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Report on the PPR Stakeholder Workshop Improved Realism in Soil Risk Assessment (IRIS) – How will pesticide risk assessment in soil be tackled tomorrow?

(Question No EFSA-Q-2009-00690)

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SUMMARY

The "Improved Realism in Soil Risk Assessment (IRIS)" stakeholder consultation workshop was organized by EFSA's PPR Panel (Panel for Plant Protection Products and their Residues) in collaboration with the Joint Research Centre (JRC) – Institute for Environment and Sustainability (IES) and held at JRC, Ispra, 12th to 14th May 2009. A total of 86 participants from Member States, the agrochemical industry, consulting companies, academia, JRC and EFSA attended.

IRIS aims were to inform stakeholders about on-going activities regarding risk assessment of pesticides in soil in the context of the revision of the Guidance Documents on Persistence in Soil (SANCO 9188/VI/97 rev 8, published in 2000) and on Terrestrial Ecotoxicology (SANCO/10329/2002) as well as to collect feedback from stakeholders about this on-going work. This report summarises the outcome of the workshop and was prepared by the IRIS participants with EFSA's support.

Key words: risk assessment of pesticides in soil, environmental fate, terrestrial ecotoxicology, persistence of pesticides in soil, exposure assessment

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INTRODUCTION AND OBJECTIVES

The stakeholder consultation workshop on "Improved Realism in Soil Risk Assessment (IRIS)" was organized by EFSA's PPR Panel (Panel for Plant Protection Products and their Residues) in collaboration with JRC-IES and held at JRC, Ispra, from 12th to 14th May 2009. Participants were invited to register through www.efsa.europa.eu from 15th December 2008 to 15th February 2009. A total of 97 candidates expressed their interest in participating. Participants were selected based on their expertise in the scientific field (soil ecotoxicology and fate of pesticides in soil), ensuring a balance between representatives of Member State (MS) regulatory authorities, private organisations (e.g. agrochemical industry representatives and consulting companies), and academia, as well as a geographical balance. A total of 86 participants from 23 different countries representing the above-mentioned stakeholder groups plus representatives of JRC, EFSA's PPR Panel, and EFSA scientific officers attended the workshop (Figure 1).

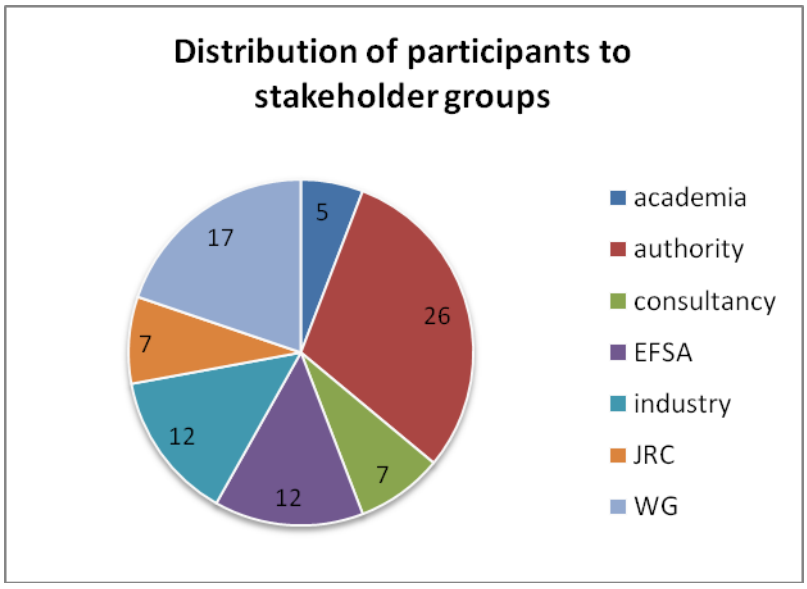

Figure 1: Participants representation of different stakeholder groups (academia, MS regulatory authorities, consultancies, EFSA (AMU, PPR, PRAPeR), industry, JRC, and members of the EFSA Working Groups on Persistence in Soil /Fate and Ecotoxicology (WG)).

IRIS' major aims were:

1) to inform stakeholders about on-going activities regarding risk assessment of pesticides in soil in the context of the revision of the Guidance Documents on Persistence in Soil (SANCO 9188/VI/97 rev 8, published in 2000) and on Terrestrial Ecotoxicology (SANCO/10329/2002);
2) to collect feedback from stakeholders.

The workshop started with overview presentations about the involved organisations, the current status of EFSA's PPR Panel activities and the programme of the workshop (please refer to Appendix A: workshop programme).

The second workshop day was dedicated to discussions for collecting stakeholders' views on specific topics. Five smaller break-out groups were constituted as follows:

- Group 1: Soil Ecoregions and Risk Assessment
- Group 2: Ecochemistry and Risk Assessment
- Group 3: Soil Management Practices
- Group 4: Handling of field accumulation and persistence studies
- Group 5: Scenario Selection for PEC calculations

Two rapporteurs were assigned to each break-out group (one from a MS regulatory authority and one from a private organisation), who summarised the discussions and documented the comments and stakeholder views for this report.

On the last workshop day, the rapporteurs of the break-out groups reported back to the plenary group of participants. This was followed by a plenary discussion on "How to improve realism in soil risk assessment?", for which two additional rapporteurs (MS representatives) were appointed.

The conclusions of the break-out groups and the plenary discussion are summarised in the following sections. These summaries were prepared by the respective rapporteurs and sent out for peer review to all workshop participants before publication.

ECOTOXICOLOGICAL ASPECTS: BREAK-OUT GROUPS 1 AND 2

Group 1 (Soil Ecoregions and Risk Assessment) and Group 2 (Soil Ecochemistry and Risk Assessment) started their break-out groups with a joint session with presentations covering the following topics:

- Bioavailability and suitable soil metrics in risk assessment of PPPs
- Defining Soil Ecoregions for soil exposure scenarios
- The litter layer in the context of the risk assessment of pesticides

After clarification questions, the participants split up into the two groups for discussion sessions followed by a joint session at the end of the day. In the following sections, the presentations and the outcome of the break-out groups are summarized.

1. Break-out Group 1: Soil Ecoregions and Risk Assessment (Rapporteurs: Lise Samsøe-Petersen and Kevin Brown)

The session was based on the presentations "*Defining Soil Ecoregions for soil exposure scenarios*" and "*The litter layer in the context of the risk assessment of pesticides*".

During the presentation "*Defining Soil Ecoregions for soil exposure scenarios*", the soil ecoregions concept, introduced by EFSA (2009)[1], was presented. It can be summarized stating that exposure assessments in soil could be refined using ecoregion maps to define ecologically relevant exposure scenarios. This concept is based on the following principles:

- Europe can be divided into a number of regions defined by soil properties and climate;
- each region supports specific soil organism communities that may play different roles in supporting relevant soil ecosystem services;
- species could be grouped based on similar ecological traits[2], that may influence the way they are exposed to chemicals;
- the combination of soil properties, climate and the potential soil community, define an ecoregion;
- each ecoregion is characterized by a different set of exposure scenarios (e.g. depth profiles) that are defined by ecological traits (e.g. behaviours influencing the depth where the species live in soil).

During the presentation "*The litter layer in the context of the risk assessment of pesticides*", the relevance of litter in the context of risk assessment of pesticides was presented. The consideration of the litter layer is important for the following reasons:

[1] Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects. *The EFSA Journal* (2009) 922, 1-90.

[2] A **trait** is a measurable morphological, ecological or physiological (etc) characteristic of an individual or, in our case, a species. Examples of traits can be as follows: Morphological traits (e.g. size, permeability of exoskeleton, lipid content, complexity of the nervous system), Physiological traits (e.g. mode of respiration, detoxifying enzymes or digestive strategy), Ecological traits (e.g. mobility, feeding behavior, trophic level, place in the food web). Taxonomically different species can share (almost) the same traits, meaning that they are exposed in the same way. Using the trait approach improves the definition of the exposure scenarios.

- Litter may act as a sink for pesticides due to its often high adsorption capacity, i.e. concentrations in the litter layer can be higher than in the mineral soil below.
- At the same time, the litter layer is a habitat for many soil organisms.
- Even more importantly, some important species such as earthworm vertical burrowers (e.g. *Lumbricus terrestris*) are living in the soil but approach the litter layer for feeding purposes.
- Any impact on organisms living in or on the litter may delay the decomposition of the organic material, thus impacting nutrient cycles (OECD 2006).
- Litter, reducing the evaporation, improving the soil structure and earthworm channels, may strongly influence water flow and pesticide displacement.

Thus, the litter layer can be considered as an additional uptake pathway. Therefore, the litter layer should be included when selecting exposure scenarios for risk assessment procedures.

The Chair initiated the session and raised the main points to be discussed by the participants:

- Is the soil ecoregions concept sound and clear?
- Is the Exposure Scenarios concept sound and clear?
- What practical implications have to be considered for using the concepts of eco-regions?
- What practical implications have to be considered for using the concepts of exposure scenarios?
- What questions need to be solved to do the risk assessments using these concepts?

The outcome of the break-out group is summarised in the following sections:

1.1. Question 1. Is the soil ecoregions concept sound and clear?

The participants felt that land use could have a major and possibly driving effect on the composition of soil organisms. The presented Soil Ecoregion concept was discussed and it was stressed that the project is still in the early stages of development. Data from the presentation on Soil Ecoregions was largely derived from forests and grassland. Without data from crop systems it was felt that the concept may not be applicable. The participants felt that an analysis of the data comparing within and between ecoregions would be needed to validate the concept.

The development and recognition of ecoregions should be based on analysis of data and statistical analysis. There is currently a scarcity of data from agricultural crops. However, for earthworms at species level and to some extent for other soil communities, there exists industry data from the control plots of field studies conducted throughout Europe. One industry delegate offered such data during the meeting and more data would be gratefully accepted. These data could be very helpful in the ecoregions project but site soil characteristics would also be necessary if such data were provided.

Concerns were raised that there would be different ecoregion maps for different taxa. For example, since earthworms are different in the North to the South due to the influence of the last ice age, there could be different maps for worms, Collembola, Isopods etc. This was found to be a misunderstanding of the organism component of the ecoregions. Each ecoregion has one community composed of specific trait groups across taxa; this is referred to as the

"focal community". Use of the ecoregion concept could inform which soil profiles would be relevant for different elements of the focal community.

The participants discussed the potential regulatory application of ecoregions and felt that it was important to define protection goals first.

For EU registration the use of ecoregions would be likely to provide a greater probability to find one safe use. This has to be critically discussed. For national registration, regulators would be able to use the realistic worst case. It was not clear if these concepts would only apply to persistent chemicals or if they would also apply to all pesticides. It was confirmed by EFSA that the concept, if valid, may be taken forward to the revision of the Terrestrial Guidance Document. An evaluation of the usefulness of the concept is foreseen before taking the concept over for risk assessment.

The focal community concept of ecoregions is based on the presence of dominant taxa. There was some concern in the group about the limit for assignment or selection of such taxa and for making the decision as to what was important or not. It was explained that there must be clear differences in community structure to differentiate between ecoregions.

In summary the group response to question 1 was:

- The concept of soil ecoregions is understood and clear.
- Data needs to be gathered and evaluated to develop the concept and determine whether it is valid.
- If the concept is found to be valid, there needs to be careful consideration as to how it can be applied to risk assessment.
- What are the improvements of using ecoregions compared to the current system?

1.2. Question 2. Is the Exposure Scenarios concept sound and clear?

If it is ecologically relevant then the concept should be followed because you have the information to calculate an appropriate exposure value for the community at risk.

The use of different soil profiles for calculating PEC values (Predicted Environmental Concentrations) relevant for different organisms was clear, but the justification for the use of this in risk assessment will depend on protection goals. Consideration of the chemistry of the product was also discussed.

The group was not convinced that enough data is available at the moment to use the concept.

Regarding the question of considering litter in particular, it was recognised that this is not an issue in most conventional annual agriculture but is applicable to perennial crops. It was noted that Corine provides 5 categories for such crops.

There was concern about the litter community for off crop risk assessment. It would be possible to use data from grassland as a permanent crop to litter for the off crop scenario. In crops with rows, such as orchards and vines it was recognised that there were differences between the litter community within rows and between rows.

More information about the fate of pesticides in litter layers was needed. As described for the ecoregions question, there was concern that the group was debating Ecologically Relevant Concentrations so as to calculate PEC values without knowing which organisms they were to be applied to. Recognising that the ecology behind the focal soil community will determine

what the relevant soil layers will be, there was a call for a "soil community bible", similar to that for birds (Buxton et al. 1988) and mammals (Gurney et al. 1988), but with a simpler Risk Assessment procedure.

Some delegates emphasised that litter organisms should not be dealt with twice; they should be covered either under non-target arthropods or under soil fauna.

The delegates considered what the "Exposure Scenarios Concept" could be used for. It was envisaged by the group as being a refinement step that would come after a screening first tier step. Given the multitude of PEC/soil profile combinations it would be appropriate to take the realistic worst case of all the scenarios as the tier 1 test. However, to do this meaningfully there could be a need to look again at the existing laboratory tests. However, these may need to be improved or completely re-designed to make them relevant.

1.3. Questions 3 & 4. What practical implications have to be considered for using the concepts of ecoregions and exposure scenarios?

The break-out group re-formulated the two questions 3 and 4 into a single question to say:

What can the concepts of ecoregions and exposure scenarios be used for?

If found to be valid, they could be used for exposure refinement of risk assessment in conjunction with focal communities.

The concepts could lead to a need for different input data (Ecotox tests).

There was a discussion about how the large array of possible PECs from different soil layers and the resulting TER values would actually be used to conduct a risk assessment. Whilst it was technically possible to try and complete a full matrix of values for a compound, the break-out group envisaged it being used in practice to look in detail when a specific need was triggered. The group did not want to see a very complicated "FOCUS terrestris"!

1.4. Question 5. What questions need to be solved to do the risk assessments using these concepts?

Whilst the break-out group was receptive to both the concepts, it was felt that – after their development - there is a need for sufficient checks and balances in place to ensure that they are valid and meaningful for being applied to risk assessment.

For litter, it was considered imperative to gather and evaluate more data on the fate of pesticide residues in this matrix. The suitability of the current tier 1 testing may need to be re-considered. Furthermore, several questions asked above need to be solved before introducing these concepts in the risk assessment:

- What improvements could be expected from using eco-regions compared to the current system?
- What are the protection goals for the soil community?
- How could litter organisms be handled in risk assessment?
- What could an off-crop risk assessment look like?

2. Break-out Group 2: Ecochemistry and Risk Assessment (Rapporteurs: Roger Holten and Thorsten Leicher)

The session was based on the presentation "*Bioavailability and suitable soil metrics in risk assessment of PPPs*". During this presentation, part of the Scientific Opinion on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects was presented (EFSA, 2009[3]). In particular, the scientific rationale behind the Panel's conclusion was explained in detail.

The Chair initiated the session and raised the main points to be discussed by the participants:

- Is the pore water concept sound and clear when compared to the total content concept?
- What are the pros and cons for using one concept or the other, also in the context of effect testing and biomagnification assessment?
- What questions need to be solved to do the RA using these concepts?

The outcome of the break-out group is summarised in the following sections.

2.1. Ecochemistry

During the discussion, the group recognised that the pore water concept is sound as long as it concerns the route of exposure for the affected organism. There is some scientific evidence that pore water concentrations of pesticides, chemicals and metals in soil can describe biological effects on certain types of in-soil living animals, e.g. earthworms or enchytraeids. However, additional routes of uptake might be relevant as well, such as feeding on particles etc. Other organisms may have other exposure routes and this must be addressed. Therefore a broader scientific exploration of the pore water concept was suggested, where it can be demonstrated for a range of pesticides that the concept is also valid for different soil types and for other organisms than earthworms. Validation of the risk assessment output should also be performed (see below).

The use of pore water concentrations might be an option for higher tier exposure refinement in order to avoid otherwise necessary higher tier effect studies. In addition, the concept might be used to extrapolate results gained in single field studies to other regions with other soil properties compared to the test site. Therefore, regions, scenarios and methods for the modelling of pore water concentrations of pesticides and chemicals in soil should be validated against field data and defined accordingly.

2.2. Risk Assessment

A general key point in the discussion of the group was the clear need for well-defined protection goals for the soil risk assessment of plant protection products. One approach might be to differentiate between in-crop and off-crop areas. The group agreed that beside the structure of the in-soil living community the function of the soil is of high importance. Ideally, protection goals should be defined by risk managers early in the process, providing the basis for the definition of a protective and pragmatic risk assessment scheme for soil.

The current approach in risk assessment is based on the use of the total content of active substances calculated for the upper layer of the soil, e.g. 0-5 cm. Uncertainties within this

[3] Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects. *The EFSA Journal* (2009) 922, 1-90.

approach are mainly covered by the use of safety factors. Within the discussion it was highlighted by many participants that, from a regulatory point of view, this approach was protective for the environment and is well established throughout the EU Member States. Before a change in the risk assessment paradigm towards the use of pore water concentration of active substances instead of the total content approach is envisaged, it should be shown that the outcome of the risk assessment is significantly improved. However, the currently available scientific data do not allow a clear decision on which concept would be more appropriate in the future. Therefore, a thorough validation of the pore water concept is necessary (comparison of risk assessment conclusions performed with total soil vs. pore water concentration) and a risk/benefit analysis of a possible change in the risk assessment paradigm has to be carried out. There was a clear consensus within the group that if the outcome of a validation demonstrates that a risk assessment based on the pore water concept results in a significantly better and more predictive risk assessment, then the concept could be subsequently adapted within the regulation process of plant protection products. Some participants expressed their concerns on the increased complexity caused by increasing the number of scenarios to be used in the risk assessment compared to the current situation. Within the group, there was a clear demand for a pragmatic and simple approach for the future risk assessment scheme regardless of the exposure metrics (total soil or pore water concentration).

2.3. Conclusion

The group recognized that there is some evidence that the pore water concept is scientifically sound. This concept may describe biological effects caused to organisms like earthworms or enchytraeids after exposure to pesticides. However, this concept has not yet been developed to a level where it can be used routinely by regulators as a basis for the soil risk assessment of plant protection products.

Before changing the current approach in soil risk assessment, a two-step validation process is needed. The group agreed that a thorough scientific validation of the pore water concept has to be conducted for different organisms and for a set of compounds where comparisons should be done for:

(i) a range of physical-chemical parameters
(ii) different modes of action
(iii) different soil types

In a second step, it will be necessary to analyse whether the use of the pore water concept in soil risk assessment, compared to the current approach of total content, significantly improves or changes the predictability of the subsequent risk assessment.

PESTICIDE FATE ASPECTS: BREAK-OUT GROUPS 3, 4 AND 5

Group 3 (Soil management practices) and Group 4 (Handling of Soil Accumulation and field persistence studies) took place in parallel and started with a common introduction session with four presentations:

- Overview of soil and crop management practices and consequences for exposure assessments
- Handling of field experiments in exposure assessment for terrestrial effect assessment

- Determination of SFO DegT50 (half-life) values for Model Input
- The appropriateness of FOMC Kinetics in the context of long-term accumulation calculations

Groups 3 and 4 discussed their respective topics and then met-up again to report back to each other. The two groups continued then as joint group 5 to discuss "Scenario Selection for PEC calculations". Group 5 also started with some introductory presentations by working group members:

- Introduction: The tiered assessment scheme and the role of the Tier-2 scenarios
- The use of pedotransfer functions for estimating soil bulk density
- Dealing with uncertainty in pesticide fate model scenarios for pesticide registration
- Procedure for developing the Tier-2 scenarios and results of selection procedure
- Effect of soil pH on the sorption of ionisable compounds

The presentations and the outcome of the break-out groups are summarised in the following sections:

3. Break-out Group 3: Soil / Crop Management Practices (Rapporteurs: Arnaud Boivin, Gerhard Görlitz)

3.1. Soil management practices

The session was based on the presentation "*Overview of soil and crop management practices and consequences for exposure assessments*". The Chair initiated the session and raised the main points to be discussed by the participants:

- What crop-tillage combinations should be considered in the risk assessment?
- Should crop rotation be included in the risk assessment for annual crops?
- Should cover crops be included in the risk assessment for permanent crops?
- Are presently used crop interception tables (FOCUS) sufficient?

As a general point it was emphasized by one of the participants that regional differences in management practices must be considered when developing scenarios for the Northern, Central and Southern zones.

3.2. Summary of Discussion

Tillage depth:

Tillage must only be considered for long term assessments, if the substance is carried over into the next year. No impact of tillage on short term PEC_{soil} is to be expected.

Tillage practices vary widely between different crops and may also be substantially different for the same crop in different regions or countries. Therefore the decision of which crop-tillage combinations should be considered in the risk assessment should be based on a careful inventory of the existing practices for different crops and regions. However, while it was recognised that tillage practices have a major impact, it also seems very important that risk assessment concentrates on practices that are of major importance for a combination of crop

and region. It therefore seems necessary to set a threshold (i.e. consider a certain practice only if it is applied to more than x% of a crop in a region). As an example it was mentioned that in some regions, minimum/no tillage practices represent less that one percent of the cultivated area. In these cases, it is questionable whether specific scenarios are needed to cover such a practice. It may be helpful to consider financial support programs given to conservation tillage practices as a data source for the inventory; however it may be possible that some of these programs are established even if there is no evidence that this practice is suitable for the area.

It is quite clear that tillage practices will also influence the distribution of OM and the bulk density in the soil profile during the year and over several years. The amount of plant residue left on soil surface may be relevant in the risk assessment as it influences soil humidity and temperature. As a consequence, these factors influence the degradation of pesticides.

However, it seems overly sophisticated to include these indirect effects of tillage in modelling. Similarly it is advisable to consider long term effects on the carbon cycle only when scenarios are updated and when the changes lead to an improvement of the risk assessment.

A critical question for long term (accumulation) calculations is the definition of reasonable tillage, i.e. mixing depths, for conventional and reduced tillage. Since data from the introductory presentation (by Ettore Capri) show that reduced tillage also involves significant mixing over a 15 to 25 cm layer of the soil whereas conventional tillage mixes down to a depth of 20 to 40 cm, it appears reasonable to combine conventional and reduced tillage for the risk assessment with a mixing depth of 20 cm, whereas 5 cm are to be used for no tillage (frequently also called zero tillage) situations.

Crop rotation

It was further discussed whether crop rotation should be included in the risk assessment for annual crops. As a starting point it was mentioned that the FOCUS groundwater scenarios do not consider different crop rotations. However, they consider that some crops are not planted every year. It was agreed that for most crops rotation would be too specific for the standard risk assessment, but may be sensible at higher tiers. However, some crops are only planted in rotations, such as peas, soybeans and potatoes: in these cases a typical rotation would also be recommended in the standard assessment. Also in this case regional differences may need to be considered, since e.g. potatoes may be cultivated year after year in Finland but not in more southern areas of Europe.

It was agreed, that cultivation practices for rice are very specific and generally need a special assessment; therefore rice should not be in the scope of this project.

Cover crops

The next discussion point was whether cover crops should be included in the risk assessment for permanent crops. Generally there was agreement that the existence or non-existence of cover crops will have a significant impact on the exposure situation for permanent crops. The point that cover crops are not specifically addressed in the FOCUSgw scenarios was also raised. As a further complicating factor practices for many crops will be significantly different in different regions, (e.g. vines in the central zone are frequently grown with cover crop, in the southern zone without cover crop). It was stated that it may also be relevant to include cover/catch crops, when a cover crop/catch crop (mustard, phacelia, oilseed rape) is

sown into the stubble after harvesting winter cereals, in order to fulfil protection against erosion, nematodes, leaching and so on.

Guidance needs to be developed on how to determine a realistic worst case for different application scenarios. It was pointed out that the assumption that bare soil is the worst case scenario is not supported by scientific evidence (e.g. crop covers like grassed strip areas are known to have a higher water infiltration capacity). There are examples, where the worst case is not directly below crop, but between rows. Therefore careful evaluation is necessary to reach a simple solution which gives an overall worst case and not an addition of worst cases. It was agreed that it may be possible to estimate exposure within rows from interception by crop and eventual interception by cover crop. Between rows interception by cover crop needs to be considered and drift may sometimes be important, but simple application of Ganzelmeier tables may not always be applicable to drift between rows.

Crop interception

The importance of crop interception to determine the initial load to the soil is quite clear. The discussion concentrated on the question whether the presently used crop interception tables (FOCUS 2000) are sufficient. FOCUS tables were determined by a conservative procedure, taking into account that wash off is not separately considered. Members of the FOCUS groundwater scenarios group need to be asked to improve transparency on their data basis and a literature check is recommended to determine whether new and better values are available; if this is the case, then the FOCUS tables should be re-evaluated.

3.3. Conclusion

For risk assessment tillage practices must be considered for the long term (accumulation) calculations. For risk assessment purposes a simplification of the manifold practices into 2 clusters is recommended: Tillage (including conventional and reduced or conservation tillage) with a mixing depth of 20 cm and "No Tillage" (or "zero tillage") with a mixing depth of 5 cm. Tillage practices vary by crop and region. A cut-off value should be employed to concentrate risk assessments on major and regionally important practices.

Crop rotation should be considered in standard assessments only for crops/regions for which it is a general practice but may be used in higher tier assessments.

Cover crops may have a major impact on risk assessment, however it is difficult to generalise as the worst case needs a specific analysis of the exposure routes and the influencing factors.

A literature check is recommended to confirm whether the crop interception factors determined by FOCUSgw in 2000 are still state of the art.

4. Break-out Group 4: Handling of field accumulation and soil persistence studies (Rapporteurs: Elena Alonso-Prados, Neil Mackay)

Four topics were discussed during the break-out session:

- How to handle initial loss processes in field studies to derive a DegT50 to be used in the exposure assessment?
- How to use/choose lab, field and accumulation DegT50 values for exposure assessment?
- Use of accumulation studies to derive DegT50

- Use of FOMC (First-Order Multi-Compartment) kinetics in accumulation calculations

In the sections below, summaries of the information presented and the discussion on each topic are presented. Afterwards, other issues arising during the break-out and plenary sessions are presented.

4.1. How to handle initial loss processes in field studies to derive a DegT50 to be used in the exposure assessment

Summary of the topic

It was explained that the environmental fate of pesticides in the immediate soil surface might be different to the fate in the subsurface because of the type of processes occurring in the top mm of the soil layer. Among the soil surface processes, runoff, raindrop splash, volatilization and photolysis were mentioned. It was acknowledged that some of these processes are difficult to reproduce in models. The significance of certain chemical processes can be generally simulated but surface effects are less easily addressed (e.g. simulation of surface volatilisation, primarily driven by air-water partitioning is heavily influenced by accuracy of surface moisture content simulations) whilst others can be indirectly modelled (e.g. current regulatory models do not include a separate photolytic DegT50 but their influence can be simulated via biphasic models – to illustrate this point reference was made to the presentation "Determination of SFO DegT50 (half life) values for model input" by Ian Hardy). Uncertainties characterise simulation of run-off, although attempts are often made to minimise this through study design and siting (e.g. no slope). Raindrop splash erosion is a physical process that is not specifically simulated by models but the kinetic energy of impact has the effect of incorporating surface residues into the top mm of soil and protecting residues through soil redistribution – rainfall events thereby reduce the significance of direct photolysis.

The approach proposed for the analysis of field persistence experiments consisted of two steps:

- Step 1: The measured decline of the residues was divided into two phases in order to identify the fraction of chemicals dissipating in the soil surface (Phase I) and subsurface (Phase II).
- Step 2: Derivation of DegT50 for the pesticide degradation trend in Phase II to be used in terrestrial risk assessment.

Options to characterise Phase I

Three approaches were presented in order to characterise Phase I. The first two were based upon simple rainfall criteria (assuming certain rainfall depths may be required to remove residues from the soil surface) after which Phase II starts. The third was based upon the application of a biphasic kinetic model to obtain the fraction which is dissipated at the soil surface (Phase I).

Options to quantify Phase II

Two further options were presented for Step 2 based on inverse modelling. The first could be based upon the biphasic kinetic approach described above to characterise slow phase kinetics as representing Phase II behaviour. It is noted that biphasic approaches (mainly DFOP but

also including HS kinetics) used to evaluate Phase I and II behaviour may be performed with normalised datasets and thereby allow for direct determination of Phase II DegT50 for modelling purposes. The second option involved derivation of a Phase II DegT50 *via* inverse modelling with PELMO or PEARL after excluding the early data points from Phase I.

Summary of the discussion

During the discussion, it was recognised that loss processes in surface soil occur and may influence the fate of the chemicals in the top soil layer (≤ 5 mm). It was agreed that they should be considered in the environmental risk assessment. Nevertheless, greater clarity was demanded regarding the criteria and strategies to include them in the evaluation process.

The approaches proposed to estimate the rapidly dissipating fraction at the soil surface were discussed (Step 1). The rain-driven criterion was not the preferred one by the stakeholders. Regarding the kinetic modelling criteria, it was agreed that this approach is straightforward when a clear biphasic pattern is observed. However, it could involve the risk of minimising the statistical significance of the kinetics because of the exclusion of a large number of points. On the other hand, concerns arose on how to tackle loss processes when field dissipation curves are well fitted by simple first-order kinetics (SFO). High quality SFO fits imply that Phase I processes are not significant and may not be influential. However, marginally improved biphasic representations may imply that removal of early sampling points is warranted although this may affect the quality for subsequent kinetics *via* a reduced dataset. Elimination of data points should consequently be avoided. Therefore, greater clarity of guidance regarding criteria under which otherwise high quality SFO fits would be set aside was requested. In such cases, it would be necessary to justify that surface-loss processes are not occurring. It was highlighted that the procedure may become quite complex and a degree of simplicity or pragmatism would be appreciated.

4.2. How to use/choose lab, field and accumulation DegT50 values for exposure assessment

Summary of the topic

A tiered approach was presented for obtaining DegT50 to be used as input parameters throughout the exposure assessment scheme. Currently, field studies are considered as higher-tier assays in the regulatory framework and tend to over ride lab studies, however, the Working Group did not find scientific underpinning for this.

The approach proposed for deriving DegT50 values starts by using the mean or median of $DegT50_{lab}$. In successive steps, the WG proposed to use the mean DegT50 from lab together with DegT50 of phase II of field dissipation and accumulation studies.

Summary of the discussion

Stakeholders mentioned that field dissipation studies are designed to study exposure under real conditions of use, where faster processes can occur due to a range of circumstances. Laboratory studies are conducted under controlled conditions, where no new nutrient inputs are added. Stakeholders considered that field studies should be viewed as a higher tier as they are more realistic. Disagreement between stakeholders and the WG regarding whether the status quo (e.g. consideration of field data as a more realistic higher tier refinement) was defensible meant that a consensus on this issue could not be reached. Concerns also arose in

the break-out session when only a few $DegT50_{field}$ are available to be used as input data in the exposure assessment.

4.3. Use of accumulation studies to derive DegT50

Summary of the topic

There are concerns in the WG on whether the DegT50 value(s) derived from accumulation studies are accurate enough to be used in the exposure assessment.

During the presentation, it was mentioned that soil accumulation studies are designed to monitor residues after repeated applications over a number of years. However, only a few measurements per year are usually available. Moreover, the application on a full-grown crop may influence the amount of pesticide reaching the soil surface. Because of the design of the accumulation studies, it is not possible to estimate the fraction that penetrates into the soil separately from the loss by true degradation. It was acknowledged that influence of foliar interception can be taken into account but wash-off potential is less easily addressed. In this way, only the DegT50 needs to be fitted. However, this parameter may be strongly influenced by incorrect estimates of the fraction that penetrates into the soil matrix.

Summary of the discussion

It was highlighted that the variation in the designs of accumulation studies would limit their potential to derive a DegT50 value to be used in the exposure assessment. The key point in deriving DegT50 would depend on the quality of the study. It was mentioned that generally accumulation potential in soil is handled by modelling rather than by use of experimental data. However, it should be taken into account that accumulation studies may give additional information on the possible phytotoxicity, ecotoxicity and residues on succeeding crops. The discussion on this topic continued in break-out group 5. It was noted by industry representatives that an assembly of 14 field soil accumulation studies were offered as a means of allowing further evaluations.

4.4. Use of FOMC (First-Order Multi-Compartment) kinetics in accumulation calculations

Summary of the topic

FOMC kinetics is conceptualised as an infinite set of static compartments into which the dose of a compound is distributed at the time of application, with each of those compartments having a first-order degradation rate associated with it. A gamma function is used to describe a probability density function (pdf) for the distribution of unique degradation rates (statistically some will be zero). The result is a relatively simple equation that can simulate a bi-phasic pattern of degradation with only three parameters - M0, α and β.

The use of FOMC kinetics has some drawbacks for its implementation in pesticide models to evaluate long-term accumulation because: a) the degradation is time-dependent; b) it is often difficult to optimise to a unique solution; c) it is based on a static model assumption whereas exposure models are based on dynamic system assumptions; d) residues after repeated applications may not be distributed into identical gamma function pdfs; e) extrapolation beyond the experimental period is not recommended.

Summary of the discussion

There was a general agreement in the break-out session with recommendations of the WG that FOMC kinetics should not be used for accumulation assessment because of the difficulties with not reaching unique solutions and with long-term persistence predictions beyond the experimental period. However, clarification is needed regarding the implications of this recommendation for groundwater modelling.

4.5. Other topics arising during the break-out and plenary sessions

A question arising during the break-out session was how to handle field persistence under Nordic/Baltic conditions. It was mentioned that a proposed scenario in the Northern zone would take into account these agroclimatic conditions. However, clarification was requested regarding the effect of temperature and the photo period on the degradation of compounds under Northern sunlight conditions.

Finally, during the presentation of the conclusions of break-out group 4, the need of an approach to handle the persistence of metabolites was highlighted. It is clear that proposals for characterisation of Phase I and II behaviour have the potential to eliminate Phase I processes that are influential in the formation of distinct metabolites (e.g. photolysis). Recommendations to eliminate fast phase I behaviour for modelling purposes may be incoherent in the context of metabolite risk assessment. Further clarifications regarding the relevance of certain recommendations (primarily designed for parent substance) to metabolite risk assessment appear warranted.

4.6. Conclusion

Overall, the influence of the loss processes in surface soil on the fate of the chemicals in the top soil layer was recognised. However, clear guidance and criteria (with a certain degree of simplicity and pragmatism) were demanded. Stakeholders considered that field studies should be viewed as a higher tier and not only for modelling purposes, as they are more realistic than laboratory studies regarding the fate and behaviour of pesticides.

The limitation of accumulation studies to derive a DegT50 to be used in exposure assessment was recognised and it was also noted that currently the accumulation potential in soil is frequently addressed through theoretical calculations rather than through experimental data. However, it was noted that accumulation studies can give useful information under real conditions to be considered during the risk assessment.

There was general agreement in the break-out session with recommendations of the WG that FOMC kinetics should not be used for extrapolation to accumulation assessment. However, clarification was requested regarding the implications of this recommendation for groundwater modelling.

Finally some concerns regarding how to handle persistence of metabolites were noted.

5. Break-out Group 5: Scenario Selection for calculating PECs (Rapporteurs: Giovanna Azimonti, Tim Jarvis)

5.1. Scenario Selection Proposals

All the discussion was focussed on tier 2 approach for PECs calculation as tier 1 is not yet available nor designed. Concerns were raised on the availability of 6 scenarios for arable crops but no scenarios for permanent crops and others: this will leave too much "space" for interpretation and proposals from the notifier side if no clear guidance exists. The audience felt that tier 1 could probably solve the PECs calculation for the majority of the compounds: therefore the major expectation is in the development of this tier.

5.2. Summary of Discussion

The discussion addressed mainly six topics:

1. Dealing with uncertainty
2. Development of scenarios
3. Availability of scenarios
4. Comparing pore water concentrations
5. Effect of pH
6. Usefulness of field accumulation studies

Dealing with uncertainty

Jan Vanderborght gave a detailed presentation dealing with numerical calculations of uncertainties in the approach used for tier 2 soil scenarios. In subsequent discussions there were questions raised from the floor concerning the appropriateness of 25% CV assumption for DegT50. This value of the variation in degradation rates in studies had come from published work by Allan Walker but there were some views from the floor that the coefficient of variation of data (particularly field derived) from regulatory submissions was rather higher than this. It was therefore proposed that a trial run with a single scenario should be undertaken with an arbitrary value for the CV (e.g. 40%) to determine if the effect on the magnitude of the soil PEC would be significant

Development of scenarios

Aaldrik Tiktak gave a detailed presentation on the development of the tier 2 scenarios for arable crops with conventional tillage. He then provided subsequent clarification on the Organic Carbon content map which is a model of OC and not real values – hence there was a need to provide a sanity check of the selected scenarios (i.e. the Northern EU scenario containing 40% OM).

The presentation posed the question of what combination of spatial vulnerability and degradation rate vulnerability should be used to obtain the overall 90th percentile vulnerability for the scenario. The audience agreed with the Workgroup proposal to use median/mean DegT50 value and not worst case (hence spatial vulnerability would be at 95th percentile).

Availability of scenarios

During discussions it was confirmed that the tier 2 scenarios for annual crops with conventional tillage will be available in 2009 (both for pore water and total content). EFSA clarified that others should ideally be produced, but there were timeframe constraints. There was a request from the audience for permanent crops to be addressed next. A delegate queried how users would select which other scenarios should be used and it was considered to be the responsibility of the notifier to make a case for the scenario that they used for the regulatory submission. Following on from this point a further delegate asked if notifiers could have access to data to construct their own scenarios. In response EFSA stated that this would have to be agreed with JRC (the data holder) and this would depend on how much data was required. Moreover, EFSA confirmed that guidelines are to be prepared to clarify how the output of "new scenarios" proposed by the notifier has to be delivered.

Comparing pore water concentrations

A delegate noted that since PEC values for pore water are being developed it would also be important to have guidance on calculating this parameter in the effect tests (since at least historically, this parameter has not been measured). There have been some discussions about this in the EFSA BUGS working group (dealing with ecotoxicological effects to soil organisms) but full consideration would have to await the Terrestrial Guidance Document revision and this had not started yet.

Effect of pH

The PEC values would vary for ionisable substances depending on the soil pH (particularly for the pore water value) and hence some further considerations for dealing with this were proposed in a presentation by Ian Hardy. The audience was in agreement that the proposed approach was reasonable. There was a view from some in the audience that there might be a "self compensating effect of pH sensitive substances" i.e. higher toxicity when less bioavailable but it was agreed that there was only indirect evidence for this. Nobody was aware of data directly supporting this.

Usefulness of field accumulation studies

In addition to earlier discussions undertaken in break-out group 4, views were expressed in break-out group 5 that accumulation studies were difficult to interpret (including determining if particular studies represented a 90th percentile worst case for the pesticide in question). Some regulators present indicated that they were currently only used for confirmatory purposes (of theoretical plateau PEC values) but others noted that they could still be useful. People felt that there were seldom sufficient data points for DegT50 calculations in accumulation studies. However, there was little appetite to try and design better studies. It was also noted that GIS approach could be helpful to design better accumulation studies and show the representativeness of such studies. A delegate from the US-EPA noted that in the USA the regulators have dropped the requirement for accumulation studies in favour of longer dissipation studies.

5.3. Conclusion

Clear and simple guidelines are required to address both the presented tier 2 and the possible new scenarios proposed by notifier.

The quick development of a "strong" Tier 1 is highly recommended.

SUMMARY OF PLENARY DISCUSSION ON IRIS – IMPROVED REALISM IN SOIL RISK ASSESSMENT

(Rapporteurs: Simon Hoy, Werner Pol)

The following is a summary of points raised by stakeholders in the final plenary discussion. It also includes some important general issues which were mentioned in the Plenary and earlier break-out groups but which were not covered under the specific topics given to those groups.

6. Summary of Plenary Discussion

Firstly, the stakeholders wished to thank the EFSA PPR unit and working group(s) for their work thus far on developing the guidance and for inviting them to this workshop to express their views. Appreciation was also given to JRC for their valuable scientific co-operation and for hosting the IRIS workshop.

During the Plenary there was much discussion over the importance of different soil depths and soil layers in the proposed soil risk assessment. Some stakeholders were not clear how the need to consider different soil layers was being established, or how it might be implemented in practice. The use of a 20 cm soil depth for reduced tillage situations was questioned and there was also concern about the number of unnecessary soil PEC values and scenarios which might result according to some of the proposals. There was clearly a need to tie up the ecoregions concept analysis and the exposure calculations with the agronomic information on soil management practices. In particular, the role of the litter layer was discussed. It was not clear to stakeholders in which crops/situations this was really important and whether the litter layer should be included with the soil assessment or with other areas of risk assessment (e.g. surface dwelling non-target arthropods (NTAs)). If included with the soil assessment, it was then not clear what the most relevant exposure metric for the litter layer would be.

A major role for the soil ecology sub-group was considered to be in determining the appropriate soil layers, depths and metrics for the key soil organisms. However, the focal groups for the soil risk assessment first needed to be clarified in the regulations and the availability of suitable tests methods should also be confirmed. Confirmation of the averaging concept over different zones could also be explored further by the ecology group.

Some stakeholders were not clear how 40% organic matter (OM) soils fitted in with the ecoregion approach. It was determined that the basis of this scenario was a 90th percentile vulnerable site from the Northern EU zone (which was found in Estonia from JRC soil maps). Stakeholders wondered how relevant such a soil was for agricultural production and also the scale of any such land use - and they considered that an additional 'plausibility check' would be helpful. If such soils were relevant only in certain Member States (MS), then it might be better to deal with them locally rather than in an EU-wide or zonal assessment.

It was questioned how well the three geo-political zones proposed in the new PPPs Regulation fitted with the ecoregion concept. It was clear that these zones were not based on ecological principles or on soil characteristics, and even climatically they were quite crude. However, the fate group had shown that exposure differences between these zones are relatively small and therefore, it was questioned whether it was worth the effort of making this differentiation between zones. Could the variability be taken into account by a single realistic worst case calculation (particularly at Tier 1)? Stakeholders felt that the key differentiation between zones may rely more on crop type, soil depth/profile and associated

organism community rather than fate scenarios. Therefore, this was mainly a question for the soil ecologists to resolve. This applies for both exposure concepts, i.e. whether soil pore water or total content.

Many questions from stakeholders revolved around whether and when the soil pore water (pw) exposure concept was a necessary or useful alternative (or addition) to total soil content (tc). This was also extensively discussed in some break-out groups. It was apparent that the more vulnerable sites for pore water exposure are not the same for total content and therefore, this may lead to some important choices for risk assessment. However, this may not be such an important issue since soil risk assessments are based on real crop situations and must cover all vulnerable situations over a relevant spatial scale. The key distinction was in setting the level of coverage and precaution correctly at each tier, with clear triggers for moving on to more refined higher tier assessments. Whilst lower tier assessments needed to be precautionary, they should also have enough filtering capacity to avoid unnecessary higher tier assessments. It was felt that the new pore water information might be useful in, for example, helping to refine exposure assessments and avoid triggering such higher tier effects studies, or to assist with the choice of field study sites when these were required.

In standard risk assessments, regulatory ecotoxicologists liked to compare like-with-like (in terms of exposure and effects). It was questioned, for example, whether for soil risk assessments we should be comparing pw-with-pw; tc-with-tc; initial-with-initial; measured-with-measured, measured-with-modelled, modelled-with-modelled... The timescale of the assessment (whether acute or chronic) is also important in determining the appropriate effects, endpoints and exposure levels to compare with each other - for example when determining whether to use maximum initial, mean measured or time-weighted average (TWA) exposures. Different exposure patterns in the test and field may also need to be considered, particularly for impersistent compounds and with multiple applications.

Often the 'best' effects endpoint was felt by many stakeholders to be a measured endpoint but current soil ecotoxicological test protocols did not require this and there were no standard tools to derive it. If measured endpoints would be necessary in future, then guidance and revised protocols would be needed. Updates to OECD and ISO protocols were possible but would take time (and sufficient prioritisation) to come through. Extraction and analysis of exposure concentrations was also expensive, difficult to measure and appropriate methods were not always apparent. Modelling of exposure in tests was an alternative, but in both cases guidance is needed on how to mimic the exposure in ecotoxicological tests. However, measurement (or modelling) of pore water or total content concentrations would need to be justified to determine whether this extra step and cost was really necessary. At present, many stakeholders did not feel that this was justified given the relatively few 'failures' in existing soil risk assessments and the relative ease and costs of conducting already well established higher tier effects tests.

Ideally there needed to be a cost / risk / benefit analysis before establishing any new approach. This should focus, in particular, on the triggers for the different Tiers of assessment and ideally the level of precaution at each tier. Historical and current data could be used for such a 'validation' and a comparison with the existing system; however, there may be problems with accessing relevant data. Publicly available information (e.g. in draft assessment reports (DARs)) was not always sufficiently detailed and actual study reports with raw data may be required. At least one of the industry representatives at IRIS did offer to provide access to relevant data.

Stakeholders felt that potentially a lot of work was required to develop Tier 3 approaches when they might be used infrequently and would, in any case, have to be quite region and crop/use specific. Since higher tier effects studies are not often triggered at present, the focus of any further work should be on establishing an appropriate Tier 1 exposure and effects assessment.

There was some consensus amongst stakeholders that **if** pore water **is** the most relevant metric, then it would be scientifically correct to move towards such an approach. However, there were conflicting views about whether there were sufficient data to support this view, or any regulatory need to make that decision at present. Some felt there was enough information to justify the approach scientifically but others felt that the above-mentioned validation and historical analysis was required first. There was, however, general agreement in the plenary that further case-studies were required (encompassing a range of relevant soils and pesticide chemistry) in order to substantiate any new approach for regulatory use.

The initial stakeholder consultation had determined a number of practical problems with using the original 'persistence guidance document'. At that stage, a full-blown soil risk assessment guidance document was not envisaged and so some MS soil ecotoxicologists did not respond to this consultation. Whilst good progress had been made in some areas, a number of problematic issues had not been addressed by the PPR working group and some were actually listed as 'restrictions' (e.g. seed treatments, band applications, how to deal with metabolites and bound residues), or it was unclear how the group's proposals would address them. The group was, therefore, urged to re-visit the initial consultation to see what 'problem areas' could most usefully be addressed.

7. Conclusions of the Plenary Discussion

In overall summary, a number of more general points were raised by stakeholders relating to EFSA's procedures for revising this and other guidance documents. All stakeholders welcomed and appreciated the efforts of the PPR working groups but many questioned the real drivers for change given that current soil risk assessments seem to be simple, effective and sufficiently precautionary, at least for earthworms and soil microbial functions. Whilst it was acknowledged that the existing regulatory system and triggers had also not been 'validated', many stakeholders felt that uncertainties in soil risk assessment are well covered by current safety factors and questioned whether every area of uncertainty needs to be understood in detail. Based on existing legislation (at least Annex VI of Dir. 91/414/EEC), decision-making principles had only been established for earthworms and soil microbial functions and whilst there were revised proposals for Annex II and III data requirements, there had, as yet, been no change to the ecotoxicology uniform principles.

Until it was clear what the regulatory protection goals for soil would be under the regulation to replace 91/414/EEC, many stakeholders felt that major changes to the risk assessment guidance were premature. Depending upon whether the protection goals were principally agronomic and 'functional' (e.g. microbially mediated nutrient cycling, OM breakdown) or 'structural' (e.g. effects on earthworm populations and other soil macro-invertebrate communities), or both - then different risk assessment approaches might be followed. What type, level and duration of effects (i.e. recovery period) were 'acceptable' in relation to exposure patterns and other agronomic factors, should also be considered.

It was acknowledged that these were risk management decisions outside the remit of EFSA. However, the Commission and EFSA were asked by stakeholders to reconsider their procedures to ensure that MS risk managers and risk assessors were consulted very early in the process - to establish clear protection goals and areas requiring revision. This would help focus efforts where they are really needed. At present the revision process for guidance documents appeared to be academically driven and bottom-up rather than top-down. Given that the principle users of the guidance documents are MS and industry risk assessors, who work according to legislation, there needed to be greater synergy between the science and regulation. Although EFSA's concerns about public perception were well understood, it was also questioned whether their position on excluding active industry involvement always helped to create the most suitable guidance.

Some stakeholders pointed out the need to have a clear transition period when implementing new guidance, with clear cut-off dates for implementation and a process for dealing with historical data. This need was acknowledged by EFSA and further development of the guidance documents (as opposed to PPR Opinions) would be taken forward by the Commission and MS. Stakeholders also proposed that the influence of any new exposure predictions on other areas of assessment (e.g. residues, following crops, groundwater) should be considered by cross-checking with other guidance. It was pointed out that soil DT50/DegT50 was often the most relevant value in these areas and there was now clearer direction on how to derive DegT50s and use information from field studies.

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APPENDIX A – WORKSHOP PROGRAMME

FIRST WORKSHOP DAY (12 MAY 2009)

Presentations in Plenary, *Chairs: Mark Egsmose, Karin Nienstedt, Stephanie Bopp*

14:00-14:10 Official Workshop Opening: Welcome Address
Leen Hordijk, Director of JRC-IES (Institute for Environment and Sustainability)

14:10-14:30 Panel on Plant Protection Products and their Residues (PPR)
Work Programme for updating and developing EU Guidance Documents
Muriel Dunier-Thomann, Head of Unit PPR, EFSA

14:30-14:50 Soil research and policy support at JRC
Ciro Gardi, Luca Montanarella, Land Management and Natural Hazards Unit, IES

14:50-15:10 Is it presently possible to assess the spatial distribution of agricultural pesticides in Europe? A screening study based on available data.
Alberto Pistocchi, Giovanni Bidoglio, Rural Water and Ecosystem Resources, IES

15:10-15:30 Ongoing revision of Guidance Documents in the environmental / terrestrial field
Mark Egsmose, Karin Nienstedt, Stephanie Bopp, PPR Unit, EFSA

16:00-16-30 The usefulness of total concentrations and pore water concentrations as metrics for the assessment of ecotoxicological effects in soil
Mark Montforts, RIVM (EFSA PPR Panel Member)

16:30-17:15 Exposure assessment in soil for terrestrial effect assessment
Jos Boesten, Alterra (EFSA PPR Panel Member)

17:15-17:30 Introduction to next day, break-out sessions
Stephanie Bopp, Karin Nienstedt, Mark Egsmose, PPR Unit, EFSA

SECOND WORKSHOP DAY (13 MAY 2009)

9:00-12:30 Break-out sessions

12:30-14:00 Lunch

14:00-18:00 Break-out sessions

Details on following page:

Group 1 Soil Ecoregions and Risk Assessment and **Group 2** Ecochemistry and Risk Assessment

9:00-9:40	Bioavailability and suitable soil metrics in risk assessment of PPPs *(Willie Peijnenburg, John Jensen)*	
9:40-10:20	Defining Soil Ecoregions for soil exposure scenarios *(Paulo Sousa, Christine Kula, Jörg Römbke)*	
10:20-10:45	The litter layer in the context of the risk assessment of pesticides *(Jörg Römbke, Ettore Capri, Christine Kula, Paulo Sousa, Mark Montforts)*	
11:15-16:30	**Group 1: Soil Ecoregions and RA** *Chair: Christine Kula* *Rapporteurs: Lise Samsøe-Petersen, Kevin Brown*	**Group 2: Ecochemistry and RA** *Chair: Matthias Liess* *Rapporteurs: Roger Holten, Thorsten Leicher*
17:00-18:00	Joint meeting of all Ecotoxicology Participants, *Chair: Robert Luttik* Rapporteurs report back from groups 1 and 2, Synthesis of day 2 Ecotoxicology groups	

Group 3 Soil Management Practices**, Group 4** Handling of field accumulation studies, and **Group 5** Scenario selection for PEC calculations

9:00-9:10	Short introduction to the day program *Chairs: Walter Steurbaut, Damia Barcelo*	
9:10-9:40	Overview of soil and crop management practices and consequences for exposure assessments *(Ettore Capri)*	
9:40-10:10	Handling of field experiments in exposure assessment for terrestrial effect assessment *(Jos Boesten)*	
10:10-10:20	Determination of SFO DegT50 (half-life) values for Model Input *(Ian Hardy)*	
10:20-10:30	The appropriateness of FOMC Kinetics in the context of long-term accumulation calculations *(Ian Hardy)*	
11:00-12:30	**Group 3: Soil Management Practices** *Chair: Michael Klein* *Rapporteurs: Arnaud Boivin, Gerhard Görlitz*	**Group 4: Handling of field accumulation and persistence studies** *Chair: Richard Bromilow* *Rapporteurs: Elena Alonso-Prados, Neil Mackay*
14:00-14:15	Short summary of discussions in Group 3 and 4 by rapporteurs	
Group 5: Scenario Selection for PEC calculations *Chair: Christopher Lythgo, Rapporteurs: Giovanna Azimonti, Tim Jarvis*		
14:15-14:30	Introduction: The tiered assessment scheme and the role of the Tier-2 scenarios *(Aaldrik Tiktak, Jos Boesten)*	
14:30–14:40	The use of pedotransfer functions for estimating soil bulk density *(Ian Hardy)*	
14:40-15:10	Dealing with uncertainty in pesticide fate model scenarios for pesticide registration *(Jan Vanderborght, Aaldrik Tiktak)*	
15:25–16:00	Procedure for developing the Tier-2 scenarios and results of selection procedure *(Aaldrik Tiktak, Jan Vanderborght)*	
16:00-16:10	Effect of soil pH on the sorption of ionisable compounds *(Ian Hardy, Richard Bromilow)*	
16:10-18:00	Discussion of scenario selection, Synthesis of day 2 (rapporteurs) and outlook on day 3	

THIRD WORKSHOP DAY (14 MAY 2009)

Feedback presentations from the break-out groups to the plenary and discussion in plenary

Chairs: Mark Egsmose, Karin Nienstedt and Robert Luttik

9:00-9:10 Introduction to the program of the day

9:10-9:40 Feedback from Group 1 Soil Ecoregions and Risk Assessment (*Lise Samsøe-Petersen, Kevin Brow)* and Group 2 Ecochemistry and Risk Assessment (*Roger Holten, Thorsten Leicher)*

9:40-10:10 Feedback from Group 3 Soil Management Practices (*Arnaud Boivin, Gerhard Görlitz),* Group 4 Handling of field accumulation and persistence studies (*Elena Alonso-Prados, Neil Mackay),* and Group 5: Scenario Selection for PEC calculations (*Giovanna Azimonti, Tim Jarvis)*

10:30-12:00 Plenary Discussion on "How to improve Risk Assessment in Soil" (*Rapporteurs: Simon Hoy, Werner Pol)*

12:30-12:50 Summary of the plenary discussion (*Werner Pol, Simon Hoy)*

12:50-13:00 Outlook and closing remarks (*Mark Egsmose, Karin Nienstedt, Stephanie Bopp)*

APPENDIX B – LIST OF PARTICIPANTS

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APPENDIX C – GLOSSARY / ABBREVIATIONS

EFSA	European Food Safety Authority
FOCUS	Forum for the co-ordination of pesticide fate models and their use
FOMC model	First order multi-compartment model
GD	Guidance Document
IRIS	Improved Realism in Soil Risk Assessment (EFSA-PPR Stakeholder Workshop)
MS	Member State
NTA	Non-target arthropods
OECD	Organisation for Economic Co-operation and Development
OM	Organic Matter
pdf	probability density function
PEC	Predicted Environmental Concentration
PPP	Plant Protection Product
PPR Panel / Unit	Panel / Unit on Plant Protection Products and their Residues
RA	Risk Assessment
DegT50	Degradation time Term with no association to any particular type of kinetics to describe the time taken for a 50% decline in mass or concentration of a substance to occur by degradation from the environment or an environmental compartment after it has been applied to, formed in, or transferred to, an environmental compartment.
DT50	Disappearance/Dissipation time Term with no association to any particular type of kinetics to describe the time taken for a 50% decline in mass or concentration of a substance to occur by dissipation from the environment or an environmental compartment after it has been applied to, formed in, or transferred to, an environmental compartment.