cm. These soil properties can directly be used for scenarios for annual crops. However, in permanent crops organic matter cannot be assumed to be uniformly distributed within this top 30 cm soil layer. For this reason, Beulke et al. (2015) introduced correction factors for calculating the depth distribution of organic matter in the top 30 cm (Table 5). Notice that the correction factors corresponding to the ecotoxicological averaging depth have to be applied and that the correction factors are different for situations with and situations without mechanical cultivation (Table 5).

Weather data and the water flux at the bottom of the ecotoxicological averaging depth

The mean annual water flux at the bottom of the ecotoxicological averaging depth was calculated with PEARL for all FOCUS-crops. For each crop, the dominant FOCUS zone per regulatory zone (Table B.9) was selected for modelling (the dominant FOCUS zone is defined as the zone with the largest crop area.) From these simulations, the following ratio was calculated:

$$f_q = \frac{q_{avg,FOCUS}}{(P+I)_{avg,FOCUS}} \quad \text{(B2)}$$

where $q_{avg,FOCUS}$ (dm d^{-1}) is the mean annual flux at the bottom of the ecotoxicological averaging depth in the FOCUS scenario and $(P+I)_{avg,FOCUS}$ (dm d^{-1}) is the sum of the mean annual precipitation P and irrigation I of the FOCUS scenario. The above procedure requires the availability of maps of (P+I) for every pixel and every crop. The following procedure was used to obtain these maps:

- for non-irrigated crop-scenario combinations, precipitation at the respective location was selected;
- for irrigated crop-scenario combination, the sum of precipitation and simulated irrigation was selected; so when a crop is irrigated, it is assumed that the sum of precipitation and irrigation is constant in the entire FOCUS zone; this is justified because low rainfall amounts will be compensated for by high irrigation amounts and vice versa (see also Figure 4 in Tiktak et al., 2004).

Table B.1 gives the properties of the FOCUS zones, Table B.2 gives the mean annual irrigation amounts and Tables B.3-B.5 give an overview of f_q values for each FOCUS-crop combination. Differences of f_q values between the scenarios are relatively small. The reason is that these ratios are primarily affected by the vertical distribution of roots, which generally shows only limited variability between the FOCUS scenarios. This also justifies the use of the original FOCUS soils for these calculations and not the soil building blocks in Table B.8.

Table B.1: FOCUS groundwater climatic zones (Hiederer, 2012) and climate properties of the FOCUS scenarios (FOCUS, 1999)

FOCUS zone	Total mean annual precipitation (mm)	Mean annual temperature (°C)	Mean annual precipitation of FOCUS scenario (mm)	Mean annual temperature of FOCUS scenario (°C)
Châteaudun	< 600	5 to < 12.5	648	11.3
Hamburg	600 to < 800	5 to < 12.5	786	9.0
Jokioinen	All[a]	< 5	650	4.1
Kremsmünster	800 to < 1000	5 to < 12.5	899	8.6
Okehampton	≥ 1000	5 to < 12.5	1038	10.2
Piacenza	800 to < 1000	≥ 12.5	857	1.2
Porto	≥ 1000	≥ 12.5	1150	14.8
Sevilla	< 600	≥ 12.5	493	17.9
Thiva	600 to < 800	≥ 12.5	500	16.2

[a] No distinction in precipitation for temperatures < 5 °C (see Hiederer, 2012)

Table B2: Irrigation applied for all regulatory zone-crop combinations (based on calculations with PEARL). The dominant FOCUS zone as listed in Table B.9 was used for modelling.

	Regulatory zone		
Crop	**North**	**Centre**	**South**
Apples	0	0	1003
Bare soil (between the rows)	0	0	0
Beans (field and vegetables)	0	260	0
Bush berries	0	266	771
Cabbage	0	185	496
Carrots	0	175	524
Citrus	-	-	737
Cotton	-	0	238
Grass	0	0	0
Grass (between the rows)	0	0	0
Hops	-	0	0
Linseed	0	0	612
Maize	0	267	0
No crop (fallow)	0	0	0
Oil seed rape (summer)	0	0	0
Oil seed rape (winter)	0	0	0
Olives	-	-	721
Onions	0	0	90
Peas (animals)	0	0	0
Potatoes	0	0	0
Soybean	0	247	491
Spring cereals	0	0	0
Strawberries	0	277	505
Sugar beets	0	0	0
Sunflowers	0	384	0
Tobacco	-	360	657
Tomatoes	0	181	155
Vines	-	241	790
Winter cereals	0	0	0

Table B3: Ratio (f_q) of the mean annual water flux at 1 cm depth and the mean annual precipitation plus irrigation for all regulatory zone-crop combinations. The dominant FOCUS zone as listed in Table B.9 was used for modelling.

	Regulatory zone		
Crop	**North**	**Central**	**South**
Apples	0.72	0.72	0.79
Bare soil (between rows)	0.54	0.54	0.46
Beans (field)	0.65	0.63	0.65
Bush berries	0.72	0.68	0.72
Cabbage	0.64	0.61	0.57
Carrots	0.64	0.61	0.64
Citrus	-	-	0.88
Cotton	-	0.65	0.59
Grass	0.72	0.72	0.72
Grass between rows	0.72	0.72	0.64
Hops	-	0.62	0.62
Linseed	0.67	0.67	0.61
Maize	0.66	0.64	0.66
No crop (fallow)	0.54	0.54	0.46
Oild seed rape (summer)	0.65	0.65	0.65
Oild seed rape (winter)	0.65	0.65	0.65
Olives	-	-	0.71
Onions	0.63	0.63	0.55
Peas (animals)	0.65	0.58	0.65
Potatoes	0.63	0.63	0.63
Soybean	0.70	0.69	0.68
Spring cereals	0.67	0.59	0.67
Strawberries	0.66	0.63	0.62
Sugar beets	0.67	0.67	0.67
Sunflowers	0.69	0.70	0.69
Tobacco	-	0.67	0.64
Tomatoes	0.68	0.64	0.58
Vines	-	0.72	0.74
Winter cereals	0.64	0.58	0.64

1928 **Table B4:** Ratio (f_q) of the mean annual water flux at 5 cm depth and the mean annual precipitation
1929 plus irrigation for all regulatory zone-crop combinations. The dominant FOCUS zone as listed in
1930 Table B.9 was used for modelling.

	Regulatory zone		
Crop	**North**	**Central**	**South**
Apples	0.71	0.71	0.78
Bare soil (between rows)	0.54	0.54	0.46
Beans (field)	0.64	0.62	0.64
Bush berries	0.71	0.67	0.70
Cabbage	0.63	0.59	0.54
Carrots	0.63	0.60	0.61
Citrus	-	-	0.87
Cotton	-	0.64	0.57
Grass	0.70	0.70	0.70
Grass between rows	0.70	0.70	0.61
Hops	-	0.61	0.61
Linseed	0.64	0.64	0.59
Maize	0.65	0.62	0.65
No crop (fallow)	0.54	0.54	0.46
Oild seed rape (summer)	0.64	0.64	0.64
Oild seed rape (winter)	0.64	0.64	0.64
Olives	-	-	0.70
Onions	0.62	0.62	0.53
Peas (animals)	0.64	0.56	0.64
Potatoes	0.61	0.61	0.61
Soybean	0.67	0.66	0.65
Spring cereals	0.66	0.56	0.66
Strawberries	0.64	0.62	0.55
Sugar beets	0.65	0.65	0.65
Sunflowers	0.68	0.69	0.68
Tobacco	-	0.66	0.61
Tomatoes	0.66	0.63	0.56
Vines	-	0.72	0.73
Winter cereals	0.63	0.57	0.63

1931

1932 **Table B5:** Ratio (f_q) of the mean annual water flux at 20 cm depth and the mean annual precipitation
1933 plus irrigation for all regulatory zone-crop combinations. The dominant FOCUS zone as listed in
1934 Table B.9 was used for modelling.

	Regulatory zone		
Crop	**North**	**Central**	**South**
Apples	0.64	0.64	0.68
Bare soil (between rows)	0.54	0.54	0.46
Beans (field)	0.55	0.54	0.55
Bush berries	0.63	0.59	0.58
Cabbage	0.55	0.50	0.36
Carrots	0.56	0.53	0.45
Citrus	-	-	0.79
Cotton	-	0.55	0.45
Grass	0.58	0.58	0.58
Grass between rows	0.58	0.58	0.44
Hops	-	0.60	0.60
Linseed	0.53	0.53	0.44
Maize	0.57	0.53	0.57
No crop (fallow)	0.54	0.54	0.46
Oild seed rape (summer)	0.54	0.54	0.54
Oild seed rape (winter)	0.59	0.59	0.59
Olives	-	-	0.66
Onions	0.55	0.55	0.41
Peas (animals)	0.55	0.44	0.55
Potatoes	0.53	0.53	0.53
Soybean	0.53	0.53	0.47
Spring cereals	0.58	0.45	0.58
Strawberries	0.57	0.55	0.19
Sugar beets	0.55	0.55	0.55
Sunflowers	0.60	0.62	0.60
Tobacco	-	0.61	0.43
Tomatoes	0.57	0.54	0.45
Vines	-	0.66	0.66
Winter cereals	0.57	0.48	0.57

1935 ### B.1.2 Tier-1 parameterisation

1936 There are two sets of Tier-1 scenarios, i.e. one set for annual crops and one set for permanent crops.
1937 The Tier-1 scenarios apply to the 95th-percentile concentration in the entire area of annual or
1938 permanent crops. The scenarios for annual crops were derived using the statistical procedure as
1939 described in EFSA (2010) and Tiktak et al. (2013) and the scenarios for permanent crops were derived
1940 using the procedure described in Beulke et al. (2015). Their properties are given in Tables 1-4. In
1941 permanent crops there are two types of cultivation systems with different soil profiles. The depth
1942 distribution of soil properties within the top 30 cm layer was obtained using the correction factors in
1943 Table 5.

1944 The scenarios for annual crops were selected using a version of the analytical model that did not
1945 consider leaching of the substance from the averaging layer. Furthermore, the Tier-1 scenarios do not
1946 refer to a specific crop. This implies that precipitation at the scenario location may not correspond
1947 with realistic worst-case situations. For this reason, the flux at the bottom boundary of the averaging
1948 layer was calculated using the following procedure:

1949 • the 10th percentile of precipitation within the regulatory zone was used instead of precipitation at
1950 the scenario location;
1951 • the crop giving the lowest leaching fraction was used.

Notice that the 10th percentile is a realistic worst case given that wash-off from the crop canopy is not considered in Tier-1.

For consistency reasons, the procedure above has been used for both annual crops and permanent crops (See Table B.6).

Table B.6: Mean annual precipitation (*P*) and the ratio of the mean annual water flux at 1, 5 and 20 cm depth and the mean annual precipitation for the Tier-1 scenarios. The 10th percentile of precipitation and the worst-case of the leaching factor in each regulatory zone are used.

Scenarios	P (mm yr^{-1})	f_q at 1 cm (-)	f_q at 5 cm (-)	f_q at 20 cm (-)
ACTN and ACLN	568	0.54	0.54	0.53
ACTC and ACLC	528	0.54	0.54	0.44
ACTS andACLS	445	0.46	0.46	0.19
PCTN and PCLN	654	0.54	0.54	0.53
PCTC and PCLC	564	0.54	0.54	0.44
PCTS and PCLS	473	0.46	0.46	0.19

B.1.3 Tier-2 parameterisation

At Tier-2, the analytical model uses the same spatial data as at Tier-1; however, all data including precipitation, irrigation, temperature, the FOCUS zone and the f_q ratio refer to the scenario location. When the substance is applied to the canopy, the fraction of the dose reaching the soil should be obtained from Tables 11 and 12). Notice that these tables are based on average wash-off values over a period of 20 years because this generates exposure concentrations that are close to those simulated with the numerical models (Appendix D). Finally, the worst case of the three regulatory zones was used to derive the default fraction that reaches the soil. Because Tier-2 is based on the area of intended use and not on the total crop area, this tier also requires the crop areas as derived from the CAPRI2000 dataset for annual crops and the assessment done by Beulke et al. (2015) for permanent crops – see Hiederer (2012) and Beulke et al. (2015) for details and file names. When used for substances whose $DegT_{50}$ or K_{om} is pH-dependent, the pH of the topsoil is needed as well. The pH-value in the EFSA spatial dataset is the pH-H_2O so the applicant may need to apply the procedure in Section 3.3.1 to convert the pH-value as measured in the sorption or degradation experiment.

The scenario prameterisation for permanent crops is different for in-row and between-row exposure assessments (Section 1.3.2): Between-row areas are typically non-irrigated but often mechanically cultivated (for citrus, vines, olives and hops). In addition areas between the rows may be without cover (bare soil) or are covered by grass depending on the permanent crop type (Table B.7). Note that the models already account for the correct scenario parameterisation depending on the exposure assessment selected by the user.

Table B.7: Differences in scenario parameterisation with respect to in-row and between-row soil exposure assessment in permanent crops grown in rows (based on common cultivation to practices as given in Beulke, 2015). These differences apply to both the analytical model and the numerical models.

Permanent crop	Exposure assessment	Irrigation	Focus crop	Mechanical cultivation[b]
Pome and stone fruit	In-row	Yes/No[a]	Apples	No
	Between-row	No	Grass	No
Bush berries	In-row	Yes/No[a]	Bush berries	No
	Between-row	No	Grass	No
Citrus	In-row	Yes/No[a]	Citrus	No
	Between-row	No	No cover (bare soil)	Yes
Olives[c]	In-row	Yes/No[a]	Olives[c]	Yes
	Between-row	No	No cover (bare soil)	Yes
Vines	In-row	Yes/No[a]	Vines	No
	Between-row	No	No cover (bare soil)	Yes
Hops[c]	In-row	Yes/No[a]	Hops[c]	No
	Between-row	No	No cover (bare soil)	Yes

[a] Drip irrigation depending on the FOCUS zone (see Table B.10)
[b] Mechanical cultivation is characterized by a specific top soil organic matter profile and perfect mixing over the top 5 cm two times a year
[c] Not a FOCUS GW crop (for parameterization approach refer to Beulke, 2015)

B.2. Scenarios for the numerical models

The Tier-3A scenarios must to be selected using the following procedure, which will also need to be implemented in the PERSAM tool (Section 3.5.1):

- The maps obtained in Tier-2 are transferred into maps of the vulnerability score. (The vulnerability score is 0% for the pixel with the lowest concentration and 100% for the pixel with the highest concentration; see EFSA (2012) for details.)
- From this map select all pixels with a vulnerability score between 94% and 96%;
- Calculate for this subset of pixels the median value of temperature, precipitation plus irrigation, organic matter of the top 30 cm of the soil and – when applicable – the pH of the topsoil.
- Select the pixels with properties closest to the median value of these properties. This comes down to optimising the following objective function:

$$O = \sum_{i=1}^{n} \frac{|p_i - p_{50}|}{p_{50}} \qquad \text{(B3)}$$

where O is the objective function to be minimised, p is the property (temperature, $P+I$, organic matter or pH), p_{50} is the median of these properties, i is an index and n is the number of properties.

This procedure avoids the selection of scenarios with extreme properties. Notice that the effect of both leaching and washoff are included in the selection of the scenario, because both processes are included in the Tier-2 calculation. However, because the Tables in Appendix D are based on average values of 20 years, it cannot fully be ensured that the models used at Tier-3A will not deliver higher wash-off values. However, the effect of these differences is accounted for in the model adjustment factors.

Different scenarios must be selected for the concentration in total soil and the concentration in pore water and for the parent compound and for each metabolite. In principle a separate scenario needs to be developed for each ecological averaging depth. However, if only one depth is needed in the effects assessment, only one scenario needs to be developed and other results do not need to be reported. It is finally considered acceptable to base the scenario selection only on the peak concentration (so no individual scenarios for different TWA values).

This scenario selection procdedure will deliver the geographical coordinates of the scenario. Using these coordinates, the following information can be looked up in the EFSA spatial dataset:

- arithmetic mean annual temperature (°C);
- mean annual precipitation (dm d^{-1});
- organic matter content of the top 30 cm of the soil (kg kg^{-1});
- pH of the topsoil (–);
- soil textural class (course, medium, medium fine, fine, very fine, no mineral).

Scenarios for PEARL and PELMO are build by combining the above five properties with crop and weather data from the dominant FOCUS groundwater scenarios (EC, 2014) within each regulatory zone. In permanent crops grown in rows, scenario selection is always based on the soil and cropping system in the treated rows.

B.2.1. Soil profiles

In addition to the properties of the topsoil (0-30 cm), PEARL and PELMO need properties of the subsoil (30 cm – 200 cm). These can be obtained using average soil profiles, which were based on all arable soil profiles available in the Soil Profile Analytical Database of Europe (v1). Averages were calculated for the 0-30 cm soil layer, the 30-60 cm soil layer, the 60-100 cm soil layer and the 100-200 cm soil layer (cf. FOCUS, 2000) and are shown in Table B.8. The use of average soil profiles is considered acceptable, because the evaluation depth for the exposure assessment is 1-20 cm (see EFSA, 2010 for additional considerations).

The scenario selection procedure returns the soil textural class at the scenario location. Based on this, the soil textural distribution (clay, silt and sand) can be assigned using the values in Tables B.8. Organic matter of the subsoil is calculated with the equation:

$$f_{om} = f_{z,om} f_{om,0} \tag{B2}$$

where f_{om} (kg kg^{-1}) is the mass fraction of organic matter, $f_{z,om}$ (-) is the organic matter content relative to the topsoil organic matter content, and $f_{om,0}$ (kg kg^{-1}) is the organic matter content of the topsoil, which has been derived in the scenario selection procedure. Notice that $f_{z,om}$ depends on the soil textural class, see Table B.8. In the case of permanent crops, additional scaling factors apply to the 0-30 cm soil layer as well – see section "differentiation of soil properties of the topsoil" below.

Soil bulk density is derived from the organic matter content using Eqn. B1. Soil hydraulic functions as required by PEARL can be obtained from the soil textural class using the HYPRES pedotransfer rules (Wösten et al., 2004) and are also listed in Table B.8. The consequence of using these so-called class pedotransfer rules is that the soil hydraulic properties are considered to be independent of organic matter content and density of the soil. The water content at field capacity and the water content at wilting point required by PELMO were estimated with the analytical function proposed by van Genuchten (1980):

$$\theta(h) = \theta_r + \frac{\theta_s - \theta_r}{\left(1 + \left|\alpha h\right|^n\right)^{-m}} \tag{B3}$$

where θ (m^3 m^{-3}) is the volume fraction of water, h (cm) is the soil water pressure head, θ_s (m^3 m^{-3}) is the volume fraction of water at saturation, θ_r (m^3 m^{-3}) is the residual water content in the extremely dry range, α (cm^{-1}) and n (-) are empirical parameters, and m (-) can be taken equal to:

$$m = 1 - \frac{1}{n} \tag{B4}$$

The depth of the soil profile is assumed to be 2 m. The lower boundary condition of the hydrological model is not expected to have a large effect on the predicted concentration in top soil. For pragmatic reasons, a free-drainage boundary condition was therefore assumed for all scenarios.

Table B.8: Mean soil profiles for the soil textural classes at the soil map of Europe. The soil profiles (totalling 534) were calculated using all arable soil profiles in the SPADE database.

Coarse											
Depth[a]	**Sand**	**Silt**	**Clay**	$f_{z,om}$ [b]	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	83.2	11.6	5.2	1.0	1.0	0.4	0.03	0.0383	1.377	0.6	1.25
30-60	84.4	10.6	5.0	0.5	0.5	0.37	0.03	0.0430	1.521	0.7	1.25
60-100	85.6	10.0	4.4	0.3	0.3	0.37	0.03	0.0430	1.521	0.7	1.25
> 100	85.8	9.5	4.7	0.1	0.0	0.37	0.03	0.0430	1.521	0.7	1.25
Medium											
Depth	**Sand**	**Silt**	**Clay**	$f_{z,om}$	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	39.5	41.5	19.0	1.0	1.0	0.44	0.01	0.0310	1.180	0.121	-2.42
30-60	38.8	41.1	20.1	0.5	0.5	0.40	0.01	0.0250	1.169	0.108	-0.74
60-100	40.3	38.9	20.8	0.3	0.3	0.40	0.01	0.0250	1.169	0.108	-0.74
> 100	41.0	38.3	20.7	0.1	0.0	0.40	0.01	0.0250	1.169	0.108	-0.74
Medium fine											
Depth	**Sand**	**Silt**	**Clay**	$f_{z,om}$	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	8.7	71.0	20.3	1.0	1.0	0.43	0.01	0.0080	1.254	0.023	-0.59
30-60	8.6	68.8	22.6	0.5	0.5	0.41	0.01	0.0080	1.218	0.040	0.50
60-100	7.7	68.4	23.9	0.3	0.3	0.41	0.01	0.0080	1.218	0.040	0.50
> 100	7.5	69.9	22.6	0.1	0.0	0.41	0.01	0.0080	1.218	0.040	0.50
Fine											
Depth	**Sand**	**Silt**	**Clay**	$f_{z,om}$	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	16.2	39.2	44.6	1.0	1.0	0.52	0.01	0.0370	1.101	0.248	-1.98
30-60	16.5	37.9	45.6	0.5	0.5	0.48	0.01	0.0200	1.086	0.085	-3.71
60-100	16.1	38.4	45.5	0.3	0.3	0.48	0.01	0.0200	1.086	0.085	-3.71
> 100	15.9	38.6	45.5	0.1	0.0	0.48	0.01	0.0200	1.086	0.085	-3.71
Very fine											
Depth	**Sand**	**Silt**	**Clay**	$f_{z,om}$	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	4.8	30.7	64.5	1.0	1.0	0.61	0.01	0.0270	1.103	0.150	2.50
30-60	7.2	25.6	67.2	0.5	0.5	0.54	0.01	0.0170	1.073	0.082	0.00
60-100	9.0	23.5	67.5	0.3	0.3	0.54	0.01	0.0170	1.073	0.082	0.00
> 100	10.6	20.0	69.4	0.1	0.0	0.54	0.01	0.0170	1.073	0.082	0.00
Organic											
Depth	**Sand**	**Silt**	**Clay**	$f_{z,om}$	f_z	θ_s	θ_r	α	n	K_s	λ
0-30	61.0	8.8	29.0	1.0	1.0	0.77	0.01	0.0130	1.204	0.080	0.40
30-60	70.0	10.0	20.0	1.1	0.5	0.77	0.01	0.0130	1.204	0.080	0.40
60-100	61.4	10.0	20.0	1.1	0.3	0.77	0.01	0.0130	1.204	0.080	0.40
> 100	69.1	10.0	20.0	1.1	0.0	0.77	0.01	0.0130	1.204	0.080	0.40

a) Depth (cm) is the depth, sand (%) is the sand content, silt (%) is the silt content, clay (%) is the clay content, $f_{z,om}$ (-) is the organic matter content relative to the topsoil organic matter content, f_z (-) is the depth dependence of degradation in soil, θ_s ($m^3\ m^{-3}$) is the volume fraction of water at saturation, θ_r ($m^3\ m^{-3}$) is the residual water content in the extremely dry range, α (cm^{-1}) and n (-) are empirical parameters of the van Genuchten equation, K_s ($m\ d^{-1}$) is the saturated hydraulic conductivity, and λ (-) is a shape parameter.

For the top 1 cm, the thickness of the numerical compartments was set to 2 mm, because the evaluation depth of the exposure assessment can be as small as 1 cm. The layer thickness was 1 cm for the 1-30 cm soil layer, 2.5 cm for the 30-100 cm soil layer, and 5 cm for the 100-200 cm soil layer.

The dispersion length was set to a value of 2.5 cm for the layer 0-60 cm and 5 cm for the layer 60-200 cm. The value for the topsoil differs from the value used in FOCUS (2010), because the evaluation depth is 1-20 cm, whereas the evaluation depth for the FOCUS scenarios is 100 cm. For short travel distances, a lower value of the dispersion coefficient is needed (Vanderborght et al., 2007) All other soil parameters, including the depth dependence of transformation, were set to the default values published by FOCUS (2010).

The scenario prameterisation for permanent crops is different for in-row and between-row exposure assessments (Section 1.3.2): Between-row areas are typically non-irrigated but often mechanically cultivated. In addition areas between the rows may be without cover (bare soil) or are covered by grass depending on the permanent crop type (Table B7). Note that the models already account for the correct scenario parameterisation depending on the exposure assessment selected by the user.

B.2.2. Weather data

Weather data is always based on the FOCUS groundwater weather series of the dominant FOCUS scenario within each regulatory zone (see Table B.9 for the list of dominant FOCUS zones). The advantage of this procedure is that the applicant does not need to request data in addition to the data that is available in the EFSA spatial database and in the FOCUS groundwater scenarios. This deviation from the original procedure described in EFSA (2010) is considered justifiable because long-term accumulation of a substance is primarily affected by the long-term average temperature and to a lesser extent by daily weather conditions. To guarantee consistency in the tiered approach, temperatures and precipitation in the FOCUS weather series have to be scaled to the temperature and precipitation at the scenario location:

$$T_{day,scenario} = T_{day,FOCUS} + T_{avg,scenario} - T_{avg,FOCUS} \quad \text{(B5a)}$$

$$P_{day,scenario} = \frac{P_{avg,scenario}}{P_{avg,FOCUS}} P_{day,FOCUS} \quad \text{(B5b)}$$

where $T_{day,scenario}$ is the daily mean temperature at the soil exposure scenario location, $T_{avg,scenario}$ is the mean annual temperature at the soil exposure scenario location, $T_{avg,FOCUS}$ is the mean annual temperature of the FOCUS groundwater scenarios (Table B.3), $P_{day,scenario}$ (dm d^{-1}) is the daily mean precipitation at the scenario location, $P_{avg,scenario}$ is the mean annual precipitation at the scenario location, $P_{avg,FOCUS}$ is the mean annual precipitation of the FOCUS scenario and $P_{day,FOCUS}$ is the mean annual precipitation of the FOCUS scenario (Table B.4) . Notice that scaling of temperatures is based on the "normal" mean annual temperature and not on the Arrhenius weighted temperature.

All other weather data - including evapotranspiration - are kept to their original values.

Both PEARL and PELMO have the option to scale temperatures and precipitation automatically using the equation above. The advantage is that the original FOCUS weather files can be kept and that only one parameters needs to be input to the model. The scaling parameters (ΔT (^{o}C) and f_P (-)) that need to be input are given by the equations:

$$\Delta T = T_{avg,scenario} - T_{avg,FOCUS} \quad \text{(B6a)}$$

$$f_p = \frac{P_{avg,scenario}}{P_{avg,FOCUS}} \quad \text{(B6b)}$$

B.2.3. Crop data

At Tier-3A crop and weather data are taken from the dominant FOCUS scenario in the regulatory zone (Table B.9; see Table B.6 for definitions of FOCUS zones). The crop area is based on the list of CAPRI crops (Hiederer, 2012) and permanent crops (Beulke et al., 2015) (see Table 8 and 9 for the link between CAPRI and permanent crops and FOCUS crops).

In some cases the dominant FOCUS scenario cannot be linked to a FOCUS crop. This is particularly the case for those FOCUS crops that are only parameterised for a few FOCUS scenarios, e.g. linseed and soybeans. In those specific cases the most appropriate crop was selected for parameterising crop development (i.e. preferably a crop in the same regulatory zone). Note that weather data is in those cases still taken from the dominant FOCUS zone.

Table B.9: Dominant FOCUS scenario per regulatory zone and crop to be used at Tier-3A. If a FOCUS crop is not available for the respective combination, a second best alternative is selected. In the header, DS is the dominant scenario, AR means the relative area of this dominant scenario (as a percentage of the total area of the respective crop in the respective zone) and FO is the FOCUS crop to be used at Tier-3A. Shaded cells indicates combinations where dominant scenario does not have a FOCUS crop.

Crop		North			Centre			South		
FOCUS	**CAPRI/Permanent crop**	**DS**	**AR**	**FO**	**DS**	**AR**	**FO**	**DS**	**AR**	**FO**
Apples	Pome and stone	HA	88	HA	HA	62	HA	SE	46	SE
Beans	Pulses	HA	56	HA	CH	50	HA	HA	47	TH
Bush berries	Bush berries	HA	85	HA	CH	65	CH	SE	43	SE
Cabbage	Other vegetables	HA	70	HA	CH	47	CH	SE	33	SE
Carrots	Other vegetables	HA	70	HA	CH	47	CH	SE	33	TH
Citrus	Citrus	-	-	-	-	-	-	SE	82	SE
Cotton	Texture crops	-	-	-	HA	46	TH	TH	53	TH
Grass	Grass	HA	75	HA	HA	38	HA	HA	55	HA
Hops	Hops	-	-	-	HA	56	HA	HA	68	HA
Linseed	Texture crops	HA	60	OK	HA	46	OK	SE	53	OK
Maize	Maize	HA	52	HA	CH	54	CH	HA	32	HA
No crop (fallow)	Fallow	HA	58	HA	HA	47	HA	SE	31	SE
Sseed rape (summer)	Rapes	HA	57	OK	HA	50	OK	HA	76	OK
Seed rape (winter)	Rapes	HA	57	HA	HA	50	HA	HA	76	HA
Olives	Olives	-	-	-	-	-	-	SE	53	SE
Onions	Other vegetables	HA	75	HA	HA	74	HA	SE	21	TH
Peas	Pulses	HA	56	HA	CH	50	CH	HA	47	HA
Potatoes	Potatoes	HA	68	HA	HA	51	HA	HA	45	HA
Soybean	Soybean	HA	95	PI	CH	64	PI	TH	35	PI
Spring cereals	Cereals	HA	56	HA	CH	48	CH	HA	34	HA
Strawberries	Other vegetables	HA	70	HA	CH	47	HA	SE	33	SE
Sugar beets	Sugarbeet	HA	63	HA	HA	50	HA	HA	51	HA
Sunflowers	Sunflower	JO	87	PI	CH	83	PI	HA	24	PI
Tobacco	Tobacco	-	-	-	CH	61	PI	SE	37	TH
Tomatoes	Other vegetables	HA	70	CH	CH	47	CH	SE	33	SE
Vines	Vines	-	-	-	CH	57	CH	SE	33	SE
Winter cereals	Cereals	HA	56	HA	CH	48	CH	HA	34	HA

CH, Châteaudun; HA, Hamburg; JO, Jokioinen; KR, Kremsmünster; OK, Okehampton; PI, Piacenza; PO, Porto; SE, Seville; TH, Thiva. See Table B.6 for further details

B.2.4. Irrigation data

Irrigation is applied at all tiers in line with the respective dominant FOCUS zone. The FOCUS zones where irrigation is considered to take place are Châteaudun, Piacenza, Sevilla, Porto and Thiva (see Table B.10). In case of annual crops sprinkler irrigation (weekly irrigation) is applied, whereas for permanent crops (in-row exposure assessment) weekly drip (surface) irrigation is assumed. Note that

for between-row exposure assessments for permanent crops no irrigation is assumed at all. Irrigation for annual crops is assumed from crop emergence to start of senescence. In case of evergreen permanent crops (citrus and olives) the irrigation period is the entire year. For other permanent crops, the irrigation periods are defined from start of leaf development to start of senescence.

Table B.10: Irrigation settings for all crop-scenario combinations.

	Regulatory zone		
Crop	**North**	**Central**	**South**
Apples	No	No	Sur
Bare soil (between rows)	No	No	No
Beans (field)	No	Spr	No
Bush berries	No	Spr	Spr
Cabbage	No	Spr	Spr
Carrots	No	Spr	Spr
Citrus	-	-	Sur
Cotton	-	No	Spr
Grass	No	No	No
Grass between rows	No	No	No
Hops	-	No	No
Linseed	No	No	Spr
Maize	No	Spr	No
No crop (fallow)	No	No	No
Oild seed rape (summer)	No	No	No
Oild seed rape (winter)	No	No	No
Olives	-	-	Sur
Onions	No	No	Spr
Peas (animals)	No	No	No
Potatoes	No	No	No
Soybean	No	Spr	Spr
Spring cereals	No	No	No
Strawberries	No	Spr	Spr
Sugar beets	No	No	No
Sunflowers	No	Spr	No
Tobacco	-	Spr	Spr
Tomatoes	No	No	No
Vines	-	No	No
Winter cereals	No	No	No

'Sur' indicates surface (drip) irrigation

'Spr' indicates sprinkler irrigation

B.2.5. Soil management

Soil cultivation (tillage) is applied in case of annual crops assuming perfect mixing of the top 20 cm of the soil layer 1 month before emergence. In case of permanent crops, situations with mechanical cultivation are already reflected by the top soil organic matter profile. In addition, situations with mechanical cultivation are considered to account for tillage (perfect mixing) to a soil depth of 5 cm two times a year (1st of May and the 15th of June). In contrast to annual crops, mechanical cultivation for permanent crops is specific to the crop and exposure assessment (Table B.11).

2143 **Table B.11:** Soil management setting for annual and permanent crops.

Crop type	Crop	Tillage (ploughing to 20 cm)	Mechanical cultivation*	
			In-row exposure	Between-row exposure
Annual crops	All	Yes		
Permanent crops	Pome and stone fruit	No	No	No
	Bush berries	No	No	No
	Vines	No	No	Yes
	Citrus	No	No	Yes
	Olives	No	Yes	Yes
	Hops	No	No	Yes
Permanent grass	-	No	No	

2144 * Mechanical cultivation is accompanied by tillage (perfect soil mixing) to a soil depth of 5 cm

2145 ### B.2.6. The warming-up period

2146 As described in Section 3.4.2, the warming-up period consists of a multiple of six years and each six-
2147 year period consists of the same meteorological time series. It is important that this six-year time
2148 series has an approximately "average" air temperature. If the temperature of this six-year series is too
2149 low, then the all-time maximum of the concentrations is likely to happen in the first of the 20-year
2150 evaluation period, which is undesirable.

2151 Therefore, for each of the FOCUS Groundwater scenarios the six-year averages of the Arrhenius air
2152 temperatures of the meteorological time series were calculated (see Table B.12). This gives 15
2153 possible options for six-year periods for each scenario (starting in 1907 to 1921). Next, the average
2154 Arrhenius air temperature of all 15 options was calculated (e.g. 10.57 °C for Hamburg as shown in
2155 Table B.12). Subsequently, the desired six-year period was selected using the criteria: (i) that its
2156 Arrhenius temperature is lower than this average and (ii) that its Arrhenius temperature is closest to
2157 this average. For example, for Hamburg this is the period 1913–1918 because its Arrhenius
2158 temperature of 10.49 °C is lower than the 10.57 °C average and is closer to 10.57 °C than all the other
2159 periods with an average Arrhenius temperature below 10.57 °C.

2160 This gives the following six-year time series for the warming-up periods:

2161 • FOCUS GW Châteaudun: 1911–1916;
2162 • FOCUS GW Hamburg: 1913–1918;
2163 • FOCUS GW Jokioinen: 1916–1921;
2164 • FOCUS GW Kremsmünster: 1915–1920;
2165 • FOCUS GW Okehampton: 1912–1917;
2166 • FOCUS GW Piacenza: 1910–1915;
2167 • FOCUS GW Porto: 1919–1924;
2168 • FOCUS GW Sevilla: 1917–1922;
2169 • FOCUS GW Thiva: 1918–1923.

2170 **Table B.12:** Annual average air temperatures and annual average Arrhenius air temperatures of the
2171 FOCUS GW scenarios

Year	Scenario Châteaudun			Scenario Hamburg		
	Annual average temperature (°C)	**Annual average Arrhenius temperature (°C)**	**Average of Arrhenius temperature of previous 6 years (°C)**	**Annual average temperature (°C)**	**Annual average Arrhenius temperature (°C)**	**Average of Arrhenius temperature of previous 6 years (°C)**
1907	11.04	12.86		9.90	11.84	
1908	11.69	13.97		9.18	11.19	
1909	11.20	12.41		9.32	10.69	
1910	10.64	11.97		8.32	9.88	
1911	10.77	12.43		7.53	9.36	
1912	10.57	12.12	12.63	7.99	9.62	10.43
1913	11.46	13.06	12.66	8.29	10.06	10.13
1914	11.98	13.65	12.61	9.03	11.01	10.10
1915	11.59	13.62	12.81	9.38	11.22	10.19
1916	11.03	12.59	**12.91**	8.47	9.93	10.20
1917	10.29	12.36	12.90	8.23	10.22	10.34
1918	10.58	12.52	12.97	8.75	10.49	**10.49**
1919	10.54	12.59	12.89	8.15	9.80	10.44
1920	11.76	13.08	12.79	9.63	11.09	10.46
1921	12.35	14.13	12.88	9.79	11.30	10.47
1922	12.45	14.15	13.14	10.33	11.64	10.75
1923	11.14	13.12	13.26	9.30	11.00	10.88
1924	11.29	12.91	13.33	9.97	11.87	11.12
1925	10.81	12.24	13.27	8.62	10.15	11.17
1926	12.66	14.24	13.47	9.78	11.80	11.29
Average			**12.97**			**10.57**

2172

Year	Scenario Jokioinen			Scenario Kremsmünster		
	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)
1907	5.49	7.31		8.88	11.01	
1908	2.68	5.06		8.70	10.94	
1909	3.38	5.67		8.88	10.52	
1910	2.60	6.02		7.94	9.74	
1911	3.49	6.25		8.45	10.52	
1912	3.53	6.62	6.15	7.75	9.80	10.42
1913	3.53	5.99	5.93	8.07	10.19	10.28
1914	4.70	6.89	6.24	8.39	10.73	10.25
1915	4.59	7.36	6.52	8.70	11.11	10.35
1916	4.55	6.96	6.68	7.74	9.55	10.31
1917	2.22	6.29	6.68	7.65	10.32	10.28
1918	3.22	6.44	6.65	8.14	10.55	10.41
1919	2.21	5.10	6.50	8.03	10.50	10.46
1920	3.89	6.97	6.52	9.09	11.00	**10.51**
1921	5.75	7.57	**6.55**	9.30	11.03	10.49
1922	5.80	7.31	6.61	8.97	10.86	10.71
1923	5.80	7.46	6.81	8.65	10.90	10.81
1924	5.77	7.43	6.97	9.28	11.75	11.01
1925	3.49	6.25	7.17	8.93	11.00	11.09
1926	4.70	6.89	7.15	10.43	12.72	11.38
Average			**6.61**			**10.58**

2173

Year	Scenario Okehampton			Scenario Piacenza		
	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)
1907	10.20	11.74		13.15	15.60	
1908	10.53	12.43		12.64	15.01	
1909	10.12	11.17		12.72	14.86	
1910	9.56	10.74		12.26	14.63	
1911	9.38	10.90		12.84	15.51	
1912	9.74	11.11	11.35	13.65	15.85	15.24
1913	10.05	11.37	11.29	13.09	15.67	15.26
1914	10.58	12.20	11.25	13.26	16.10	15.44
1915	10.66	12.24	11.43	14.23	16.76	**15.75**
1916	10.11	11.41	11.54	12.10	14.59	15.74
1917	9.23	10.97	**11.55**	12.41	15.56	15.75
1918	9.61	11.01	11.53	12.91	15.79	15.74
1919	9.46	11.07	11.48	14.44	16.98	15.96
1920	10.69	11.72	11.40	13.25	15.70	15.90
1921	11.11	12.49	11.45	13.04	15.53	15.69
1922	11.19	12.42	11.61	13.48	16.05	15.94
1923	9.99	11.47	11.70	13.73	16.64	16.12
1924	11.00	12.55	11.95	13.77	16.28	16.20
1925	10.31	11.66	12.05	13.61	16.33	16.09
1926	11.41	12.89	12.25	14.04	16.55	16.23
Average			**11.59**			**15.80**

2174

Year	Scenario Porto			Scenario Sevilla		
	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)
1907	14.31	15.26		16.94	18.66	
1908	14.44	15.53		16.94	18.91	
1909	14.37	15.14		17.12	18.33	
1910	14.56	15.44		17.35	19.06	
1911	14.56	15.63		17.58	19.34	
1912	14.56	15.52	15.42	17.63	19.63	18.99
1913	15.23	16.40	15.61	18.26	20.00	19.21
1914	14.82	15.72	15.64	17.62	19.23	19.26
1915	14.95	15.93	15.77	17.92	19.54	19.47
1916	14.58	15.60	15.80	17.31	18.88	19.44
1917	15.04	16.55	15.95	17.94	19.65	19.49
1918	14.69	16.04	16.04	17.73	19.00	19.38
1919	14.77	15.83	15.95	18.43	19.52	19.30
1920	15.31	16.20	16.03	18.18	19.10	19.28
1921	15.81	16.76	16.16	18.63	19.71	19.31
1922	14.94	15.99	16.23	18.32	19.39	**19.39**
1923	14.34	15.49	16.05	17.78	19.05	19.29
1924	14.47	14.94	**15.87**	18.64	20.47	19.54
1925	15.17	16.17	15.93	18.42	20.25	19.66
1926	14.85	15.52	15.81	19.68	21.56	20.07
Average			**15.88**			**19.41**

Year	Scenario Thiva		
	Annual average temperature (°C)	Annual average Arrhenius temperature (°C)	Average of Arrhenius temperature of previous 6 years (°C)
1907	16.61	18.56	
1908	15.72	17.22	
1909	16.51	18.10	
1910	15.73	17.23	
1911	16.29	17.76	
1912	15.78	17.48	17.73
1913	16.30	17.99	17.63
1914	16.12	17.98	17.76
1915	16.00	17.63	17.68
1916	16.08	17.53	17.73
1917	16.63	18.17	17.80
1918	16.18	17.84	17.86
1919	16.30	18.25	17.90
1920	16.59	18.55	17.99
1921	15.61	17.18	17.92
1922	16.27	17.92	17.99
1923	15.31	17.12	**17.81**
1924	16.26	17.91	17.82
1925	16.64	18.33	17.83
1926	17.29	18.86	17.89
Average			**17.82**

Appendix C. Scenario and model adjustment factors

C.1. Derivation of scenario adjustment factors

In EFSA PPR Panel (2012a), the assessment of the predefined scenarios for annual crops (95th spatial percentile of the concentration in total soil and soil pore water for the total area of annual crops in the EU), as well as the scenario adjustment factors (then called crop extrapolation factors), were based on the first release of a set of spatial data published in 2011, later referred to as the EFSA spatial data version 1.0 (Hiederer, 2012). In 2012, the new release of the EFSA spatial data version 1.1 was made available and published on the European Soil Portal of the European Commission JRC (http://eusoils.jrc.ec.europa.eu/library/data/efsa/).

In principle, these changes in the EFSA spatial data introduced would require a full reassessment of the location and properties of the Tier-1 scenarios. However, the working group decided not to do this but to reassess the scenario adjustment factors, which are based on the 95th percentile crop ratio as follows:

$$\zeta = \frac{P_{95,x}}{P_{Tier1}} \quad \text{(C1)}$$

where $P_{95,x}$ is the spatial 95th percentile of the concentration for the area of crop x and P_{Tier1} is the PEC calculated at Tier-1 (calculated with the simple analytical model without any adjustment factors). Calculations were made with the simple analytical model for all CAPRI crops or crop groups that are in Tables 8 and 9. This was carried out for the standard substances 1 to 19 (refer to EFSA PPR Panel (2012a) for substance properties) for all regulatory zones and for an evaluation depth z_{eco} of 1 and 20 cm considering the peak concentration only. Results are given in Tables C.1-C.4.

Table C.1: Minimum and maximum scenario adjustment factors for concentration in the total soil ($C_{T,peak}$) in annual crops based on the standards substances 1 to 19

CAPRI crop or crop group	z_{eco} 1 cm						z_{eco} 20 cm					
	North		Central		South		North		Central		South	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Barley	1.78	1.80	1.16	1.18	1.09	1.12	1.78	1.81	1.16	1.29	1.09	1.17
Common wheat	1.25	1.29	1.10	1.13	1.10	1.13	1.21	1.29	1.10	1.19	1.10	1.20
Durum wheat	NC	NC	1.06	1.12	0.93	0.98	NC	NC	1.06	1.22	0.87	0.98
Fallow	1.83	1.91	1.24	1.26	1.07	1.07	1.72	1.91	1.24	1.31	1.07	1.09
Floriculture and flower bulbs	0.80	0.84	0.97	0.98	1.11	1.13	0.75	0.84	0.96	0.98	1.11	1.19
Maize	1.04	1.13	1.07	1.11	1.09	1.09	0.93	1.13	1.07	1.13	1.09	1.12
Oats	2.28	2.50	1.35	1.36	1.01	1.03	2.28	2.77	1.35	1.41	1.00	1.03
Oilseed rapes	1.26	1.29	1.14	1.17	1.12	1.15	1.24	1.29	1.14	1.28	1.12	1.23
Other fresh vegetables	1.42	1.49	1.26	1.29	1.04	1.04	1.42	1.52	1.22	1.29	1.04	1.07
Potatoes	1.55	1.59	1.62	1.63	1.26	1.27	1.57	1.58	1.60	1.63	1.26	1.32
Pulses	1.22	1.27	1.19	1.20	1.09	1.13	1.17	1.27	1.19	1.23	1.09	1.18
Rye	1.32	1.36	1.42	1.46	1.10	1.12	1.28	1.36	1.42	1.51	1.10	1.16
Soya beans	NC	NC	0.96	0.98	0.90	0.94	NC	NC	0.95	0.98	0.83	0.94
Sugar beets	1.10	1.14	1.33	1.33	1.10	1.14	1.11	1.14	1.33	1.35	1.10	1.21
Sunflowers	NC	NC	0.92	0.97	1.04	1.05	NC	NC	0.86	0.97	1.01	1.05
Texture crops	1.77	1.77	1.06	1.13	0.94	1.01	1.77	1.77	1.06	1.22	0.94	1.01
Tobacco	NC	NC	1.05	1.06	1.05	1.05	NC	NC	1.05	1.07	1.03	1.05

Max, maximum; Min, minimum; NC, no crop.

Table C.2: Minimum and maximum scenario adjustment factors for the concentration in the liquid phase ($C_{L,peak}$) in annual crops based on the standards substances 1 to 19

CAPRI crop or crop group	z_{eco} 1 cm						z_{eco} 20 cm					
	North		Central		South		North		Central		South	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Barley	0.96	0.98	0.94	0.98	1.00	1.03	0.96	1.02	0.94	1.02	0.95	1.03
Common wheat	0.96	0.98	1.00	1.03	0.87	0.97	0.96	1.03	1.00	1.03	0.87	1.00
Durum wheat	NC	NC	0.97	0.99	1.04	1.11	NC	NC	0.97	1.01	0.94	1.11
Fallow	0.96	0.98	0.93	1.02	1.03	1.08	0.96	1.03	0.93	1.03	0.99	1.08
Floriculture and flower bulbs	NC	NC	0.63	0.80	0.99	1.08	NC	NC	0.63	0.80	0.98	1.08
Maize	0.94	0.98	1.02	1.18	0.90	0.97	0.94	1.01	0.99	1.18	0.90	1.03
Oats	0.63	0.84	0.89	1.00	1.11	1.20	0.63	0.86	0.89	1.01	0.98	1.20
Oilseed rapes	0.96	0.98	0.92	0.95	0.84	0.92	0.96	1.04	0.92	1.01	0.84	1.00
Other fresh vegetables	0.94	0.97	1.02	1.05	1.13	1.25	0.94	0.99	1.00	1.05	0.97	1.25
Potatoes	0.90	0.97	0.96	1.00	0.99	1.07	0.90	1.10	0.96	1.03	0.98	1.07
Pulses	0.89	0.97	0.94	0.98	1.01	1.04	0.89	0.97	0.94	1.02	0.98	1.04
Rye	0.94	0.97	0.87	0.98	1.08	1.16	0.94	1.05	0.87	1.02	1.05	1.16
Soya beans	NC	NC	1.02	1.23	0.90	0.99	NC	NC	0.99	1.23	0.90	0.99
Sugar beets	0.96	0.98	1.00	1.03	0.87	0.99	0.96	0.99	1.00	1.04	0.87	0.99
Sunflowers	NC	NC	1.02	1.23	1.01	1.03	NC	NC	0.98	1.23	0.99	1.03
Texture crops	0.58	0.74	0.95	0.96	1.05	1.12	0.58	0.76	0.95	1.03	0.96	1.12
Tobacco	NC	NC	0.98	1.03	0.91	1.11	NC	NC	0.95	1.03	0.77	1.11

Max, maximum; Min, minimum; NC, no crop.

Table C.3: Minimum and maximum scenario adjustment factors for concentration in the total soil ($C_{T,peak}$) in permanent crops based on the standards substances 1 to 19

CAPRI crop or crop group	z_{eco} 1 cm						z_{eco} 20 cm					
	North		Central		South		North		Central		South	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Berries	0.90	0.94	0.83	0.85	0.84	0.90	0.90	0.97	0.83	0.90	0.85	0.90
Permanent grass	0.96	0.93	0.93	1.00	0.98	1.02	0.96	1.04	0.96	1.00	0.98	1.06
Pome fruit	0.87	0.89	0.77	0.81	0.86	0.95	0.87	0.95	0.80	0.86	0.88	0.95
Stone fruit	NC	NC	0.57	0.66	0.71	0.83	NC	NC	0.64	0.72	0.73	0.83
Vines	NC	NC	0.75	0.81	0.81	0.86	NC	NC	0.73	0.82	0.73	0.86
Citrus	NC	NC	NC	NC	0.61	0.72	NC	NC	NC	NC	0.46	0.72
Olives	NC	NC	NC	NC	0.67	0.77	NC	NC	NC	NC	0.51	0.77
Hops	NC	NC	0.79	0.84	0.97	0.98	NC	NC	0.77	0.88	0.90	1.00

Max, maximum; Min, minimum; NC, no crop.

Table C.4: Minimum and maximum scenario adjustment factors for concentration in the liquid phase ($C_{L,peak}$) in permanent crops based on the standards substances 1 to 19

CAPRI crop or crop group	z_{eco} 1 cm						z_{eco} 20 cm					
	North		Central		South		North		Central		South	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Berries	1.02	1.27	0.89	0.97	0.88	0.93	1.01	1.27	0.92	0.97	0.83	0.93
Permanent grass	0.95	1.10	0.89	0.94	0.47	0.61	0.96	1.09	0.88	0.97	0.47	0.73
Pome fruit	1.05	1.19	1.01	1.05	0.97	1.04	1.06	1.20	0.99	1.09	0.97	1.12
Stone fruit	NC	NC	1.18	1.29	1.01	1.12	NC	NC	1.17	1.39	0.99	1.18
Vines	NC	NC	1.21	1.32	1.00	1.11	NC	NC	1.21	1.36	1.00	1.13
Citrus	NC	NC	NC	NC	1.00	1.11	NC	NC	NC	NC	1.00	1.13
Olives	NC	NC	NC	NC	1.03	1.12	NC	NC	NC	NC	1.02	1.13
Hops	NC	NC	0.91	0.99	0.95	1.08	NC	NC	0.95	1.07	0.71	1.09

Max, maximum; Min, minimum; NC, no crop.

In line with the approach taken in EFSA PPR Panel (2012a), the working group proposes to use the maxima of the values in Tables C.1-C.4 of each regulatory zone (rounded up) to be used as scenario adjustment factors in Tier-1 (Table C.5).

Table C.5: Ranges (and final values) of the new scenario adjustment factors in comparison with ranges of the former crop extrapolation factors for the three regulatory zones and for both the concentration in total soil ($C_{T,peak}$) and the concentration in the liquid phase ($C_{L,peak}$)

	Scenario adjustment factor [(a)]					
	$C_{T,peak}$			$C_{L,peak}$		
	Min	Max	Final [(c)]	Min	Max	Final [(c)]
North	0.75	2.77	**3.0**	0.58	1.05	**1.5**
Central	0.86	1.51	**2.0**	0.63	1.23	**1.5**
South	0.83	1.23	**1.5**	0.77	1.25	**1.5**

(a): Based on the standard substances 1 to 19
(b): Based on the substances P1, P2 and P3
(c): Rounded up to ensure consistency in the tiered approach

C.2. Derivation of model adjustment factors

The model adjustment factors, as derived in EFSA PPR Panel (2012a), were based on simulations with PEARL and PELMO for 19 substances. In these simulations, only *DegT50* and K_{om} were changed. However, at Tier-3A, users can change other substance properties, such as the Freundlich adsorption coefficient (*1/n*), the molar activation energy (E_{Act}), the moisture dependence of degradation exponent (*B*) and the transpiration stream concentration factor (*TSCF*). Changing these parameters may affect the model adjustment factors; because it cannot a priori be guaranteed that the predicted concentrations are lowered by changing these parameters.

To investigate the effect of these four parameters on the model adjustment factors, a simple sensitivity analysis was carried out. In this analysis, for each parameter, three runs were performed, i.e. one with the lower limit of plausible values, one with the normal value, as reported in EFSA PPR Panel (2012a), and one with the upper limit of plausible values. All parameters were varied one-by-one and 19 substances (reported in EFSA PPR Panel, 2012a) were simulated. The following range of parameters was considered:

- *1/n* was varied between 0.7 and 1.0. This range is based on Boesten et al. (2012).
- E_{Act} was varied between 35 and 115 kJ mol^{-1}. According to EFSA (2007), 95 % of the reported values are within this range.
- *B* was varied between 0.1 and 1.5 (EFSA, 2012a).
- *TSCF* was varied between 0 and 1, i.e. the full range of possible values in the numerical models.

C.2.1. Results

Results are summarised in Figures C.1 to C.4. Each figure shows the ratio between the results obtained by PEARL and the results obtained by PERSAM. The maximum of all these ratios is the required model adjustment factor.

Effect of the Freundlich exponent

Figure C.1 shows that the effect of the Freundlich exponent on the concentration in total soil is negligible (only some effect is visible, which is because of slightly different mobility and hence transport of the pesticide from the top layer). The predicted ratio is always below the model adjustment factor for the scenario as reported in EFSA PPR Panel (2012a), so adaptation of this factor is not necessary.

For the concentration in pore water, a clear effect is visible. An exponent of 0.7 leads to a higher ratio PEARL/PERSAM, an exponent of 1.0 leads to a lower ratio. For the CL and CT scenarios, the ratio is higher than the original model adjustment factor for the respective scenario.

Effect of the molar activation energy

In the simulations, the same value for the molar activation energy was used in PEARL and PERSAM. Results are shown in Figures C.3 and C.4.

A lower value of the molar activation energy leads to a higher ratio of the predicted concentration in total soil, whereas a higher value leads to a lower ratio (Figures C.3 and C.4). This effect is most pronounced when using an evaluation layer of 20 cm. This is most probably caused by the difference in the molar activation energy used in the model and the molar activation energy used in the calculation of the Arrhenius-weighted average temperature that has been used for the scenario selection procedure (the scenarios were selected assuming E_{Act} of 65.4 kJ mol^{-1}). For the ACTN scenario and an evaluation depth of 20 cm, the original model adjustment factor is (slightly) exceeded.

For the concentration in liquid phase, the effect is generally in the same direction. However, the original model adjustment factors were not exceeded.

Effect of the moisture dependence of degradation

A low value of the exponent in the moisture dependence of degradation leads to higher concentrations in total soil and hence a higher ratio PEARL/PERSAM (Figures C.5 and C.6). For the lowest value (B = 0.1), the original model adjustment factor is exceeded in many cases.

For the concentration in pore water, the effect is in the same direction but less pronounced. The original model adjustment factor is slightly exceeded in one case (scenario ACLS, TWA = 56 days).

Effect of the transpiration concentration stream factor

A lower transpiration concentration stream factor leads to higher concentrations in total soil and hence a higher ratio PEARL/PERSAM (Figures C.7 and C.8). This effect is most pronounced for the 20 cm evaluation layer. For this evaluation layer, the model adjustment is exceeded in five out of six cases.

For the concentration in pore water, no effect is observable for the 1 cm evaluation layer. For the 20 cm layer, the effect is in the same direction as for the concentration in total soil but the model adjustment factor is exceeded in only one case (scenario ACLS).

C.2.2. Conclusions

Based on these findings, the model adjustment factors would have to be changed to the following values (see EFSA PPR Panel (2012a), page 45 for the old values):

- f_m = 1.2 (was 1.1) for the peak concentration in total soil for z_{eco} = 1 cm.
- f_m = 2.0 (was 1.3) for the peak concentration in total soil for z_{eco} = 20 cm.
- f_m = 2.0 (was 1.7) for all TWA concentrations in total soil.
- f_m = 2.5 (was 2.0) for all pore water concentrations in North and Central Zones.
- f_m = 4.0 (was 3.0) for all pore water concentrations in South Zone.

Note that these findings are based on only two evaluation depths, i.e. 1 cm and 20 cm. Furthermore, worst-case combinations of parameters (i.e. $TSCF$ = 0 in combination with $1/n$ = 0.7) have not been studied. If such combinations had been studied, higher model adjustment factors would have been calculated. For the sake of simplicity, and to ensure consistency within the tiered approach, it is therefore proposed to use model adjustment factors that are rounded up, i.e. f_m = 2 for all concentration in total soil scenarios and f_m = 4 for all concentration in pore water scenarios. These model adjustment factors should be used in all tiers where the analytical model is used.

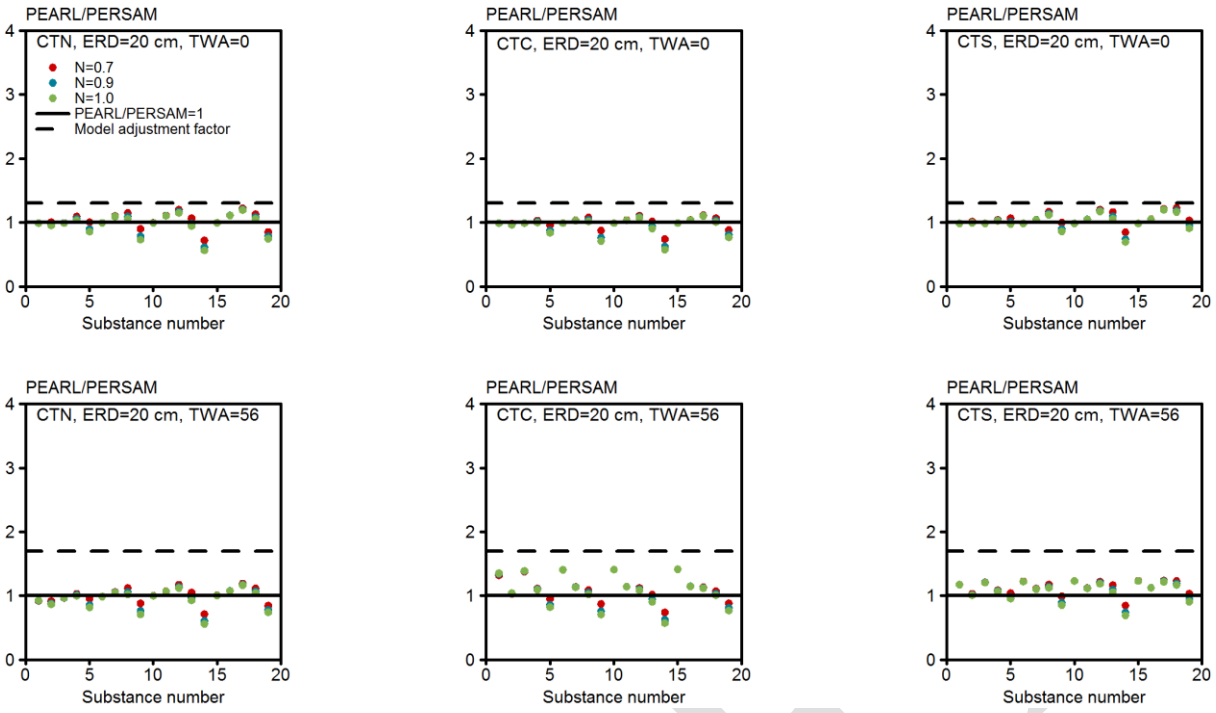

Figure C.1: Effect of the Freundlich exponent on the ratio between the concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

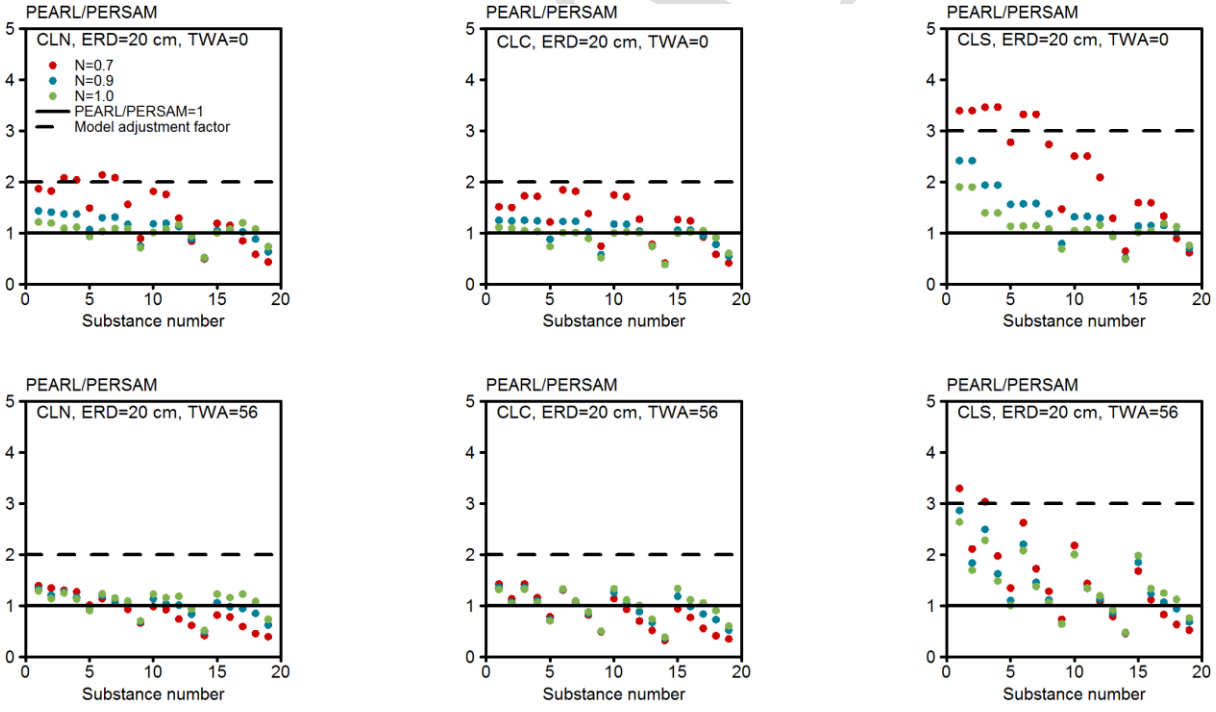

Figure C.2: Effect of the Freundlich exponent on the ratio between the concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

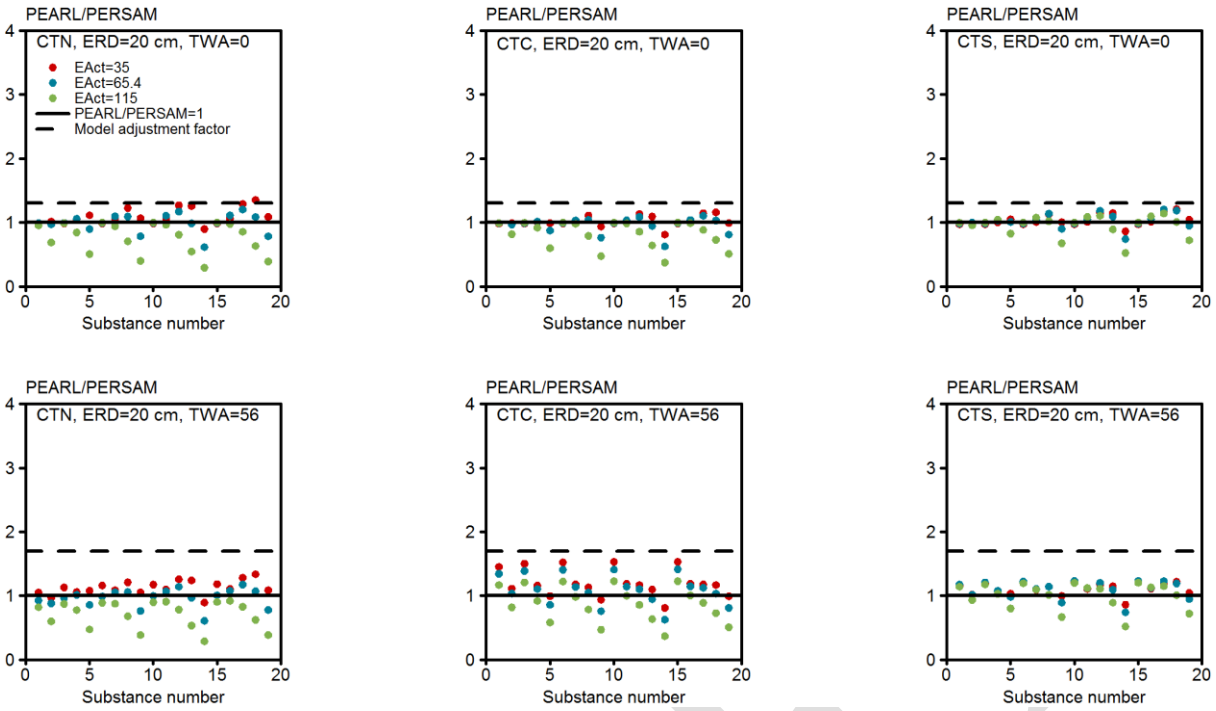

Figure C.3: Effect of the molar activation energy on the ratio between the concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

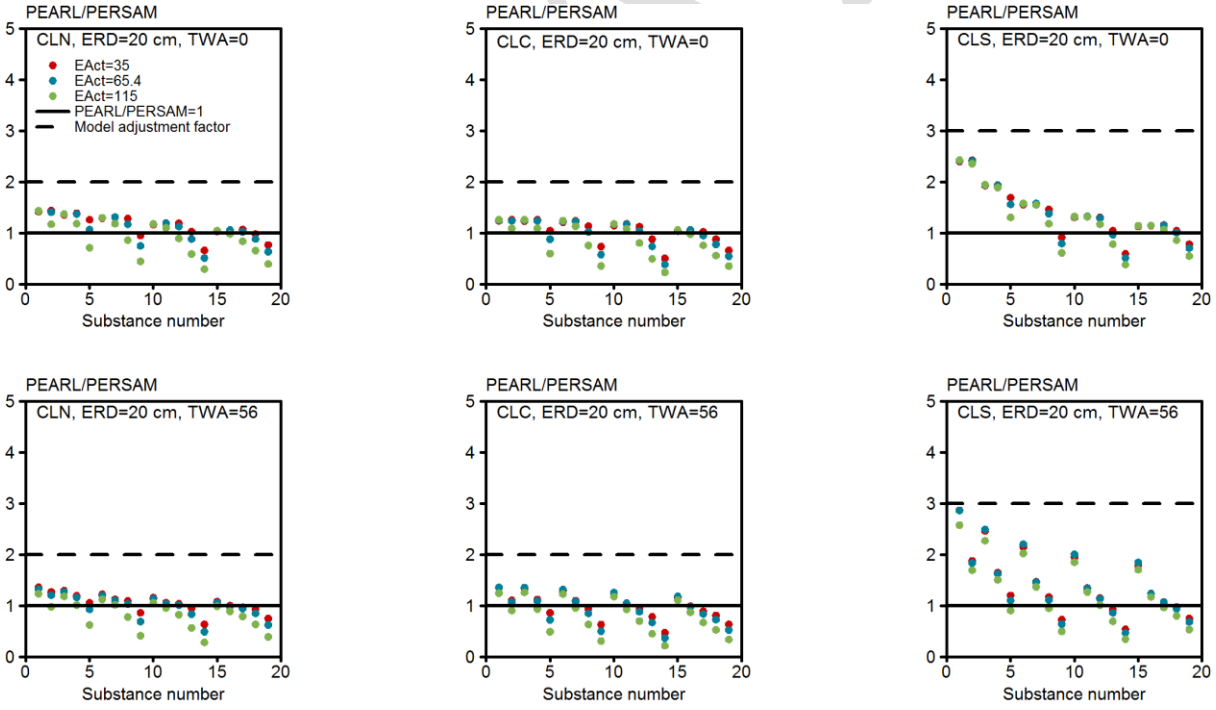

Figure C.4: Effect of the molar activation energy on the ratio between the concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

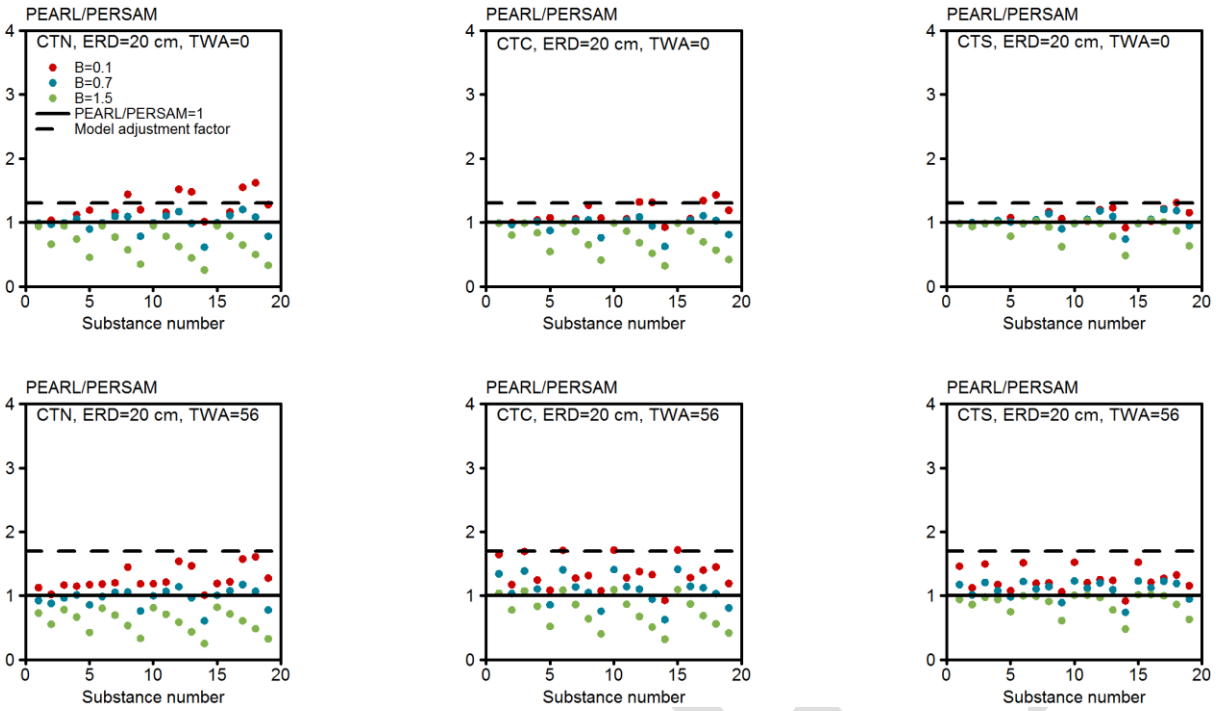

Figure C.5: Effect of the exponent in the equation of soil moisture on the ratio between the concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

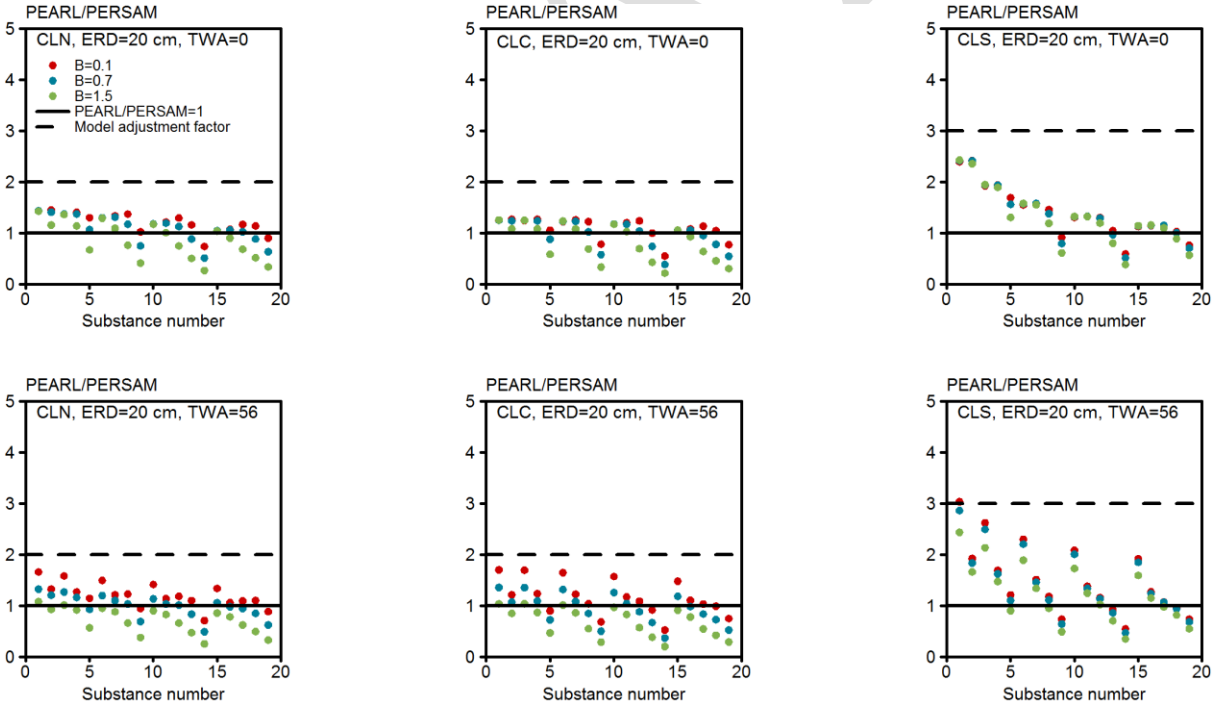

Figure C.6: Effect of the exponent in the equation of soil moisture on the ratio between the concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

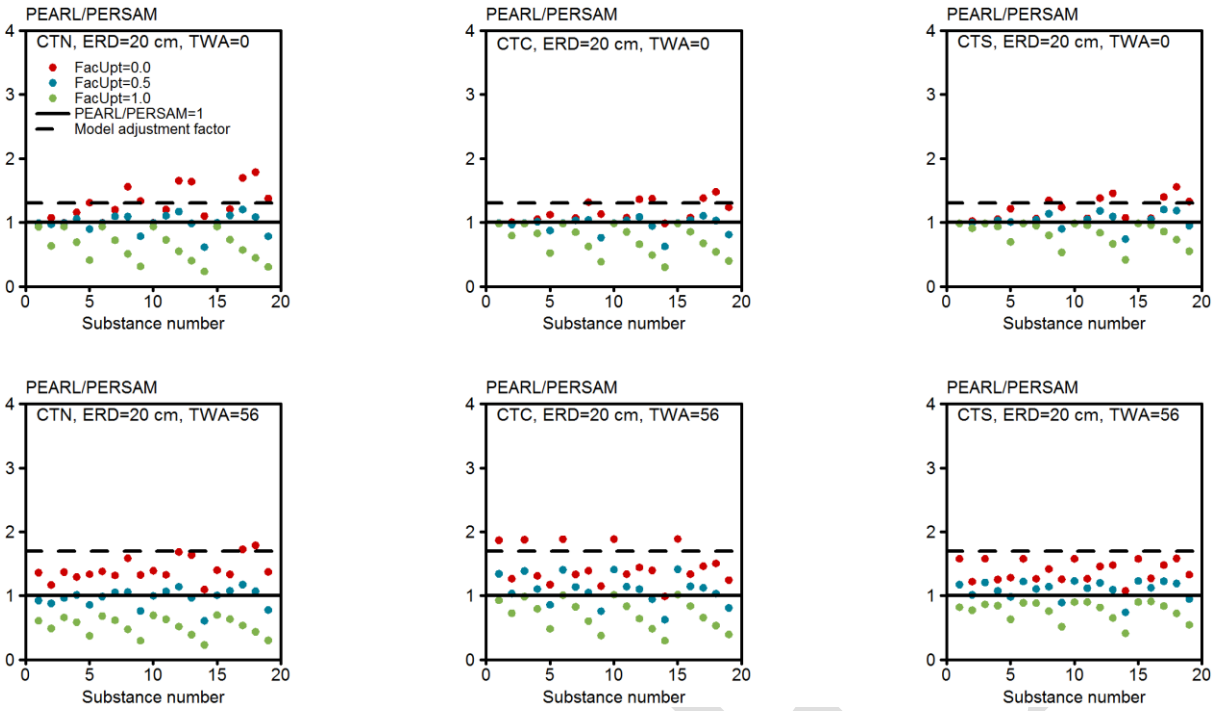

Figure C.7: Effect of the transpiration concentration stream factor on the ratio between the concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

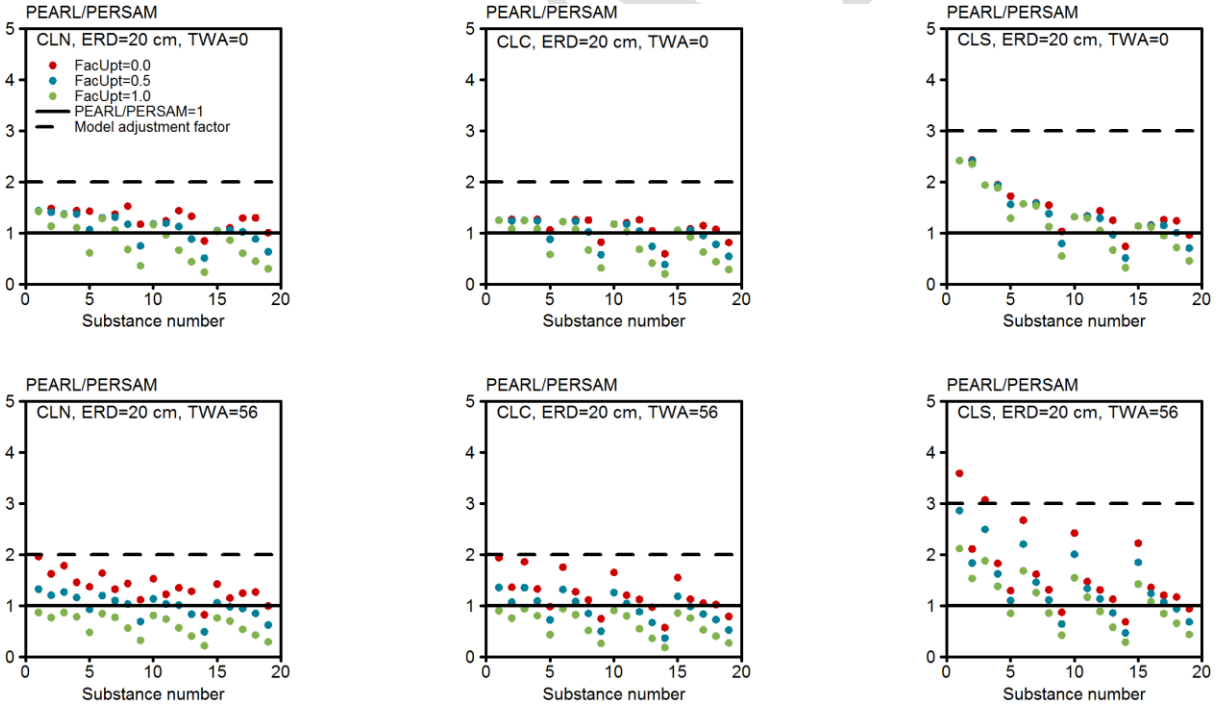

Figure C.8: Effect of the transpiration concentration stream factor on the ratio between the concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: TWA concentration (56 days). The dashed line is the model adjustment factor reported in EFSA PPR Panel (2012a)

Appendix D. The table of the fraction of the dose reaching the soil

D.1. Introduction

Since the introduction of the FOCUS groundwater scenarios in 2001, it has been common practice in the leaching assessment at the EU level to use the FOCUS interception tables to correct the dosage that reaches the soil surface. It was assumed that all intercepted substances will dissipate on the plant surface and will thus never reach the soil. EFSA PPR Panel (2012a) considered this approach not defensible and proposed to use, as defaults in the exposure assessment, a wash-off factor of 0.1 mm^{-1} and a half-life of 10 days for the decline of dislodgeable foliar residue on plants. Crop canopy processes and foliar wash-off can be simulated by PEARL and PELMO. However, for Tier-2 this would require running one of the numerical models before running PERSAM. For this reason, tables of the fraction of the dose reaching the soil were created. This was carried out by calculating this fraction for all relevant crop–location combinations with PEARL and PELMO with the intention to use the average result in the form of a table similar to the FOCUS interception tables. The calculation procedure was as follows:

- Runs were made with one application per year, so the simulation time was 26 years of which the last 20 years were evaluated.
- At the application time, a dose of 1 kg ha^{-1} was applied to the plant surface.
- For each year, the annual wash-off (kg ha^{-1}) was calculated using a wash-off factor of 0.1 mm^{-1} and a half-life of 10 days for the decline of dislodgeable foliar residue on plants, and this annual wash-off was transformed into an annual fraction washed off (division by 1 kg ha^{-1}).

Calculations were made with PELMO with applications on the 5th, 15th and 25th of each month. Calculations were made only for periods when a crop was present.

The results in the wash-off tables are based on absolute application dates. The FOCUS tables are based on crop development stages using so-called BBCH codes (Meier, 2001). How these two tables are linked is described in Section D4.

D.2. How to deal with differences in wash-off between the 20 years?

The above-mentioned runs provided 20 fractions washed off, each corresponding to a different year over 20 years. It is a point of debate whether the correction of the FOCUS interception tables should be based on the maximum of these 20 fractions or on the average fraction. To explore the consequences of these two options, scenario calculations were made with PEARL for the scenario ACTN [10] sugar beets, substance P3 (*DegT50* = 200 days, K_{om} = 1 000 l kg^{-1}), annual application of 1 kg ha^{-1} on 25 August (a simulation period of 26 years) and ecotoxicological averaging depths of 1 and 20 cm. The interception (according to the FOCUS interception table) was 90 %. The PEARL wash-off calculations for this scenario, as described above, showed that the average annual wash-off fraction was 0.639 and that the maximum annual wash-off was 0.974.

Subsequently, three types of PEARL calculations were made and results compared:

- Annual application of 0.1 kg ha^{-1} to the soil, 0.9 kg ha^{-1} on the crop and simulation of wash-off by PEARL using the wash-off factor of 0.1 mm^{-1} and a half-life of 10 day for the decline on plants; this calculation is referred to as “simulated wash-off”.
- Annual application of 0.675 kg ha^{-1} to the soil surface, corresponding with the annual average wash-off fraction; this calculation is referred to as “average wash-off”.

[10] ACTN is a historical scenario (EFSA, 2015b)

- Annual application of 0.977 kg ha^{-1} to the soil surface, corresponding with the maximum annual wash-off fraction; this calculation is referred to as "maximum wash-off".

The calculation of these soil loads of 0.675 and 0.977 kg ha^{-1} was based on the equation:

$$A_{soil} = ((1 - f_i) + f_i f_w) A \quad \text{(D1)}$$

where A_{soil} is the soil load (kg ha^{-1}), A is the dosage (kg ha^{-1}), f_i is the fraction of the dose that is intercepted by the crop (–) and f_w is the fraction (–) washed off.

The time course for the concentration in total soil averaged over the top 20 cm in Figure D.1 shows that use of the average wash-off fraction leads to a time course that is close to the PEARL run in which the plant processes were simulated. Use of the maximum wash-off fraction resulted in a considerable overestimation of the plateau value, which is the result of assuming that the maximum wash-off occurs every year.

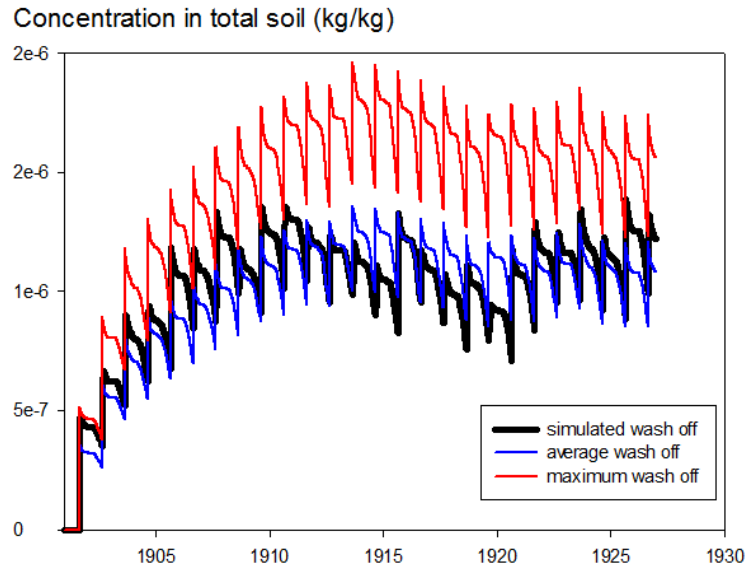

Figure D.1: Concentration in total soil (average over top 20 cm) as a function of time as calculated with PEARL for the scenario ACTN and sugar beets, substance P3 (*DegT50* = 200 days, K_{om} = 1 000 l kg^{-1}), annual application of 1 kg ha^{-1} on 25 August for the three types of PEARL calculations as indicated in the graph

The results for the concentration in total soil in the top 1 cm (Figure D.2) are different from those of the top 20 cm. In this case, the annual fluctuations dominate the time course of the concentration and the background plateau level does not play a role. Because the endpoint of the simulation is the maximum value over the whole simulation period, use of the maximum wash-off leads to a good correspondence with run with the simulated wash-off and use of the average wash-off leads to an underestimation. The pattern, as shown in Figure D.2, is probably representative for this scenario when ecotoxicological averaging depths deeper than 1 cm are considered for substances that do not accumulate.

The results of the PEARL run with the simulated plant processes (Figure D.2) show that the annual peak concentrations vary by a factor near to 3. Comparison of the different runs in Figure D.2 indicates that this variation is mainly caused by the differences in the wash-off from year to year. In the scenario selection procedure for the exposure assessment of soil organisms by EFSA PPR Panel (2012a) it was assumed appropriate to use a 100th percentile of the concentration in time based on the assumption that there would be only small differences between peak concentrations between different years (EFSA PPR Panel, 2012a, p. 31). The line for the simulated wash-off in Figure D.2 shows that this is not the case for this scenario for the concentration in total soil in the North Zone when

combinations of substances and ecotoxicological averaging depths are considered that do not lead to accumulation. Thus, for uses that lead to a high fraction intercepted by the crop, the exposure assessment goal of an overall 90th percentile should, in principle, have led to a scenario selection procedure that included the wash-off process. However, such a procedure is, as yet, impossible given the limited knowledge on the processes that determine the wash-off (see EFSA PPR Panel, 2012a). Moreover, it would also have made the exposure assessment overly complicated because then different approaches would be needed for uses with low and high crop interception.

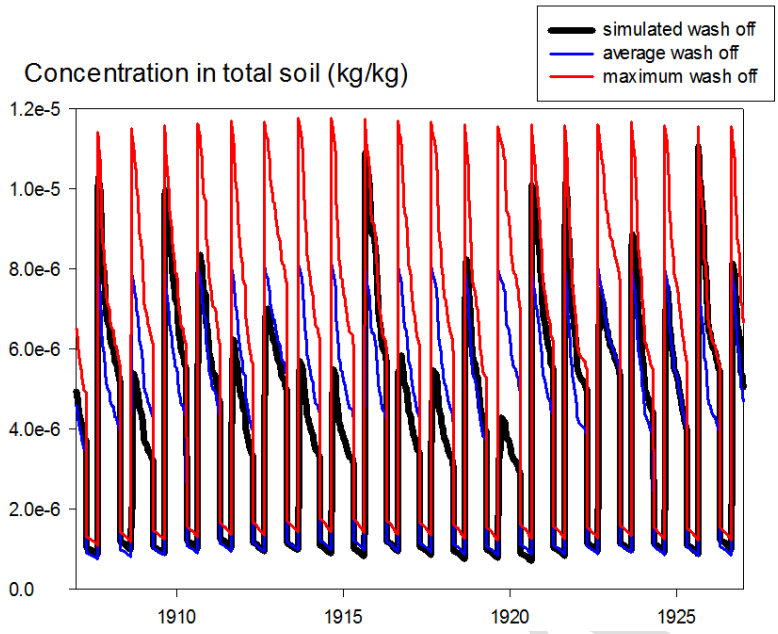

Figure D.2: Concentration in total soil (average over top 1 cm) as a function of time as calculated with PEARL for the scenario ACTN and sugar beets, substance P3 (*DegT50* = 200 days, K_{om} = 1 000 l kg^{-1}), annual application of 1 kg ha^{-1} on 25 August for the three types of PEARL calculations as indicated in the graph

In view of the foregoing, and because the wash-off factor of 0.1 mm^{-1} is considered a conservative default value (EFSA PPR Panel, 2012a), it is proposed to base the approach on the annual average wash-off fraction; so the maximum annual wash-off will not be considered.

D.3. Fraction of the dose reaching the soil calculated with PEARL and PELMO

Reinken et al. (2013) identified significant differences between PEARL and PELMO with respect to the parameterisation of wash-off calculations. The working group analysed these differences and concluded that these were primarily caused by differences in the calculation of the crop cover fraction. The description of crop development was therefore harmonised. In both PEARL and PELMO, it is now assumed that the Leaf Area Index (LAI) increases linearly between emergence date and the date at which the maximum LAI occurs. Furthermore, it was decided to base the crop cover needed in the wash-off calculations on Beer's law:

$$SC = 1 - e^{-\kappa LAI} \qquad \text{(D2)}$$

in which κ is the extinction coefficient for diffuse solar radiation (set to 0.39 based on Kroes et al., 2008).

Following harmonisation differences between PEARL and PELMO are, generally, small, indicating that the harmonisation process has been successful.

D.4. Development of the table for the fraction of the dose reaching the soil

The table that is needed in the regulatory exposure assessment should consider the worst-case fraction of the dose that reaches the soil (f_{soil}) for each crop. This fraction considers crop interception at the

time of application as well as wash-off in the following days (where the latter is, of course, affected by dissipation processes at the plant canopy). Crop interception is based on the crop of the dominant FOCUS zone in each regulatory zone (Table B.9). After harmonisation with PEARL, wash-off fractions are calculated with PELMO only following the recommendations in EFSA PPR Panel (2012a) (i.e. using a default wash-off factor of 0.1 mm^{-1} and a half-life of 10 days for the decline of pesticide residues on plants).

The wash-off factors are based on calculations with PELMO over 26 years, of which the last 20 years were used considering annual applications for every scenario–crop combination. For each of these scenarios, 36 simulations were performed with different application dates (always on the 5th, 15th or 25th of every month). In the simulations it was assumed that crop interception was 100 %. However, as PELMO considers harvesting of crops and application of pesticide to crops with different sequences, simulations were not carried out for those situations where application would be on the date of harvest.

The wash-off fraction was calculated based on the average wash-off in PELMO for the last 20 years of the simulations (see Section D.2 for a justification for taking the average wash-off fraction).

In order to combine these wash-off fractions with reasonable crop interception values all application dates had to be linked to BBCH crop stages (Meier, 2001). Gericke et al. (2010 found a linear relationship between date and the BBCH code for annual crops. This implies that it is justifiable to use linear interpolation starting at the date of emergence (BBCH 09) and ending at the date of harvest (i.e. BBCH 99 in the case of annual crops or BBCH 50 in the case of biennial crops, such as onions, sugar beet or cabbage). However, to improve the link for winter crops with a dormancy shortly after emergence, BBCH stage 19 was attached to the spring point which gives two separate linear phases (i.e. BBCH 09 – 19 and 20 – 99 or 20 – 50, respectively). For consistency reasons a linear relationship between date and the BBCH code was applied for permanent crops as well, starting from first leaf development (BBCH 09) to start of senescence (BBCH 89). In case of evergreen permanent crops (citrus and olives) as well as permanent grass (established turf) crop interception is considered the same all year round (EFSA, 2014). In order to account for seasonal variability in wash-off fractions due to seasonal changes in rainfall patterns four wash-off periods (January to March, April to June, July to September and October to December) were defined for these crops. The actual wash-off fraction was calculated according to the following equation:

$$W_{act} = \frac{W_{100}\, CI}{100} \qquad \text{(D3)}$$

where W_{act} (–) is the actual wash-off fraction (i.e. the wash-off fraction considering the appropriate crop interception), W_{100} is the wash-off fraction considering 100 % interception (i.e. the results of the above simulations) and CI (%) is the actual crop interception according to the EFSA crop interception tables. Finally, f_{soil} (i.e. the value that should be used in the exposure assessment) was calculated according to following equation:

$$f_{soil} = \frac{(100 - CI)}{100} + W_{act} \qquad \text{(D4)}$$

where f_{soil} (–) is the fraction of the dose reaching the soil.

Table D.1: Fraction of the dose reaching the soil (f_{soil}) considering crop interception and canopy dissipation processes as a function of crop development stage for annual crops. Calculations are done for the dominant FOCUS zone and final figures are the maximum of the three regulatory zones rounded to the next higher 0.05.

Crop	Regulatory zone	Dominant FOCUS	Crop parameter	BBCH code[(a)(b)]				
				00–09	10–19	20–39	40–89	90–99

		zone						
Beans (vegetable and field)	North	HA	HA (fields)	1.00	0.84	0.79	0.73	0.45
	Centre	CH	HA (fields)	1.00	0.86	0.88	0.83	0.39
	South	HA	TH (veg.), 1st	1.00	0.90	0.91	0.61	
			TH (veg.), 2nd	1.00	0.93	0.93	0.74	0.26
	Max. (rounded)			**1.00**	**0.95**	**0.95**	**0.85**	**0.45**
Cabbage(c)	North	HA	HA, 1st	1.00	0.85	0.82	0.55	
		HA	HA,2nd	1.00	0.87	0.84	0.57	
	Centre	CH	CH, 1st	1.00	0.90	0.89	0.52	
		CH	CH, 2nd	1.00	0.90	0.90	0.57	
	South	SE	SE, 1st	1.00	0.87	0.91	0.43	
		SE	SE, 2nd	1.00	0.90	0.92	0.53	
	Max. (rounded)			**1.00**	**0.90**	**0.95**	**0.60**	
Carrots(c)	North	HA	HA, 1st	1.00	0.88	0.71	0.48	
		HA	HA ,2nd	1.00	0.88	0.76	0.59	
	Centre	CH	CH, 1st	1.00	0.89	0.80	0.59	
		CH	CH, 2nd	1.00	0.91	0.80	0.48	
	South	SE	TH ,1st	1.00	0.95	0.86	0.39	
		SE	TH ,2nd	1.00	0.93	0.90	0.27	
	Max. (rounded)			**1.00**	**0.95**	**0.90**	**0.60**	
Cotton	Centre	HA	TH	1.00	0.84	0.76	0.72	0.50
	South	TH	SE	1.00	0.91	0.85	0.57	0.15
	Max. (rounded)			**1.00**	**0.95**	**0.85**	**0.75**	**0.50**
Linseed	North	HA	OK	1.00	0.79	0.67	0.72	0.34
	Centre	HA	OK	1.00	0.79	0.67	0.72	0.34
	South	SE	OK	1.00	0.85	0.83	0.71	0.17
	Max. (rounded)			**1.00**	**0.85**	**0.85**	**0.75**	**0.35**
Maize	North	HA	HA	1.00	0.84	0.77	0.71	0.57
	Centre	CH	CH	1.00	0.85	0.84	0.80	0.53
	South	HA	HA	1.00	0.84	0.77	0.71	0.57
	Max. (rounded)			**1.00**	**0.85**	**0.85**	**0.80**	**0.60**
Onions(c)	North	HA	HA	1.00	0.94	0.90	0.81	
	Centre	HA	HA	1.00	0.94	0.90	0.81	
	South	SE	TH	1.00	0.96	0.94	0.77	
	Max. (rounded)			**1.00**	**1.00**	**0.95**	**0.85**	
Peas	North	HA	HA	1.00	0.77	0.71	0.68	0.41
	Centre	CH	CH	1.00	0.78	0.76	0.61	0.32
	South	HA	HA	1.00	0.77	0.71	0.68	0.41
	Max. (rounded)			**1.00**	**0.80**	**0.80**	**0.70**	**0.45**
Oil seed rape (summer)	North	HA	OK	1.00	0.75	0.59	0.68	0.52
	Centre	HA	OK	1.00	0.75	0.59	0.68	0.52
	South	HA	OK	1.00	0.75	0.59	0.68	0.52
	Max. (rounded)			**1.00**	**0.75**	**0.60**	**0.70**	**0.55**

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Crop	Regulatory zone	Dominant FOCUS zone	Crop parameter	BBCH code[(a)(b)]				
				00–09	10–19	20–39	40–89	90–99
Oil seed rape (winter)	North	HA	HA	1.00	0.64	0.41	0.56	0.31
	Centre	HA	HA	1.00	0.64	0.41	0.56	0.31
	South	HA	HA	1.00	0.64	0.41	0.56	0.31
	Max. (rounded)			**1.00**	**0.65**	**0.45**	**0.60**	**0.35**
Sugar beets[(c)]	North	HA	HA	1.00	0.88	0.72	0.61	
	Centre	HA	HA	1.00	0.88	0.72	0.61	
	South	HA	HA	1.00	0.88	0.72	0.61	
	Max. (rounded)			**1.00**	**0.90**	**0.75**	**0.65**	
Soybeans	North	HA	PI	1.00	0.83	0.84	0.79	0.56
	Centre	CH	PI	1.00	0.80	0.79	0.70	0.52
	South	TH	PI	1.00	0.83	0.84	0.78	0.43
	Max. (rounded)			**1.00**	**0.85**	**0.85**	**0.80**	**0.60**
Straw-berries	North	HA	HA	1.00	0.84	0.74	0.74	0.68
	Centre	CH	HA	1.00	0.85	0.83	0.82	0.60
	South	SE	SE	1.00	0.90	0.83	0.86	0.44
	Max. (rounded)			**1.00**	**0.90**	**0.85**	**0.90**	**0.70**
Sunflowers	North	JO	PI	1.00	0.87	0.75	0.72	0.55
	Centre	CH	PI	1.00	0.92	0.86	0.84	0.43
	South	HA	PI	1.00	0.88	0.77	0.72	0.56
	Max. (rounded)			**1.00**	**0.95**	**0.90**	**0.85**	**0.60**
Tobacco	Centre	CH	PI	1.00	0.75	0.79	0.80	0.37
	South	SE	TH	1.00	0.72	0.81	0.82	0.84
	Max. (rounded)			**1.00**	**0.75**	**0.85**	**0.85**	**0.85**
Tomatoes	North	HA	CH	1.00	0.71	0.71	0.71	0.66
	Centre	CH	CH	1.00	0.80	0.82	0.76	0.62
	South	SE	SE	1.00		0.84	0.58	0.52
	Max. (rounded)			**1.00**	**0.80**	**0.85**	**0.80**	**0.70**
Crop				**BBCH code[(d)]**				
				00–19	**20–29**	**30–39**	**40–69**	**70–99**
Spring cereals	North	HA	HA	1.00	0.90	0.60	0.65	0.70
	Centre	CH	CH	1.00	0.89	0.56	0.64	0.64
	South	HA	HA	1.00	0.90	0.60	0.65	0.70
	Max. (rounded)			**1.00**	**0.90**	**0.60**	**0.65**	**0.70**
Winter cereals	North	HA	HA	1.00	0.85	0.47	0.52	0.60
	Centre	CH	CH	1.00	0.86	0.59	0.55	0.60
	South	HA	HA	1.00	0.85	0.47	0.52	0.60
	Max. (rounded)			**1.00**	**0.90**	**0.60**	**0.55**	**0.60**

(a): The BBCH code is a decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001).
(b): BBCH 00–09: bare to emergence; BBCH 10–19: leaf development; BBCH 20–39: stem elongation; BBCH 40–89: flowering; BBCH 90–99: senescence and ripening.
(c): These crops are harvested at BBCH 50 and therefore the value 1 should be used for crop stage 50–99.
(d): BBCH 00–19: bare to leaf development; BBCH 20–29: tillering; BBCH 30–39: stem elongation; BBCH 40–69: flowering; BBCH 70–99: senescence and ripening.

Table D.2: Fraction of the dose reaching the soil (f_{soil}) considering crop interception and canopy dissipation processes as a function of crop development stage or season for permanent crops. Calculations are done for the dominant FOCUS zone and final figures are the maximum of the three regulatory zones rounded to the next higher 0.05.

Crop	Regulatory zone	Dominant FOCUS zone	Crop parameter	BBCH code			
				00–09	10–69	71–75	76–89
Apples	North	HA	HA	0.76	0.76	0.73	0.72
	Centre	HA	HA	0.76	0.76	0.73	0.72
	South	SE	SE	0.71	0.53	0.48	0.62
	Max. (rounded)			**0.80**	**0.80**	**0.75**	**0.75**
				BBCH code			
				00–09	**10–69**		**71–89**
Bush berries	North	HA	HA	0.79	0.76		0.68
	Centre	CH	CH	0.78	0.72		0.65
	South	SE	SE	0.76	0.53		0.50
	Max. (rounded)			**0.80**	**0.80**		**0.70**
Hops	Centre	HA	HA	0.79	0.74		0.72
	South	HA	HA	0.79	0.74		0.72
	Max. (rounded)			**0.80**	**0.75**		**0.75**
				BBCH code				
				00–09	**11–13**	**14–19**	**53–69**	**71–89**
Vines	Centre	CH	CH	0.78	0.72	0.69	0.73	0.71
	South	SE	SE	0.76	0.71	0.62	0.50	0.61
	Max. (rounded)			**0.80**	**0.75**	**0.70**	**0.75**	**0.75**
				Season			
				Jan-Mar	**Apr-Jun**	**Jul-Sep**	**Oct-Dec**
Citrus	South	SE	SE	0.58	0.44	0.32	0.60
	Max. (rounded)			**0.60**	**0.45**	**0.35**	**0.60**
Olives	South	SE	SE	0.56	0.41	0.31	0.58
	Max. (rounded)			**0.60**	**0.45**	**0.35**	**0.60**
Permanent grass	North	HA	HA	0.48	0.59	0.59	0.51
	Centre	HA	HA	0.48	0.59	0.59	0.51
	South	HA	HA	0.48	0.59	0.59	0.51
	Max. (rounded)			**0.50**	**0.60**	**0.60**	**0.55**
Grass between rows	North	HA	HA	0.48	0.59	0.59	0.51
	Centre	CH	CH	0.46	0.58	0.55	0.48
	South	SE	SE	0.46	0.32	0.22	0.45
	Max. (rounded)			**0.50**	**0.60**	**0.60**	**0.55**

Appendix E. Calculating the average fraction of dose reaching the soil between the rows in permanent crops based on FOCUS surface water drift values

The approach described here more in detail is based on the FOCUS (2001) drift curves as applied in the aquatic exposure assessment. For between row-exposure it is assumed that drift will occur from one side only. FOCUS (2001) defines five different spray spray drift curves for permanent crops depending on the crop type and the crop development stage (Table E.1). The fraction of the dose reaching the soil (f_{soil}) at a given distance (m) to the crop canopy owing to drift is given by:

$$f_{soil} = \frac{Ad^{B}}{100} \quad \text{(E1)}$$

Where d (m) is the distance to the crop canopy, and A and B are regression parameters specified in FOCUS (2001) for each individual crop. As there is no median drift load given it is proposed to use the percentile closest to the median (i.e. the 67th percentile mentioned in FOCUS (2001) (Table E.1). Note that in FOCUS (2001) two separate regression terms are used with the additional parameters C, D and a split point. However, in case of permanent crops the distance up to 10 m is entirely covered by Eq. E1.

Table E.1: Drift regression parameters A and B for permanent crops as specified in FOCUS (2001).

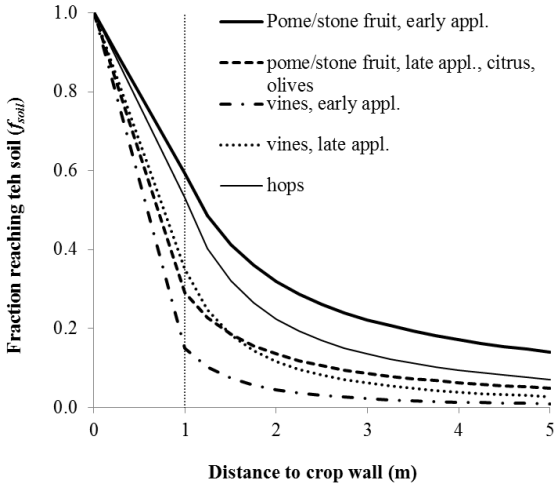
Percentile	Pome/stone fruit, early application		Pome/stone fruit, late application, citrus, olives		Vines, early application		Vines, late application		Hops	
	A	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**
90	66.702	-0.7520	60.396	-1.2249	15.793	-1.6080	44.769	-1.5643	58.247	-1.0042
82	62.272	-0.8116	42.002	-1.1306	15.461	-1.6599	40.262	-1.5771	66.243	-1.2001
77	58.796	-0.8171	40.120	-1.1769	16.887	-1.7223	39.314	-1.5842	60.397	-1.2132
74	58.947	-0.8331	36.273	-1.1616	16.484	-1.7172	37.401	-1.5746	58.559	-1.2171
72	58.111	-0.8391	34.591	-1.1533	15.648	-1.7072	37.767	-1.5829	59.548	-1.2481
70	58.829	-0.8644	31.640	-1.1239	15.119	-1.6999	36.908	-1.5905	60.136	-1.2699
69	59.912	-0.8838	31.561	-1.1318	14.675	-1.6936	35.498	-1.5844	59.774	-1.2813
67	**59.395**	**-0.8941**	**29.136**	**-1.1048**	**14.948**	**-1.7177**	**35.094**	**-1.5819**	**53.200**	**-1.2469**

In FOCUS (2001), the minimum distance for the calculation of drift loads for permanent crops is 3 m. In the absence of commonly agreed data on drift values at shorter distances, extrapolation of Eq. E1 to 1 m to the crop canopy is considered to be acceptable. However, it is recommended to further collect data to adequately address non-uniform distribution of pesticides in permanent crops (Section 4.4). The drift load for the remaining distance from 0 – 1 m to the crop wall is calculated by linear interpolation, whereby f_{soil} at the edge of the crop wall is assumed to be 1 (Figure E.1).

The average fraction of the dose ($f_{soil,avg.}$) reaching the soil between the crop wall and a given distance to the crop wall via drift is given by the integral below the entire curve divided by the distance to the crop wall (the left part in Eq. E2 gives the area below the linear term of the curve, the right part the area below the potency term):

$$f_{soil,avg} = \frac{x_1\left[Ax_1^{B} + \frac{100 - Ax_1^{B}}{2}\right] + \frac{A}{B+1}\left(x_2^{B+1} - x_1^{B+1}\right)}{100x_2} \quad \text{(E2)}$$

where x_1 is 1.0 m and x_2 is the distance to the crop wall (m), and A and B are the regression parameters. The average fraction of the dose reaching the soil equals the dose rate assessment factor for the between-row area ($f_{dose,between\text{-}row}$) as defined in Section 4.4.



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2527 **Figure E.1:** Fraction of dose (f_{soil}) reaching the soil via drift on the basis of the FOCUS surface water
2528 drift curves (FOCUS, 2001). Soil loads for distances < 1 m are calculated by linear interpolation.

2529 Table E.2 gives average fractions of the dose ($f_{soil,avg.}$) reaching the soil between the crop wall and a
2530 given distance to the crop wall (1 – 5 m) based on the FOCUS surface water drift curves (FOCUS,
2531 2001). These fractions are in a range from 0.3 – 0.8 depending on the crop, the crop stage and the
2532 distance to the crop wall. In other words, if the intended application rate for an air blast application in
2533 permanent crops is 1 kg ha^{-1}, the area between the rows is considered to receive 0.3 – 0.8 kg ha^{-1} via
2534 drift.

2535 **Table E.2:** Calculated average fraction of the dose ($f_{soil,avg.}$) reaching the soil between the crop wall
2536 and a given distance to the crop wall (1 – 5 m) based on FOCUS surface water drift curves (FOCUS
2537 2001), rounded to the nearest 0.1.

Distance to the crop wall (m)	Pome/stone fruit, early application	Pome/stone fruit, late application, citrus, olives	Vines, early application	Vines, late application	Hops
1	0.8	0.6	0.6	0.7	0.8
2	0.6	0.4	0.3	0.4	0.6
3	0.5	0.3	0.2	0.3	0.4
4	0.4	0.3	0.2	0.3	0.3
5	0.4	0.2	0.1	0.2	0.3

Appendix F. Row treatments in the numerical models

As described in Appendix A.2, two types of concentrations are needed in the case of row treatments, i.e. (i) the concentration between the treated rows and (ii) the concentration in the treated rows. This appendix describes how the refined exposure assessment procedure will be incorporated into the numerical models.

It is assumed that the concentration between the treated rows equals the plateau concentration (see Eqn. A17). In the numerical models, this plateau concentration will be reached directly before the application causing the maximum concentration in time. This concentration needs to be calculated by the model. The concentration in the treated rows needs to be calculated according to an equation akin to Eqn. A18. So for the application causing the highest concentration, the models should use the corrected dose A/f_{row}. The problem with this calculation is that the year that the maximum concentration occurs is not known *a priori*. The solution would be running the models two times:

- In the first run, the model is run normally and the year that the maximum concentration occurs is extracted from the output (the models already give this output).
- In the second run, the model uses the corrected dose (i.e. A/f_{row}) for all applications in the year that the maximum concentration is reached. The peak concentration needed in the exposure assessment is then the maximum concentration for this year.

Pragmatic solution

The alternative to this rather complicated procedure would be to perform two additional calculations within the numerical models. In this procedure, the model is run using the dosage averaged over the entire field. Using normal procedures, the maximum concentration in time can be looked up. This concentration is hereafter called $C_{T,averaged\_field}$ because it results from applications using the dose averaged over the field.

The maximum concentration between the rows ($C_{T,between\_rows}$) and the maximum concentration in the rows (C_{T,in_rows}) can now be calculated using the equations:

$$C_{T,between\_rows} = C_{T,averaged\_field} - \frac{A_{year}}{\rho z_{eco}} \quad \text{(F1)}$$

$$C_{T,in\_rows} = C_{T,between\_rows} + \frac{A_{year}}{f_{row}\rho z_{eco}} \quad \text{(F2)}$$

where ρ (kg dm^{-3}) is the dry bulk density of the soil, f_{row} (-) is the fraction of the soil treated and z_{eco} (dm) is the ecotoxicological averaging depth.

So the idea is to subtract first the average dose to obtain the concentration between the rows (equal to the plateau concentration before the last application) and then add the corrected dose to obtain the peak concentration in the rows. Notice that if ρ is not constant with depth, this should be accounted for using a weighted averaging procedure.

In the case of the concentration in pore water, the following steps should be implemented: (i) the maximum pore water concentration should be looked up, (ii) the corrections in Eqn. F1 and F2 should be applied to the total concentration, and (iii) the pore water concentration should be calculated using the normal algorithms in the models.

This procedure can be combined with the pragmatic solution for the rapidly dissipating fraction of Appendix G, provided that first the calculation procedure for this rapidly dissipating fraction is carried out and thereafter the procedure described here.

Appendix G. Use of the rapidly dissipating fraction derived from field dissipation studies

EFSA (2014a) provided guidance for the calculation of the rapidly dissipating fraction at the soil surface (F_{field}) from field dissipation studies. Here, guidance is provided as to how available F_{field} values can be used to estimate the F_{field} for the exposure scenario.

The estimation of F_{field} for the required scenario can be subdivided into two steps:

- Is the fast decline observed in field dissipation studies also expected to occur in the required exposure scenario?
- If yes, which value of F_{field} is to be used?

With respect to the first step, the answer is "no" ($F_{field} = 0$) unless the notifier provides plausible arguments to support the position that a fast initial decline is expected to occur in the required exposure scenario. Let us consider two examples: a case YES where this is indeed expected and a case NO where this is not expected. In case YES, the field dissipation study was in Germany and it showed a fast initial decline of 70 % of the dose as a result of photodegradation. The required exposure scenario for this case was spraying onto bare soil in southern Europe in the spring. In case NO, we have the same field study but now the required exposure scenario is spraying onto a crop with 80 % deposition on the crop and 20 % on the soil with most of the soil usually in the shadow of the plants.

For the second step, it is proposed to use the worst-case value of four accepted values. For example, four field dissipation studies show F_{field} values of 30, 40, 60 and 80 % for studies in France, UK, Germany and Spain under normal agricultural use conditions. If fewer or more than four such values are available, it is proposed to use an estimate of the 12.5th percentile. This is approximately the same as the worst-case value of four values (ignoring the difference between a quantile of a sample population and the true population).

Unlike the *DegT50*, for which the uncertainty was accounted for by selecting a scenario that represents a higher spatial percentile (EFSA PPR Panel, 2010b), the uncertainty and spatial and temporal variability of the surface loss processes (F_{field}) were not considered in the scenario selection. Therefore, it is considered appropriate to use a 12.5th percentile of F_{field}. The basis for using the worst-case value of four values is that, in EU regulatory practice, field dissipation studies with four soils are usually required.

Once the 12.5th percentile F_{field} is available, the next step is to use this value in the exposure assessment. We recommend including the fast surface decline only in tiers that use the numerical models.

The correction based on F_{field} should apply to only the fraction of the dose that directly reaches the soil surface (see Figure 7) since it is unlikely that fast dissipation processes play an important role for the fraction that is washed off from the canopy.

The guidance below is based on the following assumptions: (i) F_{field} is an input parameter of the simulation model, (ii) F_{field} has to be specified for each application of the substance and (iii) F_{field} is used in the model as follows:

$$A_{ism} = f_{soil}\left(1 - F_{field}\right)A \qquad \text{(E1)}$$

where A_{ism} is that part of the dose (kg ha^{-1}) that is assumed to reach the soil surface on the day of application (the part that penetrates immediately into the soil matrix) and F_{field} (–) is the rapidly dissipating fraction.

The procedure is to switch off both photochemical transformation (in case this is simulated) and volatilisation (by setting the saturated vapour pressure to zero) in the numerical models because these

loss processes are included in F_{field}. This procedure assumes that runoff of substance is negligibly small (less than 1 % of the dose). When this condition is not met, the model input value of F_{field} has to be corrected to result in the sum of F_{field} and runoff equalling the target F_{field}.

The procedure for the handling of the fast surface decline is given by the following steps:

- run the model for the required simulation period using this 12.5th percentile F_{field};
- select from this run the year at which the all-time-high concentration occurs;
- take the model input file of this run and perform the calculation of the next model run (see next item) outside the shells of the models using this model input file as a starting point;
- run the model a second time but now with a zero F_{field} for the year in which the all-time-high concentration occurs. If there is only one application per year, set F_{field} to zero for this application, when there are more applications per year, set F_{field} to zero only for the application in the all-time-high year that leads to the all-time-high concentration (usually the last application in the year). This implies that in case of repeated applications it is assumed there is enough time available for the rapid dissipation before the next dosage is applied.

Setting F_{field} to zero (point iii) in the all-time-high year is necessary because otherwise the all-time-high concentration would be systematically underestimated because the rapid dissipation takes some time.

Pragmatic solution

An alternative to this procedure of running the model twice is the following pragmatic solution (similar to the pragmatic solution in Appendix F):

- run the model using this 12.5th percentile F_{field};
- select from this run the year at which the all-time-high concentration occurs;
- in case of the concentration in total soil, this concentration is called $C_{T,uncorrected}$ because it also includes rapid dissipation of the dosage that generates the all-time high (which is inappropriate as described above);
- the corrected concentration can then be calculated as

$$C_{T,corrected} = C_{T,uncorrected} + \frac{f_{soil,last}\, F_{field,last}\, A_{last}}{\rho\, z_{eco}} \qquad \text{(G2)}$$

  where the subscript '*last*' refers to the last application in the year (assuming that this leads to the all-time high concentration which will usually be the case). This equation adds again the amount that was substracted in the model simulations to account for rapid dissipation of part of this last application.

In the case of the concentration in pore water, the following steps should be implemented: (i) the maximum pore water concentration should be looked up, (ii) the correction in Eqn. G2 should be applied to the total concentration, and (iii) the pore water concentration should be calculated using the normal algorithms in the models.

This procedure can be combined with the pragmatic solution for the in-row applications (Appendix F), provided that first the correction for the rapidly dissipating fraction is carried out and thereafter the procedure for the in-row applications.

Appendix H. Examples on how the EFSA Guidance Document can be used

Worked examples will be provided in the final version of this Guidance Document.

Appendix I. Results of simulations for example scenarios and application of one example substance

I.1. Procedure

Experience with releases of the FOCUS groundwater scenarios has shown that it is desirable (as a basic quality check) to run all models for all scenarios and to compare annual average water balances and output for an example substance. Calculations were performed for all crop–scenario combinations with PEARL and PELMO for one strongly sorbing and persistent example substance "P" using an ecotoxicological averaging depth of 20 cm (considering only the peak concentration, no TWA values). It was assumed that this substance P was applied annually at a rate of 1 kg ha^{-1} one day before emergence of the crop (the substance was applied to the soil surface). The scenarios were selected with the analytical model using the procedure described in Appendix A.

The K_{om} of substance P at reference conditions was 1 000 l kg^{-1} and it's *DegT50* in topsoil at 20 °C and field capacity was 730 days. The K_{om} under air-dry conditions was assumed to be 100 000 l kg^{-1} (i.e. 100 times the K_{om} value at reference conditions). The log K_{ow} of substance P is 3.8 so the transpiration stream concentration factor (*TSCF)* was set at 0.15 according to EC (2014).

Furthermore, the conversion factor of 1.724 was used for the relationship between K_{om} and K_{oc}. In line with EFSA (2007), the molar activation energy E_{Act} was assumed to be 65.4 kJ mol^{-1} (Q_{10} = 2.58). Other substance properties were set equal to substance D as defined by EC (2014).

A warming-up period of 54 years was used for all scenarios, because the *DegT50* value at the average scenario temperature was greater than 1 000 days for all six scenarios.

Calculations are based on PERSAM, PEARL kernel version xxx and PELMO version xxx. Note that these models are still under development. Results may change when updated models are released.

I.2. Results

Results still to be generated

Appendix J. Excel sheet for the fraction of the dose reaching the soil

The Excel sheet provides background information on how the fraction of applied substance reaching the soil was derived. It will be made available when the final Guidance Document is released.

Appendix K. Detailed description of the input files of PEARL and PELMO

A document describing the model parameterisation in detail will be made available when the final Guidance document is released.