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

EU part

Plant protection products

Chapter 5 Fate and behaviour in the environment: behaviour in soil; leaching

version 3.0; October 2025

ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 5 Fate and behaviour in the environment; behaviour in soil; leaching

Category: Plant Protection Products

General introduction 4
1. EU framework 4
1.1. Introduction 4
1.2. Data requirements 4
1.3. Risk assessment 5
1.3.1. General 5
1.3.2. First tier; model calculation 5
1.3.3. Higher tier assessment 6
1.3.4. Metabolites 7
1.3.5. Protected crops 7
1.3.6. PEC calculations in case of indoor mushroom cultivation 8
1.3.7. Agreements Central Zone Steering Committee 8
1.4. Approval 9
1.4.1. Approval of the active substance 9
1.4.2. Evaluation of the plant protection product 10
1.4.3. Decision making for the plant protection product 11
1.5. Developments 11

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 5 Leaching			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014	§1.5, p. 24	Data requirement for the active substance: full text taken from Commission Regulation (EU) No 283/2013
2.1	October 2016	§1.3.4, p.5	Section on groundwater assessment for protected crops
		§1.5, p.9	Update of the latest version of the relevant Guidance document and the consequences for submission of active substance and plant protection product dossiers.
2.2	January 2018	Paragraph 1.3.6, page 6	Instructions for modelling the exposure to groundwater of mushroom cultivation have been incorporated in the Evaluation Manual
2.3	Februari 2019	Paragraph 1.3.7	New version of the working document included
2.4	January 2020	1.	Sentence included on the administrative EFSA guidance
2.5	April 2021	Paragraph 1.3.3 1.5	Implementation of the EFSA GD on Aged sorption as from 1 April 2021
2.6	July 2022	Paragraph 1.5	Consequences of version 2.3 of the Generic Guidance for Tier 1 FOCUS Ground Water Assessments .
2.7	September 2023	Paragraph 1.5	FOCUS PELMO 5.5.5. corrected to FOCUS PEARL 5.5.5
2.8	February 2024	Paragraph 1.3.2, 1.3.3, 1.5	Implementation of the EFSA Guidance on soil phototransformation products in groundwater (2022) and Generic Guidance for FOCUS Tier 1 Ground Water assessments (version 2.4; March 2023) as from 1 January 2024.
2.9	April 2025	1.3.5	Implementation of the *Interim working document on the interzonal core assessment of greenhouse uses - environmental fate* as from 1 September 2024
3.0	October 2025	1.2 and 1.5	Hyperlinks restored Consistency with implementation of the ECJ judgment (**C-308/22**)

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the potential for leaching to groundwater of an active substance of a plant protection product and its metabolites, degradation products and reaction products and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009.

1. EU FRAMEWORK

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

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

1.1. Introduction

Commission Regulation (EU) No 546/2011 stipulates that Member States assess whether and to what extent a plant protection product may reach groundwater when used consistent with the directions for use. Where this possibility exists, Member States should by means of an appropriate Community validated model evaluate the concentration of the active substance and of the metabolites, degradation products and reaction products that are present in the groundwater at the place in question in case of application consistent with the directions for use.

As long as no Community validated calculation model has been enacted, Member States in particular base their evaluation on the results of the studies into the mobility and persistence in the soil as referred to in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009. For the other general chemical parameters of a substance that are required as input data for the model reference is made to Chapter 2 Physical-chemical properties.

Guidelines for evaluation of the aspect leaching are described in FOCUS Degradation Kinetics, FOCUS Groundwater and Assessing Potential for Movement of Active Substances and their metabolites to Ground Water in the EU. Accompanied by Generic Guidance for Tier 1 FOCUS Ground Water Assessments and Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

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

The data requirements regarding leaching of the active substance to groundwater are described in part A of Commission Regulation (EU) No 283/2013, point 7.1 (fate and behaviour in the soil) and 7.5 (monitoring data).

The data requirements regarding leaching of the plant protection product to groundwater are described in part A of Commission Regulation (EU) No 284/2013, point 9.1 (fate and behaviour in soil) and 9.2.4 (estimation of concentrations in groundwater).

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2023/C 344/02 and Commission Communication 2023/C 344 01.

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

1.3. Risk assessment

1.3.1. General

Central question in the EU approval procedure of active substances is whether safe scenarios exist in Europe. The answer to this question indicates whether a so-called safe use of a substance exists somewhere in Europe. The question whether a use can be permitted throughout whole Europe is not relevant for the approval of an active substance. For the zonal applications of plant protection products a safe use needs to be demonstrated for every use of the product for which the applicant seeks authorisation.

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

1.3.2. First tier; model calculation

In European framework the evaluation of leaching is based on the FOCUS groundwater approach. The FOCUS groundwater approach comprises a set of nine leaching scenarios, consisting of weather, soil and crop data which together are representative of agriculture in Europe. The scenarios and their derivation are described in detail in the FOCUS Groundwater report.

The scenarios should describe an overall vulnerability approximating the 90th percentile of all possible situations (this percentile is often referred to as a realistic worst case). The overall 90th percentile is approximated by using a 80th percentile value for soil and a 80th percentile value for weather conditions.

The scenarios have been implemented as sets of input data for four simulation models. Calculations are based on year-averaged concentrations at 1 metre depth for a series of 20, 40 or 60 years (depending on the application frequency) and different climatological conditions. The four models are FOCUS PEARL (which is also used in the national leaching assessment), FOCUS PELMO, FOCUS PRZM and FOCUS MACRO. Information on the models and installation packages can be found on the following website: http://esdac.jrc.ec.europa.eu/projects/ground-water.

In the first tier model results for the predicted concentration in groundwater are evaluated against the leaching criterion of 0.1 µg/L (see § 1.4.3). Three situations are possible. The 80th percentile leaching concentration of the active substance and all relevant metabolites:

1. exceeds 0.1 µg/L for all relevant scenarios;
2. is equal to or lower than 0.1 µg/L for all relevant scenarios;

3. exceeds 0.1 μg/L for some relevant scenarios and is equal to or lower than 0.1 μg/L for the other relevant scenarios.

In case of the first situation, inclusion in Commission Implementing Regulation (EU) No 540/2011 is not possible unless data from a higher tier are available that overrule the model calculations.

In case of the second situation, the result of having evaluated a 'realistic-worst case' approach means that there is sufficient confidence that the substance is safe in the majority of the situations in the EU. This does, however, not preclude the possibility of leaching in strongly sensitive situations within specific Member States but these situations cannot be widespread and can be evaluated at Member State level.

In the third situation, e.g. when the 80th percentile leaching concentration for the active substance and all relevant metabolites is equal to or lower than 0.1 μg/L for at least one relevant scenario, the substance can in principle be included in 540/2011 with regards to groundwater leaching. The scenarios are representative of important agricultural areas within the EU, which means identification of at least one safe use is significant in terms of agricultural use in the EU. The scenarios that result in concentrations ≤ 0.1 μg/L, together with the results of some already existing research from a higher tier, help to indicate the significance of the safe use of such a substance.

Guidance for performance of a first tier assessment is presented in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments.

For the simulation of metabolites that are formed by soil photolysis of an active substance and trigger further assessment, the EFSA Guidance on soil phototransformation products in groundwater (2022) should be followed. A separate tiered assessment scheme has been developed for the phototransformation products (photo-TP). In Tier 1 a separate simulation is performed, in which the photo-TP is simulated as parent substance with the application rate of the active substance corrected by the ratio of molar masses of active substance and soil photo-TP.

1.3.3. Higher tier assessment

The report 'Assessing Potential for Movement of Active Substances and their metabolites to Ground Water in the EU' describes the approaches for higher assessments (i.e. Tier 2, Tier 3 and Tier 4). A tiered approach is presented in which earlier tiers are more stringent than later tiers, but require less information and effort from the applicant.

Tier 2 approaches consist of either parameter refinements for modelling (e.g. non-equilibrium sorption measurements according to the DG SANTE Guidance on Aged sorption implemented from 1 April 2021) or scenario refinements (e.g. GIS data, hydrogeological data; characterisation of vulnerable situations or 'risk areas' to enable more targeted simulations for specific crops).

Combinations of the modelling and refined parameters from Tier 2, as well as higher tier leaching experiments set into context by modelling, or advanced spatial modelling and other modelling approaches, are classified as Tier 3.

Tier 4 concerns the use of groundwater monitoring data. Ground water monitoring data are seen as the highest tier of assessment since the actual concentrations in ground water are directly measured rather than being estimated by modelling approaches or approximated from

small scale field studies. Monitoring data can include the results of dedicated analyses of ground water by notifiers or other agencies (i.e. water companies, environment agencies etc) where there needs to be a detailed initial assessment of the relevance of the monitoring points (for example, by knowledge of historical compound usage in the area and characteristics of the aquifer) and when minimum quality criteria in relation to these aspects have been demonstrated.

For the higher tier simulation of photo-TP, the EFSA Guidance on soil phototransformation products in groundwater (2022) should be followed. In case Tier 1 simulations for photo-TP according to the EFSA Guidance on soil phototransformation products in groundwater (2022) (see § 1.3.2) result in a PEC_{gw} value > 0.1 μg/L, an assessment of their relevance can be performed (see § 1.3.4) to demonstrate that the photo-TP can be considered non-relevant. Alternatively, a Tier 2 assessment can be performed. In Tier 2 the PECgw of the active substance and its transformation products are simulated according to the complete degradation scheme including the photolytic and the biodegradation pathway. The simulations should be performed in FOCUS PELMO 5.5.3 and subsequent versions, using either default values for the photolytic degradation rates (Tier 2A) or normalised degradation rates derived from field experiments (Tier 2B).

1.3.4. Metabolites

Metabolites for which FOCUS calculations or other higher tier data show that the concentration exceeds 0.1 μg/L can be evaluated for their relevance (see § 1.4) according to the Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. The determination of the relevance of metabolites in groundwater follows a tiered approach, which procedure covers aspects of efficacy and human toxicology besides aspects that are relevant for the environment.

The following steps are part of the evaluation:
Step 1: exclude metabolites that give no cause for concern;
Step 2: quantify potential groundwater contamination;
Step 3: 'Hazard' evaluation: Identification of relevant metabolites;
- Stage 1 of step 3: screening for biological activity;
- Stage 2 of step 3: screening for genotoxicity;
- Stage 3 of step 3: screening for toxicity;

Step 4: Exposure evaluation – threshold of concern approach;
Step 5: Refined risk assessment for non-relevant metabolites.

For a detailed elaboration of these steps we refer to the Guidance Document

1.3.5. Protected crops

The EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments came into force on the 1st of December 2015 for both submission of active substance and plant protection product dossiers. Leaching to groundwater from protected crop systems may occur, depending on environmental conditions, the construction technology of the system and the substance properties. For all protection structures mentioned in Table 1 of the Guidance, except closed buildings, walk-in tunnels and greenhouses, it is proposed to use current open-field approaches for exposure of groundwater described in § 1.3.1 -1.3.3. The models that are generally used to calculate leaching and drainage from open-field cultivation can equally well be used to calculate leaching and drainage from walk-in tunnels and greenhouses if appropriate scenarios are available. The procedure to develop such scenarios is described in the Guidance. In addition, an example scenario for a leaching assessment for soil-bound crops in walk-in tunnels and greenhouses is presented in Appendix A. For the

groundwater assessment no tiered approach is explicitly presented in the Guidance for walk-in tunnels and greenhouses. However, it is stated that “Current risk assessment procedures for the receptor groundwater may be too conservative for walk-in tunnels and greenhouses”. Therefore Ctgb considers it acceptable to use the first tier assessment procedure for open-field cultivation as a first tier for a groundwater assessment for walk-in tunnels and greenhouses.

From 1st of September 2024 onwards the assessment of protected uses in greenhouses should follow the *Interim working document on the interzonal core assessment of greenhouse uses - environmental fate* that was published in March 2024. The working document is based on recommendations by the EFSA GD on protected crops (2014) and FOCUS Air (2008) using workable, agreed standard models and simple calculations. The proposed assessment is intended to cover all types of greenhouses and cultivation types.
The working document requires all nine standard FOCUS leaching scenarios to be considered for all active substances and metabolites. This groundwater assessment is only relevant for greenhouses without sealed floors/impermeable soil and/or recirculation systems. According to the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments “for soil-less cultivation systems leaching to groundwater can be considered not relevant”. However, to account for all cultivation systems or methods falling under ‘greenhouse uses’ this risk assessment should always be included in the interzonal core dossier. The conclusion on the relevance of the assessment for the intended uses and decision on acceptable uses and applicable risk mitigation measures is left to the national level.

1.3.6. PEC calculations in case of indoor mushroom cultivation

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

The calculated corrected dose rate (guidance how to derive this corrected dose rate can be found in the Evaluation Manual 2.2., chapter 5 Persistence, §1.3.6) can be applied in regular PEARL, PELMO and MACRO modelling.

Settings in PEARL and PELMO

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

1.3.7. Agreements Central Zone Steering Committee

On the public part of CircaBC, agreements of the central zone steering committee are presented. Applicants are advised to check this site when preparing a zonal dossier for agreements published after the finalisation of the current version of the Evaluation Manual. The bullet points are published in the category Health and Food Safety in the interest group PPP Zonal. In the “Library” there is a separate space for the central zone steering committee in which the publically available documents are presented.

Currently the following agreements are included:

Meeting CZSC March 2014:
The use of the Q10 value in zonal dossiers of plant protection products was discussed (see bullet points of the meeting on CIRCABC). Conclusion of the discussion was that the Q10 value is regarded as a substance specific parameter (independent whether it is measured or defined by a default value), which is agreed upon in the approval of the active substance. In line with the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 9), this value should also be used in plant protection dossiers following approval of an active substance. This means that for active substances for which a Q10 value of 2.2 was used in the DAR, the same value must be used in zonal dossiers of plant protection products. Only if the use of a normalisation of the soil degradation endpoints based on the new Q10 value of 2.58 results in a more favourable endpoint and is necessary to demonstrate a safe use, can this new active substance data be accepted in a zonal dossier. If no Q10 value was agreed on during approval of the active substance (e.g. no FOCUS modelling available at that time), the new Q10 value of 2.58 should be used for pragmatic reasons.

Meeting CZSC May 2014:
It was discussed whether kinetic evaluations are product data or active substance data (see bullet points of the meeting on CIRCABC). All Member States agreed that kinetic evaluations concern active substance data since the endpoints from active substance studies (concerning degradation rate) are re-evaluated yielding new active substance endpoints. Therefore kinetic evaluations need to be dealt with according to the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 9). This means that only when a kinetic evaluation results in a more favourable endpoint and is necessary to demonstrate a safe use, this new active substance data be accepted in a zonal dossier.

Meeting CZSC January 2016:
In November 2014 a meeting of FATE-experts from regulatory authorities of the Central Zone was held in Vienna, targeted at harmonisation of the fate assessment of a Central Zone core assessment. After the meeting a working document was prepared describing the procedure for the assessment of environmental fate and behaviour of applications for authorisation and re-authorisation of plant protection products in the Central zone.
The working document has been placed on the public part of CIRCABC and has the full title: Working document of the Central Zone in the Authorisation of Plant Protection Products, Section 5, Environmental Fate and Behaviour.

Meanwhile, the working document has been slightly revised. This new version 1.1 is placed on the public part of CIRCABC and has the full title: Working document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour .
This version should be used from December 2018 onwards.

1.4. Approval

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

1.4.1. Approval of the active substance

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

1107/2009.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect leaching to groundwater are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier
The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites
Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.10. Fate and behaviour concerning groundwater
An active substance shall only be approved where it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

As already mentioned in § 1.3.1, the central question in the EU approval procedure of active substances for the aspect leaching to groundwater is whether one or more safe uses can be established for a representative formulation.

1.4.2. Evaluation of the plant protection product

The principles for the evaluation of plant protection products are presented in Commission Regulation (EU) No 546/2011(Uniform Principles) Part I section B. The texts specifically applicable to the aspect leaching to groundwater are presented below. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.1.2. Member States shall evaluate the possibility of the plant protection product reaching the groundwater under the proposed conditions of use; if this possibility exists, they shall estimate, using a suitable calculation model validated at EU level, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the groundwater in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.
As long as there is no validated EU calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies as provided for in the Annex to Regulation (EU) No 544/2011 and Regulation (EU) No 545/2011.
This evaluation will also take into consideration the following information:
(i) the specific information on fate and behaviour in soil and water as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
(ii) other relevant information on the active substance such as:
- molecular weight,
- solubility in water,
- octanol/water partition coefficient,

- vapour pressure,
- volatilization rate,
- hydrolysis rate in relation to pH and identity of breakdown products,
- dissociation constant;

(iii) all information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011, including the information on distribution and dissipation in soil and water;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(v) where relevant, data on dissipation including transformation and sorption in the saturated zone;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use;

(vii) where relevant, monitoring data on the presence or absence of the active substance and relevant metabolites, degradation or reaction products in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues; such monitoring data shall be interpreted in a consistent scientific way.

1.4.3. Decision making for the plant protection product

The principles for decision making on the authorisation of plant protection products are presented are presented in Commission Regulation (EU) No 546/2011 Part 1 section C. The texts specifically applicable to the aspect leaching to groundwater are presented below. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.1.2. No authorisation shall be granted if the concentration of the active substance or of relevant metabolites, degradation or reaction products in groundwater, may be expected to exceed, as a result of use of the plant protection product under the proposed conditions of use, the lower of the following limit values:

(i) the maximum permissible concentration laid down by Directive 2006/118/EC of the European Parliament and of the Council*; or

(ii) the maximum concentration laid down when approving the active substance in accordance with Regulation (EC) No 1107/2009, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was approved in accordance with Regulation (EC) No 1107/2009, unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

The maximum permissible concentration laid down by Directive 2006/118/EC for active substances in pesticides, including their relevant metabolites, degradation and reaction products is 0.1 μg/L. A definition of a relevant metabolite is included Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. This Guidance also describes the procedure to evaluate the relevance of a metabolite (see § 1.3.4). Metabolites which are evaluated as being non-relevant do not need to comply with leaching criterion of describe in Part 1 section C section under point 2.5.1.2.

1.5. Developments

In July 2014 the "EFSA Guidance Document for evaluating laboratory and field dissipation

* OJ L 372, 27.12.2006, p. 19.

studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil" was published (hereafter referred to EFSA Guidance Document DegT50). The guidance describes a procedure for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. In the SCoPAFF-Legislation meeting on 11 and 12 December, the EFSA Guidance Document DegT50 (EFSA, 2014) was noted with an entry into force date of May 1st 2015. Updated versions of the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version 2.2, May 2014) and Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (version 1.1, December 2014) have been published to accommodate the EFSA DegT50 Guidance. Both updated documents have also an implementation date of 1 May 2015.

The approaches outlined in the EFSA Guidance on DegT50 for deriving $DegT50_{matrix}$ values should be implemented for all submissions for approval or renewal of an active substance. Ctgb will NOT require applicants to update soil DT50 values in line with the EFSA Guidance on DegT50 for plant protection product submissions. We request that applicants continue to use the EU agreed endpoints listed in the List of Endpoints (LoEP) in line with the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8) which states that new active substance data may only be used if this results in an endpoint which leads to a more favourable risk assessment compared to the endpoint listed in the LoEP and a safe use can only be demonstrated by using the new endpoint (provided that the studies are valid). When the active substance has been approved/renewed based on this guidance document, than automatically all submissions for plant protection product authorisation based on this substance will comply with this guidance.

In 2012 EFSA, and in particular its Scientific Panel on Plant Protection Product and their Residues (PPR Panel), was asked by the Commission (DG SANCO) to deliver a scientific opinion on the final report of the FOCUS Groundwater working group "Assessing potential for movement of active substances and their metabolites to groundwater in the EU" (version 1). The PPR panel published two opinions in 2013: one opinion on lower tiers and one on higher tiers. In October 2014, an updated version of the FOCUS report was published which incorporated the observations and recommendations of the EFSA PPR panel opinions (version 3, October 2014). The Generic Guidance for Tier 1 FOCUS Ground Water Assessments has been updated (version 2.2, May 2014) to incorporate the opinion on lower tiers. Both updated documents and the EFSA Guidance on DegT50 had an implementation date of 1 May 2015.

The most important changes that were made in version 2.2 of the Generic Guidance for Tier 1 FOCUS Ground Water Assessments, based on the PPR opinions and the EFSA Guidance on DegT50, are listed below:

1. use of a geometric mean Koc/Kom as input for modelling;
2. use of a geometric mean $DegT50_{matrix}$ value based on laboratory degradation or field degradation or combined laboratory and field degradation rates;
3. recommended default value of 0 for the TSCF (Transpiration Stream Concentration Factor);
4. use of a realistic worst case adsorption value, in case of pH dependent sorption;
5. updated crop interception values for some crops;
6. recommendation to use more than one FOCUS model for the risk assessment.

The first four points are considered by Ctgb to be (related to) substance properties for which EU agreed endpoints are established at time of the approval of the active substance. For all submissions for approval or renewal of an active substance the Guidance needs to be

followed on these points. For submissions for authorisation of plant protection products, we will continue to accept the EU agreed endpoints for the Koc/Kom and TSCF value as input for modelling, in line with the Guidance document on the evaluation of new active substance data post approval. The last two points are not related to substance properties and need to be included in both active substance dossiers and plant protection product dossiers from 1 May 2015 onwards.

In 2012 the Food and Environment Research Agency (FERA) published a guidance proposal on the conduction of aged sorption studies and their use in risk assessment: Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. Following a recommendation from the EFSA Pesticide Steering Network, EFSA asked their PPR panel to prepare a scientific opinion on this document. The PPR main was unable to prepare a complete evaluation of the document due to the fact that the underlying data was not made available. Therefore the PPR panel only prepared a statement in which it was recommended not use the FERA guidance for the time being. In the Statement, the EFSA PPR panel agreed in general with the experimental and modelling approaches that were proposed in the guidance. Some revisions of the guidance were requested regarding the interpretation of aged sorption data, and how the data is used in the tiered risk assessment. Additional testing on 'real world data' was requested for some of the proposed changes. The guidance was revised in September 2016 in response to the recommendations by EFSA. As a follow-up to the publication of the EFSA Scientific Opinion (EFSA, 2018), the Chemicals Regulation Division (CRD) of the Health and Safety Executive (UK) updated the guidance based on the recommendations in the EFSA PPR Opinion (EFSA, 2018). The EFSA PPR panel (2018) tested the guidance using three substances and concluded that the guidance could generally be well applied and resulted in robust and plausible results. A final draft of this guidance document was submitted by the Chemical Regulation Division (CRD) UK, in October 2019 to the European Commission.

The Standing Committee on Plants, Animals, Food and Feed agreed that the DG SANTE GD "Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments" will be applicable as from 1 April 2021 (date of dossier submission) to dossiers submitted under Regulation (EC) No 1107/2009.

In June 2021, FOCUS PEARL version 5.5.5 and FOCUS PELMO version 6.6.4 were released. These versions were released to accommodate the Tier 2 exposure assessment of soil organisms described in the EFSA guidance (EFSA, 2017). In addition, the Generic Guidance for Tier 1 FOCUS Ground Water Assessments was updated (version 2.3, June 2021). The most important changes in version 2.3 are listed below:

- additional guidance on pesticide property parameter derivation when degradation or sorption in soil is dependent on pH or other soil properties;
- reference to DG SANTE "Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments";
- reference to the OECD 106 evaluators checklist.

In the SCoPAFF meeting of March 2023, the EFSA Guidance on soil phototransformation products in groundwater has been taken note. This Guidance document should be used for the assessment of soil phototransformation products for applications made after 1 January 2024. In addition, the Generic Guidance for FOCUS Tier 1 Ground Water assessments has been updated to implement this new EFSA Guidance document. The new version of the Generic Guidance for FOCUS Tier 1 Ground Water assessments (version 2.4; March 2023) should also be used for applications made after 1 January 2024. Currently no version of

FOCUS PEARL is available with the features needed for a Tier2a/2b assessment as described in the EFSA Guidance on soil phototransformation. EFSA has requested the developers of FOCUS PEARL to also include the functionality for photolytic degradation in PEARL; it is expected that a new version of FOCUS PEARL, capable of a Tier 2 assessment, will be released in the near future.