Panel on Plant Protection Products and their Residues

Project Plan for developing guidance on exposure assessment in soil for terrestrial effect assessment at the EU level (Revision of 9188/VI/97 rev. 8: Guidance Document Persistence in Soil)

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Prepared by the environmental fate and ecotoxicological working groups for the revision of guidance on persitence in soil

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1.1 Introduction

FOCUS (1997) developed the first guidance at EU level for exposure assessment in soil. This included a simple approach for estimating PEC_{SOIL} but FOCUS (1997) was unable to develop first-tier scenarios (in contrast to subsequent FOCUS workgroups that developed such scenarios for surface water and groundwater). FOCUS (2006) developed detailed guidance on estimating degradation rate parameters from laboratory and field studies, but did also not develop exposure scenarios. Nevertheless there is need at EU level for such scenarios in view of ongoing discussions in PRAPeR experts groups on PEC_{SOIL}.

The existing Guidance Document on Persistence in Soil (9188/VI/97 rev 8) published in 2000 did not include scenarios either. The intention with the new guidance document is to revise the existing Guidance Document on Persistence in Soil (9188/VI/97 rev 8) published in 2000 to include European exposure scenarios for soil. The update will not include guidance PBT classification or guidance that has been replaced by newer guidance e.g. in FOCUS kinetics.[1]

1.2 Aim

The revision of the persistence in soil guidance document will provide notifiers and Member States guidance in the area of environmental fate and behavior of pesticides in soil in the context of the review of active substances notified for inclusion in Annex I of Directive 91/414/EEC as well as for review of plant protection products for national registrations in Member States.

The aim of this revision is to develop a tiered approach for exposure assessment in soil at EU level including:
(i) development of a range of scenarios representing realistic worst-case conditions for the climatic zones as defined for the FOCUS Groundwater scenarios and in addition to include ecological considerations, and
(ii) appropriate definition of the role of results of field persistence and soil accumulation experiments in the tiered assessment.

The exposure assessment is considered to be part of the terrestrial ecotoxicological effect assessment. This implies that it has to consider all types of concentration that are considered relevant for assessing the ecotoxicological effects. These concentrations are

[1] Sanco/10058/2005, version 2.0, June 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. The web-address of FOCUS kinetics is: http://viso.jrc.it/focus/dk/ .

called Ecotoxicologically Relevant types of Concentration, abbreviated to ERC (Boesten *et al.*, 2007). See Figure 1 for a graphical representation of the relationship between the effect and exposure assessments.

When developing the FOCUS groundwater scenarios, realistic worst-case conditions were defined as spatial 90th percentile PEC_{GW} values within agricultural area of use of the pesticide in each of some ten different climatic zones across the EU. Based on this, nine groundwater scenarios were developed and each of these nine scenarios intended to deliver the 90th percentile PEC_{GW} for one of the climatic zones. The workgroup proposes to use a similar approach: it is proposed to develop a limited number of scenarios that each represents a spatial 90th percentile PEC_{SOIL} for a certain zone (the definition of the zones will be based not only on climatic but also on ecological considerations as described in Section 1.3). Such a spatial 90th percentile PEC_{SOIL} has to be based on a distribution of individual PEC_{SOIL} values. Each of these individual PEC_{SOIL} values is intended to be a correct estimate for an individual agricultural field where the pesticide is applied. So if necessary, the assessment procedure will separately account for the spatial variability within such an individual field.

Risk-managers in MSs are specifically asked whether this proposal is in line with their expectations?

It may be possible to develop scenarios for multiple percentiles but this will take more time and may endanger keeping the project deadline of 11/2 to 2 years.

1.3 Proposed methodology

The ecotoxicological experts will investigate the difference in soil communities over Europe (EU-27). This will include soil properties, climate, as well as biogeographically information. It is assumed this information is partly available in the JRC and EEA databases; and should be combined to find a practical and meaningful aggregation level for bio-zones or ecozones. The collembola and the earthworms will be targeted as representatives of two guilds[2] covering important soil services and a relevant part of soil biodiversity. Ecozones will then be defined as regions with shared ecological properties.

The ecotoxicological experts will consider the ecological services of soil, including but not restricted to habitat, nutrient cycling, biofiltering capacity, and fertility. Assuming

[2] A guild is any group of species that exploit the same class of environmental resources in a similar way. Species are grouped together based on their niche requirements and not in terms taxonomic positions.

that ecosystem structure will protect the ecosystems services, i.e. soil functions, it is foreseen that the biodiversity for the respective ecozones is the envisaged protection goal. The biodiversity of the ecozones is operationalized in protecting key guilds (groups of organisms with similar niche requirements and roles in an ecosystem). To assess these guilds, model species, which are a function of the specific guild in a particular zone, will be identified.

The ecotoxicological experts will design the architecture of the methodology for the final proof that the protection goals will be met, and which exposure profiles are needed for that purpose. They will not draft the whole assessment scheme with all practicalities.

Traditionally, the total content of pesticide in the top 5 cm of soil is used in the terrestrial risk assessment. However, there are indications that soil pore water may be a better measure for effects. The available evidence for this will be reviewed by ecotoxicological experts. On that basis it will be decided whether the soil pore water concentration needs to be included in the risk assessment.

At the start of the project, the working hypothesis is to develop two tiered approaches for the following types of ERC:

1) total content of pesticide averaged over top 1, 5 or 30 cm of soil for various time windows (peak, TWA for 7, 14, 28, 56, 180 and 365 d)
2) pore water concentration of pesticide averaged over top 1, 5 or 30 cm of soil for the same time windows

The moments in time for which the exposure is calculated, will be kept flexible (to cover all foreseeable potential future needs)[3]

Next step is to develop tiered exposure flow charts for the selected types of ERC. Figure 2 shows a first preliminary draft for such a flow chart. Tier 1 is a simple model based on conservative assumptions. Tier 2 will consist of not more than 10 point scenarios that are intended to represent realistic worst case exposure in EU agriculture and horticulture (similar to FOCUS groundwater and surface water scenarios) taking into account agricultural practices. Tier 3 is an option to use more tailored scenarios (e.g. including crop rotations) but this tier will not be developed in detail. Within all tiers, the degradation half-life (*DegT50*) for topsoil at 20^{o}C and field capacity (used as input into the models) can be based on a tiered approach: (i) considering only values from laboratory studies, (ii) including also values from field studies and (iii) including

[3] E.g. in a recent Dutch proposal for terrestrial effect assessment three such times are defined linked to three different ecotoxicological protection goals: (1) all-time maximum of the ERC during the use period of the pesticide needed for protection goal "Functional Redundancy", (2) two years after last pesticide application needed for protection goal "Community Recovery", and (3) seven years after last pesticide application needed for protection goal "Ecological Threshold"; see van der Linden et al. (2006).

additionally values from soil accumulation studies. The review by Beulke *et al.* (2000) shows that degradation rates estimated from laboratory studies usually overestimate dissipation rates in field studies. However, this review shows also that this is not the case in about 25% of the studies. Thus for each pesticide, the notifier has the burden of proof that the *DegT50* values from field experiments are valid for use in Risk Assessment.

The most sophisticated procedure for developing GIS-based scenarios is to start with a large number (e.g. 1000) of scenarios that covers the area to be considered at a scale that is as large as possible (so this would be using the best science available). This approach has been followed by the FOCUS Groundwater Workgroup for checking the acceptability of the current FOCUS groundwater scenarios. Also in the current EU FOOTPRINT project this approach is followed for runoff and drainage scenarios. So it will be attempted to follow this approach also in this guidance development.

The most recent versions of the EU-SPADE databases on soil properties (owned by JRC Ispra) will be used as a basis for developing these scenarios. This database will be freely accessible to all interested workgroup members. Similarly, data from the EU-MARS weather database are likely to be necessary (also owned by JRC Ispra).

In view of the uncertainties involved any procedure for scenario development, it is the intention to use at least two different software packages coupled to the same database of scenarios. This reduces the possibility of errors and ensures robustness of the procedure. Examples of software to be included could be MACRO, PEARL, PELMO, PRZM and other.

In the PRAPeR risk assessment review for Annex I listing according to Directive 91/414/EEC, recently a number of field persistence studies showed a slowing down of the transformation rate of persistent compounds after about half a year after application (also after normalisation of the rate to the 20^{o}C reference temperature). This might be caused by a more than proportional decrease in the soil pore water concentration due to long-term sorption kinetics. These field persistence studies will be considered while developing the methodology.

Ploughing may have a considerable effect on exposure concentrations for persistent and strongly sorbing pesticides. Thus no-tillage agriculture may result in higher exposure concentrations for such pesticides than normal agriculture. Therefore each scenario in tier 2 will include a no-tillage and a tillage option. For the no-tillage option it will be attempted to describe the course of the organic matter content in the top 20 cm of the soil on the basis of literature data. For the tillage option, it will be assumed that soil properties are homogeneous over the ploughing depth.

It seems appropriate to test the guidance by applying it for a few pesticides for which DARs (monographs) are available. Special attention will be paid to the role of field persistence and soil accumulation experiments (so for pesticides selected for this purpose, such data should be available).

1.4 Restrictions of the project

Only exposure assessment for field, not for ecotoxicological studies
The terrestrial effect assessment needs exposure assessment in two different systems: (i) exposure assessment in the field in agricultural and horticultural practice and (ii) exposure assessment in the ecotoxicological studies in laboratory or field (see Figure 2 of Boesten *et al*., 2007, for detailed explanation). Guidance development in this project will be restricted to exposure assessment in field soil in agricultural and horticultural practice and thus not include the exposure assessment in the ecotoxicological studies in laboratory or field.

No guidance for PBT classification
The guidance aims at exposure assessment as part of the terrestrial effect assessment. So the guidance does not aim to contribute to the PBT classification as mentioned in the new draft EU regulation (this PBT classification is a hazard-based approach which differs from a risk-assessment based approach).

No updates of user interfaces of software packages
The FOCUS groundwater and surface water scenarios consist of two parts:

(A) a detailed description of all scenario characteristics in appendices of reports, including characteristics of few example pesticides to generate example output.
(B) software packages including user-friendly interfaces with ready-to-use scenarios.

This project will only include part A and not part B but EFSA will encourage model developers to develop such user-friendly interfaces.

No validation against field data
Testing of the selected models against field data is not part of this particular project. There are more than 100 of such combinations of laboratory and field experiments available in literature so due to the resources needed for this validation it will not be possible within the given time frame. Moreover, the exposure assessment implies a number of additional assumptions that would not be tested by such a validation (e.g. extrapolation from *DegT50* values from studies with four soils to all soils in the EU).

No further guidance development for DT50 triggers
Further guidance development for DT50 triggers is not part of the project.

Attempted scenario development only for seed treatments and applications to ridged potato fields
It will be attempted to develop separately tier-1 calculation procedures for seed treatments and pesticides applied to ridged potato fields using conservative assumptions. However, development of tier-2 scenarios for these types of applications will not be included in view of the complexity of these issues and thus the considerable amount of additional time that this would cost. A few general recommendations will be made for tier-2 assessments based on specific examples provided from PRAPeR.

Attempted assessment only of applications to paddy rice fields
The working group intends to develop separately tier-1 calculations procedures. The feasibility of developing tier-2 scenarios within the timeframe of the project will be assessed and decided at a later stage.

No exposure assessment for off-crop scenarios.
No exposure assessment will be made for off-crop scenarios.

No assessment for microbial pesticides
Exposure assessment of microbial pesticides will not be included because this would cost considerable additional time.

No quantitative assessment of uncertainty of all guidance aspects
As far as possible, the uncertainty in the resulting exposure concentrations will be evaluated. Given the complexity of the guidance it is likely to be impossible to perform quantitative assessment for all aspects of the guidance development. The report will contain a chapter that addresses this uncertainty issue in a qualitative way within the given time frame.

Release of parent compound or soil metabolites from the bound residue fraction will not be included in the exposure assessment
Release of substances (both parent compounds and soil metabolites) from the bound residue fraction will not be included in the exposure assessment because it is anticipated (based on expert judgment) that this would have only small effects on the estimated total contents and pore water concentrations. Moreover this would require a review of available data on this item and the estimation of release rate coefficients from these data. This is considered impossible within the given time frame.

1.5 Expected results

The result of the project will be a guidance document that describes:

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(i) justification of the types of exposure concentration for which the exposure assessment has been developed
(ii) the recommended tiered approach for exposure assessment in soil including the role of field persistence and soil accumulation experiments
(iii) the methodology used for the selection of the soil exposure scenarios
(iv) detailed description of the parameterisation of the selected scenarios (including the necessary meteorological databases in digital form) for at least two models
(v) results of scenario calculations with the selected scenarios for a limited number of model pesticides
(vi) application of the proposed approach to e.g. three example pesticides.

1.6 Project organisation and externalisation

An EFSA Core Persistence in Soil working group has been formed that consists only of a number of PPR Panel members plus representatives from the PPR unit. This group meets just before or after PPR Plenary meetings as necessary. This workgroup has established two subgroups: one on environmental fate aspects and one on ecotoxicological aspects.

The aim of the ecotoxicological subgroup is to select the types of concentrations for which the exposure assessment should be developed (based on a review of relevant literature). The ecotoxicological subgroup was formed in December 2007 and will meet about once every two months or if needed more frequently. It is envisaged that this subgroup will finish its activities not later than June 2008.

The aim of the environmental fate subgroup is to develop the guidance for the exposure assessment for the selected types of concentrations as described before and to test the feasibility of guidance by applying it to a few example pesticides. The fate subgroup was formed in November 2007 and will meet about once every two months or if needed more frequently until the project is finished.

Work-packages will be externalised when agreed by the working group.

1.7 Communication

Communication with the PPR Panel
The PPR Panel will be kept informed of the progress as usual at each plenary meeting.

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Communication with risk managers at member state level
In the initial phase of the project, all relevant risk management aspects of the project will be raised through the public web consultation. If at a later stage additional risk management aspects would emerge risk managers will take be consulted.

Communication with stakeholders (including Member States, industry, NGOs)
Before the start of the project, a web-consultation (6 to 8 weeks duration) of the agreed version of the project plan will be held with stakeholders and they will have 8 weeks for commenting through the web. Based on the outcome of this consultation, if necessary, the workgroup will revise the project plan.
Once the workgroup has finalised a preliminary but complete draft of its guidance document, a workshop will be organised for stakeholder experts to present and discuss the guidance developed so far. If needed, a second workshop for stakeholder experts will be organised before the finalization of the guidance.

At the end of the project, stakeholders will again be consulted through the web (web-consultation) for comments to the draft guidance document and have a 6 to 8 weeks period for commenting. If necessary, the workgroup will revise the guidance document on the basis of the comments.

1.8 Composition of the workgroup and the subgroups

The EFSA Core Persistence in Soil working group consists of Ettore Capri, Mark Montforts, Walter Steurbaut, Herbert Köpp, Matthias Liess, Damia Barcelo Culleres, Jos Boesten and Mark Egsmose.

The fate subgroup consists of Ettore Capri, Mark Montforts, Walter Steurbaut, Jos Boesten, Damia Barcelo, Mark Egsmose and the following *ad-hoc* experts:
Aaldrik Tiktak (MNP, NL)
Michael Klein (Fraunhofer Institute, DE)
Jan Vanderborght (FZJ, DE)
Beata Houskova (JRC Ispra)
Ian Hardy (Batelle, UK)
Ludovic Loiseau (AFFSA,FR)
Richard Bromilow (Rothamsted, UK)

Other *ad-hoc* experts may be invited as needed.

The ecotox subgroup will consist of Mark Montforts, Herbert Köpp, Matthias Liess, Robert Luttik, Karin Nienstedt, Mark Egsmose and the following *ad-hoc* experts:

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John Jensen (NERI, DK)
Christine Kula (BVL, DE)
Jörg Römbke(ECT, DE)
Paolo Sousa (University of Coimbra, PR)
Willie Peijnenburg (RIVM, NL)

Other *ad-hoc* experts may be invited as needed.

1.9 References

Boesten J.J.T.I., H. Köpp, P.I. Adriaanse, T.C.M. Brock, V.E. Forbes, 2007. Conceptual model for improving the link between exposure and effects in the aquatic risk assessment of pesticides. Ecotoxicology and Environmental Safety 66: 291–308.

FOCUS (1997) Soil persistence models and EU registration. Report of the FOCUS Soil Modelling Workgroup. Available at FOCUS website http://viso.ei.jrc.it/focus.

Van der Linden A.M.A., J.J.T.I. Boesten, T.C.M. Brock, G.M.A. van Eekelen, F.M.W. de Jong, M. Leistra, M.H.M.M. Montforts and J.W. Pol., 2006. Persistence of plant protection products in soil; a proposal for risk assessment. RIVM report 601506008/2006. RIVM, Bilthoven, Netherlands.

Beulke S., I.G. Dubus, C.D. Brown and B. Gottesbüren, 2000. Simulation of pesticide persistence in the field on the basis of laboratory data – a review. Journal of Environmental Quality 29: 1371-1379.

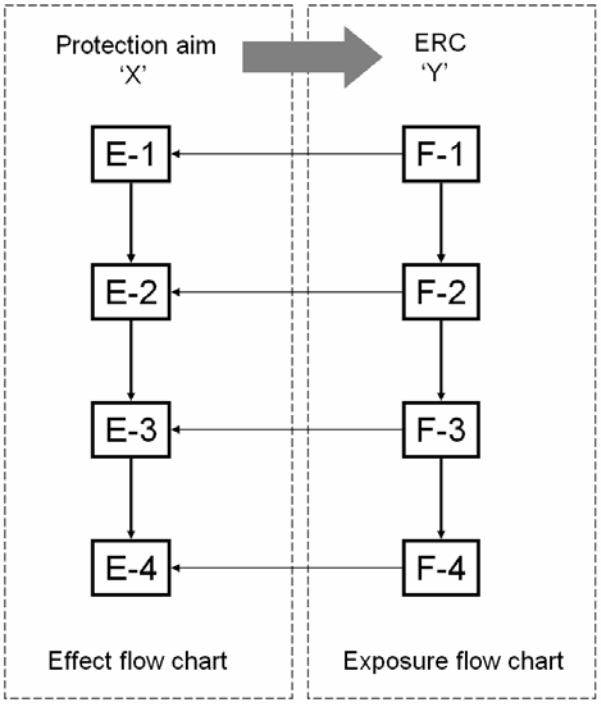

Figure 1. Tiered effect and exposure flow charts for a risk assessment addressing a protection aim 'X' which needs exposure estimates of an ecotoxicologically relevant concentration (ERC) 'Y' as indicated by the large arrow. The boxes E-1 to E-4 are four effect tiers and the boxes F-1 to F-4 are four tiers for assessment of exposure in the field ('F' from 'field'). Downward arrows indicate movement to a higher tier. Horizontal arrows from the exposure to the effect flow chart indicate delivery of field exposure estimates for comparison with effect concentrations in the effect flow chart.

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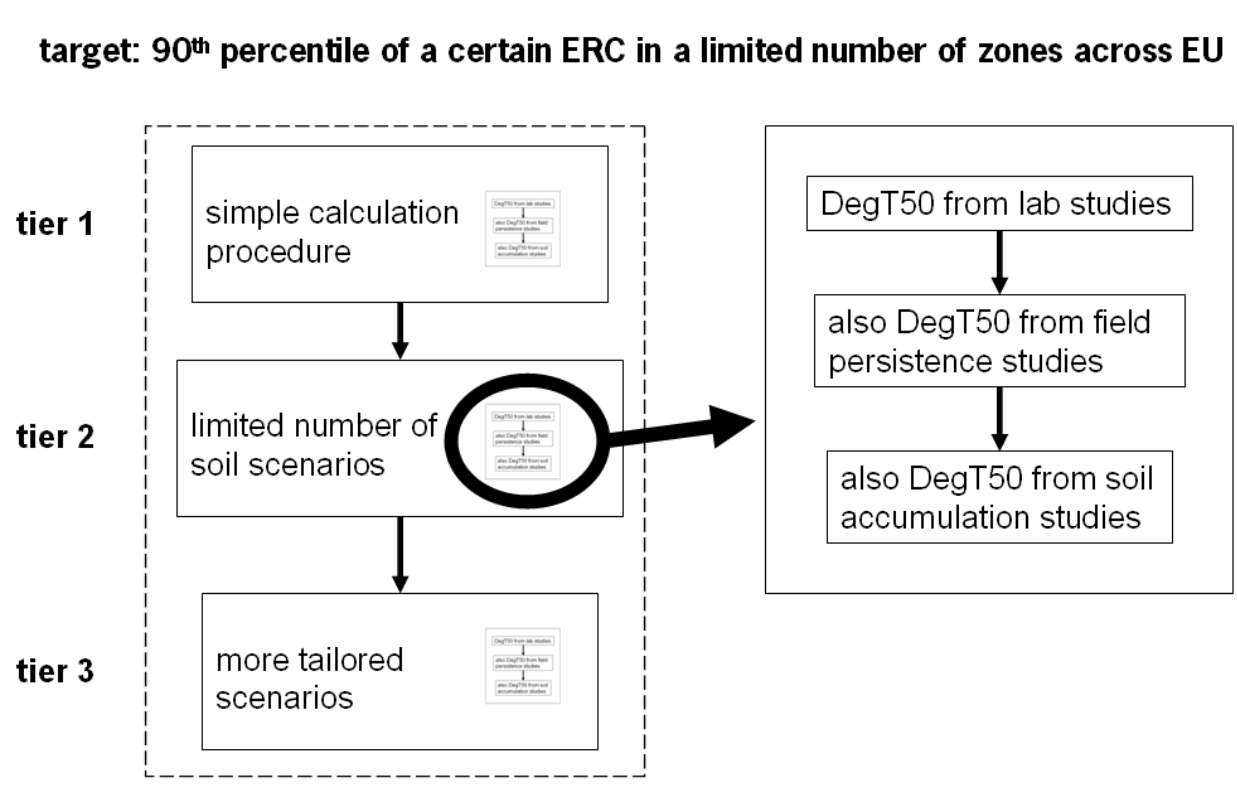

Figure 2. First draft of exposure flow chart for a certain Ecotoxicologically Relevant type of Concentration (ERC). "DegT50" is the time needed for 50% degradation in soil. . This draft applies both to the ERC 'total content in soil' and the ERC 'soil pore water concentration' but the calculation procedures and scenarios in the boxes for the three tiers will be different for these two types of ERC.