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; leaching

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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; leaching

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 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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 [3].

1.1. Introduction

Commission Regulation (EU) No 546/2011 [4] 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 [5] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [6] .

For the 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 [7] and Assessing Potential for Movement of Active Substances and their metabolites to Ground Water in the EU (working document, Tier I). Accompanied by Generic Guidance for Tier 1 FOCUS Ground Water Assessments version 2.0 January 2011.

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 [3].

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [6] must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2013/C 95/01 [8].

When according to 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. 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.
Any relevant results of the study are given as well.

The date 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 7.4 (monitoring data).

Fate and behaviour in the 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
(283/2013; 7.1.1)

7.1.1 Route of degradation

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. 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.

Result:

→ identity and formation percentage of transformation products;
→ % soil-bound residue after 100 days;
→ mineralisation rate, expressed as % CO_2 after 100 days.
(optional) DT50 of the active substance and transformation products where possible

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 and test guideline
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.
Result:
→ identity and formation percentage of transformation products;
(optional) DT50 of the active substance

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 transformation products;
→ 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

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 90 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

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)

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

7.1.2.1.3 Anaerobic degradation

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 dissipiation studies
(283/2013; 7.1.2.2.1)

7.1.1.2.2. 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.

Soil accumulation studies
(283/2013; 7.1.2.2.2)

7.1.1.2.2. Soil dissipation 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.

Result:
→ DT50 (field)
→ DT90 (field)
→ Estimation soil residue concentration
→ Possibility of accumulation of residues active substance and relevant metabolites.

Adsorption and desorption in soil
(283/2013; 7.1.3)

7.1.3.1 Adsorption and desorption

The information provided, together with other relevant data, shall be sufficient to establish the adsorption coefficient of the active substance and of its metabolites, breakdown and reaction products.

Result:
→ K_{OM} (sorption constant).

Adsorption and desorption of the active substance
(283/2013; 7.1.2.1.1)

7.1.2.1.1 Adsorption and desorption of the active substance

Circumstances in which required
Studies on adsorption and desorption of the active substance shall be provided, 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 active substance shall be reported for at least four soils.

Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR (Quantitative Structure Property Relationship) or the HPLC (High-Performance Liquid Chromatography) method shall be considered as possible alternatives. Where the batch equilibrium method cannot be applied due to weak adsorption, column leaching studies(see point 7.1.4.1) shall be considered as an alternative.

Adsorption and desorption of metabolites, breakdown and reaction products
(283/2013; 7.1.3.1.2)

7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products

Circumstances in which required
Studies on adsorption and desorption shall be provided for all metabolites, breakdown and reaction products, for which in soil degradation studies 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 exceeding 0,1 µg/L in the leachate.

Test conditions
Studies on metabolites, breakdown and reaction products shall be provided for at least three soils.

Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR or the HPLC method shall be considered as an alternative. Where the batch equilibrium method cannot be applied due to weak adsorption, column leaching studies (see point 7.1.4.1) shall be considered as an alternative.

Aged sorption
(283/2013; 7.1.3.2)

7.1.3.2 Aged sorption

As a higher tier option, information on aged sorption may be provided.

Circumstances in which required
The need to carry out a study on aged sorption shall be discussed with the national competent authorities.

Test conditions
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. The influence on the rate of degradation shall also be considered. Aged sorption data shall be compatible with the model in which those values will be used.

Mobility in the soil
(283/2013; 7.1.4)

Column leaching studies
(283/2013; 7.1.4.1)

Column leaching of the active substance
(283/2013; 7.1.4.1.1)

7.1.4. Mobility in the soil
7.1.4.1. Column leaching studies of the active substance

7.1.4.1.1 Column leaching of the active substance
Column leaching studies shall provide sufficient data to evaluate the mobility and leaching potential of the active substance.
Circumstances in which required
Studies in at least four soils shall be carried out where in the adsorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable adsorption coefficient values due to weak adsorption (such as Koc < 25 L/Kg).
Result:
→ K_{OM} (sorption constant)

Column leaching of metabolites, breakdown and reaction products
(283/2013 ; 7.1.4.1.2)

7.1.4.1.2. Aged residue column leaching
The test shall provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown and reaction products.
Circumstances in which required
Studies in at least three soils shall be carried out where in the adsorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable adsorption coefficient values due to weak adsorption (such as Koc < 25 L/Kg).

Lysimeter studies
(283/2013 ; 7.1.4.2.)

7.1.4.2. Lysimeter studies

Lysimeter studies shall be performed, where necessary, to provide information on: - the mobility in soil,
- the potential for leaching to ground water,
- The potential distribution in soil.

Circumstances in which required
The decision whether lysimeter studies are to be carried out, as an experimental outdoor study in the framework of a tiered leaching assessment scheme shall take into account the results of degradation and other mobility studies and the predicted environmental concentrations in groundwater (PEC_{GW}), calculated in accordance with the provisions of Section 9 of Part A of the Annex to Regulation (EU) No 284/2013. The type and conditions of the study to be performed shall be discussed with the national competent authorities.
Test conditions
Studies shall cover the realistic worst case situation, and the duration necessary for observation of potential leaching, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water percolating from soil columns shall be analysed at suitable intervals, while residues in plant material shall be determined at harvest. Residues in the soil profile in at least five layers shall be determined on termination of experimental work. Intermediate sampling shall be avoided, since removal of plants (except for harvesting in accordance with normal agricultural practice) and soil influence the leaching process.

Precipitation, soil and air temperatures shall be recorded at regular intervals, at least on a

weekly base.

The depth of the lysimeters shall be at least 100 cm. The soil cores shall be undisturbed. Soil temperatures shall be similar to those pertaining in the field. Where necessary, supplementary irrigation shall be provided to ensure optimal plant growth and to ensure that the quantity of percolation water is similar to that in the regions for which authorisation is sought. When during the study the soil has to be disturbed for agricultural reasons it shall not be disturbed deeper than 25 cm. *Field leaching studies*
(283/2013; 7.1.4.3)

7.1.4.3. Field leaching studies
Field leaching studies shall be performed, where necessary, to provide information on:
- the mobility in soil,
- the potential for leaching to ground water,
- The potential distribution in soil.

Circumstances in which required
The decision whether field leaching studies are to be carried out, as an experimental outdoor study in the framework of a tiered leaching assessment scheme shall take into account the results of degradation and other mobility studies and the predicted environmental concentrations in groundwater (PEC_{GW}), calculated in accordance with the provisions of Section 9 of Part A of the Annex to Regulation (EU) No 284/2013. The type and conditions of the study to be performed shall be discussed with the national competent authorities.

Test conditions
Studies shall cover the realistic worst case situation, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water shall be analysed at suitable intervals. Residues in the soil profile in at least five layers shall be determined on termination of experimental work. Intermediate sampling of plant and soil material shall be avoided (except for harvesting in accordance with normal agricultural practice), since removal of plants and soil influence the leaching process.

Precipitation, soil and air temperatures shall be recorded at regular intervals (at least on a weekly base).

Information on the groundwater table in the experimental fields shall be submitted. Depending on the experimental design, a detailed hydrological characterisation of the test field shall be carried out. If soil cracking is observed during the study this shall be fully described.

Attention shall be given to the number and the location of water collection devices. The placement of these devices in the soil shall not result in preferential flow paths.

Degradation in the saturated zone
(283/2013; 7.2.3)

7.2.3 Degradation in the saturated zone
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. 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.
Any relevant results of the study are given as well.

The date 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 (fate and behaviour in water).

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2013/C 95/02 [9].

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 and 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.

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.

Mobility in the soil
(284/2013; 9.1.2)

9.1.2 Mobility in the soil

The information made available shall provide sufficient data to evaluate the mobility and leaching potential of the active substance and metabolites, breakdown and reaction products.

Laboratory studies
(284/2013; 9.1.2.1)

9.1.2.1. Laboratory studies

Circumstances in which required
The mobility of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements set out in points 7.1.2 and 7.1.3.1 of Part A of the Annex to Regulation (EU) No 283/2013.
Test conditions
The same provisions as provided under points 7.1.2 and 7.1.3.1 of Part A of the Annex to Regulation (EU) No 283/2013 apply.

Lysimeter studies
(284/2013 ; 9.1.2.2)

9.1.2.2. Lysimeter studies

Lysimeter studies shall be performed, where necessary, to provide information on:
— the mobility in soil,
— the potential for leaching to ground water,
— the potential distribution in soil.
The decision whether lysimeter studies are to be carried out, as an experimental outdoor study in the framework of a tiered leaching assessment scheme shall take into account the results of degradation and mobility studies and the calculated PEC GW. The type of study to be conducted shall be discussed with the national competent authorities.

These studies shall be performed 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 7.1.4.2 of Part A of the Annex to Regulation (EU) No 283/2013.

Test conditions
Studies shall cover the realistic worst case situation, and the duration necessary for observation of potential leaching, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water percolating from soil columns shall be analysed at suitable intervals, while residues in plant material shall be determined at harvest. Residues in the soil profile in at least five layers shall be determined on termination of experimental work. Intermediate sampling shall be avoided, since removal of plants (except for harvesting in accordance with normal agricultural practice) and soil influence the leaching process.

Precipitation, soil and air temperatures shall be recorded at regular intervals, at least on a weekly base.

The depth of the lysimeters shall be at least 100 cm. The soil cores shall be undisturbed. Soil temperatures shall be similar to those pertaining in the field. Where necessary, supplementary irrigation shall be provided to ensure optimal plant growth and to ensure that the quantity of percolation water is similar to that in the regions for which authorisation is sought. When during the study the soil has to be disturbed for agricultural reasons it shall not be disturbed deeper than 25 cm.

Estimation of concentrations in groundwater
(284/2013 ; 9.2.4)

9.2.4. Estimation of concentrations in groundwater
The groundwater contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.
Calculation of concentrations in groundwater
(284/2013; 9.2.4.1.)

9.2.4.1. Calculation of concentrations in groundwater
PECgw estimations shall relate to the maximum number and highest rates of application, at the shortest interval, and to the time of application for which authorisation is sought.

Relevant EU groundwater models shall be run. Where specific crops and circumstances are relevant, specific scenarios for typical use situations for the regions of use, for the respective crop or other situation of use shall be used. In case the behaviour in soil is

dependent on soil parameters, respective parameters on degradation and adsorption in soil ($DegT_{50}$ and Koc values) reflecting this dependency shall be used. If identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

Suitable estimations (calculations) of predicted environmental concentration in groundwater PECgw, of active substance shall be submitted, unless it is clearly evident from the data on degradation or adsorption, taking worst case values, that leaching would be negligible under the intended areas of use.

For all metabolites, breakdown or reaction products identified as a part of the residue definition for risk assessment with respect to groundwater (see point 7.4.1 of Part A of the Annex to Regulation (EU) No 283/2013) a PECgw calculation shall be required for assessing their relevance.

Where identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

Additional field tests
(284/2013; 9.2.4.2)

9.2.4.2. Additional field tests

The need to perform additional field tests and the type and conditions of the tests to be performed shall be discussed with the national competent authorities.

1.3. Risk assessment

1.3.1. General

Central question in the European evaluation is whether safe scenarios exist in Europe. The answer to this questions 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 out of the order.

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as aerobic DT_{50} (lab) and K_{OM}) are presented in a list of endpoints (see Appendix B of Chapter 6). Risk assessment is based on comparison with endpoints.
For the application of degradation parameters, in particular standardisation for temperature and moisture content, and sorption parameters we also refer to the FOCUS Groundwater report [10] en [11].

1.3.2. First tier; model calculation

In European framework the evaluation of leaching is based on the FOCUS groundwater approach [10] en [11]. 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 report [11].
Starting point in each scenario is an about 80% sensitive soil.
The calculated concentration that needs to be compared with the criterion of 0.1 µg/l is the concentration closest to the 80% sensitive weather situation.
This year-averaged concentration is a ‘reasonable worst case’ concentration and is an approach of the 90-percentile.

The scenarios have been implemented as sets of input data for four simulation models, one of which is PEARL, which is in practice also applied for a national authorisation. The other three simulation models are MACRO, PELMO and PRZM.

Calculations in the FOCUS groundwater approach are based on year-averaged concentrations at 1 metre depth during 20 years with periodic application(s) (annually, biannually or triannually) and different climatological conditions, on the basis of average and/or median DT_{50} and K_{OM} values.
The first tier of a European evaluation yields three possible outcomes; the critical model outcome (90-percentile concentration) for a substance:

1. exceeds 0.1 μg/l for all relevant scenarios;
2. is lower than 0.1 μg/l for all relevant scenarios;
3. exceeds 0.1 μg/l for some relevant scenarios and is lower than 0.1 μg/l for other relevant scenarios.

Where a substance exceeds 0.1 μg/l for all relevant scenarios, 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.
Where the concentration of a substance is lower than 0.1 μg/l for all relevant scenarios, the choice of 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.
Where the concentration of a substance is lower than 0.1 μg/l for at least one relevant scenario, but not for all relevant scenarios, the substance can in principle be included in 540/2011 insofar as leaching to groundwater is concerned.
The scenarios are representative of important agricultural areas within the EU, which means identification of a safe use which is significant in terms of agriculture 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.
Such studies from a higher tier may be lysimeter or field leaching studies, monitoring or adequate modelling. The result of the total leaching evaluation at EU level can be used in support of local leaching evaluations at Member State level.
In Appendix 1, a checklist is presented for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil. This checklist is according to FOCUS (2006) [8].

1.3.2.1. Metabolites

Metabolites for which FOCUS calculations or other data show that the concentration exceeds 0.1 μg/l can be evaluated for their relevance according to the Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009.

Generically, all metabolites that are present in the soil must, on the basis of the results of soil gradation studies, be evaluated for their capacity to contaminate groundwater: this also applies to metabolites found in lysimeters.
Besides the possibility of submitting higher tier leaching studies, metabolites can also be evaluated for their relevance according to the Guidance Document on the assessment of the relevance of metabolites in groundwater [11].
Such an evaluation of metabolites must be submitted as minimum requirement where:
in the laboratory study into the aerobic transformation route the concentration in the soil is

at any point in time higher than or equal to 10%, or at 2 consecutive points in time higher than or equal to 5% of the amount of added active substance, or the maximum has not yet been reached at the end of the study.
Such an evaluation also applies for all metabolites that are found in lysimeter studies with a year-averaged concentration > 0.1 μg/l.
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: screen efficacy;
Stage 2 of step 3: screen genotoxicity;
Stage 3 of step 3: screen toxicity;
Step 4: Exposure evaluation – reference value approach;
Step 5: Adequate risk assessment for non-relevant metabolites.

For a detailed elaboration of these steps we refer to the Guidance Document on the assessment of the relevance of metabolites in groundwater [11].

1.3.3. Second tier; lysimeter and field studies

Second tier leaching evaluation is in European framework bases on lysimeter or field studies. Consensus about the exact evaluation methodology to arrive at 540/2011 inclusion has not yet been reached. Evaluation is based on expert judgement. It is unclear which concentration must be taken as starting point and how this could –where appropriate- be converted to other scenarios. There is no standardisation in European framework.

1.3.4. Third tier; saturated phase studies

Third tier leaching evaluation is in the European framework based on studies in the saturated phase. Consensus about the exact evaluation methodology to arrive at inclusion in Commission Implementing Regulation (EU) No 540/2011 has not yet been reached. Evaluation is based on expert judgement.

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 an 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 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).

1.4.2. Evaluation of the plant protection product

The principles for the evaluation (the Uniform Principles) regarding physical and chemical properties are presented in Commission Regulation (EU) No 546/2011 [12]. 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 leaching 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.

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 as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [4]. 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 leaching 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.

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.

1.5. Developments

The FOCUS Groundwater Group in the form of a Group focusing on harmonisation of the risk assessment for groundwater at zonal and national level in the different Member States presented a final report 'Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU' [12]. Use and evaluation of higher tier experiments and assessments are among the aspects to be considered.
http://viso.ei.jrc.it/focus/gw/docs/FinalreportGW.pdf
The Standing Committee on the Food Chain and Animal Health (SCFCAH) agreed that applicants could make use of the report, considering that it should be ascribe the status of a 'working document'. The Commission and Member States confirmed that they would use assessments that followed the tier 1 assessment procedures prescribed in the report, for regulatory decision making. To facilitate this the FOCUS work group's report, a version control document ('Generic Guidance for Tier 1 FOCUS Ground Water Assessments version 2.0 January 2011') and the groundwater modelling packages FOCUSPEARL 4.4.4,

[*] OJ L 372, 27.12.2006, p. 19.

FOCUSPELMO 4.4.3 and FOCUSPRZM GW 3.5.2 are released for use in regulatory submissions today. The report Sanco/13144/2010, version 1, 13 June 2009 supplements the original FOCUS groundwater scenarios report (Sanco/321/2000 rev.2), so the guidance contained in both reports needs be considered. The version control document 'Generic Guidance for Tier 1 FOCUS Ground Water Assessments version 2.0 January 2011' replaces the version control document 'Generic guidance for FOCUS groundwater scenarios version 1.1 April 2002.' Regulatory submissions can be made from today following the tier 1 approaches as outlined in the new report and version control document. Sanco/13144/2010, version 1 recommends regulatory submissions may continue to be made in accordance with the older Sanco/321/2000 rev.2 guidance for up to one year from April 2011. When this approach is selected applicants should ensure a Q10 of 2.58 is used, (see **Notice Board** entry of 11/Mar/2009) and provide results from FOCUSPEARL 3.3.3 and FOCUSPELMO 3.3.2 or FOCUSPEARL 3.3.3 and FOCUSPRZW GW 2.4.1 simulations, in line with the regulatory practice in place before the release of Sanco/13144/2010, version 1. The report Sanco/13144/2010, version 1, 13 June 2009 is not noted SCFCAH guidance as the European Commission has mandated the Plant Protection Product and their Residues (PPR) panel of EFSA to deliver its opinion on the report, before it will present Sanco/13144/2010 to the SCFCAH for noting.

2. APPENDICES

Appendix 1 Field studies on degradation rate

Checklist for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil copied from chapter 9 of FOCUS (2006) 'Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU pegistration' Report of the FOCUS Work Group on Degradation Kinetics. SANCO/10058/2005, version 2.0. (2006) [10]

A properly conducted field soil dissipation study should fulfil the criteria as outlined e.g. by the CTGB (Risico voor milieu: Uitspoeling naar grondwater, Bijlage 3). The most important points to consider are:

- A critical assessment of the significance of photodegradation and specific transfer processes to the overall dissipation is recommended as a first step in evaluating the appropriateness of field study results for modelling purposes, i.e. deriving a degradation kinetics for parent and/or metabolites. If these processes play an important role in the overall dissipation, techniques such as inverse modelling and information from mechanistic laboratory scale studies (e.g. soil photolysis studies) may be used to estimate parameters needed to model the individual processes, rather than lumping all the transfer process into one rate constant.
- If such losses can be considered unimportant or can be properly addressed as separate processes, a further evaluation of the field study or deriving degradation half-lives for pesticide fate modelling is possible.
- Proper measurement of the applied dose.
- The soil should be well characterised at different depths.
- The soil sampling depth and analytical method should allow to capture the bulk of the applied material.
- Meteorological measurements should be available at least for the duration of the field experiment.
- The history of pesticide use in preceding years is available. The active substance or a chemical analogue should not have been applied on the plot prior to the experiment.

All points should be checked and reported. A conclusion should be drawn whether from the field study the dissipation DT_{50} can be attributed to transformation only and whether the field DT_{50} can be used to predict leaching of the compound.

3. REFERENCES

1 Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte

2 Directive 91/414/EEC, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte

3 Commission Implementing Regulation (EU) No 540/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte

4 Commission Regulation (EU) No 546/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574598%3Acs&pos=2&page=1&lang=en&pgs=10&nbl=2&list=607713%3Acs%2C574598%3Acs%2C&hwords=&action=GO&visu=%23texte

5 Commission Regulation (EU) No 283/2013, http://eur-lex.europa.eu/Notice.do?val=724582:cs&lang=en&list=729945:cs,724582:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=

6 Commission Regulation (EU) No 284/2013, http://eur-lex.europa.eu/Notice.do?val=724566:cs&lang=en&list=729902:cs,724566:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=

7 FOCUS (2006) “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.;

8 Commission Communication 2013/C 95/01 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:095:0001:0020:EN:PDF

9 Commission Communication 2013/C 95/02 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:095:0021:0037:EN:PDF

10 Sanco/13144/2010, version 1, 13 June 2009, Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. http://viso.ei.jrc.it/focus/gw/docs/FinalreportGW.pdf

11 Generic guidance for FOCUS groundwater scenarios, version 1.1, April 2002.

12 Commission Regulation (EU) No 546/2011, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:155:0127:0175:EN:PDF

12 Performance of the FOCUS 2010 Software Packages for Performing Tier 1 Ground Water Assessments in the EU, appendix to Sanco/13144/2010 version 1