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GUIDANCE OF EFSA

EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil[1]

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ABSTRACT

EFSA was asked by the European Commission to prepare a Guidance of EFSA for evaluating laboratory and field dissipation studies to obtain degradation rate parameters ($DegT50_{matrix}$ values) of active substances of plant protection products and transformation products of these active substances in soil. This EFSA Guidance Document provides guidance for users on how to obtain $DegT50_{matrix}$ values when performing risk assessments according to Regulation EC No 1107/2009 of the European Parliament and the Council. In addition, this document provides guidance on adsorption parameter (Koc) selection and new Crop Interception values.

KEY WORDS

soil degradation, Kom, Koc, Crop Interception

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SUMMARY

EFSA was asked by the European Commission to prepare guidance for evaluating laboratory and field dissipation studies to obtain degradation rate parameters ($DegT50_{matrix}$ values) of active substances of plant protection products and transformation products of these active substances in soil. This EFSA Guidance Document provides guidance for users on how to obtain $DegT50_{matrix}$ values to be used in exposure assessment when performing risk assessments according to Regulation EC No 1107/2009 of the European Parliament and the Council (EC, 2009).

A number of Member States expressed interest in a revision of the current SANCO Guidance Document on persistence in soil (EC, 2000) during a general consultation of Member States on Guidance Documents in answer to a request by EFSA sent via the Standing Committee on the Food Chain and Animal Health. Furthermore, the previous Pesticides Risk Assessment Peer Review (PRAPeR) Unit (now Pesticides Unit) noted that the existing SANCO Guidance Document (EC, 2000) needed to be updated.

The Forum for the Co-ordination of pesticide fate models and their Use (FOCUS, 1997) developed the first guidance at EU level for exposure assessment in soil, but this did not include recommendations on how to estimate degradation rate parameters. FOCUS (2006) developed detailed guidance on estimating degradation and dissipation rate parameters from laboratory and field studies, The Plant Protection Products and their Residues (PPR) Panel produced an opinion for evaluating laboratory and field dissipation studies to obtain $DegT50_{matrix}$ values of plant protection products in soil (EFSA PPR Panel, 2010). This EFSA Guidance Document is based on the EFSA PPR Panel (2010) publication, and when this guidance is noted by the Standing Committee of the Food Chain and Animal Health it will replace EFSA PPR Panel (2010) document as EU guidance.

EFSA considers the current SANCO Guidance Document on persistence in soil (EC, 2000) not appropriate for use in exposure and risk assessment according to Regulation EC No 1107/2009 of the European Parliament and the Council (EC, 2009) as it has been replaced partly by FOCUS (2006) and this EFSA Guidance Document.

The Guidance Document contains guidance on:

- selection of $DegT50_{matrix}$ values from laboratory and field experiments for use in exposure assessment
- calculation of geomean $DegT50_{matrix}$
- design of field studies for obtaining $DegT50_{matrix}$ values in soil
- guidance on the possibility of combining $DegT50_{matrix}$ values from laboratory studies with $DegT50_{matrix}$ values obtained from field studies if certain conditions are met
- use of geomean K_{om} and K_{oc}
- use of updated crop interception values
- worked examples on how to use this guidance.

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BACKGROUND AS PROVIDED BY THE COMMISSION

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

Based on the Member State responses and the opinions prepared by the PPR Panel (EFSA PPR Panel, 2010 and PPR Panel, 2012) the Commission tasked EFSA to prepare an EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil in a letter of 31 July 2012. EFSA accepted this task in a letter to the Commission dated 9 October 2012. The Commission requests this scientific and technical assistance from EFSA according to Article 31 of Regulation (EC) no 178/2002 of the European Parliament and of the Council.

Following public consultations on the opinion (EFSA PPR Panel, 2010), Member States and other stakeholders requested "an *easy to use Guidance Document*" to facilitate the use of the proposed guidance and methodology for the evaluation of PPPs according to Regulation (EC) No 1107/2009.

Once this Guidance Document is delivered, the Commission will initiate the process for the formal use of the Guidance Documents within an appropriate time frame for applicants and evaluators.

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

EFSA, and in particular the Pesticides Unit, is asked by the Commission (DG SANCO) to draft an EFSA Guidance Documents as mentioned below:

1. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil.

The EFSA Guidance Documents should respect the science proposed and methodology developed in the adopted PPR opinion mentioned in this document (EFSA PPR Panel, 2010).

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

CONTEXT OF THE SCIENTIFIC OUTPUT

To address the Terms of References as provided by the Commission.

1. Introduction

During work conducted by the PPR Panel of EFSA to revise the Guidance Document on Persistence of Pesticides in Soil (EC, 2000), EFSA published a scientific opinion on evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil (herein referred to as the EFSA DegT50 opinion (EFSA PPR Panel, 2010)). This document builds on the scientific opinion to provide practical guidance to regulatory specialists involved with EU environmental exposure assessment of plant protection products for derivation of these values.

DegT50 values of pesticide active substances and their transformation and reaction products (hereafter referred to as 'metabolites') in soil are critical information used in plant protection product risk assessment. The values are used in the current FOCUS modelling frameworks for estimating surface water and groundwater exposure levels (FOCUS, 2001, 2009). In addition, they are used in the soil exposure scenarios developed by EFSA as a result of the revision of the Guidance Document on Persistence of Pesticides in Soil (EFSA, in preparation). Guidance on EU groundwater modelling can be found in FOCUS (2009). Guidance on EU surface water modelling can be found in FOCUS (2001). Guidance on EU soil exposure modelling will when finalised be found at EFSA (in preparation).

This guidance uses the definitions of dissipation and DTx (e.g. DT50) and degradation provided in FOCUS (2006), which considers non-extractable residues as degradation products. In addition, the PPR opinion (EFSA PPR Panel, 2010) introduced the term $DegT50_{matrix}$. This is defined as the time taken, assuming single first-order (SFO) kinetics, for 50 % of substance to disappear from the soil matrix (between approximately 1 and 30 cm depth) owing to degradation processes alone at 20 °C and field capacity (pF 2). Thus, $DegT50_{matrix}$ is a degradation half-life at reference conditions. A consequence of this definition is that the half-life derived from measurements in dark aerobic laboratory incubation studies with topsoil at 20 °C and field capacity can usually be used as a measurement of this $DegT50_{matrix}$ when FOCUS (2006) guidance is adhered to.

The exposure calculated with these scenarios and models is often very sensitive to the DT50 value used as an input value. In addition, as the models used in the exposure assessment methodology expressly require a parameter which represents degradation within the soil matrix (i.e. $DegT50_{matrix}$), it is important that calculation of soil $DegT50_{matrix}$ for use in the model is able to exclude other loss processes which could influence the observed disappearance in laboratory or field studies.

Therefore, the aims of this guidance are:

i. to provide methods to derive the $DegT50_{matrix}$ from individual laboratory and field dissipation studies;
ii. to explain how to determine whether the databases of $DegT50_{matrix}$ values from laboratory and field studies can be treated as separate databases or whether they should be pooled;
iii. to provide guidance on selecting the appropriate input value for use in exposure modelling.

As background to this guidance, work on $DegT50_{matrix}$ in soil was originally initiated in relation to new guidance on soil exposure; however, the $DegT50_{matrix}$ values calculated using this guidance should also be used in EU groundwater and surface water exposure assessment. This is because the soil degradation parameters required by the EFSA soil exposure assessment framework are also used by the EU ground- and surface water exposure models.

2. Derivation of $DegT50_{matrix}$ from laboratory and field dissipation studies

2.1. Background

The derivation of decline rates for active substances and metabolites from soil studies is addressed in detail in the FOCUS Guidance Document on Estimating Persistence and Degradation Kinetics from

Environmental Fate Studies on Pesticides in EU Registration (herein referred to as FOCUS Kinetics (FOCUS, 2006)). This guidance document does not attempt to change the methodology recommended by FOCUS Kinetics, but gives further advice on study conduct and pre-processing of data prior to calculation. Use of this guidance assumes a working knowledge and understanding of the principles of the FOCUS Kinetics guidance.

2.2. Laboratory studies

The primary laboratory study used for derivation of $DegT50_{matrix}$ in soil is the aerobic route and rate of degradation study conducted under dark conditions; current EU data requirements recommend that such studies are conducted in accordance with the OECD 307 Study Guideline. The provision of such studies is a standard data requirement for the vast majority of active substances, excluding those where there is no soil exposure as a result of use. In most cases, the primary route of decline of the applied substance and metabolites/degradation products in this study is by microbial and/or chemical processes which represent degradation within the soil matrix. In such cases, the derivation of $DegT50_{matrix}$ for an individual soil is achieved following FOCUS Kinetics guidance. In some cases, disappearance can be influenced by other routes of loss, principally volatilisation; photolysis is excluded as the study is conducted under dark conditions. Volatilisation should be accounted for in the study design by appropriate trapping methods allowing the volatilisation losses to be quantified. This route of loss can subsequently be accounted for in the kinetic evaluation. FOCUS Kinetics guidance should be followed in accounting for such losses and other experimental artefacts.

2.3. Field studies

EU data requirements in Commission Regulation (EU) No 283/2013 recommend use of 'US EPA OCSPP 835.6100 Terrestrial field dissipation' (US EPA, 2009), which is an adaptation of the earlier NAFTA guidance on the conduct of terrestrial field dissipation studies (NAFTA, 2006). At the time of writing, an OECD guidance document on the conduct of these studies that will take into account generation of data for derivation of $DegT50_{matrix}$ was in preparation. The starting point for the development of this OECD guidance was NAFTA (2006).

Derivation of $DegT50_{matrix}$ from field dissipation studies is complicated by a number of factors. The overall rate of decline is influenced by factors such as volatilisation, soil surface photolysis, leaching out of the sampled soil layers and uptake into plants, which can significantly influence the disappearance of the applied substance from the sampled soil layers in addition to degradation within the soil matrix. As a result, in many cases the initial decline of applied substance can be more rapid followed by a slower rate of decline. In addition, the influence of soil photolysis could affect the apparent formation and decline profile of any metabolites/degradation products formed, particularly if the depth of sampling is limited. Rates of decline for the applied substance (and formation and decline for metabolites) are also influenced by variations in soil temperature and moisture. Therefore, the derivation of bulk soil $DegT50_{matrix}$ values for use in exposure modelling must take these other processes and variations into account. FOCUS Kinetics provides guidance on assessing whether the field dissipation study is suitable for calculation of $DegT50_{matrix}$ by assessing the likely impact of these other loss processes, and subsequently details procedures by which the effects of varying temperature and moisture may be normalised to transfer the observed decline to the standard temperature and moisture conditions of 20 °C and pF = 2 field moisture capacity required for the $DegT50_{matrix}$ (recommendations are found in Chapter 9 of FOCUS Kinetics guidance). However, the approach described in Chapter 9 of FOCUS Kinetics still leaves uncertainty over the true representation of bulk soil matrix degradation processes within the calculated $DT50_{matrix}$.

Appropriate design of the field dissipation study can greatly help in minimising the 'surfaces processes' of volatilisation, soil surface photolysis and plant uptake. Section 2.3.1 makes recommendations for a study design which will reduce the influence of these processes on the calculation of $DegT50_{matrix}$.

2.3.1. Tailored DegT50$_{matrix}$ field studies

When designing an experiment to estimate the DegT50$_{matrix}$, all processes that can affect the fate of the test chemical, except the formation of transformation products by chemical or microbial processes or not extracted residues, should be minimised as far as possible. The processes that the design needs to minimise are leaching out of the microbially most active top 30 cm soil layers, volatilisation, soil surface photolysis, run-off and plant uptake. Therefore, field plots where the aim of the experiment is to get a best estimate of DegT50$_{matrix}$ need a design where these processes are minimised. More detailed practical guidance on designing new DegT50$_{matrix}$ experiments is outlined in Appendix A. When experiments have been carried out following the recommendations in Appendix A, kinetic fitting of the experimental results should be carried out following FOCUS Kinetics guidance (FOCUS 2006).

As the DegT50$_{matrix}$ study design deliberately attempts to exclude the influence of surface processes and leaching, it must be borne in mind that the DegT50$_{matrix}$ study may provide conservative endpoints for comparison against the field persistence criteria in the European Pesticides legislation. The option remains that field DT50 studies (considering all biotic and abiotic degradation pathways, such as photolysis) are considered for comparison against the persistence criteria. Note that the field persistence criteria for use in ecotoxicological risk assessment for soil organisms can allow the inclusion of dissipation processes other than bulk topsoil biotic and abiotic degradation.

It is possible that DegT50$_{matrix}$ values obtained from field dissipation studies may be appropriate for use in hazard assessment in relation to persistent organic pollutant (POP), persistent bioaccumulative toxic substance (PBT) and very persistent and very bioaccumulative substance (vPvB) criteria within European Pesticides legislation. As the DegT50$_{matrix}$ study design in Appendix A deliberately attempts to exclude the influence of surface processes and leaching, the relevance of field-derived DegT50$_{matrix}$ values for POP, PBT and vPvB assessment may be limited where soil surface photolysis might be expected to be a significant route of degradation for a substance. Excluding such processes from the assessment might lead to false-positive P or vP classification.

It should also be noted that, where losses other than chemical/microbial transformation processes or formation of non-extractable residues[4] have been minimised, it should also be possible to calculate DegT50$_{matrix}$ for any metabolites formed in the study.

2.3.2. Existing field studies not tailored for DegT50$_{matrix}$ (legacy studies)

The PPR DegT50 opinion (EFSA PPR Panel, 2010) also advised of a procedure to be taken where surface processes have not been minimised. This involves consideration of degradation rate of the decline curve after cumulative rainfall and/or irrigation of 10 mm has occurred. This procedure is useful for calculation of DegT50$_{matrix}$ for the applied substance. However, as it is possible that soil photolysis may have influenced degradation before this point, it is possible that the observed metabolite residues will also have been influenced by photolytic processes. Therefore, where this procedure has been applied for the active substance, it is considered that kinetic parameters for metabolites may not be wholly reflective of bulk soil matrix degradation applying to metabolites. In addition, the exclusion of initial data points for the metabolite is likely to create significant problems for any calculations attempted for the metabolites. Therefore, a study should not usually be used for calculating the DegT50$_{matrix}$ of any primary metabolite that is formed before 10 mm of rainfall has occurred or secondary metabolites formed later when its precursor was formed before 10 mm of rainfall. As stated, rainfall may be supplemented by irrigation. Note that, when the observed formation

[4] 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. Definition from Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

of a metabolite is below 5 % on a molar basis before 10 mm of rainfall, it is proposed that a metabolite $DegT50_{matrix}$ and kinetic formation fraction might still be derived. This 5 % value is considered justifiable as only amounts above this value are considered significant amounts in the regulatory framework. In addition, if a clear pattern of decline of the metabolite is apparent after 10 mm of rainfall has occurred and 10 mm of rain also occurs after the maximum observed formation, then on a case-by-case basis it might be justified to estimate a $DegT50_{matrix}$ value. However, any associated kinetic formation fraction that might be derived would normally be considered unreliable.

The recommended approach is to conduct inverse modelling using the time-step normalisation procedure on the dataset (as described in FOCUS Kinetics, Chapter 9) and then to apply the following decision-making flow charts to derive the most appropriate kinetic model to the dataset and thus derive the $DegT50_{matrix}$. The initial approach is to use the flow chart in Figure 1, which uses both SFO and double first-order in parallel (DFOP) kinetics.

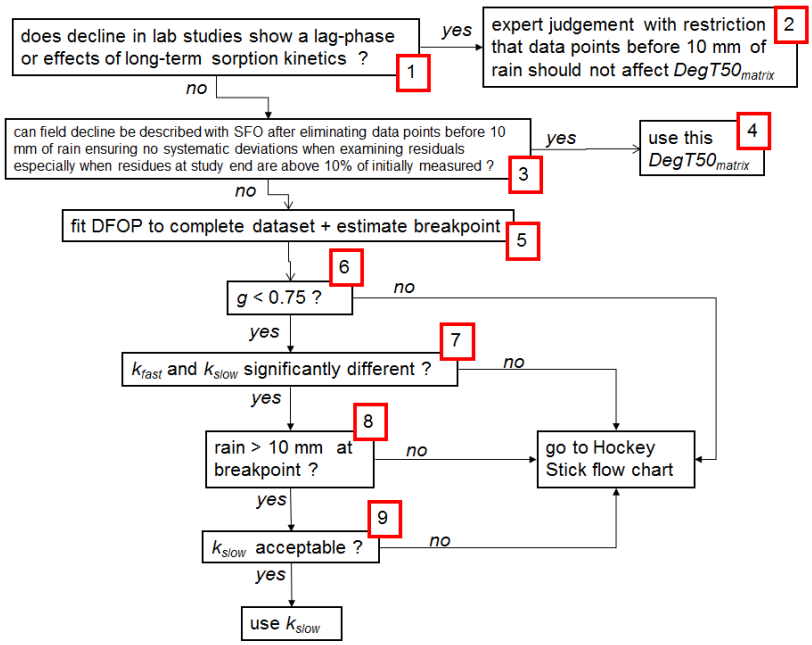

Figure 1: Flow chart for assessment of results of field dissipation studies after analysis with the SFO or DFOP models. The numbers 1 to 9 act as references to descriptions of the corresponding boxes in the main text

Box 1 in Figure 1 checks whether the decline in laboratory studies shows a lag phase or indicates a slowing down of the decline due to long-term sorption kinetics. A lag phase is reasonably easy to interpret. Assessment of effects of long-term sorption kinetics is more difficult, but an appreciable slowing down of the decline in combination with a microbially active soil is an indication of long-term sorption kinetics. Should instances of a lag phase or indications of aged sorption occur, go to Box 2.

Box 2 recommends that where a lag phase or long-term sorption kinetics are observed in the laboratory studies, data points in the field study before 10 mm of rain/irrigation occur are eliminated and expert judgement should be used to assess the $DegT50_{matrix}$ value.

Box 3 is reached if there is no lag phase in the laboratory studies or if no effects of long-term sorption kinetics are observed in these studies. Here, the data points before 10 mm of rain/irrigation are eliminated and it is checked whether the decline of the remaining data points can be described well with SFO. This check should be based on the criteria of FOCUS Kinetics, i.e. a visual assessment of the goodness of fit combined with a χ^2 test for the goodness of fit and a *t*-test to evaluate the confidence in the parameter estimates (FOCUS, 2006, p. 81). Special attention should be paid to the

visual assessment when residues at study end are above 10 % of those initially measured in line with FOCUS (2006).

Box 4 is reached if an acceptable description with SFO kinetics is possible in Box 3 and the resulting $DegT50_{matrix}$ value can be used.

Box 5 is reached if no acceptable description with SFO is possible in Box 3. Box 5 prescribes that the complete dataset be fitted to DFOP (so including again the data points before 10 mm of rain/irrigation) and to estimate the breakpoint time. The DFOP model is defined as:

$$m = m_{ini}\left(g\ \exp(-k_{fast}\,t) + (1-g)\ \exp(-k_{slow}\,t)\right) \quad (1)$$

where:

m = total mass in the system (kg)

m_{ini} = total mass in the system at the start (kg)

g = fraction of total mass in the system applied to the fast-degrading compartment (dimensionless)

k_{fast} = rate coefficient in the fast-degrading compartment (d^{-1})

k_{slow} = rate coefficient in the slow-degrading compartment (d^{-1})

t = time (d).

The breakpoint time is defined as the time when the degradation in the fast degrading compartment is replaced by the degradation in the slow compartment and has to be estimated for DFOP kinetics because the slope of the DFOP curve decreases gradually. According to EFSA PPR Panel (2010), the breakpoint time for DFOP kinetics ($t_{b,DFOP}$) is estimated to be equal to three half-lives of the fast-degrading compartment. This corresponds with:

$$t_{b,DFOP} = \frac{3 \ln 2}{k_{fast}} \quad (2)$$

Box 6 checks whether the parameter g of Eqn 1 is below 0.75. If $g > 0.75$, the estimated breakpoint time may be too short so the test of the 10 mm rain/irrigation criterion may generate a negative result, whereas in reality there was enough rain/irrigation at the true breakpoint time (i.e. the moment after which the fitted decline is dominated by k_{slow}). So if g is below 0.75, it is recommended that the hockey-stick (HS) flow chart (Figure 2) be applied because the estimate of the breakpoint time is not sufficiently reliable.

Box 7 checks whether the k_{fast} and k_{slow} rate constants from the DFOP fit are significantly different. This is considered necessary because the breakpoint time will be quite uncertain if this is not the case. Significantly different in Box 7 means that the 95 % confidence intervals of k_{fast} and k_{slow} do not overlap. If they are not significantly different, it is recommended that the HS flow chart (Figure 2) be applied.

Box 8 tests whether the cumulative rain/irrigation is at least 10 mm at the estimated breakpoint time. Whilst the time for 10 mm rainfall/irrigation will have been measured in true time, it is important to compare the estimated breakpoint time (expressed in normalised time) with the time for 10 mm rainfall/irrigation measured in normalised time. In practice, it is likely to be possible to estimate the normalised time for 10 mm rainfall/irrigation from the results of the time-step normalisation. Alternatively, it may also be estimated by considering the number of samples taken in the field study before 10 mm of rain/irrigation occurred. Table 1 shows an example of a time series of true and normalised time and the corresponding cumulative rainfall. Let us assume that the breakpoint was

found at a normalised time of 2.3 days. Table 1 shows that cumulative rainfall at that time was greater than or equal to 12 mm, so the criterion in Box 8 has been fulfilled.

Table 1: Example of a time series of true and normalised time and corresponding cumulative rainfall

True time (days)	Normalised time (days)	Cumulative rainfall (mm)
0	0	0
2	1	5
4	2	12
8	4	20
20	10	70

If greater than 10 mm of rainfall/irrigation has not fallen before the breakpoint, k_{slow} has to be rejected because it is too strongly influenced by processes in the top millimetres of the soil. In such a case, go to the hockey-stick (HS) flow chart because this has an iteration option to use the data after modification.

Box 9 is reached if cumulative rainfall/irrigation was at least 10 mm at the breakpoint. The problem considered here is that k_{slow} may not be acceptable, for example because it is based on only a few data points or because the data show considerable scatter. Testing of the acceptability of k_{slow} must be carried out by following procedures identical to those recommended by FOCUS Kinetics, i.e. a visual assessment of the goodness of fit for the slow phase of the decline (after $t_{b,DFOP}$) combined with a χ^2 test for the goodness of fit (acknowledging this relates to the whole curve) and a *t*-test to evaluate the confidence in the estimated k_{slow} (FOCUS, 2006, p. 81). If k_{slow} is acceptable, the bottom box of the flow chart is reached and k_{slow} can be used. If not, the option is offered to go to the HS flow chart.

If the flow chart in Figure 1 results in a useful k_{slow}, then the resulting $DegT50_{matrix}$ value can be calculated as $\ln 2/k_{slow}$ and the rapidly dissipating fraction F_{field} can be calculated from the difference between the initial areic mass A_0 (kg/ha) and the areic mass at the breakpoint time (A_{tb}) according to the following equation:

$$F_{field} = \frac{A_0 - A_{tb}}{A_0} \tag{3}$$

F_{field} is used subsequently in exposure calculations to describe the rapidly dissipating fraction at the soil surface. Details of how F_{field} is used will be found in the relevant EFSA PPR Panel (2010) and future EFSA guidance documents on PEC calculations.

Figure 1 indicates that Box 6 is not absolutely necessary because a negative test of the 10 mm rainfall/irrigation criterion will in any case lead to the HS flow chart. Box 6 is included because the test of $g < 0.75$ does not require any effort, and this test may prevent unnecessary efforts in Box 7. An additional advantage of including Box 6 is that it prevents underestimation of F_{field} in the event that the 10 mm rain/irrigation criterion were to be fulfilled. The concept of the parameter F_{field} was developed by EFSA (2010) to describe the rapidly dissipating fraction at the soil surface. The possibilities for use of F_{field} in environmental exposure assessments as described in EFSA (2010) are considered to be insufficiently developed at present, and at the time of writing this guidance document it is not recommended that F_{field} be used in regulatory assessments. Details of how to use F_{field} will be developed by, and presented in, future EFSA guidance documents on predicted environmental concentrations (PECs) in soil (EFSA, in preparation).

As noted above, there may be reasons why the approach using SFO or DFOP kinetics does not offer a robust calculation of *DegT50*. Therefore, the following flow chart using HS kinetics can be used

(Figure 2). The HS model is based on the assumption that the mass in the system declines according to first-order kinetics but at a certain point in time ('the breakpoint') the rate coefficient changes:

$$\begin{aligned} t \le t_{b,HS} \quad & m = m_{ini}\exp(-k_1 t) \\ t > t_{b,HS} \quad & m = m_{ini}\exp(-k_1 t_{b,HS})\exp(-k_2 (t - t_{b,HS})) \end{aligned} \tag{4}$$

where:

$t_{b,HS}$ = breakpoint time (d) in the HS model

k_1 = rate coefficient until $t_{b,HS}$ (d^{-1})

k_2 = rate coefficient after $t_{b,HS}$ (d^{-1}).

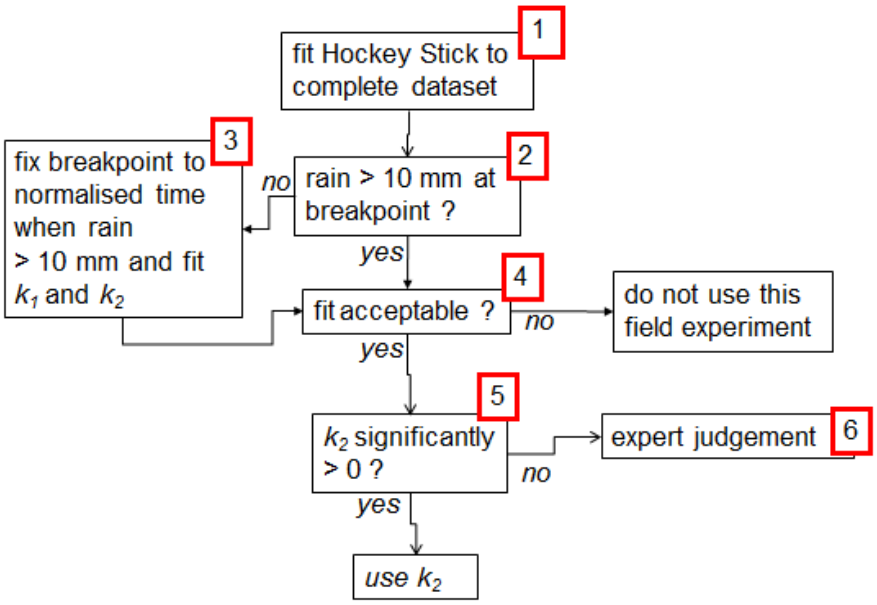

Figure 2: Flow chart for assessment of results of field dissipation studies after analysis with the hockey-stick model. The numbers 1 to 6 act as references to descriptions of the corresponding boxes in the main text

Box 1 prescribes a fit to HS kinetics (after time-step normalisation) using the complete dataset.

Box 2 tests whether the cumulative rain/irrigation is at least 10 mm at the breakpoint time (it is important that the normalised time for 10 mm rainfall to have occurred is used for comparison with the breakpoint time, which will be in normalised time; see the example of Table 1). This is a prerequisite for further use of the fitted k_2 value. However, if this is not the case, k_2 has to be rejected because it is too strongly influenced by processes in the top millimetres of the soil.

Box 3 offers then the option to fix the HS breakpoint at the time when 10 mm of rain/irrigation has fallen and to refit both k_1 and k_2. This is required where the breakpoint time from the initial fitting occurs before 10 mm rainfall has occurred.

Box 4 checks whether the fit is acceptable following the procedures recommended by FOCUS Kinetics, i.e. a visual assessment of the goodness of fit combined with a χ^2 test for the goodness of fit. If this is not the case, then it is recommended not to use this field experiment because a good fit is a prerequisite for using any fitted parameter value.

Box 5 checks whether the k_2 value differs significantly from zero using a *t*-test, as recommended by FOCUS (2006, p. 81). If this is the case, use of this k_2 value is recommended. If this is not the case, the flow chart continues in Box 6.

Box 6 recommends using expert judgement. In the case considered here, the fit is acceptable but the *t*-test shows that k_2 does not significantly differ from zero. So the data show a k_2 that is too small to be measured accurately on the time scale of the field experiment. Such cases may sometimes result in $DegT50_{matrix}$ values exceeding even 10 000 days (e.g. due to some scatter in a limited number of data points). The scientific opinion (EFSA PPR Panel, 2010) considers it very unlikely that the degradation rate in a laboratory incubation study with a certain soil (at constant soil moisture and temperature) is systematically and consistently faster than the degradation rate within the soil matrix in the agricultural field from which this soil was collected (at the same temperature and moisture content). This is used as a starting point to provide in the remainder of this paragraph some suggestions for this expert judgement. If a laboratory $DegT50_{matrix}$ value is available for the soil from the field study, it is recommended that the field study data be refitted after 10 mm rainfall using a k_2 fixed to the corresponding value from the laboratory study (i.e. $\ln(2)/DegT50_{matrix}$). If this results in an acceptable fit, it is recommended that this laboratory $DegT50_{matrix}$ value be used as the endpoint of this field study. If no laboratory $DegT50_{matrix}$ is available for the soil from this field study, it is recommended to use instead the upper limit of the 95th confidence interval of the laboratory $DegT50_{matrix}$ values as a basis to refit the data. If this gives an acceptable fit, it is recommended to use this upper limit $DegT50_{matrix}$ as the endpoint of this field study. If the observed decline is faster than indicated by the refitted decline curve (either based on the laboratory $DegT50_{matrix}$ from the soil considered or based on this upper limit of the $DegT50_{matrix}$), then it is recommended to use the k_2 value from Box 5 because there is no a priori reason to consider this k_2 as unrealistic. If the observed decline is slower than indicated by the refitted decline curve, expert judgement should be used, possible approaches are either assuming a default $DegT50_{matrix}$ of 1 000 days or deriving a $DegT50_{matrix}$ from the assumption that 10 % decline occurred between the breakpoint time and the end of the field experiment (based on the argument that such a decline, if it occurred, would be difficult to detect in view of scatter in experimental data). Note that section 2.4 describes further checks for individual field $DegT50_{matrix}$ values that are significantly longer than the laboratory $DegT50_{matrix}$ values.

In the flow chart of Figure 2 it is not considered a problem if $k_1 < k_2$ as site selection should exclude sites where accelerated degradation might occur (i.e. when a substance or related substances have been applied previously at the study site) and because if the breakpoint is after 10 mm rainfall k_2 will reflect the bulk soil matrix degradation.

If the flow chart in Figure 2 results in a useful k_2, then the resulting $DegT50_{matrix}$ can be calculated as $\ln 2/k_2$. It is meaningful to calculate the rapidly dissipating fraction F_{field} only if $k_1 > k_2$. If this is the case, F_{field} can be calculated on the basis of the difference between the initial areic mass and the areic mass at the breakpoint time t_b (Eqn 3).

As follows from the guidance above, the values of k_{fast} (DFOP kinetics) and k_1 (HS kinetics) are not subsequently used in the exposure assessment. These values are not be considered reliable because the normalisation process considers only the effect of soil temperature and soil moisture on the degradation rate within the bulk soil matrix, which has no meaning for surface losses due to indirect photolysis or volatilisation.

2.4. Further information on interpreting field-derived $DegT50_{matrix}$

The $DegT50_{matrix}$ values estimated using the flow charts in Figures 1 and 2 should be interpreted with consideration of existing information in the registration dossier on the potential for volatilisation and indirect photolysis (see section 2.2 of EFSA PPR Panel (2010) for further details). It is recommended to check whether any of the individual $DegT50_{matrix}$ values are significantly longer (*t*-test at 5 % level) than the laboratory $DegT50_{matrix}$ values. As described in EFSA PPR Panel (2010, p. 56), the test

evaluates if a single observation Z_1 is larger than predicted by the distribution of the laboratory studies (X_n) assuming that the $DegT50_{matrix}$ is log-normally distributed. So the following hypotheses are tested:

$$H: E(\ln(Z_1)) > E(\ln(X)) \quad against \quad H_0: E(\ln(Z_1)) = E(\ln(X))$$

The resulting Student's *t*-test is:

$$t = \frac{\ln(Z_1) - \mu_{lab}}{\sqrt{\sigma_{lab}^2 \cdot \left(\frac{1}{N} + 1\right)}} > t_{N-1,95\%}$$

(5)

where:

μ_{lab} = mean of the logarithms of laboratory $DegT50_{matrix}$ values

N = number of laboratory $DegT50_{matrix}$ values

σ_{lab} = standard deviation of logarithms of laboratory $DegT50_{matrix}$ values

$t_{N-1,95\ \%}$ = quantile of Student's *t*-distribution for $N-1$ degrees of freedom and a significance level of 5 %.

This test can be performed easily with the Excel sheet (EFSA DegT50 Endpoint Selector) that is provided together with this guidance.

The background of this recommendation is as follows. In general, $DegT50_{matrix}$ values from field studies are expected to be lower than $DegT50_{matrix}$ values from laboratory studies, but the opposite may happen occasionally. The scientific opinion (EFSA PPR Panel, 2010) considers it very unlikely that a laboratory study with a certain soil shows a systematically and consistently faster degradation rate than a field study with the same soil at the same temperature and moisture content. It is far more likely that a field $DegT50_{matrix}$ that is significantly longer than the geomean laboratory $DegT50_{matrix}$ is caused by systematic errors in the inverse modelling procedure. It can also happen by coincidence because the number of measured laboratory and field $DegT50_{matrix}$ values in a dossier may be limited to four. In such a case, the magnitude of the effects of conservative assumptions in the inverse modelling procedure should be assessed; if these effects are so large that they may explain the difference with the laboratory $DegT50_{matrix}$ values, then it is considered justifiable to discard the $DegT50_{matrix}$ value of this field study. See section 3.3 of this guidance document for details of how to deal with the situation in which field $DegT50_{matrix}$ values are higher than laboratory $DegT50_{matrix}$ values. As outlined in section 2.3.2, the inverse modelling procedure in this guidance means applying the time-step normalisation approach originally described by FOCUS Kinetics (FOCUS, 2006).

The assessment of when 10 mm of rainfall has occurred influences the calculation of $DegT50_{matrix}$. Spatial variation in daily rainfall may be considerable on a scale of 100 km^2. As 10 mm is not a large amount of rainfall/irrigation, the time needed for 10 mm rainfall/irrigation since application may show considerable spatial variation at such a scale. Therefore, it is advisable to measure cumulative rainfall between soil sampling times at the experimental field or at a distance of less than 1 km; this should be taken into account in the study protocol for field dissipation studies. In legacy studies, rainfall may not have been measured in available field dissipation studies. In such cases, it is recommended that rainfall data from weather stations no more than 20 km distance from the experimental field should be used. The applicant should make clear that there is no climatological barrier (e.g. mountains or hills; note, this not an exhaustive list of climatological barriers) between the rainfall station and the experimental field.

The proposed procedure considers only the possibility of time-step normalisation. FOCUS Kinetics guidance also describes another normalisation, i.e. rate normalisation (FOCUS, 2006). This procedure is based on the principle that the simulated daily transformation rate is corrected for differences between the actual temperature and moisture content and the temperature and moisture content at reference conditions (i.e. 20 °C and pF = 2). This guidance recommends that time-step normalisation should be used and that rate constant normalisation should not be conducted. The reasons for this are that rate constant normalisation is a more complex procedure, is less transparent, is less intuitive and is harder to interpret for many users and appears to offer no real advantage over time-step normalisation.

3. Guidance for estimating model input parameters for the required exposure scenarios

3.1. Background

This chapter describes the selection process for choosing appropriate exposure modelling parameters. Please note that this procedure does not address how to derive modelling parameters where the substance demonstrates a dependence of $DegT50_{matrix}$ on soil properties such as pH or clay content. It is recommended that, in these cases, FOCUS guidance on selection of input parameters is followed.

The purpose is to obtain a median $DegT50_{matrix}$ value for the population of agricultural/horticultural field soils in the area of use of the substance. The median of the population can be estimated with the geometric mean, so in principle it has to be assessed whether all soils studied can be considered to be part of this population of soils. It is proposed to assess this very pragmatically as follows:

- exclude studies conducted on volcanic soils because their chemical and physical properties differ substantially from those of temperate mineral soils;
- accept studies conducted on soils from temperate regions outside the EU provided their pH, organic matter and clay contents are within the range of values to be expected for topsoils in the EU;
- in the case of field dissipation studies outside the EU, check whether temperature and precipitation for the trial site are comparable to those in the EU where the assessed crop is grown.

The main procedures described here detail how to:

i. calculate the geometric means of the laboratory and field degradation rates;

ii. determine whether the databases of laboratory and field degradation rates should be treated separately or combined for the selection of modelling input parameters.

3.2. Calculation of geometric means of laboratory and field $DegT50_{matrix}$ values

This EFSA guidance recommends use of the geometric means of degradation rates as input into exposure models. Therefore, the first part of the procedure to determine the appropriate soil degradation rate is to determine the geometric mean of the laboratory-derived database on aerobic $DegT50_{matrix}$ values and the geometric mean of the field derived $DegT50_{matrix}$ values. Appendix D of this guidance provides a geomean estimator which can be used for this purpose. Appendix D also provides a spreadsheet (EFSA DegT50 Endpoint Selector) that can be used to calculate the geometric means of these two separate (laboratory and field) databases and allows the necessary comparisons to be made. The background on this calculation is given in Appendix A of EFSA PPR Panel (2010).

3.3. Selection procedure for obtaining modelling endpoints from laboratory and field $DegT50_{matrix}$ datasets

The second part in the procedure is to determine whether the degradation rates from the separate laboratory and field databases are statistically different. Historically, $DegT50_{matrix}$ values from field

dissipation studies have usually been treated as distinct from and 'higher tier' than $DegT50_{matrix}$ values from laboratory studies as $DegT50_{matrix}$ values from field studies are commonly lower than those from laboratory studies. The use of separate databases of values in a tiered assessment implies that there must be a clear and valid justification for treating them as distinct databases.

The flow chart in Figure 3 describes the process for deciding whether or not the $DegT50_{matrix}$ values from laboratory and field dissipation databases can be treated separately.

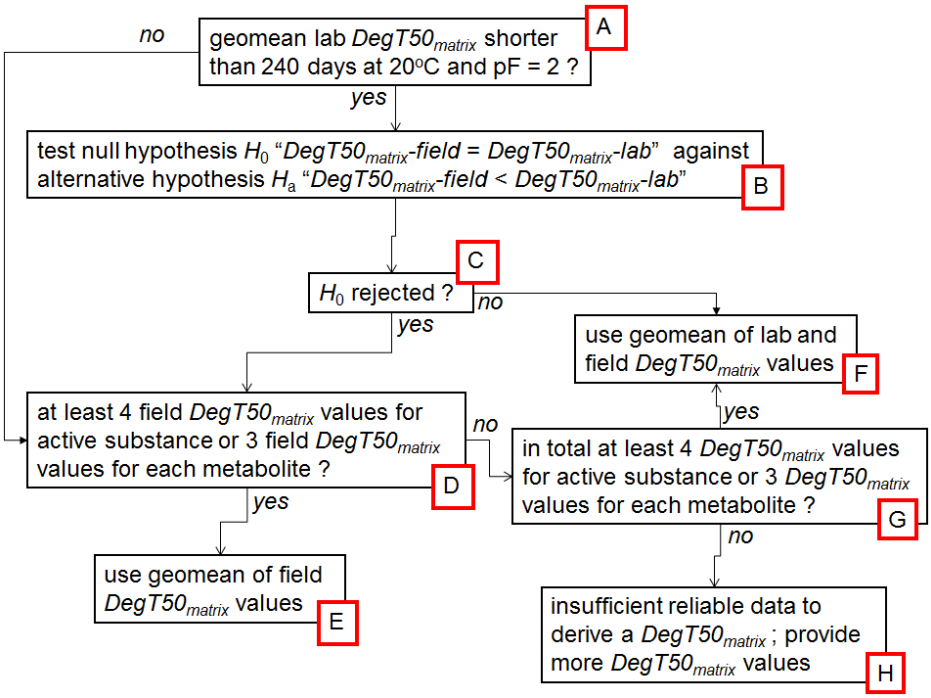

Figure 3: Flow chart for assessment of $DegT50_{matrix}$ values from laboratory and field dissipation studies for selection of geomean $DegT50_{matrix}$ values for environmental exposure modelling when a geomean is appropriate. The letters A to E act as references to the descriptions of the corresponding boxes in the main text

Box A tests whether the geomean laboratory $DegT50_{matrix}$ value is higher than 240 days. If so, there will be, on average, less than 29 % decline during the 120 d incubation of the OECD study, making it difficult to measure such low degradation rates. For such slowly degrading compounds, it is acceptable not to perform a difference test between laboratory and field values but to continue with the field values (i.e. go straight to Box D). If the geomean laboratory $DegT50_{matrix}$ value is lower than 240 d, Box B tests the null hypothesis that the geomean $DegT50_{matrix}$ values from laboratory and field are equal against the alternative hypothesis that the geomean $DegT50_{matrix}$ from the field is lower (using the EFSA *DegT50* Endpoint Selector described in Appendix D).

If this null hypothesis is not rejected (Box C), this guidance recommends pooling all the laboratory and field $DegT50_{matrix}$ values and calculating the geomean (Box F). If the null hypothesis is rejected, then discard the laboratory studies and move to Box D. In this box it is tested whether at least four field $DegT50_{matrix}$ values are available for active substance, or three in case of metabolites. The three/four values are based on the data requirement for laboratory $DegT50_{matrix}$ values in Commission Regulation (EU) No 283/2013 in accordance with Regulation 1107/2009. If this is indeed the case, then the geomean field $DegT50_{matrix}$ is calculated as the endpoint of this flow chart (Box E). If fewer than three/four values are available, then Box G checks whether the sum of the laboratory and field $DegT50_{matrix}$ values is at least four for active substance and three for metabolites. If this is not the case, the uncertainty of the estimated geomean is considered too high and it is proposed to provide more

$DegT50_{matrix}$ values (Box H). If at least three/four values are available, this guidance proposes to pool all the laboratory and field $DegT50_{matrix}$ values (so back to Box F).

Appendix A (section 8.1) of EFSA PPR Panel (2010) gives details of how to assess whether the $DegT50_{matrix}$ values from field studies are lower than those from laboratory studies. The method for determining whether $DegT50_{matrix}$ values from laboratory and field databases are significantly different uses a value, α, which is critical to this comparison. This guidance uses an α value of 25 %. In deciding on this value, the Working Group noted that the α value of 25 % is more likely to result in a differentiation between laboratory and field degradation datasets than lower numerical values of α. It was also noted following consultation with Member States via the EU Commission Standing Committee on the Food Chain and Animal Health that there was no clear desire to pursue a more conservative assessment than was the practice before this guidance, in which laboratory and field degradation datasets are treated separately.

As described above, if the outcome of the comparison of laboratory and field databases is that they are not significantly different, the geomean of the combined databases is calculated and used as the input parameter in exposure modelling; Appendix D provides a spreadsheet (EFSA DegT50 Endpoint Selector) to calculate the geometric mean estimator for the median of the sample population. If the laboratory and field datasets are determined to be significantly different and the geomean field $DegT50_{matrix}$ value is lower than the geomean laboratory $DegT50_{matrix}$, the field-derived geomean $DegT50_{matrix}$ value is used.

It is possible that, in some cases, the geomean field $DegT50_{matrix}$ value is significantly higher than the geomean $DegT50_{matrix}$ value from laboratory studies. Based on the available knowledge on microbial and chemical degradation processes of pesticides in soil and on the review of field tests of simulation models of persistence by Beulke et al. (2000), it is considered very unlikely that the degradation rate in a laboratory incubation study with a certain soil (at constant soil moisture and temperature) is systematically and consistently faster than the degradation rate within the soil matrix in the agricultural field from which this soil was collected (at the same temperature and moisture content). Therefore, the flow chart in Figure 3 does not test the hypothesis whether the $DegT50_{matrix}$-field is longer than the $DegT50_{matrix}$-lab.

The variation in $DegT50_{matrix}$ values at pF 2 and 20 °C between different soils is very large: the EFSA PPR Panel (2010) compiled the available data and found that distributions of $DegT50_{matrix}$ values have variation coefficients of about 50 %. So if there are four $DegT50_{matrix}$-lab values and four $DegT50_{matrix}$-field values, it may happen by coincidence that the geomean $DegT50_{matrix}$-field value is higher than the geomean $DegT50_{matrix}$-lab value.

If geomean $DegT50_{matrix}$-field value is clearly significantly higher than the geomean $DegT50_{matrix}$-lab value, it is recommended not to follow the flow chart of Figure 3 but instead to analyse the reason for this difference in detail and to decide case by case based on the results of this analysis. This analysis should also include a critical assessment of the procedures followed in the laboratory studies. Appendix F provides an example. As described by EFSA PPR Panel (2010, p. 30) and in section 2.4, it may be justifiable to discard a $DegT50_{matrix}$ value obtained from a field study by time-step normalisation if it is significantly higher than the $DegT50_{matrix}$ values obtained from laboratory studies. The justification is that the time-step normalisation procedure is not straightforward and contains a number of assumptions. These may include:

(i) the assumption that the simulation model used for time-step normalisation accurately simulated the time courses of temperature and moisture content of the soil, and;

(ii) the assumption that the model parameters accounting for the effect of temperature and moisture on the degradation rate (i.e. the default Arrhenius activation energy E_A of 65 kJ/mol and the default moisture exponent B of 0.7) were valid for this combination of soil and substance.

A further justification is that it is, in general, unlikely that the $DegT50_{matrix}$ value obtained in field experiments is higher than that obtained in laboratory experiments. If a field $DegT50_{matrix}$ value is significantly higher than the laboratory $DegT50_{matrix}$ values, then it should be checked whether the uncertainty in the time-step normalisation procedure is so large that it can bridge the gap between this field $DegT50_{matrix}$ and the highest laboratory $DegT50_{matrix}$ value. If the uncertainty is smaller, then the field $DegT50_{matrix}$ value should not be discarded because it is, of course, possible that the degradation in this field soil is by coincidence longer than for any of the other soils studied (populations of $DegT50_{matrix}$ values have variation coefficients of about 50 % so there is a large variation between $DegT50_{matrix}$ values from different soils). The possible reasons for this are discussed in more detail in the following paragraphs.

As described by EFSA PPR Panel (2010), the inversely modelled $DegT50_{matrix}$ will usually decrease (faster degradation) with increasing E_A. The possible effect of using the default E_A of 65 kJ/mol can be checked by repeating the time-step normalisation procedure with E_A = 115 kJ/mol (i.e. approximately a 95th percentile E_A value). If this leads to a $DegT50_{matrix}$ that is within the range of the laboratory $DegT50_{matrix}$ values, the field $DegT50_{matrix}$ value can be discarded.

As described by EFSA PPR Panel (2010), the inversely modelled $DegT50_{matrix}$ value decreases (faster degradation) with increasing moisture exponent B. Often, the effect of soil moisture is ignored in the time-step normalisation procedure (which corresponds to B = 0). The possible influence of ignoring the effect of soil moisture or of using the default B value of 0.7 can be checked by repeating the time-step normalisation procedure with values of the exponent B of 1.5 (high value) and 2.9 (extremely high value). If this leads to a $DegT50_{matrix}$ value that is within the range of the laboratory $DegT50_{matrix}$ values, the field $DegT50_{matrix}$ value can be discarded.

As described by EFSA PPR Panel (2010), if the simulated moisture content for the layer in which most of the substance is located is too high, this may also lead to the inversely modelled *DegT50* value being too high. EFSA PPR Panel (2010, p. 17) also indicated that the numerical models probably overestimate the moisture content of the top millimetres during a drying cycle in the field. This could be checked by simulations with the numerical models using compartment thicknesses of around 1 mm for the top layer: if during most of the field experiment most of the substance remains in the top centimetre of soil and if for more than 75 % of the time there are rain-free periods of more than three days, then the field $DegT50_{matrix}$ value can be discarded.

If at the end of the procedure it is concluded that field $DegT50_{matrix}$ values represent degradation within the soil bulk matrix and the field $DegT50_{matrix}$ values are still higher than the laboratory $DegT50_{matrix}$ values, the field and laboratory datasets should be combined to obtain the geometric mean, as described in Box F of Figure 3.

Worked examples on how to apply this procedure can be found in Appendices E and F of this guidance.

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APPENDICES

Appendix A. Guidance on designing field studies to be used for obtaining degradation rates ($DegT50_{matrix}$) values in upper topsoil

In addition to this guidance, study directors should consult the NAFTA guidance document for conducting terrestrial field dissipation studies (NAFTA, 2006), particularly section II. Note that, when finalised, any future OECD guidance on terrestrial field dissipation studies is also expected to be applicable. Unless indicated to the contrary below, guidance contained in the NAFTA (2006) document is considered appropriate, This means that, when a different recommendation is given in this EFSA guidance, this should be adhered to as it replaces the guidance from the NAFTA (2006) document. Note that, to facilitate using this guidance, the structure of this appendix, including section titles, mirrors those of section II of the NAFTA (2006) document.

A. Information on the test substance

The test substance can be the active substance to be marketed or a transformation product of the test substance for which a field $DegT50_{matrix}$ value is desired.

Usually, if transformation products are used as a test substance, they will have reached levels that trigger assessment in appropriate laboratory (lab) soil aerobic, anaerobic or photolysis experiments. These levels and, where applicable, lab DegT50 triggers for field studies can be found in the legal data requirements of Regulation (EC) No 1107/2009. If reliable transformation $DegT50_{matrix}$ values can be derived from experiments where precursors in a transformation pathway have been dosed, then applicants have discretion over whether and for which transformation products they might carry out field experiments, where a transformation product is applied as test substance. The test substance should be prepared/formulated so that it can be evenly applied to a test plot, so that variation in the mass of test substance applied per unit area is minimised. Preparation as a formulation may not be necessary when the test substance is soluble in or miscible with the diluents being employed in the experiment. The formulation does not need to be a typical end use product. End use products that have been used to treat seeds or are ready to use granules should usually be avoided, as the use of these will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling. The only time a study with an end use product has to be performed (according to legal products data requirements of Regulation (EC) No 1107/2009) is when the test substance is the commercialised formulated active substance and the commercialised formulation technology affects the rate of release of the active substance from the formulation, so would affect the $DegT50_{matrix}$ value that would be estimated for the test substance and the kinetic formation fraction that would be estimated for a transformation product.

B. Field plot systems

Test plots should never be cropped at the time of application as this will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling. An experimental design where plots are only maintained bare throughout the experiment has to be followed when plant uptake cannot be excluded as a significant route of dissipation for any of the compounds of interest. Where robust data are available in the dossier to allow it to be confirmed that crop uptake is not a significant route of dissipation from soil for any of the compounds of interest (for example evidence from following crop metabolism studies), it is an option that both plots maintained bare and plots where grass will germinate be prepared, with parallel experiments being set up on both plot types at each study site. When this option is followed, grassed plots can be seeded after the test substance has been mechanically incorporated (see section E.2). Alternatively, grassed plots can be pre-seeded so that the grass crop will emerge after application, when test substance incorporation is to be achieved via irrigation (see section E.2). When results from parallel maintained bare and grass-emerged plots are available, soil root zone models should be parameterised for the conditions of the experimental

sites,[5] to provide an interpretation of what contribution plant uptake may have made to any difference in DT values between maintained bare and grass emerged plots, as compared to the contribution of plant roots to potentially having enhanced microbially mediated degradation in grass-emerged plots. $DegT50_{matrix}$ values should be derived from the grass-emerged plots only when such modelling confirms that plant uptake was not contributing significantly to the DT values estimated from the grass-emerged plots.

C. Site selection

As the purpose of these experiments is to obtain a median $DegT50_{matrix}$ for the population of agricultural/horticultural fields in the area of use of the substance (in the EU), sites can be randomly selected from this population. It is also considered appropriate to use sites located in temperate regions outside the EU provided their pH, organic matter and clay contents are within the range of values to be expected for topsoils in the area of use of the substance in the EU. Use of sites with a mineral content derived from volcanic activity where there has been limited pedology is considered inappropriate because the chemical and physical properties of soils as these sites differ substantially from those of temperate mineral soils. For other aspects of site selection, the NAFTA (2006) guidance can be considered. Note that sites where soil characteristics mean that significant movement of substances of interest out of the microbially active topsoil layers might occur should be avoided for experiments used to estimate $DegT50_{matrix}$. For example, sites where soils have coarse textures combined with low organic carbon, such as the 'Borstel' soils typically used in European lysimeter experiments, should be avoided.[6]

D. Field plot design

When designing an experiment to estimate $DegT50_{matrix}$ in topsoil, all processes that can affect the fate of the chemical, except the formation of transformation products or not extracted residues (such as leaching, volatilisation, soil surface photolysis, runoff and plant uptake) should be minimised as far as possible. Therefore, test plots should be level without any slope. See also section E.2 for more information on the approaches to be taken to minimise surface processes impacting on the $DegT50_{matrix}$ estimates. The basic $DegT50_{matrix}$ field study design evaluates field degradation in topsoil in bare ground plots or may additionally include plots where grass emerges after application (see section B above), but should exclude the influence of surface processes as far as is practical. The study design should encompass the range of environmental conditions that reflect the actual usage of the test substance, though surface processes should be excluded, even if these might occur as a result of the actual usage. The studies should also include an untreated control plot. The control plot's purpose is both to ensure that the pesticide is not present prior to application and to provide a sufficient quantity of soil for carrying out the necessary analytical method fortification and recovery experiments that must be carried out throughout the experiment. The plot preparation/cultivation depth and mixing of samples from the control plot should mirror that of the treated plots to minimise different matrix effects in recovery experiments. Measures to prevent contamination of the control plot from treated plots, in particular spray drift at the time of application, should be made. Because of field-scale variability, the experimental units in each study should be replicated. The considerations of the NAFTA (2006) guidance regarding replication in section D, Field plot design, are considered appropriate. At least three subplots should be used as the basis for the replicated sampling strategy.

[5] When using the soil root zone models recommended by FOCUS, the transpiration stream concentration factor(s) (TSCF) needed for each compound should be calculated from measured logPow values, in line with FOCUS recommendations.

[6] The *DegT50* may be used as an input parameter for the assessment of leaching to groundwater and surface water. The purpose of the evaluation of the laboratory and field dissipation studies is to obtain a geomean *DegT50* for the population of agricultural/horticultural field soils in the area of use of the substance (EFSA, 2010, p. 9). In principle, it is undesirable to avoid field dissipation studies in which significant leaching occurs, because the *DegT50* value derived from these studies may contribute in a relevant way to the median *DegT50* value used for the leaching assessment. However, there is currently no guidance available to derive appropriate *DegT5*0 values from studies in which significant leaching occurs. In principle, this is possible using inverse modelling procedures with numerical models but it is impossible to develop such guidance within the given time frame. Therefore, it is currently not recommended to select field study sites in which significant leaching might be expected to occur.

E. Procedure

1. Site characterisation

Consideration of the NAFTA (2006) guidance is considered appropriate (excepting the use of the word dissipation where degradation would be pertinent in this context).

2. Application of the test substance

The test substance should be applied to the surface of test plots as evenly as possible, formulated as necessary, as already discussed in section A, above. For active substances at least the maximum proposed/intended annual total dose use rate, as will be stated on the label should be used. When necessary, the active substance should be applied at a rate greater than the maximum proposed use rate, to ensure that analytical quantification/detection limits for the compounds of interest enable ≤ 10 %/≤ 5 % of initial measured soil residues for the active substance to be determined respectively. Where the test substance is a transformation product, the application rate should cover at least the maximum formation level expected considering the results of the relevant laboratory experiments. As for the active substance, when necessary an application rate greater than this should be used when it is necessary to ensure that analytical quantification/detection limits for the compounds of interest enable ≤ 10 %/≤ 5 % of initial measured soil residues to be determined respectively.

Recommended equipment for pesticide delivery to experimental plots should be of high precision, suited for the particular pesticide formulation (some pesticides may need to be homogenised by a continuous mixing device in the tank) and fitted with a device to keep drift loss to a minimum.

Only a single application should be made to each test plot. The applied mass per surface area should be measured in parallel in two ways. The first is based on measurements of (i) the speed of the spray boom or other application method, (ii) the flow rate of the liquid from the nozzles or other flow rate and (iii) the concentration of the pesticide in the diluent. The second is based on measurements of deposition of pesticide on the soil surface (e.g. spray cards). The results of these two estimates of the applied mass per surface area should be compared with the mass per surface area recovered from the soil sampled at the day of application.

Following application of the substance, one of the following procedures should be employed to minimise the impact of surface processes (e.g. photolysis, volatilisation) on the $DegT50_{matrix}$ value that can be estimated for each test plot.

- Incorporation of the substance in the soil immediately after spraying to the soil surface; mixing should be over a target depth of 7 cm. A plot power harrow can be used for this with most soil textures. Following harrowing the plots should be rolled.

- Injection of the substance within the top layer (0–30 cm) of the soil, followed by mixing through the soil over a minimum target depth of 7 cm. Again a plot power harrow can be used to achieve this. Following harrowing the plots should be rolled.

- Irrigation immediately after application of the substance to the soil surface; the irrigation volume should be sufficient to reach an average penetration depth of the substance of 10 mm (to be calculated with models such as PELMO and PEARL).

- Even application of a layer of commercial fine sand to the soil surface, achieving a depth of at least 3 mm. Note that this approach should not be used if any of the substances of interest has a vapour pressure > 1×10^{-4} Pa (the function of this vapour pressure limit for this study design is to exclude that the process of volatilisation is a significant factor in the DT value that can be estimated, particularly in relation to earlier sampling times) unless other experimental evidence is available indicating that volatilisation losses from soil are not a route of

dissipation. Observations should be made and recorded to confirm that the sand layer remained in place until at least 10 mm of rainfall/irrigation has occurred.

In all cases, the first soil sampling should take place after the incorporation, irrigation or covering has taken place.

3. Study duration

It is expected that studies will be continued until the concentration of test substance has reached ≤ 10 % of initial measured test substance in the target top 10 cm soil layer or the transformation products of interest formed from the test substance have peaked and subsequently declined such that they no longer account for more than 10 % of the molar mass of the initial mass of the test substance. Movement out of the top 10 cm soil layer does not invalidate the study for the purpose of calculating the $DegT50_{matrix}$ and the $DegT90_{matrix}$ values. However, if measurement of residues of interest in the top 10 cm indicates that the decline is plateauing when > 10 % remains, the study can be terminated, provided the study has included a winter and spring period, so that it can be excluded that the reason for the plateau observed was not simply colder winter temperatures.

4. Management

Consideration of the NAFTA (2006) guidance is considered appropriate, except tillage operations before application should ensure that soil mixing is as even as possible over the top 15 cm of soil, an even fine seed bed type tilth is achieved over the top 7 cm of soil and that any cultivation incorporating the substance after application results in even incorporation over at least the top 7 cm soil layer.

5. Irrigation

Treated plots that are maintained bare may not require irrigation except in the following situations.

- This is the strategy used to move the test substance into the soil immediately after application (see section E.2 above for further details).
- Some soil textures (for example where there is a high clay content) may benefit from irrigation during prolonged dry periods to facilitate the sampling of intact soil cores.
- Study durations can also be prolonged if there are extended dry periods reducing microbial activity, in which case irrigation can be used as a tool to optimise (shorten) study durations.

Irrigation for these purposes is appropriate. The irrigation amounts applied should aim to keep soil moisture contents in the top 30 cm below field capacity, so substances of interest remain within the microbially active topsoil. When plots have grass cover, irrigation to sustain the grass is appropriate. Again the irrigation amounts applied should aim to keep soil moisture contents in the top 30cm below field capacity.

6. Environmental conditions and monitoring

Consideration of the NAFTA (2006) guidance is considered appropriate, except that the use of tracers to track the potential depth of leaching is not pertinent, as the study design should minimise the potential for substances to leach from the upper soil layers. It is advised that best practice is for the daily average soil temperatures that have to be measured to be determined at a depth of 10 cm.

7. Soil sampling

Consideration of the NAFTA (2006) guidance is considered appropriate, though references to DT75 should be replaced by DT90 in the context of the EU data requirements. Soil sampling should usually proceed to a depth of 1 metre, except at sites where the soil is so shallow that this is not physically possible. For samples taken immediately after application, a depth of 30 cm can be accepted, except

when injection to this depth or deeper was used as the method of application. Depth segments should continue to be analysed until the depth is reached where a segment no longer contains the compounds of interest at levels above the limit of detection for the analytical method. The time intervals chosen for sampling should be based on the results of laboratory studies and other field studies, if available. Sampling frequency should take into account lab *DegT* estimates with increased frequency of sampling for compounds with lower $DegT50_{matrix}$ values. The number and distribution of sample times should also be sufficient to adequately characterise the formation and decline of the transformation products of interest. A minimum of eight time intervals should be sampled. Significantly more sampling times than this may be required when a number of transformation products are of interest and kinetic fitting of both formation and decline of these needs to be determined.

It is recommended to divide the experimental plots into at least three subplots and to take, at random, at least 10 samples from each subplot. The diameter of the sampling core should be at least 5 cm. It is important that NAFTA (2006) guidance section E.7.f. on the handling of samples is adhered to. All samples from one subplot and the same depth segment may be mixed before analysis.

It is unacceptable to mix all samples from the plot for each depth segment into one sample because it is essential for the $DegT50_{matrix}$ time-step normalisation procedure that there is information on the uncertainty of the measured residue at each sampling time. This allows measured time points with a large uncertainty to be allocated a lower weight in the inverse modelling procedure than measured time points with a small uncertainty (e.g. often the scatter immediately after application is larger than at later sampling times).

The total mass of moist soil from each mixed sample should be recorded because it is the intention to assess the mass per surface area present in each depth segment (soil layer). If this mass of moist soil is not measured and recorded, the mass per surface area can be calculated only after the bulk density of the soil has been estimated. This estimation may be inaccurate. This inaccuracy can be avoided simply by measuring and recording the total mass of moist soil of each mixed sample. For each mixed sample, the mass of substance per sampled surface area should be calculated from the content of substance in the soil, the total mass of soil in the sample and the sampled surface area. Results from all depth segments containing detectable residues for the compound(s) of interest should be used when estimating $DegT50_{matrix}$ values. Therefore, a final manipulation of the results has to be completed. The masses per surface area of the different depth segments from the same subplot have to be summed up to give the total mass per surface area for each subplot. These total masses per surface area form the basic data for the further $DegT50_{matrix}$ estimation.

8. Sampling of other media

Consideration of the NAFTA (2006) is considered appropriate, though plant material sampling, air sampling and sampling of runoff are not relevant for $DegT50_{matrix}$ experiments.

9. Sampling strategies to increase sensitivity

Consideration of the NAFTA (2006) is considered appropriate, though plant material sampling, air sampling and sampling of runoff are not relevant for DegT50 experiments.

10. Handling and analysis of samples

Consideration of the NAFTA (2006) section E.7.f. and Appendix III is considered appropriate, though the following additional recommendations should be followed:

As the efficiency of the sample extraction procedure used influences the $DegT50_{matrix}$ that is calculated from the experiment (more efficient extraction procedures, will usually result in longer $DegT50_{matrix}$ being estimated), adequate and consistent extraction procedures should be followed for all samples taken at a trial site. It is desirable that the same extraction procedure(s) be used in all field and laboratory $DegT50_{matrix}$ experiments in a dossier. Whilst this will not be the usual situation, particularly for substances for which regulatory databases have been developed over many years, it is

preferable that similar extraction procedure(s) be used in new field $DegT50_{matrix}$ experiments to those that have been used in the laboratory soil incubations and already available soil field experiments.

Appendix B. Use of geomean K_{om} or K_{oc}

The Panel proposed to use a coefficient of variation (CV) of 0.5 and a log-normal distribution for the K_{om} or K_{oc}. As described in section 4.2.5 of EFSA (2012), the reason for not using the normal distribution is that the variable (K_{om}) has only positive values, but its use with such a large CV would give a high probability of negative values.[7] The scenario selection procedure in Chapter 4 of EFSA (2012) was based on the assumption that median substance properties will be derived from the dossiers as input parameters for the scenario calculations. The FOCUS guidance in place up to publication of this document was to use an arithmetic mean K_{om} or K_{oc} if fewer than nine values were available and the median K_{om} or K_{oc} of the sample if nine or more were available (Anonymous, 2012, p. 26). In the case of a log-normal distribution, the arithmetic mean is not an estimator for the median, whereas the geomean K_{om} or K_{oc} can be so used. The geomean as an estimator of the median of the population also has better properties than the median of the sample, and hence this is the recommendation for all sample sizes equal to or greater than the minimum required by the data requirements.

So if there are four K_{om} or K_{oc} values 30, 52, 87 and 101 L/kg, then the geomean gives 60.8 L/kg whereas the arithmetic mean is 67.5 L/kg. The arithmetic mean gives higher estimates of the median, which is a general characteristic of these means. For small sample sizes (e.g. four K_{om} or K_{oc} values in a dossier), the geomean and the arithmetic mean may differ by tens of per cents. The same may apply to the difference of the geomean and the median of the sample.

The recommendation to use the geomean K_{om} or K_{oc} applies not only to the soil exposure assessment but also to other exposure assessments (e.g. leaching to groundwater and to surface water) because the PPR Panel did not see any rationale of using an arithmetic mean for a quantity that is better described with a lognormal distribution. The FOCUS recommendation to use the arithmetic mean of the Freundlich coefficient (1/n) from the available reliable adsorption studies in modelling calculations is maintained. This is because this parameter has a population that is expected to be normally distributed.

[7] Very rarely, substances such as anions may have a small negative K_d, and for these the concept of K_{om} cannot be applied.

Appendix C. Crop interception factors

EFSA decided to launch a procurement and a grant activity to collect scientific information on crop interception and to evaluate the crop interception values proposed by FOCUS. Interception by crops reduces the amount of the plant protection product that reaches the ground underneath the crop. At some steps/tiers of exposure assessment only the plant protection product that reaches the ground is taken into account in regulatory calculations of predicted environmental concentrations (PECs) in soil, surface water and groundwater (for groundwater this is the case at the first tier). It is important that the crop interception factors used in the regulatory risk assessment are based on well-documented data and thus act as robust and representative values.

In a procurement activity, a literature review on cereals resulting in a database and a report were prepared by van Beinum and Beulke (2010). The proposals for the crop interception values for cereals were revised by the PPR Panel in an opinion (EFSA PPR Panel, 2012). In a subsequent grant activity, a literature review on other FOCUS crops resulted in a database and a report prepared by Olesen and Jensen (2013). Both reports are published on the EFSA website. The above-mentioned reports and the opinion resulted in the updating of the FOCUS crop interception values as set out in the tables below (table numbers are those of the pertinent FOCUS version control documents). Note in the tables below, the rounding criteria of Olesen and Jensen (2013) have been applied to the PPR Panel opinion (EFSA PPR Panel, 2012) cereal values.

Ground water

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

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

[#]The BBCH code is indicative (Meier, 2001).

Table 1.5: Interception by other crops dependent on growth stage

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

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

Surface water Step 2

Table 2.4.2-1: Step 2: crop interception

crop	**no interception**	**minimal crop cover**	**intermediate crop cover**	**full canopy**
BBCH-code*	00 – 09	10 – 19	20 – 39	40 – 89
Cereals, spring and winter	0	0	0.2	0.7
Citrus	0	0.8	0.8	0.8
Cotton	0	0.3	0.6	0.75
Field beans	0	0.25	0.4	0.7
Grass/alfalfa	0	0.4	0.6	0.75
Hops	0	0.2	0.5	0.7
Legumes	0	0.25	0.5	0.7
Maize	0	0.25	0.5	0.75
Oil seed rape, spring and winter	0	0.4	0.7	0.75
Olives	0	0.7	0.7	0.7
Pome/stone fruit, early and late	0	0.2	0.4	0.65
Potatoes	0	0.15	0.5	0.7
Soybeans	0	0.2	0.5	0.75
Sugar beet	0	0.2	0.7	0.75
Sunflower	0	0.2	0.5	0.75
Tobacco	0	0.2	0.7	0.75
Vegetables, bulb	0	0.1	0.25	0.4
Vegetables, fruiting	0	0.25	0.5	0.7
Vegetables, leafy	0	0.25	0.4	0.7
Vegetables, root	0	0.25	0.5	0.7
Vines, early and late	0	0.4	0.5	0.6
Application, aerial	0	0.2	0.5	0.7
Application, hand (crop < 50 cm and > 50 cm)	0	0.2	0.5	0.7
No drift (incorporation/seed treatment)	0	0	0	0

*NOTE: indicative, adapted coding, the BBCH-codes mentioned do not exactly match (Meier, 2001).

Appendix D. EFSA *DegT50* Endpoint Selector

See attached Excel sheet (Appendix D EFSA *DegT50* Endpoint Selector).

Appendix E. Worked example of faster degradation in field than in laboratory

In this example, seven $DegT50_{matrix}$ values for the active substance were derived from dark aerobic soil degradation studies in the laboratory. Kinetic fitting was performed in agreement with Focus (2006).[8] The corresponding range of $DegT50_{matrix}$ values derived, after normalisation to FOCUS reference conditions, was 67 to 221 days with a geomean (calculated using the "EFSA *DegT50* Endpoint Selector") of 109.2 days (Table 2).

In addition, nine field studies not tailored for $DegT50_{matrix}$ (legacy studies) were also available. The field soil dissipation studies available were performed in Germany, Spain, the UK and France. Following the framework presented in this guidance, seven of these field studies could be used to calculate the $DegT50_{matrix}$ value in soil.

For the seven field studies used to calculate $DegT50_{matrix}$, data relating to applied dose to the soil surface, daily temperatures, daily soil moisture conditions and daily rainfall (including the date when 10 mm rainfall/irrigation has fallen) were available in the study reports, as presented in Table 1. Scrutiny of the data suggested that 6 to 11 points would still be available after 10 mm rainfall had fallen to elaborate kinetic fittings for deriving $DegT50_{matrix}$.

Table 1: Characteristics of the field dissipation studies

Field study	Remarks	Daily temperature recorded?	Daily soil moisture recorded?	Daily rainfall	Application season	Total no of samples	No of samples after 10 mm rainfall/irrigation
1	–	Yes	Yes	Yes	Spring	13	9
2	–	Yes	Yes	Yes	Spring	13	11
3	–	Yes	Yes	Yes	Summer	14	11
4	–	No	No	No	Summer	10	–
5	–	Yes	Yes	Yes	Spring	10	6
6	Multi-application	–	–	–	Summer	–	–
7	Long-term study	Yes	Yes	Yes	Spring	10	7
8	Long-term study	Yes	Yes	Yes	Spring	10	8
9	–	Yes	Yes	Yes	Spring	14	8

In agreement with the proposed guidance, the six remaining field study datasets were normalised to FOCUS reference conditions using time-step normalisation (using the procedure described in section 2.3.2).

Following the flow chart for assessment of results of field dissipation studies after analysis with the DFOP model as presented in Figure 1, the 95 % confidence intervals of k_{fast} and k_{slow} did not overlap. Following calculation of the DFOP 'breakpoint', it was found that the breakpoint occurred after > 10 mm rainfall. The assessment subsequently showed that k_{slow} was considered acceptable and it was used to derive $DegT50_{matrix}$ values for field studies.

The resulting field $DegT50_{matrix}$ values ranged from 26 to 75 days with a geomean of 42.7 days derived from the EFSA *DegT5*0 Endpoint Selector (Table 3).

[8] 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.

Table 2: Active substance laboratory $DegT50_{matrix}$

Active substance	**Laboratory $DegT50_{matrix}$**
Soils	DT50 (days) at 20 °C and pF = 2)
1	112
2	134
3	124
4	86
5	78
6	67
7	221
Geomean (EFSA *DegT50* Endpoint Selector)	109.2

Table 3: Active substance field $DegT50_{matrix}$

Active substance	**Field $DegT50_{matrix}$**
Soils	DT50 (days) at 20 °C and pF = 2)
a	59
b	41
c	39
d	54
e	75
f	26
g	26
Geomean (EFSA *DegT50* Endpoint Selector)	42.7

According to the flow chart for assessment of $DegT50_{matrix}$, since the geomean laboratory $DegT50_{matrix}$ was less than 240 days at 20 °C, the procedure to determine whether the degradation rates from the separate laboratory and field databases are statistically different can be undertaken (Figure 3).

The null hypothesis (H0), $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab, was tested against the alternative hypothesis (Ha), $DegT50_{matrix}$-field < $DegT50_{matrix}$-lab. In this example, the EFSA *DegT50* Endpoint Selector indicated that the test confirms that field studies show shorter $DegT50_{matrix}$ that laboratory studies. The null hypothesis, $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab, is then rejected. This result indicates that the degradation in the field proceeded statistically significantly faster than in the laboratory studies (α level: 25 %). According to the flow chart (Figure 3), since at least four field $DegT50_{matrix}$ values were available for the active substance, it is recommended to use the geomean of field $DegT50_{matrix}$ of 42.2 days.

Information on degradation in laboratory and field was also available for two primary metabolites that are both formed from the parent substance (metabolite 1 and metabolite 2). The same approach as presented above in Table 1 for the active substance was followed for both metabolites to determine the accuracy of the existing field studies not tailored for $DegT50_{matrix}$ (legacy studies).

For metabolite 1, only two laboratory $DegT50_{matrix}$ values (303 and 134 days) were derived in dark aerobic soil degradation studies in the laboratory (after normalisation to FOCUS reference conditions and according to FOCUS, 2006) (Table 4). In addition, a total of five field studies were also made

available for the same compound (M1). Resulting $DegT50_{matrix}$ values were in the range of 24 days to 86 days (with a corresponding geomean calculated using the EFSA *DegT50* Endpoint Selector of 48.6 days) (Table 5).

For metabolite 2, again only two laboratory DT50 were available showing fast degradation ($DegT50_{matrix}$ after normalisation 0.6 days and 1.9 days). In addition, a single $DegT50_{matrix}$ value (1.5 days) was derived from the field.

Table 4: Metabolites laboratory $DegT50_{matrix}$

Metabolites	**Laboratory $DegT50_{matrix}$ (days) at 20 °C and pF = 2)**	
Soils	**Metabolite 1**	**Metabolite 2**
1	303	0.6
2	135	1.9
Geomean estimator for the median (From the EFSA *DegT50* Endpoint Selector)	202.2	

Table 5: Metabolites field $DegT50_{matrix}$

Metabolites	**Field $DegT50_{matrix}$ (days) at 20 °C and pF = 2)**	
Soils	**Metabolite 1**	**Metabolite 2**
a	48	nd
b	24	nd
c	47	1.5
d	58	nd
e	86	nd
Geomean estimator for the median (From the EFSA *DegT50* Endpoint Selector)	48.6	

nd = not determined

According to the flow chart for assessment of $DegT50_{matrix}$, since the geomean laboratory $DegT50_{matrix}$ was less than 240 days at 20°C, the procedure to determine whether the degradation rates from the separate laboratory and field datasets are statistically different can be performed (Figure 3).

For metabolite 1, the null hypothesis (H0), $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab, was tested against alternative hypothesis (Ha), $DegT50_{matrix}$-field < $DegT50_{matrix}$-lab. The EFSA *DegT50* Endpoint Selector indicated that the test confirms that field studies show lower $DegT50_{matrix}$ values than laboratory studies. The null hypothesis $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab is rejected. According to the flow chart (Figure 3), since in total at least three field $DegT50_{matrix}$ values for metabolite 1 were available, it is recommended that the geomean of field $DegT50_{matrix}$ of 48.6 days be used.

Then, for metabolite 2, the null hypothesis, $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab, was tested against alternative hypothesis, $DegT50_{matrix}$-field < $DegT50_{matrix}$-lab. In this example, the EFSA *DegT50* Endpoint Selector indicated that the single value does not contradict the hypothesis that it is a result from the distribution of laboratory values. The null hypothesis, $DegT50_{matrix}$-field = $DegT50_{matrix}$-lab, is not rejected. This result indicates that the dissipation in the field does not proceed statistically significantly faster than the results of the laboratory studies (α level: 5 %). According to the flow chart (Figure3), the recommendation is to use the geomean of lab and field $DegT50_{matrix}$ values of 1.1 days (calculated using both laboratory values of 0.6 and 1.9 days and the single field value of 1.5 days).

Worked example of slower degradation in field than in lab

This appendix describes an example of a substance, Sub_I (an insecticide), that showed much slower dissipation in field soil after spraying onto bare soil than expected from the laboratory $DegT50_{matrix}$ studies.

The range of $DegT50_{matrix}$ values measured in dark aerobic soil degradation studies in the laboratory (after normalisation to FOCUS reference conditions using the Q10 default of 2.58) was 18 to 90 days with a geomean of 25 days (four soils with organic matter contents between 1.5 and 2.5 %). The initial content in soil of Sub_I in these studies was 1 mg/kg.

Field soil dissipation studies were available in which Sub_I was sprayed on bare soil at four sites across the EU at a rate of 0.25 kg/ha as an emulsifiable concentrate in a volume of water of 500 L/ha. The organic matter content of the topsoil layers ranged from 1.5 to 2.5 %. The results of these field dissipation studies were normalised to FOCUS reference conditions, and resulting first-order *DegT50* values ranged from 130 to 400 days with a geomean of 200 days.

These results indicate that the dissipation in the field proceeded significantly slower than expected on the basis of the laboratory studies. The question is, then, 'What the possible cause of this?' because it is very unlikely that the degradation rate in a field soil is much slower than in a sample taken from this soil and transferred to the laboratory.

The K_{oc} value of Sub_I ranged from 15 000 to 70 000 L/kg in studies with five soils, with a geomean of 41 000 L/kg. This geomean corresponds to a K_{om} of approximately 24 000 L/kg. The water solubility of Sub_I is 0.06 mg/L at 20 °C. Its vapour pressure is low (< 1 µPa at 20 °C). Sub_I does not dissociate between pH 2 and 8. A laboratory study on soil photolysis showed a DegT50 value of about 150 days in dry soil for sunlight conditions at latitude 40 °N.

Let us consider what happens to Sub_I in the field. As described above, it was sprayed at a rate of 0.25 kg/ha in a water volume of 500 L/ha. A volume of 500 L with Sub_I at its water solubility contains 30 mg of Sub_I, i.e. 0.00003 kg. Therefore, the concentration of Sub_I in the spraying tank is approximately four orders of magnitude higher than its water solubility.

Spraying of 500 L water per ha corresponds to a water layer of 0.05 mm (1 mm is 10 000 L/ha). This will penetrate 0.2 mm into the soil (so essentially it is a thin film on the soil surface in the form of fine droplets). Evaporation rates in summer are typically 5 mm/day in southern Europe in summer. Therefore, this water layer will evaporate usually within a fraction of an hour. This gives a concentration of Sub_I in the top 0.2 mm in the order of 50–100 mg/kg. Assuming sorption equilibrium, 2 % organic matter and a K_{om} of 24 000 L/kg, gives then a concentration in the water phase of 0.1–0.2 mg/L, thus exceeding the water solubility. In view of the application as an emulsifiable concentrate this assumption of sorption equilibrium is not defensible. It is more likely that Sub_I is still encapsulated in some solid form in the dried remnants of the formulation.

Sub_I has first to dissolve before it can enter into the soil. Assuming a dissolution concentration at 50 % of the water solubility of 0.06 mg/L and a dose of 0.25 kg/ha, it will require some 800 mm of rainfall to dissolve the dose completely. After dissolution, movement of Sub_I will be slow in soil; assuming piston flow, 2 % organic matter, a K_{om} of 24 000 L/kg and a dry bulk density of 1 kg/L, it can be estimated that Sub_I moves only 0.2 mm through soil for each 100 mm of rainfall penetrating into the soil. In reality the movement is expected to be somewhat faster because of dispersion in the solute transport in soil.

Therefore, the slow dissipation of Sub_I in the field studies was caused not by slow degradation in the soil matrix but by slow dissolution from the top millimetre of soil (and perhaps also some photochemical degradation in the top millimetre of soil), followed by slow penetration into the soil matrix.

The laboratory studies were conducted at an initial content of 1 mg/kg. Assuming sorption equilibrium, 2 % organic matter and a K_{om} of 24 000 L/kg gives, then, a concentration in the water phase of 0.0025 mg/L, which is an order of magnitude lower than the water solubility of 0.06 mg/L at 25 °C. Therefore, this dissolution process was unlikely to significantly influence the results of the laboratory studies. Thus, the main difference between the laboratory and the field was that in the laboratory the substance was mixed through soil at 1 mg/kg whereas in the field spraying onto bare soil led to a concentration of 50–100 mg/kg (in a very thin top layer) which could dissolve only slowly.

The aim of the guidance is to assess the degradation rate within the soil matrix. However, these field dissipation studies do not provide information about this degradation rate. Therefore, it depends on the type of exposure assessment whether this field dissipation study contains relevant information. For example, for the groundwater leaching assessment it would be advisable to ignore this information because Sub_I is likely to degrade relatively quickly in soil after it has penetrated, for example, below 1 cm depth in soil. However, if a leaching model could be used that includes dissolution of the dose as a process, these studies could be used to calibrate the dissolution parameters in this model. The field dissipation study may also be relevant if the effects on soil organisms such as Collembola need to be assessed which live predominantly in the top few millimetres of the soil.

Glossary and abbreviations

Degradation	Loss process by which a substance is physically transformed from one chemical species to another. This can ultimately result in the formation of unextracted residues and CO_2, but not necessarily in all cases
DegT50	Description of time taken for 50 % of substance to disappear from a compartment as a result of degradation processes alone
$DegT50_{matrix}$	For aerobic laboratory studies and tailored field dissipation studies with no significant influence of surface processes or aged sorption, relates to the time taken, assuming SFO kinetics, for 50 % of substance to disappear from the soil matrix as a result degradation processes alone. For legacy field dissipation studies, relates to the DT50 corresponding to either the SFO *k* after elimination of data points before 10 mm of rain has fallen, or DFOP slow phase (k_{slow}) of HS slow phase (k_2).
DFOP	Double first-order in parallel
Dissipation	The result of one or more loss processes leading to the disappearance of a substance from an environmental matrix, e.g. soil. Loss processes contributing to dissipation include degradation within the soil matrix by biotic and/or abiotic processes, soil surface photolysis, volatilisation, plant uptake and leaching
DT50	Generic term to describe the time required for disappearance of 50 % of the residue. Ideally, which loss processes the disappearance time relates to should be clarified, e.g. *DegT50* within the soil matrix degradation, *DisT50* for dissipation processes. If the calculation of the DT50 is performed using single first-order (SFO) kinetics, the DT50 can also be referred to as a 'half-life'
F_{field}	Field rapidly dissipating fraction that is not related to degradation in the soil matrix
FOCUS	FOrum for Co-ordination of pesticide fate models and their USe
NAFTA	North American Free Trade Agreement
PBT	Persistence bioaccumulation toxicity
PEC	Predicted environmental concentration
PECSOIL	Predicted environmental concentration in soil
PPP	Plant protection product; in the context of this opinion, the term 'plant protection products' is used for both the applied formulation and the active substances
PPR	Scientific Panel on Plant Protection Products and their Residues
POP	Persistent organic pollutant
SFO	Single first-order (see also entry under DT50 above)

vPvB	Very persistent and very bioaccumulative substance