

REPORT OF EFSA

Public consultation on the draft project plan for the revision of the Guidance Document on Persistence in Soil

Prepared by the PPR Unit

(Question No EFSA-Q-2007-184)

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Contents

This compilation contains the comments received via the electronic form after the public consultation which closed at March 25th, 2008. This compilation contains the comments received for the draft project plan for the revision of the existing Guidance Document on Persistence in Soil. Comments received with respect to the existing Guidance Document are published in a separate table.

Duplicated comments received from the same contributor appear only once and comments submitted by individuals on personal capacity are published anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization.

A report on the outcome of the public consultation is published on the EFSA website:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681377888.htm

Disclaimer:

Comments submitted under the name of an organization appear with the name of the organization, but do not necessarily represent the official views of the organization.

Contributor	Section	Comment
Austrian Agency for Health and Food Safety	1.0 General comments to the document	<p>In respect to the existing FOCUS guidance documents on risk mitigation or on the risk assessment in the air, we want to emphasize that strong effort should be undertaken to make the revised guidance document as feasible as possible for the envisaged end-user (i.e. the risk evaluator). This might implement straightforward decision trees and clear guidance on calculation/modelling input parameters or higher tier approaches. A partition of the guidance document into a scientific background part and into an end-user part might be advisable.</p>
Ctgb	1.0 General comments to the document	<p>NL is pleased that the revision of the Guidance Document on Persistence in Soil in the area of Environmental Fate and Behaviour is starting in an energetic way.</p> <p>The comments given concerns the coordinated Dutch comments.</p> <p>In the Netherlands persistence has been a hot topic for a long time. Until recently, the Netherlands used a cut-off criterion, but the Netherlands Court of Appeal for Trade and Industry (CBb) ruled this to be in contravention of Directive 91/414/EEC. Because of this situation a working group has been working on a proposal for the risk assessment of persistence of plant protection products in soil [1]. This methodology is also evaluated based on data of five substances. A final draft of this evaluation report is available [2].</p> <p>Based on this evaluation process the working group is now finalising the proposal. A final Revised proposal for the risk assessment of persistence of plant protection products in soil will be available in April 2008 and will be send to the workgroup [3].</p> <p>References</p> <p>1 AMA van der Linden, JJTI Boesten, TCM Brock, GMA van Eekelen, MMS ter Horst, FMW de Jong, MHMM Montforts, JW Pol, Persistence of plant protection products in soil; a proposal for risk assessment, RIVM Report 601506008/2006. RIVM, Bilthoven, Netherlands, available at: http://www.rivm.nl/bibliotheek/rapporten/601506008.html</p> <p>2 AMA van der Linden, JJTI Boesten, TCM Brock, GMA van Eekelen, MMS ter Horst, FMW de Jong, MHMM Montforts, JW Pol, Evaluation of the 2006 proposal for risk assessment of persistence of plant protection products in soil, RIVM Report 601712002/2008. RIVM, Bilthoven, Netherlands</p> <p>3 AMA van der Linden, JJTI Boesten, TCM Brock, GMA van Eekelen, MMS ter Horst, FMW de Jong, MHMM Montforts, JW Pol, Revised proposal for the risk assessment of persistence of plant protection products in soil, RIVM Report 601712003/2008. RIVM, Bilthoven, Netherlands</p>

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Ctgb	1.0 General comments to the document	<p>It is recommended to combine the results of the different workgroups together in one new guidance document on persistence in soil.</p> <p>At the moment the unless clause in the Guidance Document on Persistence in Soil is dealt with in the Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/10329/2002 rev 2 final, 17 October 2002. This is undesirable because of the strong interaction between fate and ecotox.</p>
Danish Environmental Protection Agency	1.0 General comments to the document	<p>The Project Plan does not actually seem to aim at revising the existing Guidance Document but rather to develop soil exposure scenarios in general – therefore the title should be changed as the new guidance has nothing to do with persistence but rather with PEC soil values/scenarios in general.</p> <p>However we would recommend that also the existing document is updated in line with recent developments – e.g. revised data-requirements, FOCUS kinetics.</p>
Federal Environment Agency (German UBA)	1.0 General comments to the document	<p>We appreciate in general the work plan and extent of work the group considers. However, for PECsoil we see no urgent need to create complex scenario-based simulation models and to cause high workload for notifiers and authorities as for FOCUS GW & SW. We rather feel that easy to use calculation tools would be able to cover a stepwise tiered risk assessment approach. In any case the tiered approach must be consistent for each step and an interruption of the tiered approach like currently caused by FOCUS SW is not acceptable.</p> <p>Currently, simple calculation tools are capable of considering biphasic (non-SFO) degradation kinetics for PECsoil calculations even if multiple applications are involved (see FOCUS Deg. Kin. 2006, page 48, last sentence). However, models like PRZM, PEARL or PELMO rely on SFO kinetics only, so the peculiar situation might arise that higher-tiered modelling had to be based on surrogate degradation endpoints less certain than those used at the lower tier.</p> <p>The work plan should thus definitely encompass a deep and enduring review of the status quo of the existing risk assessment procedure at the beginning, including the current worst-case scenario, the handling of lab and field degradation, the temperature and soil moisture adjustment, the handling of bi-phasic kinetic models and, the relevance of the current scenario for the ecotox studies. The new guidance must be classified compared to the status quo. Need for revision should not alone reflect the wish of introducing new or improved scientific concepts in the assessment, but should primarily be driven by the regulatory needs, i.e. potential shortcomings of current guidance with respect to risk assessment for listing of active substances on Annex I. At the end, this guidance should create only the least possible calculation and simulation workload for notifiers and authorities. It must be easy to understand, simple to apply and helpful for the risk assessment.</p>

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Federal Environment Agency (German UBA)	1.0 General comments to the document	<p>In general, it is questionable whether there is a need for a guidance document on such a specific item like persistence in soil. To avoid inconsistency and to ease the use of GD for readers, a broader thematic approach should be used and this should also be reflected in the title of the project (in fact, the project plan already describes guidance on the calculation of residue concentrations in soil). Although it might thus even be discussed whether this could not also become a part of a revised GD on terrestrial ecotoxicology, we fear that this would be not feasible in practice due to time constraints and document-handling issues.</p> <p>If, nevertheless, it is felt that 'persistence' should be tackled in a separate document, it is not reasonable to restrict this to the soil compartment. A document on specific fate issues like persistence, bioaccumulation, long-range transport might be an idea to provide guidance for realising the intended cut-off criteria of the new regulation.</p>
Finnish Environment Institute	1.0 General comments to the document	<p>Bearing in mind the tight time limits for the risk assessment of PPP the revised guidance document should be kept very pragmatic and simple, however ensuring the high level of protection. Incorporating the latest scientific aspects should not lead to a very complicated and time consuming procedure like was the case with birds & mammals GD. In the authorities of several Member States there are diminishing resources for this work in future, and the work load must not grow too much.</p> <p>The PBT and POP properties are included as cut off criteria in the draft PPP regulation, and in our opinion it will simplify the process of risk assessment when the most persistent substances need not to be evaluated in detail. The impact of those cut off criteria should be discussed when preparing the new guidance document, in order to avoid the immediate revision of it following the new legislation.</p>
Pesticides Safety Directorate	1.0 General comments to the document	<p>It would be very useful for the Working Group to assess the likely impact of their proposals and scenarios on regulatory decision-making. This could be done in a similar way adopted by both the FOCUSgw and FOCUSsw groups, and comparing use of current methods with the proposed new methodology.</p>

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Pesticides Safety Directorate	1.0 General comments to the document	It would be very useful if the guidance document could propose selection criteria in relation to key 'trigger' values in the Directive, i.e. how many laboratory DT50 values must exceed 60 days to trigger field studies, how many field DT90s must exceed 365 days to trigger consideration of potential accumulation? In addition, there needs to be clear guidance on selection of input parameters for use with the proposed scenarios. For example, if greater than the required number of soils have been used to generate degradation/dissipation values, is it possible to use less than a worst-case value, and what should this be, e.g. 90th percentile? It would be useful to have guidance on the number of degradation/dissipation values required in relation to making regulatory decisions and selection of input parameters. The number of values required relates to how certain the assessor wishes to be, therefore there should be an assessment of the effects of increasing or decreasing the number of values on the outcome/precaution of the assessment. However, this should bear in mind the strictures from the current and revised Annex II and III data requirements.
Pesticides Safety Directorate	1.0 General comments to the document	As a general comment, we assume that the new guidance document will equally address issues relating to metabolites as well as active substances, i.e. that any modelling methods proposed/developed will be able simulate metabolites as well as active substances.
Pesticides Safety Directorate	1.0 General comments to the document	As a general comment, the overall level of protection afforded by the simple first tier calculation should be broadly the same or identical to the current 1st tier approach. Certainly the first tier approach selected should not result in an increase in the overall regulatory burden. For example, initial PEC _{soil} concentrations should be simply calculated over 5cm, with actual and TWA concentrations over time calculated on the basis of the longest acceptable DT50/90 values. The only exception to this is if the Working Group were to demonstrate that the current first tier approach is significantly over- or under-protective.
Pesticides Safety Directorate	1.0 General comments to the document	The Project Plan for the revision mentions the development of a range of scenarios representing realistic worst case conditions for climatic zones (as defined for FOCUS _{gw} scenarios) and in addition to include 'ecological considerations'. Will there be a consideration of how development of these scenarios will relate to the proposals for the zones proposed under revision of 91/414/EEC? Whilst not necessarily being within the remit of the group, COM must ensure that the scenarios are suitable for use in the zonal registration system. The development of a zonal registration system appears to be occurring in two directions - one for Annex I substance assessments under the auspices of the replacement PPP Regulation and another for product re-registration of substances already Annex I listed. Neither of these currently seem to be considering the biological, ecological, geophysical or climatic relevance of their proposed zones using higher level scientific scrutiny.

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Pesticides Safety Directorate	1.0 General comments to the document	<p>The new guidance document needs to be drawn up taking into account the likely provisions of the replacement Pesticides Regulation as well as 91/414/EEC. However, it is recognised that aspects of the new regulation which are relevant to soil protection have yet to be clearly established, e.g. protection goals and Annex VI Uniform Principles. There could be potential changes from 91/414/EEC which it would be useful to incorporate if known before this document is finalised. The revised Annexes II & III have already established some different data requirements leading more towards structural than functional protection goals. Is it envisaged by EFSA/COM that the development of the document itself could influence the direction of travel of the overall soil protection strategy?</p> <p>Given the likely integration of other pieces of legislation/frameworks/conventions into the new PPP Regulation, it would be useful to consider them (and their protection goals) at an early stage (e.g. Water Framework Directive, POPs Convention, EU Thematic Strategy for Soil Protection inc. proposals for a Soil Framework Directive). Does the workgroup propose to consider adopting the Dutch soil protection goals (footnote3) - these would need to be carefully examined by all EU MS as they may set new goals not reflected by existing or planned EU legislation. As a general point, we consider that selection of protection goals should be the responsibility of MS and COM rather than EFSA or a Working Group, and ideally before any final decision is taken on exposure calculation scenarios presented by the Working Group.</p>
Pesticides Safety Directorate	1.0 General comments to the document	We thank EFSA for the opportunity to comment at an early stage on the work plan for the new persistence guidance document. We appreciate the fact that the output of the work group will be focussed on output of practical regulatory decision-making tools, and not simply a summary of scientific knowledge in this area.
SCC	1.0 General comments to the document	<p>The current approach for PECsoil calculation is a straightforward and easily traceable solution for providing a rough estimate of the relevant concentration. Any more ambitious approach will inevitably cause additional costs and efforts.</p> <p>The initial concentration in soil (relating to 5 cm depth as worst case for risk assessment purposes) may be expected to be within the same range of magnitude in all soils even in case of multiple applications. Therefore, it seems adequate to keep the current approach at least as a first Tier solution.</p>
Swedish Chemicals Agency	1.0 General comments to the document	As the Guidance Document on Persistence in soil (9188/VI/ rev. 8, 12.07.2000) in our view has become obsolete, we welcome the initiative for a new guidance document.

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BASF SE	1.1 Introduction	[42-43] The update does not intend to replace guidance given e.g. in FOCUS kinetics. However apart from actions of the FOCUS kinetics or version control group it may be useful to hint to inconsistencies in the FOCUS kinetics document. Discussions in EU PRAPER expert meetings (as e.g. documented in the EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin) and model development on national level e.g. in Germany (ESCAPE , Estimation of Soil Concentrations After Pesticide Applications) in which the use of different kinetic models for calculation of PEC in soil are proposed demonstrate an urgent interest in this topic. It s proposed to discuss the suitability and the use of different kinetic models for calculation of PEC in soil in the revision of the GD on persistence.
Danish Environmental Protection Agency	1.1 Introduction	L 38-43: See general comment – we urge that the existing guidance doc. should be updated to reflect changes in data requirements and Developments in the FOCUS guidance documents – in particular the kinetics guidance document – and that the implications of this guidance with regard to derivation of relevant PEC values should be summarised. In addition we recommend that an initial worst case screening step should be introduced – if this step is passed it may not be necessary to performed further calculations for the majority of substances as the risk assessment for the soil compartment in many cases do not indicate any risks.
Swedish Chemicals Agency	1.1 Introduction	line 35-36: We question the need for development of specific point scenarios for soil. We therefore abstain at this stage to provide detailed comments on the suggested approach.
Swedish Chemicals Agency	1.1 Introduction	line 41-42: We agree not to include guidance for PBT classification, since any such guidance needs to be harmonised with other areas of chemicals assessment (e.g. under REACH legislation).
Swedish Chemicals Agency	1.1 Introduction	line 42-43: We also agree not to repeat guidance which is given elsewhere. We identified in the old guidance document (9188/VI/ rev. 8, 12.07.2000) only a couple of robust recommendations which needs to be addressed in the new guidance document because they are not given elsewhere (see our comments to the old guidance document).
BASF SE	1.2. Aim	[79-80] What is meant with "So if necessary, the assessment procedure will separately account for the spatial variability within such an individual fields" The project plan needs to be more explicit at this point on what the background for this statement is and what the working group is intended to deliver.

Contributor	Section	Comment
Ctgb	1.2. Aim	The proposal of the 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) is in line with NL expectations with regard to develop a limited number of scenarios that each represents a spatial 90th percentile PECSOIL for a certain zone.
Danish Environmental Protection Agency	1.2. Aim	L. 53-59: The aims stated do not in reality refer to the existing guidance document but rather to development of new PEC scenarios. The existing G.D. should also be updated as mentioned above.
Danish Environmental Protection Agency	1.2. Aim	L. 64: We support the proposed link between fate and ecotox, but would recommend not to invent new acronyms – such as ERC’s – in reality it will be substance specific what is ecotoxicologically relevant. We would prefer to stick to using the term PEC – one might add “relevant” PECs.
Danish Environmental Protection Agency	1.2. Aim	L. 78: It is improbable that the scenarios will be able to provide “correct estimate” – please avoid such terms.
Enviresearch	1.2. Aim	<p>It is good to check this guideline, but I would not like to see the soil guideline become unduly complex. I am hoping that the tier-1 advice does not change greatly from the existing situation, because it is extremely clear, simple and robust. The main clarifications that I would like to see to the existing guideline are:</p> <ul style="list-style-type: none"> > concerning the mixing depth under tillage (especially for more persistent compounds) > PEC from treated seed/tubers/bulbs etc., including some guidance on rates of transfer from the treated plant part to the soil. <p>The main pitfalls that I hope you can avoid at the tier-2 level are:</p> <ul style="list-style-type: none"> > lack of clarity about which scenarios are important > needing to perform and report lots of calculations, when only a single calculation drives the risk assessment <p>Good luck and thank you.</p>

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Federal Environment Agency (German UBA)	1.2. Aim	<p>general and line 127ff</p> <p>The scenario approach is in principle appreciated, but...</p> <ul style="list-style-type: none"> - Spatial resolution of scenarios as well differentiation on parameter level should fit the current EU (not MS!) regulatory framework. - Instead of attempting total coverage over the whole of Europe, no more than 2-3 scenarios should be created for immediate use on EU level. Rather, criteria or even a worked-out guideline for creating scenarios should be provided, enabling single MS or regional groups of MS to develop their own tailor-made scenarios as they want and need them. - Model output should not consist in huge tables of all imaginable PECs, but should be restricted to those needed for a basic risk assessment. It should be possible to calculate further PECs on request (i.e. models should have that capability). In that respect, the intended closer cooperation with ecotox colleagues is appreciated.
Federal Environment Agency (German UBA)	1.2. Aim	<p>line 68ff</p> <p>The intention to provide a better definition of the "realistic worst case" is highly appreciated. As for now, the worst case is typically defined as "the highest DT50 figure" without clear criteria for analysing the conditions under which the numbers were achieved and without analysing the intended use of that data. This is not satisfactory. However, the idea that "the assessment procedure will separately account for the spatial variability within such an individual field" seems to be out of scale with regard to the current understanding of the protection goal and the possibilities for regulation. How should such information be used in decision-making? It would only be meaningful if the risk assessment was targeted at individuals rather than at a population inhabiting the soil of an agricultural field.</p>
Federal Environment Agency (German UBA)	1.2. Aim	<p>line 68ff</p> <p>The ecological considerations referred to in this paragraph have no counterpart in the legal background of 91/414/EEC. It is currently attempted to establish such type of considerations in the aquatic risk assessment, but as a part of higher-tiered assessments and based on the much better knowledge on the compositions of aquatic biocenoses and sensitivities of different taxa to pesticides than currently available for the soil compartment. With the limited information on species sensitivities available, we see the danger that the concept of representativeness in terms of sensitivity of few tested species for the whole (untested) biocenosis could be undermined. Hence, introduction of such a concept at the time being is considered premature. In particular, it is deemed rather inappropriate to introduce concepts of such scope via a GD on persistence in soil and not in connection with a revision of the GD on terrestrial ecotoxicology.</p>

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Federal Environment Agency (German UBA)	1.2. Aim	<p>line 58f</p> <p>It is noted that accumulation in soil is only sparsely referred to in the document and only as one of the issues of higher-tier assessment. However, in regulatory practice, accumulation in soil constitutes one of the major concerns with persistent compounds. There is, consequently, an urgent need for guidance on assessing accumulation in soil already at the lower tier. In particular, the following aspects should be addressed.</p> <ul style="list-style-type: none"> - What is the state-of-the-art for conducting and assessing field accumulation studies? - How should "simple" modelling, "complex" modelling and field studies fit into a tiered approach? - The current paradigm for PECsoil and PECsoil,accu calculation is to use field degradation data without temperature- and moisture-normalisation. However, when plateau values calculated on that basis must be compared to results from models including climate data or from field trials, meaningful results cannot be expected. Any solution for that problem requires better guidance on hierarchies in a tiered system and on estimating the degree of worst-case of a certain assessment. - Currently, the worst-case character of PECsoil,accu estimates increases with the number of years required to reach a plateau (repeated consideration of parameters already reflecting a worst case for single-year application). Is this warranted by a higher uncertainty of degradation parameters associated with more persistent compounds? Or should the calculation methods be amended (e.g., similar to consideration of multiple spray drift events) to achieve a certain degree of worst-case character independent of the number of years required for reaching a plateau?
Finnish Environment Institute	1.2. Aim	<p>In principle the development of several scenarios taking into account the climatic conditions is agreed. However, the procedure should be kept very simple and pragmatic and not too much time consuming. It should be kept in mind that the time limits for the risk assessment are very tight and there are also other parts which need work. The 90th percentile approach for PECsoil values is agreed.</p>
INIA	1.2. Aim	<p>1.- We acknowledge the inclusion of the working hypothesis that develops tiered approaches for terrestrial risk assessment, using total content of pesticides and pore water concentration, and keeping flexibility for different time windows. This approach indicates a step forward with respect to the old approach. Nevertheless, we would appreciate the inclusion of a methodology for the terrestrial risk assessment of those substances which main route of dissipation is the soil air phase (fumigants) and for the application of pesticides in the drip irrigation system.</p>

Contributor	Section	Comment
INIA	1.2. Aim	<p>2.- The project plan refers to the approach followed by FOCUS GW to develop leaching scenarios. However, it is not clear from FOCUS (2000) and Doc. 4952/VI/95 how the environmental stations were selected in order to cover 90th percentile PEC. Under our understanding, and taking into account that the new regulation establishes a zonal evaluation process throughout Europe, the resulting scenarios should show, as much as possible, the spatial and seasonal variability of climatic , agronomic and soil ecological characteristics among and within the different big European zones (Nordic, Temperate, maritime Continental and Mediterranean).</p> <p>Therefore, the selection of variables for the identification of the scenarios should avoid as much as possible any type of subjectivity based on qualitative criteria selected under expert judgement (e.g why max 10 scenarios?). Nowadays, there are scientific tools that can be used for the selection of climatic scenarios. For example, principal component analysis (CPA) is extensively used to characterise the variability of different meteorological variables (J. Clim 12: 2894-2919) . This methodology has been already used in the European project FOOTPRINT to identify different environmental scenarios for pesticide fate modelling (Environ. Pollut., 2007). In this case 16 climatic scenarios were identified. They may be used as a start point for a critical analysis. For example, FOOTPRINT project identified 3 scenarios for the Mediterranean Region. On the other hand, Mazzoleni et al 1992 analysed 444 weather-recording stations in the Mediterranean basin by cluster analysis and PCA and identified 8 main Mediterranean climatic types (Vegetatio 98: 1-12).</p>
Pesticides Safety Directorate	1.2. Aim	<p>In lines 79 and 80 there is reference to the assessment procedure accounting for the spatial variability within individual fields. Whilst we recognise that such spatial variability exists we feel it may be beyond the scope of the existing data requirements to fully understand the significance of this appropriately for all substances (current and future data requirements under 91/414 are likely to require no more than 4 different soil types to assess degradation rates as a minimum). It should also be noted that neither the current soil, ground- or surface water exposure assessments take explicit account of such spatial variability. The level of protection afforded by the soil scenarios should be consistent with other areas of the current risk/exposure assessment.</p>

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Pesticides Safety Directorate	1.2. Aim	<p>It is noted in lines 72 of the proposed plan that the work group propose to develop scenarios that each represent a "spatial 90th percentile PECsoil for a certain zone" - it is unclear what is meant by a spatial percentile - therefore this should be clearly defined. This definition must include transparent presentation of the parameters included and description of calculations used to determine 'worst-caseness'. As an example, will consideration of the 90th percentile only include pedo-climatic parameters, or will agronomic and ecotoxicological parameters also be included?</p> <p>An additional point relating to this is that choice of substance input parameters will also influence the level of protection offered by scenarios. As an example, the protectiveness of the FOCUS ground- and surface water scenarios is considered to be encompassed by the scenarios themselves, such that mean/median substance input parameters are recommended. Current practice for PECsoil calculations is to use the realistic worst case from either laboratory or field studies. Therefore, the workgroup should make clear recommendations on choice of substance input parameters. It should also be noted that the selection of a specific percentile determines the level of protection that the risk assessment scenario will provide. The choice of a specific percentile is a risk management one, and therefore, it is proposed that the final choice of percentile should be left to MS and the Commission to decide. It would, however be useful to know what the consequences in terms of level of protection and pass/fail rates for pesticides of a range of percentiles would be.</p> <p>In addition, it would be useful if some consideration could be given as to how the scenarios relate to individual MS. Whilst it is appreciated that the main driver behind this project is in relation to Annex I listing, it would be very useful if consideration of MS and zonal applicability were included.</p>
Pesticides Safety Directorate	1.2. Aim	<p>As a supplementary comment on the development of scenarios, the approach being taken appears to be quite complex. Whilst we wish to ensure that PECsoil approaches are ecologically relevant and protective, we question whether quite complex approaches using, for example leaching models, are really required, or whether more simplistic spreadsheet approaches could suffice.</p>
SCC	1.2. Aim	<p>line 76 et sqq There may be statistical problems involved due to a combination of scales if the scenarios are intended to both represent the 90th percentile value of a certain region and account for in-field variability at the same time.</p>
Swedish Chemicals Agency	1.2. Aim	<p>line 55-56: We question the suggested development of a range of soil point scenarios. Is there really a need for this at the EU level? We do not put in question a discussion of ecological considerations.</p>

Contributor	Section	Comment
Swedish Chemicals Agency	1.2. Aim	line 58-59: We support the second aim to define the role of different results in the risk assessment.
Swedish Chemicals Agency	1.2. Aim	line 82-83: We would like to suggest to include as another aim to provide a bit more guidance on the calculation of long-term/plateau PECs. For instance, the FOCUS Degradation kinetics report (Sanco/10058/2005, ver. 2, June 2006) did not address the problem of what DT50 to use for long-term/plateau PECs in case field DT50s were calculated by different kinetic models (e.g., some values by SFO, others by FOMC). A related question which has been discussed at PRAPeR meetings is how to handle the remaining concentration in soil from previous year in plateau calculations based on FOMC kinetics (it has been argued that simply adding it to the new concentration applied means moving the remaining concentration from a slowly degrading compartment to a fast degrading compartment). We would also welcome a discussion on how large a data-base would need to be not to use the worst-case endpoint for PEC calculation, but instead some defined percentile.
BASF SE	1.3. Proposed methodology	[171-172] "No-till" agriculture may result in higher exposure concentrations for such (persistent and strongly sorbing) pesticides. Is not explained well enough why and for which circumstances this should be the case. With respect to long term exposure assessment (longer than the cropping period) a ploughing would lead to a distribution of residues in the plough layer and a dilution of concentrations by mixing the residues in greater volumes of soil. This statement is however only valid if the "no tillage" practice would not alter biological activity compared to a ploughed soil- and hence the potential for biological degradation. However evidence exists that the biological activity in the top soil 5 cm especially of no till soil is higher compared to ploughed soils. If it is attempted to consider the effect of the different courses of the organic matter content in the top 20 cm of the soils the different biological activity should not be neglected.
BASF SE	1.3. Proposed methodology	[178-181] Test of the guidance. Experience show that it is strongly to be supported that the guidance is tested and reviewed before it is implemented. A significant number of terrestrial field dissipation and field soil accumulation studies should be used for validation.

Contributor	Section	Comment
BASF SE	1.3. Proposed methodology	[92-97] Composition of soil organism communities will vary between different regions. However, soil organism communities are adapted to local environmental conditions and there is no indication for different sensitivities of these communities. This statement is supported by recent investigations on composition of macroinvertebrate communities in different biogeographical regions in Europe (Finland, France and Germany) [Schäfer, R.B.; Caquet, T.; Siimes, K.; Mueller, R.; Lagadic, L.; Liess, M. (2007), The Science of the total environment, 382 (2-3), p.272-285]. The community composition of aquatic species that are at risk of being affected by pesticides (SPEAR, criteria: physiological sensitivity towards organic pollutants and migration potential) was similar across European regions for sites that were unimpacted by agricultural activities. There is no reason to assume that the situation for soil organisms should be different.
BASF SE	1.3. Proposed methodology	[113] "soil pore water may be a better indicator for effects" ?, It should be no fundamental problem to calculate soil pore water concentrations with FOCUSgw Models like PELMO, PRZM, PEARL or with HYDRUS. However van der Linden et al. (2008) [van der Linden et al. (2008): Revised proposal for the risk assessment of persistence of plant protection products in soil. Draft version of January 2008. RIVM Report 601712003/2008] found no improvement of risk assessment when using "soil pore water concentrations" as environmental relevant concentration compared to "total concentrations". Therefore convincing evidence needs to be provided to demonstrate that risk assessment will significantly be improved by including the soil pore water as environmental relevant concentration. Including soil pore water in risk assessment would require a re-evaluation of the ecotoxicological studies, which is according to chpt. 1.4 Restrictions of the project outside the remit of this study.
BASF SE	1.3. Proposed methodology	[137-140] Point of clarification: What is specifically meant with "burden of proof that the DegT50 values from field experiments are valid..." The reasoning of this last sentence is hard to understand. Following the tiered approaches eg . FOCUS groundwater (see figure 2 [line 384] field studies are seen as being more realistic to laboratory studies. Why should there be an extra effort to demonstrate that degradation in the field is degradation in the field?

Contributor	Section	Comment
BASF SE	1.3. Proposed methodology	<p>[170-176] "No-Till" practice shall not be confounded with reduced tillage (chisselling ~25cm). Valuable data for the extent of tillage practices in the EU is available from: ECAF (European Conservation Agriculture Federation) (survey ~ 2000-2003) Main site: http://www.ecaf.org/ Data: http://www.ecaf.org/Situation.htm</p> <p>Kassa-Project on Sustainable Agriculture (EU & CIRAD) (paper in 2007) (funded by EU COM under 6th framework) Lahmar R., Arrue J.L., Denardin J.E., Gupta R.K., Ribeiro M.S.F and de Tourdonnet S., 2007. Knowledge assessment and sharing on sustainable agriculture. CD-Rom, CIRAD, Montpellier, ISBN 978-2-87614-646-4 Main site: http://kassa.cirad.fr/ Data: http://kassa.cirad.fr/results/kassa_cd_rom</p>
Ctgb	1.3. Proposed methodology	<p>In the Project Plan on page 4 it is stated: '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)'</p>
Ctgb	1.3. Proposed methodology	<p>In rev 7.0 of the revised Annex III paragraph 9.4 Estimation of concentrations in soil the following is mentioned: 'For the purposes of lower-tier PECS calculations, the bulk density of soils can be assumed to be 1.5 g/cm³ dry weight, while the depth of the soil layer is assumed to be 5 cm for applications at the soil surface or application methods that do not cultivate the soil to achieve even incorporation following application (for example most shallow drilled seed treatments), and 20 cm when incorporation using mechanical cultivation following application is involved.'</p> <p>It is advised to keep the depth of 20 cm in mind. Also in light of the option of tillage and this depth in practice.</p>

Contributor	Section	Comment
Ctgb	1.3. Proposed methodology	<p>In the Project Plan on page 5 it is stated: '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.</p> <p>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.'</p> <p>No update of software packages is foreseen in this project plan but it is advised to harmonise the number of models and the principles behind them as much as possible.</p>
Danish Environmental Protection Agency	1.3. Proposed methodology	<p>L. 109: It is highly unlikely that "final proof" of meeting the protection goals can be derived. Furthermore the protection goals are not very clear – in fact there is a need to discuss and define the relevant protection goals for the soil compartment risk assessment as recommended during the discussion concerning the revision of the ecotox. data requirements (Annex II and III).</p>
Danish Environmental Protection Agency	1.3. Proposed methodology	<p>L 120-121: This is a good example of the need to link fate and ecotox as the proposed values are probably not the ecotoxicologically relevant ones. The use of TWAs have long been debated in ecotox assessment – and are hardly ever used – and in particular not for soil assessments because the ecotox studies are based on 1 initial dosing. Therefore the majority of soil assessment are based on initial (peak) PEC values – and all the time points given are never used.</p> <p>As mentioned before we recommend that an initial worst case screening step should be introduced – if this step is passed it may not be necessary to performed further calculations for the majority of substances as the risk assessment for the soil compartment in many cases do not indicate any risks.</p>
ECPA	1.3. Proposed methodology	<p>Line 170ff: The project proposal considers no-tillage (also called zero tillage) and tillage (also called conventional tillage) as soil management measures. In addition to these, minimum tillage (also called conservation tillage) should be added as an option for evaluating exposure concentrations for persistent and strongly sorbing pesticides.</p>

Contributor	Section	Comment
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 156ff</p> <p>It is appreciated that existing methodology and tools should be used. We agree that models like PRZM, PELMO or PEARL may be used for assessing residue dynamics in the top soil layer when guidance is made available how they should be parametrised. It is obvious that this different parametrisation as compared to GW assessments should primarily relate to the solute downward transport. But the proposed use of at least two models per scenario seems to reflect primarily the will to remain consistent to an earlier PPR opinion on use of models in GW assessment. As the different predictions of GW entries by the models were mostly attributed to vertical solute transport phenomena, is there a stringent reason why this should also hold for parametrisations with reduced solute downward transport?</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 143ff</p> <p>As discussed before, the primary goal of the EU assessment of active substances is not so much to produce highly differentiated exposure estimates for direct use in authorisation procedures, but rather to point out to MS where particular attention is required when deciding on national authorisations.</p> <p>We agree to a harmonisation of concepts, but we do not support the idea that the complete diversity of European agricultural soils must already be considered in the EU active substance assessment. Experience has shown that MS have now started developing their own FOCUS_{sw} scenarios, because the existing EU scenarios did not sufficiently cover their needs; so this attempt of covering all of Europe has already to some extent failed. To avoid unnecessary multiplication of work by calculating high numbers of PEC values with limited relevance for national authorisations, few worst-case scenarios are deemed sufficient on EU level. General criteria for building scenarios should be developed and documented to ensure methodological congruency of MS assessments on the national level.</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 140ff</p> <p>Since MS have the burden of assessing the arguments brought forward by notifiers that the DegT50 values from field experiments are valid for use in Risk Assessment, we expect that clear acceptability criteria will be defined and documented in the final GD.</p>

Contributor	Section	Comment
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>Line 136</p> <p>ii) including also values from field studies</p> <p>In this connection it should be mentioned that there is no OECD guideline for field studies. Such a guideline would be helpful for a consistent validation. Because of the absence of such guideline the revised guidance document should give guidance for evaluation and the use of field studies within the risk assessment.</p> <p>Furthermore the following question should be considered: Could a field DT50 determined e.g. in a 10 cm soil layer directly be used for calculating a PEC in a 1 cm soil layer?</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 127ff</p> <p>The proposed three tiers are deemed too many. Experience with FOCUS_{sw} has shown that Step 1 and 2 PEC_{sw} are useless for most active substances, except for very few low-toxic compounds and most metabolites. Factually, Step 3 has become the first tier for most active substances and Step 4 is required in many cases to demonstrate an acceptable risk. As a consequence, large amounts of PEC values are calculated in current practice for formal reasons without actually achieving a comprehensive and transparent description of exposure and risk. The first tier in a final GD should thus be an option for notifiers to demonstrate a safe use of their compound using a conservative generic (not scenario-based) approach. Options like crop rotation that are well known from GW assessment could be implemented already at Tier 2. Tier 3 should be left for very compound-specific refinements that have to be decided on a case-by-case level anyway. It would be highly appreciated if the final GD included an overview over possible refinement options and their respective acceptability criteria.</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 124ff</p> <p>Please focus on the immediate needs of regulators rather than trying to “cover all foreseeable potential future needs”. While it may in principle be worthwhile developing approaches for assessing the long-term fate of contaminants several years after the last contamination event, this is an issue for national soil conservation policies rather than for pesticide risk assessments under Directive 91/414/EEC.</p>

Contributor	Section	Comment
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 120f</p> <p>It has repeatedly been clarified, e.g. in the GD on terrestrial ecotoxicology, that the ecotoxicological risk assessment for soil organisms does not make use of twa concentrations. This is a direct consequence of the limitations of effect testing in soil: no flow-through systems are possible and effects are only observed at test termination. There is only one area of ecotoxicological assessment (exposure of vermivorous birds or mammals to lipophilic compounds due to accumulation in the food chain) where a twa concentration may become necessary. Please note that the appropriate length of that twa period is currently under discussion. We do wonder why the idea of providing twa PECsoil for several standard time intervals by default still remains so persistent.</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 118ff</p> <p>Modern land management methods are reducing the tillage depth to ensure sustainable soil cultivation. A tillage depth of 30 cm seems to be outdated according to current good agricultural practice. If considering accumulation for PECsoil, a soil layer of maximum 20 cm should be considered when calculating the background concentration.</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 118ff</p> <p>If complex simulation models are used, it does not seem appropriate to average concentrations within soil layers. It seems more reasonable to present a concentration at a specific soil depth like it is been done in FOCUS GW modelling for the 1 meter depth.</p>
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 112ff</p> <p>The question of pore water concentrations vs. bulk soil concentrations is basically a question regarding the role of bioavailability and should be discussed as such. But the scope and potential implications of such a discussion would go, in our opinion, beyond the remit of a work group for designing a GD on persistence in soil in the context of pesticide risk assessment.</p>

Contributor	Section	Comment
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 112ff It is postulated that “soil pore water may be a better measure for effects” to soil organisms than current PECsoil values. Before such an hypothesis is used as a justification for introducing a new concept for the risk assessment for soil, two conditions have to be met.</p> <ul style="list-style-type: none"> - It must be clearly shown that the current approach is insufficient in terms of predicted risk. - It must be clearly shown that the new approach significantly improves prediction of risk. <p>Just going for an approach because it is scientifically "nicer" would not constitute an improvement. Even less, if a new approach is connected to much increased regulatory workload.</p> <p>In our opinion, basing a risk assessment on pore water concentrations instead of bulk soil concentrations has two major disadvantages.</p> <ul style="list-style-type: none"> - It is unclear how this would be compatible to existing protocols for effect testing and what implications had to be expected on the use of existing effect data. This is even more critical considering the statement that the group does not intend providing methods for calculating exposure in test systems. - The general term “pore water” would include interstitial water in macro- and mesopores as well as the surface-adsorbed water in micropores. Analytical verification of predicted concentrations is thus complicated, since different methods must be applied to determine amounts in the different types of pore water.
Federal Environment Agency (German UBA)	1.3. Proposed methodology	<p>line 112ff The assumption that pesticide concentrations would be spread evenly over a 5 cm soil after application regardless of the properties of the compound is of course not scientifically correct. In reality, a dynamic process is to be expected, with a thin layer of the pesticide on the soil surface immediately after application and subsequent gradual translocation (by diffusion and solute transport) into the soil core. Thus, the target of the work cannot be to define a scientifically “true” value, but a simplified model description of the real situation in a regulatory meaningful manner. That is, calculation of risk descriptors using the PECsoil and available effect data must produce meaningful results in terms of actual risk. Just replacing one 5-cm PECsoil by a set of up to 120 (10 scenarios, 3 depths, soil and pore water, tillage and no-tillage) would do no more than multiply the amount of calculated figures without really improving the prediction of risk.</p> <p>It is thus strongly recommended that the currently used scenario with its implicit assumptions on soil density, soil depth etc. is analysed regarding its level of protection/conservatism, before proposals are made for the setting of parameters in a multi-scenario approach. One way of doing this could be an analysis of earthworm field study results vs. the predicted risk according to the current standard scenario.</p>

Contributor	Section	Comment
Finnish Environment Institute	1.3. Proposed methodology	In our experience the assumption of crop interception of a significant proportion of sprayed PPP leads in some cases to underestimation of the long term PECsoil, when the vegetation with pesticide residues is incorporated into the soil after the growth season. We have field experiment data with fluazinam on potato, where the calculated PECsoil is lower than the actually measured concentrations in fields with consecutive potato cultivation in several years.
Finnish Environment Institute	1.3. Proposed methodology	The different application methods of PPP needs also to be considered when developing the scenarios. For example in GW scenarios certain application methods are not fully considered, e.g. seed dressing, soil drench applications other spotwise applications, where the PPP is not evenly distributed into the soil.
INIA	1.3. Proposed methodology	1. Traditionally, the total pesticide content in the top 5 cm of soil has been used. It is proposed to explore pesticide content in the top 1 cm and 30 cm. This is a novel idea, and with a more realistic point of view. The reasoning behind this proposal needs to be addressed, and a correlation with the current ecotoxicological package should be considered. From the point of view of soil communities (meso- and macrofauna) the 30 cm value seems to be more relevant. Indeed, we find very interesting to include the ploughing effect on exposure concentration for pesticides. The popularization of no-tillage practices as a tool to minimize soil disturbance in integrated systems suggests, as the panel proposes, the adoption of two different scenarios (tillage and no-tillage) in tier 2 assays.
INIA	1.3. Proposed methodology	2. The working hypothesis should address exposure as expressed in terms of total content in soil or as pore water concentration. Specifications about ecological relevance of these measures will be needed. Thus, the concentration on the pore water or the total (bio)-available content in soil should be different. How to choose the more appropriate value? Proposals and uncertainties associated are needed.
INIA	1.3. Proposed methodology	3. It is proposed to explore the inclusion of TWA at 7, 14, 28, 56, 180 and 365 d. However, a time window of 365d may be insufficient for very persistent compounds in many cases. It is possible that more time windows is necessary for addressing this situation (e.g. plateau after 10 years). The proposal for the other time windows seems to be correlated with toxicity endpoints (duration of exposure) from the current ecotoxicological package.

Contributor	Section	Comment
INIA	1.3. Proposed methodology	<p>4. A tiered approach is proposed for PECsoil calculation for each ERC. Within all tiers it is proposed that the DegT50 for top soil at 20 °C and FC can be based on a tiered approach combining lab and field DT50 (dissipation and accumulation) normalised at 20 °C and pF 2.0 as input parameters in the models. It should be taken into account that:</p> <p>a) directive 95/36/EC, considers accumulation studies as a higher tier. It is clearly stated that they should be carried out when no reliable information can be provided by a model.</p> <p>b) FOCUS Degradation Kinetics guidance document proposes different simple PECsoil models are proposed for no SFO kinetics, which should be considered in the tiered approach.</p>
INIA	1.3. Proposed methodology	<p>The proposal to investigate the difference in soil communities over Europe is very interesting, and we hope that can be accomplished with the current databases.</p> <p>It is proposed to choose collembolan and the earthworms as representatives of two guilds covering important soil services and relevant part of soil biodiversity. However, there are references in the literature indicating that earthworms in Mediterranean agricultural areas (especially in arid and semiarid regions) are very scarce. Indeed, most of the species present are endogeic. This type of earthworm lives and feeds below ground, when it is somewhat protected from chemical and physical disturbances. Therefore, the inclusion of another representative group of soil organisms for some ecoregions needs to be explored.</p> <p>The Scientific Panel on Plant Protection Products and their Residues, on the answer to an EFSA question regarding soil ecotoxicology (EFSA-Q-2006-170), considers that the evaluation of the effects of PPP on soil organisms (other than earthworms) should include functional and structural endpoints relating to bacteria, fungi, protozoans and nematodes. Since earthworms, as it was already mentioned, are very scarce in arid and semiarid agricultural systems, nematodes, that present high abundances and high functional and taxonomical diversity, may be a promising alternative. A large database of the occurrence of soil nematodes in agrosystems is available (see review Mulder et al. 2005). Nematodes are essential for soil ecosystem functioning, they have been extensively used for assessing soil quality, and structural and functional indicators are available (such as Maturity or Soil Food Web indices).</p>
Pesticides Safety Directorate	1.3. Proposed methodology	<p>Line 125 and footnote. We note there is a suggestion to allow the calculation of exposure time points to be kept flexible, even up to 7 years after the final application. It is not clear if there is sufficient justification for calculating PECsoil values well in excess of the current requirements of the directive (i.e. peak accumulated PECsoil values and up to 100d actual and TWA concentrations). The reliability of any exposure predictions up to 7 years after the final application would be highly uncertain based on, for example, standard laboratory studies conducted for a maximum of 4 months.</p>

Contributor	Section	Comment
Pesticides Safety Directorate	1.3. Proposed methodology	Lines 127-141 concentrate on degradation parameters. The work group are aware that soil mobility may also be an important consideration in the assessment conducted. Whilst we acknowledge that leaching can be an important dissipation process, criticism has been directed at use of standard FOCUSgw scenarios for calculation of PECsoil in that leaching could be an overly significant contributor to decline of residues on such vulnerable soils. Thus scenario development should ideally focus on soils less vulnerable to leaching whilst still being ecologically appropriate.
Pesticides Safety Directorate	1.3. Proposed methodology	Line 134 makes reference to the degT50 being used as an input to the models. Line 159 lists a number of potential models that are essentially the current groundwater simulation models. If relatively detailed scenarios are going to be developed that will allow potentially more realistic predictions of long term PECsoil values, we feel the models must be able to take into account non first order or bi-phasic degradation kinetics if they are not to represent a gross over simplification of long term degradation behaviour. It should be noted that current first approaches are able to handle bi-phasic kinetics and it would be unfortunate if the higher tier approaches were not effectively at the same level of sophistication.
Pesticides Safety Directorate	1.3. Proposed methodology	Line 173: we feel the no-tillage option should be clearly defined as the first tier default position to ensure the models are appropriately conservative. Guidance should be provided to ensure the use of deeper soil horizons in the exposure assessment is fully justified.
Pesticides Safety Directorate	1.3. Proposed methodology	In line 95 there is reference to collembola and earthworms - it is recommended that the work group note any developments regarding the revision of the ecotox annexes of 91/414/EEC.
Pesticides Safety Directorate	1.3. Proposed methodology	Lines 99 – 106, the work group should take account of, for example, the PERAS workshop in considering ecotoxicological protection goals for soil.
Pesticides Safety Directorate	1.3. Proposed methodology	It is noted in lines 112 that there will be a review by the ecotoxicological experts of the importance of pore water in non-target soil studies. Whilst, this may be an important route of exposure, this does appear to be subject to some debate, and there should be an assessment of whether the existing study protocols provide sufficient information to allow the risk to be assessed. It is possible that adopting pore water assessments will require existing test guidelines to be defines.

Contributor	Section	Comment
Pesticides Safety Directorate	1.3. Proposed methodology	Lines 118-125 detail proposals to determine PEC _{soil} over the top 1, 5, and 30 cm. The later discussion on tillage also lists 20 cm. It would be useful to clarify and give justification for when each soil depth is appropriate in relation to particular ecotoxicological considerations, application, exposure or agronomic/cropping practices. Why have these particular depths been chosen? How practically would potential differences in agronomic practice (e.g. tillage or no-tillage) be considered in the soil risk assessment process - if there is the possibility of no-tillage then this could ultimately be the default worst case - the regulatory implications of this need to be fully considered.
Pesticides Safety Directorate	1.3. Proposed methodology	6. Lines 118-125 – before appropriate exposure scenarios can be developed the most appropriate measure of effects will need to be determined by the Ecotox experts. Different scenarios would need to be developed to be sufficiently protective if either pore water or total pesticide content is selected. For example, if the pore water was selected as the most appropriate measure of effects, scenarios with low organic carbon contents may prove to be the most protective. Alternatively if total pesticide content is of concern, scenarios with organic carbon contents at the upper end of the range of EU soils may need to be selected. This aspect should be considered as part of the project planning process.
SCC	1.3. Proposed methodology	line 105 The identification of model species does imply that adequate ecotoxicological information on the model species will be available. As a result, additional testing methodology may be required. Again, it should be considered that much time and effort will be involved, whereas the benefits of these additional efforts as a general approach are not clear.
SCC	1.3. Proposed methodology	line 114 The ecotoxicological relevance of a risk assessment based on exposure to soil pore water is rather controversial mostly due to the highly artificial design of corresponding ecotox tests and due to the focus on dermal exposure. Beyond that, for the estimation of soil pore water concentrations additional parameters (e.g. relating to the soil water content at changing climatic and crop coverage conditions) will have to be taken into account. This will inevitably add to the uncertainty of the PEC.
SCC	1.3. Proposed methodology	line 120/121 The determination of PEC values averaged over different soil depths may be considered adequate in view of differing properties of PPP and soil as well as different agricultural management regimes. However, from a regulatory point of view, well-defined and binding PEC values are required for the use in risk assessments.

Contributor	Section	Comment
SCC	1.3. Proposed methodology	line 140/141 If the “notifier has the burden of proof that the DegT50 values from field experiments are valid for use in Risk Assessment”, clear guidance should be provided indicating the conditions or the information needed to justify the use of field DegT50 data.
SCC	1.3. Proposed methodology	line 172 et sqq. The applicability of tillage/no-tillage options should be clearly defined if both options will be provided within the one scenario.
Swedish Chemicals Agency	1.3. Proposed methodology	line 95-97: We are surprised that micro-organisms are not included here given their fundamental role in the soil ecosystem.
Swedish Chemicals Agency	1.3. Proposed methodology	<p>line 99-106: We note that the project plan for a new guidance document focusses on exposure, not effects but nevertheless, where soil function and biodiversity is discussed modern methods to study functional and structural diversity in soil microbial communities could be considered. These methods are used and developed by e.g. these research groups:</p> <p>Uppsala Microbiomics Center, Sweden / Contact person: Assoc. Prof. Sara Hallin Sara.Hallin@mikrob.slu.se ; Phone: +46-18-673209 http://www.microbiomics.se/</p> <p>Publication: Widenfalk, A., Bertilsson, S., Sundh, I., Goedkoop, W. (2007). Effects of pesticides on community composition and activity of sediment microbes - responses at various levels of community organization. Environ. Pollut. In press.</p> <p>The methods mentioned above could be used to study potential impact of pesticides on soil communities and preferably be used during efficacy testing to get a whole growing season.</p>

Contributor	Section	Comment
Swedish Chemicals Agency	1.3. Proposed methodology	<p>line 99-106: We note that the project plan for a new guidance document focusses on exposure, not effects but nevertheless, where soil function and biodiversity is discussed modern methods to study functional and structural diversity in soil microbial communities could be considered. These methods are used and developed by e.g. these research groups: Professor Kornelia Smalla, BBA Institute for Plant Virology, Microbiology and Biosafety, Germany k.smalla@bba.de; Phone: +49 (531) 299-3814 Publication: Neumann, G. Kania, A. Weinert, N. Smalla, K. Meincke, R. Berg, G. Ros, B. Block, A. Mohler, V. Dong, X. Wenzel, G. Munch, J.C. Radl, V. Schloter, M. Impact of transgenic potatoes with overproduction of zeaxanthin on rhizosphere processes and soil quality in agricultural production. Poster presented at Rhizosphere 2, Montpellier, France 26-31 August, 2007.</p> <p>The methods mentioned above could be used to study potential impact of pesticides on soil communities and preferably be used during efficacy testing to get a whole growing season.</p>
Swedish Chemicals Agency	1.3. Proposed methodology	<p>line 112-116: We welcome a thorough discussion on relevance of total content/soil pore water content. However, we believe that not only ecotoxicological experts are needed for that discussion but also experts in the field of fate and behaviour (e.g., adsorption kinetics). We would also welcome a discussion on different extraction techniques to estimate bioavailability for various soil organisms.</p>
Ctgb	1.4. Restrictions of the project	<p>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. This is a possibility but, to link the exposure in field to ecotoxicological effects, the exposure in the ecotoxicological studies must be considered. This should be part of the Project Plan for Ecotoxicological aspects. Advise and communication of the fate side is essential.</p> <p>No further guidance is developed for DT50 triggers. This is agreed but guidance on the possible differences of types of kinetics and the effects on the persistence assessment is inevitable. In case of the proposed models only SFO is an option. SFO is not always the proper kinetics for persistent substances.</p> <p>It is questionable, because of the fact that no tier 2 scenarios will be developed for seed treatment and ridged potato fields, if the tier 1 scenario(s) for these applications will have an added value in risk assessment.</p>

Contributor	Section	Comment
Danish Environmental Protection Agency	1.4. Restrictions of the project	L. 190-193 If pore water concentrations are recommended in the exposure assessment it is crucial to provide guidance on how to derive equivalent endpoints from the ecotox studies.
Danish Environmental Protection Agency	1.4. Restrictions of the project	L. 205-206. User friendly software packages are crucial – otherwise the guidance can not be used.
Danish Environmental Protection Agency	1.4. Restrictions of the project	L. 218-219. It is acceptable that further guidance is not given – however current guidance (e.g. from revised data-rec. and FOCUS kinetics) should be incorporated in a user friendly way.
Danish Environmental Protection Agency	1.4. Restrictions of the project	L. 221- 228. This is one area where guidance is really needed – and we would find it necessary to go beyond the first tier. E.g. to consider which types of soil organisms and to what extent these organisms would be exposed to different types of treated seeds and potatoes.
ECPA	1.4. Restrictions of the project	Line 201 ff: Within the project higher tiers are planned to consist of complex environmental scenarios, which need to be run with sophisticated simulation software. Leaving the development of such software tools and the implementation of scenarios in these tools open can lead to a situation, where results depend on the used software and applied interpretation of the scenario definition. This would certainly be undesirable development. Therefore, implementation of the scenario definitions in certain software tools should be checked for consistency with the definitions given by the EFSA project group and only these tools should be applied in the regulatory context. Such tools also need strict version control in order to avoid confusion. The project proposal does not contain details, how this version control will be implemented. The project group should consider this issue and develop a recommendation.

Contributor	Section	Comment
ECPA	1.4. Restrictions of the project	<p>Line 210 ff:</p> <p>Based on the outline of the project PECsoil calculation are aimed to be more realistic, but - by doing so - will also be significantly more complex. Due to this complexity potential pitfalls might not be apparent. Therefore, it seems appropriate to validate the new approaches against field data. Especially, within the tiered approach, a check against higher tier field data, would lead to an insight, to what extent lower tier assessments can lead to either false positive or false negative results. This would also be a basis for understanding the level of protection, which can be achieved at lower tier risk assessments.</p>
Federal Environment Agency (German UBA)	1.4. Restrictions of the project	<p>line 249ff</p> <p>The assumption that release of bound residues “would have only small effects on the estimated total contents and pore water concentrations” may require reconsideration by updating the scientific basis of that statement. Substantial research has been published in that area since the pertinent SCP opinion in 1999. Of course, this “would require a review of available data on this item”, but that should be possible within the given timeframe. We agree that attempts to estimate release rate coefficients from these data would probably be premature, but this should not be used as a justification for not discussing the state-of-the-art regarding bound residues at all.</p> <p>The current approach for addressing high amounts of bound residues is based on the assumption that adverse effects would become visible after several years of consecutive use of a pesticide at the same site under constant environmental conditions. However, considerations on the possible formation mechanisms for bound residues might also suggest that release of such residues could be caused by changes in environmental conditions (pH, redox potential), e.g. due to a change in agricultural management.</p>
Federal Environment Agency (German UBA)	1.4. Restrictions of the project	<p>line 201ff</p> <p>This is not a satisfactory statement. Guidance documents are intended for helping assessors carrying out reliable risk assessments within a reasonable timeframe. This must include provision of usable tools when complex assessment procedures are proposed.</p>

Contributor	Section	Comment
Federal Environment Agency (German UBA)	1.4. Restrictions of the project	<p>line 195ff</p> <p>The proposal not to consider questions related to PBT, vPvB or POP assessments is not supported. These questions are of greatest regulatory importance and must be addressed in a Guidance Document on persistence in soil. They are definitely more urgent than a development of scientifically new approaches for PECsoil calculations. If this decision was made in order not to interfere with other activities, e.g. on OECD level, at least an attempt should be made to sketch a general framework that could be used by EU representatives for contributing to those other activities.</p>
Federal Environment Agency (German UBA)	1.4. Restrictions of the project	<p>line 186ff</p> <p>The proposal not to consider questions related to actual exposure in ecotoxicological test systems is not supported. It is even more questionable, as new concepts for expressing soil contamination via pore water concentrations are proposed, which would probably make existing assessments of ecotox studies unusable. Also, it would aggravate relating measured ecotoxicological endpoints to scenarios with different climate and soil types. Finally, it does not account for the fact that there is a clear need to express actual exposure in more recent higher-tier systems like TMEs in an agreed manner. Positively spoken, the guidance should support answering the question which is a realistic worst case combination and which is a best case combination of PECsoil and ecotoxicological endpoint.</p>
Federal Environment Agency (German UBA)	1.4. Restrictions of the project	<p>general</p> <p>The list of restrictions of the project gives rise to an impression that there was a more pronounced interest in introducing new general concepts into the exposure assessment than in helping assessors on EU and MS level by filling the gaps left by existing guidance. Please reconsider the priorities.</p>
INIA	1.4. Restrictions of the project	<p>a) It is indicated, as a restriction of the project, that only the exposure assessment for the field will be addressed. However, for practical reasons, we strongly suggest addressing also the exposure for ecotoxicological studies. We would like to summarize some of our concerns:</p>

Contributor	Section	Comment
INIA	1.4. Restrictions of the project	a.1) Monitoring exposure in ecotoxicity tests is often not properly addressed. According with many international protocols, it is recommended to monitor the exposure concentrations at least at the beginning and at the end of the test. When exposure is not properly monitored, the time at which the effect occurs in static systems is unknown, and therefore the time to base the calculations upon is unknown too. On the other hand, in the best cases, when the concentrations are available, they are expressed as total content of pesticides and not as pore water concentration. Thus, clear guidelines are needed on how to proceed when not appropriate measurements of the exposure concentrations are available. We realize that for controlled and closed test systems, relatively simple calculation approaches can be used to estimate these exposure concentrations. However, for higher tier (or uncontrolled systems), the calculation of the exposure should require more complicated procedures.
INIA	1.4. Restrictions of the project	a.2) We consider that the inclusion of time windows for TWA is a good proposal for refining risk assessment, however, the necessary parameters for estimating that concentrations are not frequently available. Please, clear guidelines and uncertainties associated to these estimations are required.
INIA	1.4. Restrictions of the project	a.3) In the current data requirements and decision making process at the EU level, in the worst case field DT90 > 1 year, or for the evaluation of potential of soil bound residues a plateau concentration is compared with ecotoxicological data from the litterbag study. The exposure is poorly defined in the litterbag protocol, therefore a critical analysis of this is recommended. Maybe it should be needed to suggest an update of the protocol. However, the panel already recommends suppressing litter bag studies in the evaluation of the risk to terrestrial environments (EFSA-Q-2006-170) and to include instead data requirements related to the effects on soil micro-and macrofauna.
INIA	1.4. Restrictions of the project	b) As mentioned in point 1.2, it is needed to develop scenarios and approaches to calculate PEC _{soil} for fumigants and for the special cases when pesticides are applied through a drip irrigation system. In other cases the application is as a seed treatment (including transplating of treated plants).
Pesticides Safety Directorate	1.4. Restrictions of the project	Line 192: We feel that some consideration of the assessment of exposure in both the field and ecotoxicological effects studies is warranted to ensure that the outputs from the model scenarios are actually usable in the terrestrial risk assessments. Exposure in the field and the effects studies should match to ensure the subsequent risk assessment is robust.

Contributor	Section	Comment
Pesticides Safety Directorate	1.4. Restrictions of the project	Line 205: We realise that the development of software packages with user interfaces can be a very time consuming task and that this is not currently part of the project plan. However to aid harmonisation of the use of the scenarios amongst industry and MS we feel that the development of user friendly interfaces should be considered as part of this project. Perhaps the composition of the work group could be extended to ensure that sufficient model developers are able to address this task as part of the project plan? As a bare minimum standard electronic parameter files should be developed for easy incorporation into the existing modelling packages.
Pesticides Safety Directorate	1.4. Restrictions of the project	Line 210 on - it is appreciated that full validation of the scenarios will not be possible, however it should be considered to carry out some form of validation to try to give the model and its associated scenarios credibility. Given the likely ready availability of suitable data that would allow such a validation to take place this aspect should be given further consideration in the project plan.
Pesticides Safety Directorate	1.4. Restrictions of the project	Lines 242 – 247: as assessment of uncertainty is very welcome, and if possible, thus should help inform MS in considering appropriateness for MS authorisations, and very importantly, for zonal registration.
Pesticides Safety Directorate	1.4. Restrictions of the project	Lines 249 – 256, bioavailability and the relevance of harsh extraction methods are sometimes used by Notifiers to argue out of certain situations. It would be useful to include a discussion of issues relating to unextracted residues taking into account additional data and latest thinking on this area and determine broad guidance on this aspect. For example, PSD has sponsored with Lancaster University in recent years which could be used in this context.
SCC	1.4. Restrictions of the project	line 207/208 The practicability of the scenario approach for both notifiers and authorities may be limited if scenarios are defined while no validated software packages are developed.
BASF SE	1.5. Expected results	[184 ff.] Restrictions of the project; It is very welcomed that the project plan restricts the topics and workload of the working group. Some remarks are deemed useful:
BASF SE	1.5. Expected results	[207-208] software packages : It is strongly recommended that software tools are made available for testing before the revised guidance is implemented. A strict version control like the FOCUS version control group has over the FOCUS models should be followed.

Contributor	Section	Comment
BASF SE	1.5. Expected results	[221 ff] "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...."
BASF SE	1.5. Expected results	Point of clarification: shall the scenarios only be developed "for seed treatments and applications to ridged potato fields" and not for spray application? Or shall additional scenarios be developed for the above mentioned application type?
Federal Environment Agency (German UBA)	1.7. Communication	line 309 We have strong reservations against the procedure that is proposed here. The presented project plan seems to describe a conceptual frame that is worked out already to a great level of detail. Assumptions on the target of the risk assessments are made that seem to reflect the ideas of the developers of the project plan and selected national policies more than the framework of Directive 91/414/EEC. Similarly, the proposed multi-tiered approach seems to reflect modelling possibilities more than regulatory needs. We deem it very questionable that the users of a future guidance document are now urged into commenting on an already quite detailed scheme line-number by line-number instead of being asked for their general opinions and needs beforehand. Experience from the new draft GD on risk assessment for birds and mammals has clearly shown that consultation of stakeholders (particularly MSs) before starting the conceptual work is absolutely vital for creating a useful guidance document.
Federal Environment Agency (German UBA)	1.7. Communication	line 306f Since the Project Plan was developed without a consultation of the authorities before (risk assessors and risk managers), we expect that after this public web consultation the workgroup will revise the Project Plan and present it to all authorities again. It is not visible which experts will be involved in later consultations. The same does apply to the invitation of ad-hoc experts in chapter 1.8. So we propose that if further support is needed, all authorities should be asked for their opinion in a simple procedure to give the working group and subgroups a better overview of the current regulatory views in the EU.

Contributor	Section	Comment
Finnish Environment Institute	1.7. Communication	Following the risk assessment of the soil organisms, risk mitigation is needed in certain cases. In Finland it is possible to restrict the use of a PPP in same field in consecutive years, if the PECsoil following the yearly use shows a risk to soil organisms and if the PECsoil leads to acceptable risk if used every second or every third year. The risk mitigation measures need to be flexible and it must be accepted that there are different climatic conditions within the Member States. Therefore it needs to be accepted that risk mitigation measures may vary among the MS.
BASF SE	Figure 1	Figure 1 from Boesten et al (2007) displays the general ideas, of interaction between effect and exposure flow charts. However it is not flexible enough to illustrate all possible interactions between exposure and effect flow charts and should be replaced with the "criss cross" model from the same paper Boesten et al (2007). Exposure assessments on all tiers may be combined with effect assessments on all tiers and vice versa. THis would result in more flexibility for notifiers and risk assessors, provided that the general principles of such tiered approaches are captured (Boesten et al. 2007): <ul style="list-style-type: none"> • Earlier tiers are more conservative than later tiers • Later tiers are more realistic than earlier tiers • Earlier tiers usually require less effort than later tiers • Jumping to later tiers (without considering all earlier tiers) is acceptable • There has to be some balance between the effort and the filtering capacity of the tier
Danish Environmental Protection Agency	Figure 1	Figure 1 This figure is to general and does not make sense in relation to the EU assessment where there are no levels/tiers of protection aims.
BASF SE	Figure 2	[384] Figure 2 Please explain in detail why in 2nd and 3rd box on the right hand side (in the zoomed area of tier 2) the information of DegT50 from field or accumulation studies) are classified as "also"
Danish Environmental Protection Agency	Figure 2	Figure 2 Presumably the right hand box should be different for the different tiers. As mentioned above we would recommend that an initial worst case screening tier should be included to avoid unnecessary work. It would be interesting to see a more detailed text for the tailored scenarios at tier 3 – as it is unclear what these could be.