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

EU part

Plant protection products

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

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Board for the Authorisation of plant protection products and biocides

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

Category: Plant Protection Products

GENERAL INTRODUCTION

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

Substances that are approved under Regulation (EC) No 1107/2009 and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 [4] and Regulation (EU) No 284/2013 [5] (SANCO/11509/2013 – rev. 0.1).

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 [**Fout! Bladwijzer niet gedefinieerd.**].

1.1. Introduction

Persistence in the soil is included in the evaluation where it cannot be ruled out that substance or product reaches the soil (see Appendix 1). The use of plant protection products may lead to accumulation of substances in the soil. The persistence of plant protection products and each of its metabolites in the soil is evaluated to prevent the authorisation of substances that accumulate in the environment, which could lead to adverse effects in the future.

The questions in §1.2.1 and §1.2.2 of this chapter are relevant for the persistence (residence time) and accumulation of plant protection products in the soil. Data concerning the nature of the metabolites and the degradation rates of active substance and metabolites are considered. These data are also used in evaluating the risk of leaching to groundwater (see chapter 6 Fate and behaviour in the environment; behaviour in soil; leaching to groundwater).

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

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

Guidelines for evaluation of the aspect persistence are described in the Guidance Document on Persistence in Soil [6] FOCUS Degradation Kinetics [7] and the Guidance Document on Terrestrial Ecotoxicology [8].

The relevant decision tree from the Guidance Document on Persistence in Soil is included in Appendix 2.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5).

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [**Fout! Bladwijzer niet gedefinieerd.**] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [4] and Commission Regulation (EU) No 284/2013 [5] of Regulation (EC) No 1107/2009 must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communications 2013/C 95/01[9].

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

Experiments carried out after 25 July 1993 should have been carried out under GLP.

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

1.2.1. Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013 [4]. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given above the headings.
Any relevant results of the study are given as well.

The data requirements regarding persistence of the active substance in the soil are described in part A of Commission Regulation (EU) No 284/2013 [5], point 7.1 (fate and behaviour in the soil) and 7.5 (monitoring data).

Fate and behaviour in soil
(283/2013; 7.1)

7.1. Fate and behaviour in soil
All relevant information on the type and the properties of the soil used in the studies, including pH, organic carbon content, particle size distribution and water holding capacity

shall be reported.

The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.
The soils used for degradation, adsorption and desorption or mobility studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.

The soils shall fulfil the following conditions:
— they shall cover a range of organic carbon content, particle size distribution and pH (preferably $CaCl_2$) values, and
— where on the basis of other information, degradation or mobility are expected to be pH dependent, for example solubility and hydrolysis rate (see points 2.7 and 2.8), they shall cover approximately the following pH (preferably $CaCl_2$) ranges: 5 to 6, 6 to 7 and 7 to 8.

Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.

A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used.

Field studies shall be carried out in conditions as close to normal agricultural practice as possible on a range of soils and climatic conditions representative of the areas of use. Weather conditions shall be reported in cases where field studies are conducted.

Route of degradation in soil

7.1.1. Route of degradation in soil
The data and information provided, together with other relevant data and information, shall be sufficient to:

(a) identify, if possible, the relative importance of the types of processes involved (balance between chemical and biological degradation); (b) identify the individual components present which at any time account for more than 10 % of the amount of active substance added, including, if possible, non-extractable residues; (c) identify, if possible, the individual components which in at least two sequential measurements, account for more than 5 % of the amount of active substance added; (d) identify, if possible, the individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached; (e) identify or characterise, if possible, other individual components present; (f) establish the relative proportions of the components present (mass balance); and
(g) permit the soil residue of concern to which non-target species are or may be exposed, to be defined.

For the purposes of this Section non-extractable residues means chemical species originating from active substances contained in plant protection products used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues or the nature of the soil matrix. These non-extractable residues are not considered to include fragments through

metabolic pathways leading to natural products.

Aerobic degradation
(283/2013 ; 7.1.1.1.)

7.1.1.1.1. Aerobic degradation
Circumstances in which required
The pathway or pathways of aerobic degradation shall be reported except where the nature and manner of use of plant protection products containing the active substance precludes soil contamination, such as indoor uses on stored products or brush applied wound healing treatments for trees.
Test conditions
Studies on the degradation pathway or pathways shall be reported for at least one soil. Oxygen levels shall be maintained at levels that do not restrict micro-organisms ability to metabolise aerobically. If there is reason to believe that the route of degradation is dependent on one or more properties of the soil, such as pH or clay content, the route of degradation shall be reported for at least one additional soil for which dependent properties are different.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label as a function of time, as between:
(a) active substance;
(b) CO_2 ;
(c) volatile compounds other than CO_2 ;
(d) individual identified transformation products referred to in point 7.1.1;
(e) extractable substances not identified; and
(f) non-extractable residues in soil.

The investigation of degradation pathways shall include all possible steps to characterise and quantify non- extractable residues formed after 100 days when exceeding 70 % of the applied dose of the active substance. The techniques and methodologies applied shall be selected on a case-by-case basis. A justification shall be provided where the compounds involved are not characterised.

The duration of the study shall be at least 120 days, except where after a shorter period the levels of non- extractable residues and CO_2 are such that they can be extrapolated in a reliable way to 100 days. It shall be longer where this is necessary to establish the degradation pathway of the active substance and its metabolites, breakdown or reaction products.

<u>Results:</u>
→ identity and formation percentage of metabolites;
→ % soil-bound residue after 100 days;
→ mineralisation rate, expressed as % CO_2 after 100 days.
(optional) DT50 of the active substance

Anaerobic degradation
(283/2013; 7.1.1.2)

7.1.1.2. Anaerobic degradation
Circumstances in which required

An anaerobic degradation study shall be submitted unless the applicant shows that exposure of the plant protection products containing the active substance to anaerobic conditions is unlikely to occur for the intended uses.

Test conditions

Point 7.1.1.1 shall apply as regards test conditions except oxygen levels which shall be minimised as to ensure that micro-organisms metabolise anaerobically.

Soil photolysis
(283/2013; 7.1.1.3)

7.1.1.3. Soil photolysis
Circumstances in which required
A soil photolysis study shall be submitted unless the applicant shows that deposition of the active substance on the soil surface is unlikely to occur or that photolysis is not expected to contribute significantly to the degradation of the active substance in soil for example due to low light absorbance of the active substance.

Result:
→ identity and formation percentage of metabolites;
→ DT50 (lab)

Rate of degradation
(283/2013; 7.1.2)

Laboratory studies
(283/2013; 7.1.2.1)

7.1.2. Rate of degradation
7.1.2.1. Laboratory studies
Laboratory studies on soil degradation shall provide best possible estimates of the time required for degradation of 50 % and 90 % ($DegT50_{lab}$ and $DegT90_{lab}$) of the active substance, its metabolites, breakdown and reaction products under laboratory conditions.

Aerobic degradation of the active substance
(283/2013 ; 7.1.2.1.1)

7.1.2.1.1. Aerobic degradation of the active substance

Circumstances in which required
The rate of degradation in soil shall be reported, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees.

Test conditions
Studies on the rate of aerobic degradation of the active substance shall be reported for three soils in addition to the one required under point 7.1.1.1. Reliable DegT50 and DegT90 values shall be available for a minimum of four different soils.

The duration of the study shall be at least 120 days. It shall be longer where this is necessary to establish the kinetic formation fractions of the metabolites, breakdown or

reaction products. If more than 90 % of the active substance is degraded before the period of 120 days expires, the test duration may be shorter.

In order to assess the influence of temperature on degradation, a calculation with an adequate Q10 factor or an adequate number of additional studies at a range of temperatures shall be performed.

Result:
→ aerobic $DT50_{lab}$
→ aerobic $DT90_{lab}$

Aerobic degradation of metabolites, breakdown and reaction products
(283/2013; 7.1.2.1.2)

7.1.2.1.2. Aerobic degradation of metabolites, breakdown and reaction products

Circumstances in which required
Aerobic degradation (DegT50 and 90 values) from a minimum of three different soils shall be provided for metabolites, breakdown and reaction products which occur in soil if one of the following conditions is fulfilled:
(a) they account for more than 10 % of the amount of active substance added at any time during the studies;
(b) they account for more than 5 % of the amount of active substance added in at least two sequential measurements;
(c) the maximum of formation is not reached at the end of the study but accounts for at least 5 % of the active substance at the final measurement;
(d) all metabolites found in lysimeter studies at annual average concentrations exceed 0.1 µg/L in the leachate.

Studies shall not be required where three DegT50 and 90 values can be reliably determined from the results of the degradation studies where the active substance is applied as test substance.

Test conditions
Test conditions shall be those indicated in Section 7.1.2.1.1 except the test substance applied will be the metabolite, breakdown or reaction product. Studies on metabolites, breakdown and reaction products shall be provided where these are necessary to obtain reliable DegT50 and 90 values for at least three different soils.

Anaerobic degradation of the active substance
(283/2013; 7.1.2.1.3)

7.1.2.1.3. Anaerobic degradation of the active substance

Circumstances in which required
The rate of anaerobic degradation of the active substance shall be reported where an anaerobic study has to be performed in accordance with point 7.1.1.2.

Test conditions
Anaerobic DegT50 and 90 values for the active substance are needed for the test conditions outlined in point 7.1.1.2. .

Result:
→ anaerobic $DT50_{lab}$
→ anaerobic $DT90_{lab}$

Anaerobic degradation of metabolites, breakdown and reaction products
(283/2013; 7.1.2.1.4)

7.1.2.1.4. Anaerobic degradation of metabolites, breakdown and reaction products

Circumstances in which required
Anaerobic degradation studies shall be provided for metabolites, breakdown and reaction products which occur in soil if they fulfil one of the following conditions:
(a) at any time during the studies account for more than 10 % of the amount of active substance added;
(b) in at least two sequential measurements account for more than 5 % of the amount of active substance added, if feasible;
(c) at the end of the study the maximum of formation is not yet reached but accounts for at least 5 % of the active substance at the final measurement, if feasible.

The applicant may deviate from such requirement by showing that DegT50 values for metabolites, breakdown and reaction products can be reliably determined from the results of the anaerobic degradation studies with the active substance.

Test conditions
Studies on metabolites, breakdown and reaction products shall be provided for one soil for the test conditions outlined at point 7.1.1.2.

Field studies
(283/2013; 7.1.2.2)

Soil dissipation studies
(283/2013; 7.1.2.2.1)

7.1.2.2. Field studies
7.1.2.2.1. Soil dissipation studies
The soil dissipation studies shall provide estimates of the time required for dissipation of 50 % and 90 % ($DisT50_{field}$ and $DisT90_{field}$) and, if possible, of the time required for degradation of 50 % and 90 % ($DegT50_{field}$ and $DegT90_{field}$), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be provided.

Circumstances in which required
Such studies shall be conducted for the active substance, its metabolites, breakdown and reaction products if one of the following conditions is fulfilled:

(a) $DegT50_{lab}$ for active substance, $DegT50_{lab}$ or $DisT50_{lab}$ for metabolites, breakdown and reaction products, in one or more soils determined at 20 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 60 days; or

(b) DegT90 lab for active substance, $DegT90_{lab}$ or $DisT90_{lab}$ for metabolites, breakdown and reaction products, in one or more soils determined at 20 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 200 days.

However, where plant protection products containing the active substance are intended for use in cold climatic conditions, the studies shall be conducted if one of the following conditions is fulfilled:

(a) $DegT50_{lab}$ for active substance, $DegT50_{lab}$ or $DisT50_{lab}$ for metabolites, breakdown and reaction products, determined at 10 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 90 days; or
(b) $DegT90_{lab}$ for active substance, $DegT90_{lab}$ or $DisT90_{lab}$ for metabolites, breakdown and reaction products, in one or more soils, determined at 10 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 300 days.
If during field studies metabolites, breakdown and reaction products which are present in laboratory studies are below the lowest technically feasible LOQ, which shall not exceed an equivalent of 5 % (molar basis) of the nominal concentration of active ingredient applied, no additional information on the fate and behaviour of these compounds shall be provided. In those cases, a scientifically valid justification for any discrepancy between laboratory and field appearance of metabolites shall be provided

Test conditions
Individual studies on a range of representative soils (normally at least four different types at different geographical locations) shall be continued until at least 90% of the amount applied has dissipated from the soil or been transformed to substances that are not the subject of the investigation.

Result:
→ $DT50_{field}$
→ $DT90_{field}$
→ Estimation soil residue concentration
→ Possibility of accumulation of residues active substance and relevant metabolites.

Soil accumulation studies
(283/2013; 7.1.2.2.2)

7.1.2.2.2. Soil accumulation studies
Soil accumulation studies shall provide sufficient information to evaluate the possibility of accumulation of residues of the active substance and of metabolites, breakdown and reaction products. The soil accumulation studies shall provide estimates of the time required for dissipation of 50 % and 90 % ($DisT50_{field}$ and $DisT90_{field}$) and, if possible, shall provide estimates of the time required for degradation of 50 % and 90 % ($DegT50_{field}$ and $DegT90_{field}$), of the active substance under field conditions.

Circumstances in which required
Where on the basis of soil dissipation studies it is established that $DisT90_{field}$, in one or more soils, is greater than one year and where repeated application is envisaged, whether in the same growing season or in succeeding years, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved shall be investigated except where reliable information can be provided by a model calculation or another appropriate assessment.

Test conditions
Long-term field studies shall be performed on at least two relevant soils at different geographical locations and involve multiple applications.

In absence of guidance being included in the list referred to under point 6 of the introduction, the type and conditions of the study to be performed shall be discussed with the national competent authorities.

Monitoring data
(283/2013; 7.5)

7.5. Monitoring data
Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, breakdown and reaction products in soil, groundwater, surface water, sediment and air shall be reported.

1.2.2. Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 284/2013 [5]. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings.
The endpoints of the study are given as well, if relevant.

The data requirements regarding persistence of the plant protection product in the soil are described in part A of Commission Regulation (EU) No 284/2013 [5], point 9.1 (fate and behaviour in the soil).

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communications 2013/C 95/02 [10].

Section 9

Fate and behaviour in the environment

Introduction

1. Predicted environmental concentrations (PEC)..

1.1. A realistic worst-case estimation shall be made of the expected concentrations of the active substance and metabolites, breakdown and reaction products:
— which account for more than 10 % of the amount of active substance added,
— which account for more than 5 % of the amount of active substance added, in at least two sequential measurements,
— for whose individual components (> 5 %) the maximum of formation is not yet reached at the end of the study, in soil, surface in soil, groundwater, surface water, sediment and air, following use as proposed or already occurring.

1.2. For the purposes of the estimation of such concentrations the following definitions apply:

(a) Predicted environmental concentration in soil (PEC_S): the level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).
(b) Predicted environmental concentration in surface water (PEC_{SW}): the level of residues, in surface water to which non-target organisms may be exposed (acute and chronic exposure).
(c) Predicted environmental concentration in sediment (PEC_{SED}): the level of residues, in

sediment to which non-target benthic organisms may be exposed (acute and chronic exposure).
(d) Predicted environmental concentration in groundwater (PEC_{GW}): the level of residues in groundwater.
(e) Predicted environmental concentration in air (PEC_A): the level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).

1.3. For the estimation of these concentrations all relevant information on the plant protection product and on the active substance shall be taken into account. Where relevant the parameters set out in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013 shall be used.

1.4. When models are used for estimation of predicted environmental concentrations they shall:
— make a best-possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
— where possible be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

1.5. The information provided shall, where relevant, include that referred to in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013.

2. For solid plant protection products, treated and coated seeds there shall be an assessment of the risk from dust drift on to non-target species during application or sowing. Until agreed dust dissipation rates are available, then likely exposure levels shall be determined using a range of application techniques, suitable dust measurement methodology and, where appropriate, mitigation measures.

Fate an behaviour in soil
(284/2013; 9.1)
Rate of degradation in soil
(284/2013; 9.1.1)

Laboratory studies
(284/2013; 9.1.1.1)

9.1.1. Rate of degradation in soil

9.1.1.1. Laboratory studies
Laboratory studies on soil degradation shall provide best possible estimates of the time required for degradation of 50 % and 90 % ($DegT50_{lab}$ and $DegT90_{lab}$) of the active substance under laboratory conditions.

Circumstances in which required
The persistence and behaviour of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013.

Where it is not possible to extrapolate from anaerobic incubation data obtained on the active substance and metabolites, breakdown and reaction products in accordance with

the requirements set out in point 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013, an anaerobic degradation study shall be submitted unless the applicant shows that exposure of the plant protection product containing the active substance to anaerobic conditions is unlikely to occur for the intended uses.

Test conditions
Studies on the rate of aerobic degradation of the active substance shall be reported for at least four soils. Soil properties shall be comparable to those used for the aerobic studies performed in accordance with point 7.1.1 and 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013. Reliable DegT50 and 90 values shall be available for a minimum of four different soils.

Studies on the rate of anaerobic degradation of the active substance shall be carried out using the same procedure and comparable soil as for the anaerobic study performed in accordance with point 7.1.1.2 of Part A of the Annex to Regulation (EU) No 283/2013.

The kinetic formation fraction and degradation rates of potentially relevant metabolites shall be established, in the studies under both aerobic and anaerobic conditions by extension of the study for the active substance, where it is not possible to extrapolate from points 7.1.2.1.2 and 7.1.2.1.4 of Part A of the Annex to Regulation (EU) No 283/2013.

In order to assess the influence of temperature on degradation, a calculation with an adequate Q10 factor or an adequate number of additional studies at a range of temperatures shall be performed.

Reliable DegT50 and 90 values for metabolites, breakdown and reaction products shall be provided for at least three soils from the studies under aerobic conditions.

Result:
→ aerobic $DT50_{lab}$
→ aerobic $DT90_{lab}$

Field studies
(284/2013 ; 9.1.1.2)

Soil dissipation studies
(284/2013 ; 9.1.1.2.1)

9.1.1.2. Field studies

9.1.1.2.1. Soil dissipation studies
The soil dissipation studies shall provide best-possible estimates of the time taken for dissipation of 50 % and 90 % ($DisT50_{field}$ and $DisT90_{field}$) and if possible the time taken for degradation of 50 % and 90 % ($DegT50_{field}$ and $DegT90_{field}$), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be reported.

Circumstances in which required
The dissipation and behaviour of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.2.1 of Part A of the Annex to Regulation (EU) No 283/2013.

Test conditions
Individual studies on a range of representative soils (normally at least four different types at different geographical locations) shall be continued until at least 90% of the amount applied has dissipated from the soil or been transformed to substances that are not the subject of the investigation.

Result:
→ $DT50_{field}$
→ $DT90_{field}$
→ Estimated soil residue concentration
→ Possibility of accumulation of residues active substance and relevant metabolites

Soil accumulation studies
(284/2013; 9.1.1.2.2)

9.1.1.2.2. Soil accumulation studies

The tests shall provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of metabolites, breakdown and reaction products.

Circumstances in which required
Soil accumulation studies shall be reported unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

Test conditions
Long term field studies shall be performed on at least two relevant soils at different geographical locations and involve multiple applications.

In absence of guidance being included in the list referred to under point 6 of the introduction, the type and conditions of the study to be performed shall be discussed with the national competent authorities.

Estimation of concentrations in soil
(284/2013; 9.1.3)

9.1.3. Estimation of expected concentrations in soil
PEC_s estimations shall relate both to a single application at the highest rate of application for which authorisation is sought, and to the maximum number at the shortest interval and highest rates of application for which authorisation is sought, and shall be expressed in terms of mg of active substance per kg of dry soil.

The factors which shall be considered in making PEC_s estimations relate to direct and indirect application to soil, drift, run off, and leaching and include processes such as volatilisation, adsorption, hydrolysis, photolysis, aerobic and anaerobic degradation. Appropriate soil layer depths shall be used depending on the application method and soil cultivation. Where ground cover is present at time of application, the impact of crop interception in reducing soil exposure may be included in estimations.

Initial PEC_s, immediately after application, shall be provided for the active substance,

metabolites, breakdown and reaction products. Appropriate short-term and long-term PEC_s calculations (time weighted averages) shall be provided for the active substance, metabolites, breakdown and reaction products with respect to data from ecotoxicological studies.

Calculation of plateau concentrations in soil shall be provided where on the basis of soil dissipation studies it is established that DisT90 > one year, and where repeated application is envisaged, whether in the same growing season or in succeeding years.

1.3. Risk assessment

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

1.3.1. First tier assessment

The first tier risk assessment for persistence has in EU context been elaborated in the Guidance Document on Persistence in Soil [11]. The first tier assessment involves testing of the behavioural triggers (DT50 and soil-bound residues and mineralisation). For the application of degradation parameters, in particular standardisation for temperature and moisture content, we also refer to the FOCUS Groundwater report [12] and FOCUS Degradation Kinetics [7].

1.3.2. Higher tier assessment

In the Guidance Document on Persistence in Soil [11] the higher tier risk assessment (unless clause) consists of weighing the measured, calculated or otherwise established plateau concentration of the active substance in the soil against an unacceptable impact on the environment (See also appendix 2).

Over the years this has evolved to using the PIECsoil plus PECplateau in the higher tier risk assessment. This is common practice in the EU-dossiers.

The Guidance Document on Terrestrial Ecotoxicology [8] contains a tiered approach for substances with a $DT90_{field}$ >100 days for the risk assessment for soil non-target organisms . However, over the years this tiered approach has proven to have some shortcomings, especially concerning the final step that is based on the litterbag test. Over the years it became clear that this test is not sensitive and at this moment there seems to be general consensus amongst most of the EU member states that this test is not sufficient to fulfill the highest tier step of the persistency risk assessment. Generally speaking, a ‘structural’ approach (based on species specific endpoints) is preferred to ‘process’ based approach (endpoints based on soil processes, such as decomposition). In addition, it should be noted that in the data requirements under Regulation (EC) No. 1107/2009 (Commision Regulations (EU) 283/2013 and 284/2013) the litterbag test is no longer included..

Another shortcoming of the decision tree in the GD on Terrestrial Ecotoxicology is the $DT90_{field}$ trigger (i.e. $DT90_{field}$ > 100d): this trigger does not match with the higher tier decision criterium for persistency in soil (DT90 > 1 year or DT50 > 90 days; see 1.4.2 below).

Based on the above, Ctgb uses the following approach for the higher tier persistency risk assessment, which is loosely based on the GD on Terrestrial Ecotoxicology, and on the

current EU risk assessment practice such as it has evolved over the last 5-10 years.

- If the first tier criteria for persistence in soil are not met, an ecotoxicological risk assessment is performed based on the $PIEC_{soil}$+$PEC_{plateau,soil}$.
- The $PIEC_{soil}$+$PEC_{plateau,soil}$ is tested against all endpoints for soil organisms that are available in the dossier. I.e.: soil-dwelling arthropods (tested in soil), earthworms, soil micro-organisms, other soil macro-organisms.
- For a persistent substance, a test with either *Folsomia candida* or *Hypoaspis aculeifer* is in principle preferred by Ctgb. However, if in the EU-dossier for Annex I listing for the substance of concern it is explicitly decided that these tests are not necessary based on the GD on Terrestrial Ecotoxicology, and the dossier did not have to comply with the data requirements under 283/2013 and 284/2013, Ctgb will follow that approach. It should be noted that the data requirements for *Folsomia candida* and *Hypoaspis aculeifer are changed* under 283/2013 and 284/2013. [a]
- In the risk assessment for secondary poisoning of birds and mammals (via earthworms), the $PEC_{soil,twa\ 21\ d}$ + $PEC_{plateau,soil}$ is used.
- If a litterbag is available, it is taken into account in the risk assessment. It can be used to draw conclusions on the effects on organic matter decomposition. However, the litterbag cannot be used as a final higher tier step that overrules risk identified with the species specific endpoints.
- There are two routes for further higher tier: via higher tier fate studies, showing that the a.s. meets the persistency criteria, or via higher tier ecotox testing (e.g. soil community field tests).

For glasshouse uses a risk assessment for soil is also performed for persistent substances and, if applicable, their persistent metabolites. The risk assessment for persistence in soil is based on a long term time scale, for which a change in land use cannot be excluded. Furthermore, it is assumed that the soil under glasshouses can become available again for other destinations on the long term. For changed land use no additional use of plant protection producs is assumed, therefore the endpoints are tested against the $PEC_{plateau,soil}$ (i.e. without summing up the $PIEC_{soil}$.
For persistent metabolites case-by-case justifications can be provided to waive additional data.
The approach above is used until the revised Guidance documents on Persistence in Soil and Terrestrial Ecotoxicology are adopted (see also par.1.5 Developments).

1.3.3. Calculation concentration active substance and metabolites in the soil

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

The concentration active substance in the soil is calculated on the basis of the FOCUS document ‘Soil persistence models and EU registration’ [13]. The concepts of FOCUS FOCUS Degradation Kinetics [7] and the Guidance Document on Terrestrial Ecotoxicology [8] are applied. The equations below for calculating concentrations in soil can be used for the active substance as well as for metabolites, where the dose (D) of the metabolite is determined by multiplying the dose level of the active substance by the

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

formation percentage and relative molecule mass of the metabolite in question.

Calculation of initial concentration ($PIEC_{soil}$)

The soil concentration of sprayed substances directly after a single application is calculated as:

$$PIEC_{soil} = D * (1- f_{int}) / (100 * d * \rho)$$

where:
$PIEC_{soil}$ = Predicted Initial Environmental Concentration (mg a.s./kg soil)
D = dose (g/ha)
f_{int} = crop interception (fraction)
d = depth (cm)
ρ = dry bulk density of the soil (g/cm^3)

A dry bulk density of the soil of 1.5 g/cm^3 and a dose reaching the top 5 cm of the soil (d = 5 cm) is assumed. For substances that are incorporated into the soil, the $PIEC_{soil}$ is set for the top 20 cm of the soil.

For determination of the fraction intercepted by the crop (f_{int}) we refer to Tables 1.4 and 1.5 in Chapter 1.3 of the FOCUS Groundwater report [14], which are included in Appendix 3 to this chapter.

For substances that are applied several times per season at equal doses, the $PIEC_{soil}$ immediately after the last application is determined by using the following equation:

$$PIEC_{soil}(\text{last application}) = PIEC_{soil}(\text{first application}) * (1-e^{-nki})/(1-e^{-ki})$$

where:
n = number of applications
$k = \ln 2/DT50\ (day^{-1})$
i = interval between two consecutive applications (days)
DT50 = half life in soil (days)

Degradation of the substance in the period between applications is taken into account on the basis of DT50 , the interval between applications, and frequency. Where adequate field data are available, these can be applied for the half life value (see the FOCUS document for further details [13]).

Calculation of time-weighted average concentration ($PEC_{soil}(t)$)

$PEC_{soil}(t)$ is the average concentration in the soil over a certain period of time (e.g. a period of time corresponding with the exposure duration in a toxicity test). This is determined by:

$$PEC_{soil}(t) = PIEC_{soil} * (1-e^{-kt})/kt$$

where:
$k = \ln 2/DT50\ (day^{-1})$
t = duration of toxicity test (days)
DT50 = half life in the soil (days)

Calculation of average plateau concentration (Plateau PEC_{soil})

In case of several applications with intervals of i days, finally a plateau concentration will be reached. Where this plateau has been reached, the concentrations will fluctuate

between a maximum immediately after an application and a minimum immediately before the following application. The time-weighted average plateau concentration is determined by:

Plateau PEC_{soil} = $PIEC_{soil}$(first application) / ki

Calculation of maximum plateau concentration (Maximum Plateau PEC_{soil})
The maximum plateau concentration immediately after an application is determined by:

Maximum Plateau PEC_{soil} = $PIEC_{soil}$ (first application) / (1- e^{-ki})

1.4. Approval

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

1.4.1. Approval of the active substance

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

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect persistence in the soil 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.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [15].

These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects. The specific principles Environmental effects, part Behaviour and distribution in the environment as regards persistence are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011 [15].

2.5.1.1. Member States shall evaluate the possibility of the plant protection product reaching the soil under the proposed conditions of use; if this possibility exists they shall estimate the rate and the route of degradation in the soil, the mobility in the soil and the change in the total concentration (extractable and non-extractable [(b)] of the active

[b] Non-extractable residues (sometimes referred to as "bound" or "non-extracted" residues) in plants and soils are defined as chemical species originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the

substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.
This evaluation will take into consideration the following information:
(i) the specific information on fate and behaviour in soil as provided for in the Annex to Regulation (EU) No 283/2013 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,
- dissociation constant,
- photodegradation rate and identity of breakdown products,
- hydrolysis rate in relation to pH and identity of breakdown products;
(iii) all information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013 including the information on distribution and dissipation in soil;
(iv) where relevant, other authorized uses of plant protection products in the area of proposed use containing the same active substance or which give rise to the same residues.

1.4.3. Decision making for plant protection products

The principles for decision-making as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [15]. These concern the relevant sections of the introductory principles, the general principles and the specific principles. The specific principle Environmental Effect, part Behaviour and distribution in the environment regarding persistence are in the text below printed in a grey frame.
This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011 [15].

2.5.1.1. No authorisation shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:
- during tests in the field, persist in soil for more than one year (i.e. DT90 > 1 year and [(c)] DT50 > 3 months), or
- during laboratory tests, form non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days,

unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, according to the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

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chemical nature of these residues. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

[c] In practice the word ‘and’ is replaced by ‘or’. The reason for this is that since the triggers based on linear degradation are nearly the same, if other degradation kinetics than SFO are accepted, like FOMC (first order multi compartment), DFOP (double first order in parallel) and DFOS (double first order in serie) a persistent substance will not be triggered and there is a need to use ‘or’ instead of ‘and’.

1.5. Developments

1. New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). Until the revision of these guidance documents is finished, the methods as described in 1.3.2 are used for the higher tier persistency risk assessment.
2. European Food Safety Authority, 2013. Guidance of EFSA on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal in prep.
3. Furthermore a new Guidance document on treated seed is currently under development, Draft “Authorization of plant protection products for seed treatment” (SANCO/10553/2012 version January 2014).

2. APPENDICES

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

To answer the above question it is important whether the substance, during or after the application in a not entirely closed system consistent with good agricultural practice, comes into contact with the soil or not.

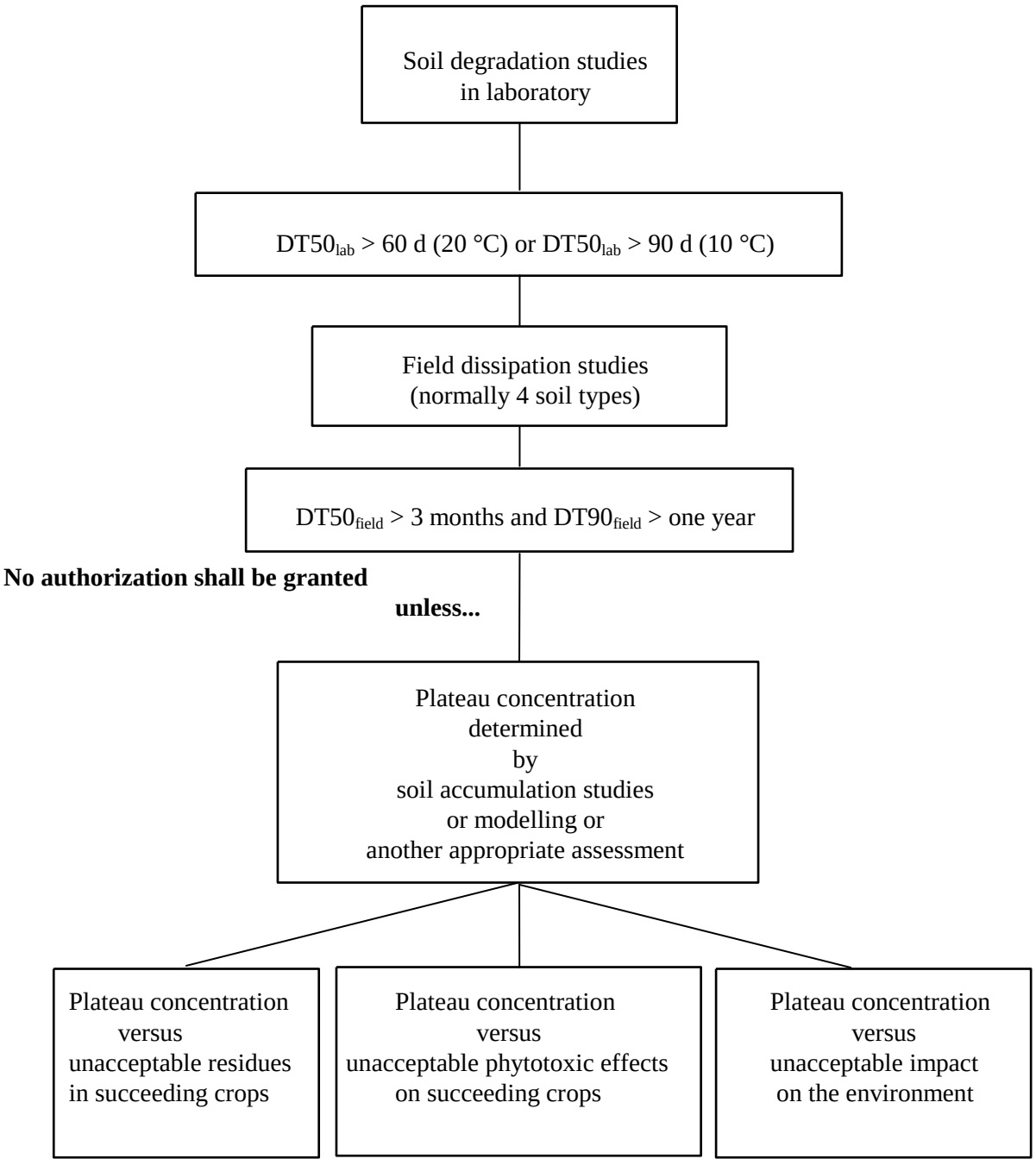
The first thing that matters is whether the application takes place in the open, or in enclosed spaces (greenhouses (cultures on substrate), barns, bee hives etc.). During applications in enclosed spaces, it is not ruled out *a priori* that the product reaches the soil. This can only be ruled out if the applied water is collected for re-use, or is discharged to a sewage treatment plant in a controlled manner. In the some cases of treatment in enclosed spaces, persistence is relevant. For permanent structures used for cropgrowing direct exposure to soil, both for soilbound and non-soilbound crop, as a result of the use of a product is not considered a relevant route of exposure.

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

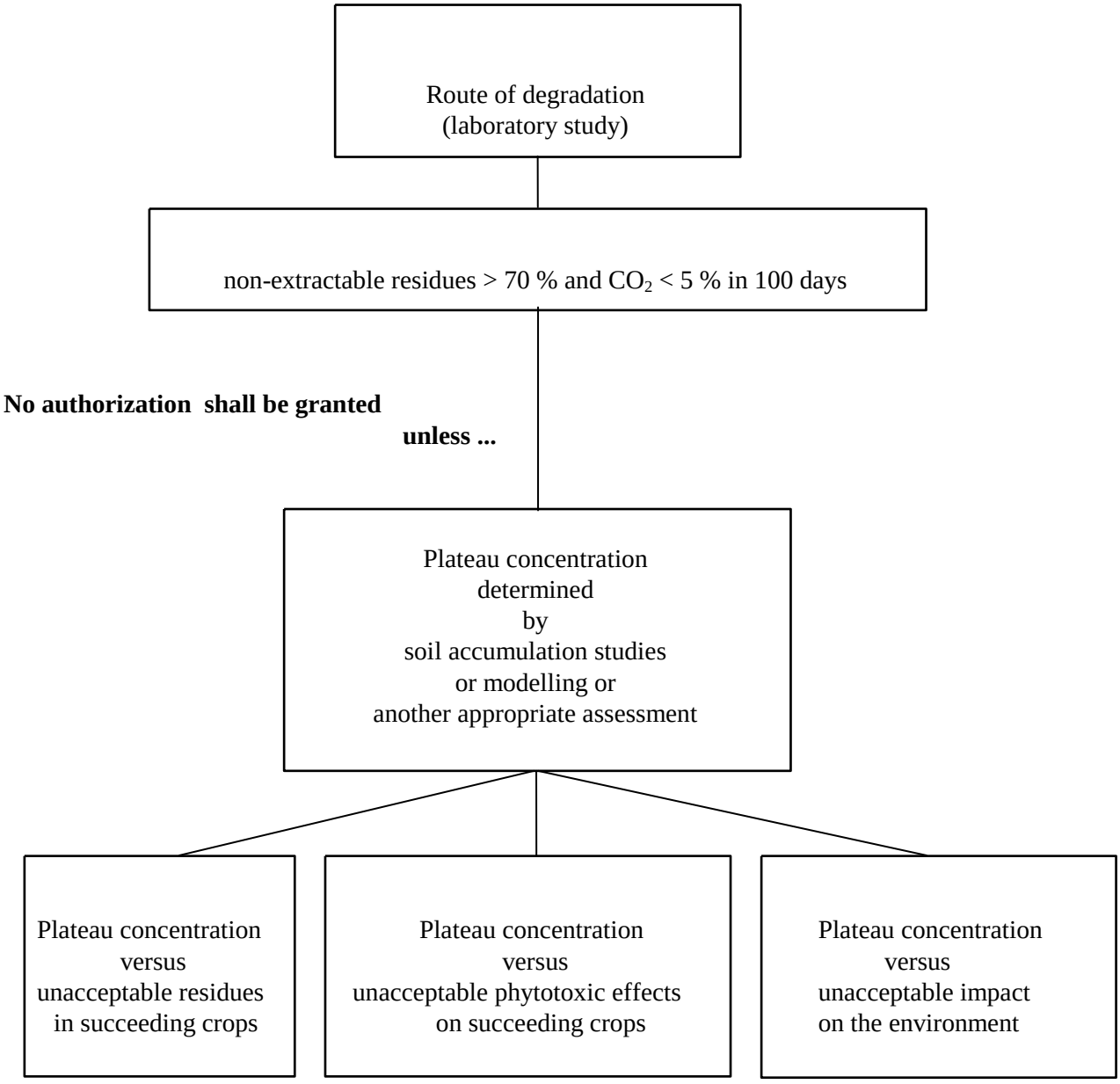
There are uses where the actual use of the plant protection product takes place at another location, other than the crop cultivation itself (seed treatment, treatment of propagation material, tray treatment etc.). In those cases, the situation of the crop cultivation itself should serve as a basis. This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

Appendix 2 Desicion tree for persistent sustances (taken from Guidance Document on Persistence [11])

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



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



Appendix 3 Interception tables

The following Tables 1.4 and 1.5 from Chapter 1.3 of the FOCUS Groundwater report [14] are used for determination of the fraction intercepted by the crop (f_{int}).

Tables 1.4 and 1.5 give interception data for separate growth stages of different crops. Note that the interception data in Tables 1.4 and 1.5 are only valid for applications made directly onto the crop. Examples where these data do not apply include herbicide applications made beneath orchard crops and vines, directly onto bare soil; for such applications zero interception should be assumed, and simulations should be made with the field-averaged application rate.

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

Crop	**stage**				
Apples	without leaves 50	flowering 65	foliage development 70	full foliage 80	
Bushberries	without leaves 50	flowering 65	flowering 65	full foliage 80	
Citrus	all stages 70				
Vines	without leaves 40	first leaves 50	leaf development 60	flowering 70	ripening 85

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

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

The BBCH code is indicative (BBCH, 1994).
A value of 90 is used for applications to established turf
* BBCH code of 20-29 for tillering and 30-39 for elongation

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