Opinion of the Scientific Committee on Plants on the Draft Guidance Document on Persistence in Soil (DG VI - 9188/VI/97-Rev.5 of 20.12.1998) - (Opinion expressed by the Scientific Committee on Plants on 24 September 1999)

1.0 Terms of reference

The draft Guidance Document on **Persistence in Soil** had been referred to the Scientific Committee on Plants for consultation and a number of specific question with the following questions:

1. Do the criteria for conducting field dissipation studies adequately reflect a 'realistic worst case' (chapter 3)?

2. What is the opinion of the SCP with regard to the use of the Arrhenius equation to extrapolate degradation over different temperatures (c.f. Special Aspects of Laboratory Studies)?

3. What is the opinion of the SCP with regard to the relevance of non-extractable residues (chapter 6)?

2.0 Background

The draft Guidance Documents on Aquatic Ecotoxicology, on Terrestrial Ecotoxicology and on Persistence in Soil had been developed as a working documents of the Commission, with the purpose to provide guidance to Member States and to notifiers on the use of the respective chapters of Annexes II, III and VI of Directive 91/414/EEC [1]. They should ensure a uniform and harmonised approach of evaluation and risk assessment of active substances and plant protection products in the EC (European Community) review and in Member States. They were referred to the Scientific Committee on Plants for opinion. The Committee had also been supplied with the reports of the FOCUS [2] group and with comments from Member States and from ECPA on the draft guidance documents. This paper is written in response to the **Persistence in Soil** draft guidance document.

3.0 General observations

The guidance document intends to provide an overview of issues which need to be considered during the evaluation of soil persistence in the context of Directive 91/414/EEC. In a revised format it can be expected to contribute to better consistency and transparency in decision-making both on EC and Member State level. The document should be revised regularly, in order to reflect changes of test guidelines and of scientific knowledge. Particularly, the following areas are likely to require more detailed guidance in the near future:

a) Calculation of PEC [3] 's for soil (water, sediment and air are also required) e.g. Kloskowski **et al** (1999);

b) Calculation of the formation and degradation of metabolites;

c) Interpretation of inverse modelling data and other available data to determine the impact of soil temperature and moisture on degradation time with particular respect to colder climates;

d) Accounting for changes in bioavailability over time;

e) The use of standard methodologies to determine the most appropriate rate constant;

The SCP supports the need for a guidance document on Persistence in Soil but is of the opinion that there is scope for improved presentation, greater clarity and attention to the scientific justification of the specific guidance provided. This document responds to the questions put to the SCP by the Commission and in addition the Committee also noted the following aspects:

3.1 Terminology

There appears to be general confusion over the definitions of and differences between, persistence and non-extractable /bound residues. A section should be included in the Introduction or Persistence chapters to clarify the use of the terms.

3.2 Introduction / Overall presentation

The Persistence in Soil guidance document should cross-reference, and be compatible with, the guidance documents on Terrestrial Ecotoxicology and Aquatic Toxicology and - as much as possible at this stage - with the document on relevant metabolites. It should also reference the FOCUS document Soil Persistence Models and EC Registration (Document 7617/VI/96).

A number of comments from Member States and others state that there should be an upper limit for persistence. The SCP believes that arbitrary cut off points have no scientific validity and the environmental and agricultural significance of persistence should be assessed as outlined in the current guideline. Reference could be made to long term studies which investigate the influence of soil persistence and its impact on non-target soil organisms and agricultural productivity **e.g**. Bromilow **et al** (1996).

3.3 Persistence

The guidance document states that soil is the compartment of concern with regard to persistence. The SCP notes that persistence can also be an issue in other environmental compartments such as water, sediment or air. Since this guidance document is specific to soil a reference should be made to sources of information on persistence in the other compartments.

3.4 Determination of DT50/DT90 [4] and influential factors

3.4.1 Criteria for conducting field dissipation studies

The guidance document proposes that the decision for the conductance of field dissipation studies should be triggered by the result of a realistic worst case laboratory degradation study.

The SCP agrees with this proposal provided the points noted in the second paragraph of the chapter **'Criteria for conducting field dissipation studies'** are taken into account **i.e.** 'unless there is a convincing justification to disregard individual results'.

For example, if the worst case laboratory soil degradation rate derives from a soil which is representative of a current or potential use of the product, then the resulting value should be used as the trigger value. If however, a worst case laboratory degradation rate derives from a soil which is not representative of current or future use then the use of this worst case trigger would not be realistic **e.g.** the soil was selected to clarify relationships between degradation and pH or moisture content. This approach differs from the procedure adopted by the FOCUS group of using a mean value to characterise half-life for the purposes of predictive modelling. Mean values are used by FOCUS since soil and climate scenarios are already selected as realistic worst case.

It is also suggested that the wording of the second paragraph in this chapter is modified as follows:

'Generally, field studies have to be conducted in those cases where the $DT50_{lab}$ (for calculation see below) determined in the laboratory at 20 °C and at a moisture content of the soil related to a pF value of 2.0 to 2.5 (suction pressure) is greater than 60 days. The decision for the conductance of field dissipation studies should be triggered by the results of realistic worst case **laboratory** degradation studies. In general, to assess whether an active substance is persistent or not, the worst case degradation value from laboratory studies should be used, unless there is convincing justification to disregard individual results (e.g. due to methodological problems) **or it can be shown that the most unfavourable situation is an outlier.** A detailed consideration should be carried out if there is any special correlation to the soil type, e.g. pH dependence. Test conditions as specified in the Annexes II and III, points 7.1.1.2.1 and 9.1.1.1, respectively, for conductance of these studies should be followed as close as possible.'

3.4.2 Other comments

a) This chapter states 'at a moisture content of the soil related to a pF 2.0 to 2.5 (suction pressure)'. In the past there has been a great deal of variation in the moisture content and pressure status used for laboratory degradation studies causing difficulty in data interpretation and comparison. pF is not a commonly used term in some countries and it is suggested that the International Standard unit of measurement of Pascals is used to indicate the recommended suction range **i.e. -20** to **-32 kPa.**

b) The term 'cold climatic conditions' is not defined in this document. The definition should be referenced or included here.

3.5 Methods for calculation of DT50/90-values

3.5.1 General recommendations

The SCP considers that a determination coefficient (r^2) of >0.7 is not a reliable indicator of either accuracy or fit of a degradation curve. A coefficient as low as 0.71 could indicate that the data are variable and/or that degradation does not proceed via first order kinetics thus

incorrect assessments and extrapolation could be made. If this simplistic approach is maintained it is suggested that a higher determination coefficient of 0.85-0.9 is used.

Equations to calculate DT50/90 from first order kinetics or biphasic degradation are not clearly presented in this chapter. Consideration should be given to the presentation of a stepwise procedure starting with simple first order degradation and then proceeding to more complex kinetics. Guidance on how to estimate degradation when using two rate constants should also be included. In the case of complex degradation kinetics it may be necessary to sample at a number of time points to fully characterise the relationship. The use of the equations could be illustrated by examples (as in the FOCUS Soil Persistence Models document).

The guidance document should make it clear that the 'hinge point' referred to does not represent an instantaneous change in the degradation process as it currently suggests but is the product of the limitations of sampling intensity and does not reflect gradual changes in processes and possible bioavailability.

A number of curve fitting procedures are now available e.g. Gustafson and Holden (1990) or ModelManager (1999) and it is generally agreed that the work of Timme **et al** (1986) has now been superseded and should not be cited. Whatever the curve fitting approach used, it should be justified and should be plausible for future extrapolation.

The guidance document suggests that exclusion of 3 data points from the calculation of DT50 when a lag phase is identified may cause only two data points to remain for calculation. The guidance document should clarify that at least five sampling times, including zero time, must be available after excluding the 3 points of the lag phase. The SCP agrees that the length of the lag phase must also be quoted.

3.5.2 Special aspects of laboratory studies

The use of the Arrhenius equation has recently been discussed by the experts involved in the FOCUS group on Soil Persistence Models and EC Registration (Doc. 7617/VI/96). The group included a number of international independent experts who concluded that the use of the Arrhenius equation could be used to estimate transformation rates at 10°C from measurements made at 20°C. They stated that 'some debate still continues as to the suitability of the Q_{10} values for countries where average temperatures may be lower than 10°C but at present no solutions are available to the problem'. Members of the SCP concur with this view and suggest a stepwise investigation whereby any issues of particular concern can be clarified in the context of the data requirements in 91/414/EEC Annex II, 7.1.1.2.2. It is agreed that the equation will fail at low temperatures due to freezing and there is a need to collate existing data for degradation of plant protections products at temperatures below 10°C in order to improve future assessments. Uncertainty over the persistence of the active substance in cold temperatures is covered by the use of the trigger value for field dissipation studies of a DT50 value > 90 days (rather than 60 days) when assessing degradation at 10°C.

3.5.3 Special aspects of field dissipation studies

The content of this chapter should be reconsidered by the authors to include a number of key issues commented on below.

The section referring to other routes of dissipation is misleading as it states that 'volatilisation is not an important factor for most compounds' however it may be a dominant factor for some active substances. A full assessment of all factors which influence dissipation rates should be considered including volatilisation, photolysis and leaching in order to describe the behaviour of the plant protection product.

It would be useful to provide guidance with respect to depth of sampling. The Committee considers that core samples taken to determine dissipation rates should not be taken below 50 cm depth. Residue data from deeper layers are most relevant to leaching.

This chapter does not explore the critical issue of whether dissipation studies should be carried out on a bare soil plot or on a cropped plot. The SCP proposes that a stepwise procedure be adopted whereby an initial assessment should be made using bare soil plots and applying the formulated product at a typical time of year for its intended use. If resulting data give cause for concern then the notifier could make a case to justify the assessment of field dissipation rates under more realistic conditions with crop present in order to determine the effect of interception and other processes influenced by the presence of a crop such as photolysis and volatilisation on field dissipation rates. For example, a fungicide applied after growth stage 30 in cereals will be considerably intercepted by the crop. A herbicide applied at growth stage 11/12 will be minimally intercepted.

Another key issue not addressed is the problem often encountered in measuring soil residues from field dissipation studies whereby day 0 concentrations for the active substance are below nominal and then increase at day 1. The determination of the field dissipation rate is clearly influenced by the initial concentration and supporting data should justify choice of concentration used, together with relevant information such as, volatilisation, photolysis and accuracy of the application method.

Paragraph 4 of this chapter concerning interpretation of field data should refer to the FOCUS Soils Persistence Models and EC Registration Document 7617/VI/96 when discussing the effects of different variables on the dissipation of a product in addition to referencing specific authors.

3.5.4 Use of data from other geographical areas

The SCP disagrees with the guidance document which states that 'field dissipation studies will always be conducted in European countries' and believes that if it can be demonstrated that dissipation data generated outside of Europe is comparable to soil/climatic and agricultural conditions within Europe it should be accepted as part of the data submission.

4.0 Determination of the soil accumulation potential

This fifth paragraph of this chapter should refer to the Guidance document on Terrestrial Ecotoxicology with regard to accumulation and the effects of persistent substances on terrestrial organisms.

5.0 Plateau concentration versus unacceptable residues, effects and impact

The first paragraph states that 'persistent substances give rise to long-term exposure of organisms in the environment'. This statement does not take into account the bioavailability of the persistent substance to non-target organisms or succeeding crops.

Reference to the guidance document on terrestrial ecotoxicology should be made in this chapter.

5.1 Unacceptable impact on the environment

All mentions of FOCUS should be fully referenced. This chapter refers to realistic worst case scenarios whereas FOCUS scenarios are actually chosen on the basis of their vulnerability and mean Koc [5] and DT50 values are used. Given that summary papers on groundwater and surface water scenarios will be available shortly (see 5.1.1 and 5.1.2 below) this chapter should perhaps simply reference this work which addresses these concerns in detail. Full reports from FOCUS are expected in 2000.

5.1.1 Groundwater

A summary paper concerning the FOCUS groundwater scenarios will shortly be available (Boesten **et al,** in press).

5.1.2 Surface water

A summary paper concerning the FOCUS surface water scenarios will shortly be available (Linders, in press).

6.0 Non-extractable residues

6.1 The 'unless' statement for non-extractable residues

This chapter of the document does not really provide any structured guidance for the reader concerning the interpretation or significance of bound residues, it is really a literature review which provides differing evidence on the scientific issues. It is however, clear from both historical and recent research that small fractions of the 'bound' residue may be released by a variety of processes and become potentially bioavailable.

It is the opinion of the SCP that the fractions of bound residue which are released are small and any concern over their ecotoxicology or effect on succeeding crops will have been addressed during studies required under Annex II and III for the active substance and relevant metabolites. The small fractions released from bound residues therefore have no additional significance from a regulatory view point. The SCP therefore believes that it is not necessary to discuss the issue of bound residues in detail in the guidance document and there should be no additional study requirements provided that appropriate and satisfactory long-term tests have been carried out.

Paragraph 2 states that 'levels of accumulation can be provided by a model calculation or by another appropriate assessment.' This section should refer back to Chapter 4, Determination of the soil accumulation potential. It should also provide reference to the FOCUS soil modelling workgroup document (Doc. 7617/VI/96) and other guidance documents, for example Kloskowski **et al** (1999).

The decision making scheme flow charts at the back of the guidance document are not referenced in the text. The chart "Part I" could be referenced in Chapter 4. The SCP recommends omitting the chart "Part II" because the plateau concentration in this chart has to be the plateau of the soil bound residue (it cannot be justified to assess the plateau of the parent compound in the case of >70% non-extractable residues). However, this is mentioned nowhere in the text and no guidance is given on how the plateau level of the soil bound residue should be assessed.

Executive Summary

1. Answers of the SCP to the specific questions

1. Do the criteria for conducting field dissipation studies adequately reflect a 'realistic worst case' (chapter 3)?

The draft guidance document proposes that the decision for the conductance of field dissipation studies should be triggered by the result of a realistic worst case laboratory degradation study. The SCP agrees with this proposal provided the points noted in the second paragraph of this chapter **'Criteria for conducting field dissipation studies'** are taken into account **i.e.** 'unless there is a convincing justification to disregard individual results'. For example, if the worst case laboratory soil degradation rate derives from a soil which is representative of a current or potential use of the product, then the resulting value should be used as the trigger value. If however, a worst case laboratory degradation rate derives from a soil which is not representative of current or future use then the use of this worst case trigger would not be realistic **e.g.** the soil was selected to clarify relationships between degradation and pH or moisture content.

2. What is the opinion of the SCP with regard to the use of the Arrhenius equation to extrapolate degradation over different temperatures (c.f. Special Aspects of Laboratory Studies)?

The use of the Arrhenius equation has recently been discussed by the experts involved in the FOCUS group on Soil Persistence Models and EC Registration (Doc. 7617/VI/96). The group included a number of international independent experts who concluded that the use of the Arrhenius equation could be used to estimate transformation rates at 10°C from measurements made at 20°C. They stated that 'some debate still continues as to the suitability of the Q_{10} values for countries where average temperatures may be lower than 10°C but at present no solutions are available to the problem'. Members of the SCP concur with this view and suggest a stepwise investigation whereby any issues of particular concern can be clarified in the context of the data requirements in 91/414/EEC Annex II, 7.1.1.2.2. It is agreed that the equation will fail at low temperatures due to freezing and there is a need to collate existing data for degradation of plant protections products at temperatures below 10°C in order to improve future assessments. Uncertainty over the persistence of the active substance in cold temperatures is covered by the use of the trigger value for field dissipation studies of a DT50 value > 90 days (rather than 60 days) when assessing degradation at 10°C.

3. What is the opinion of the SCP with regard to the relevance of non-extractable residues (chapter 6)?

It is clear from both historical and recent research that small fractions of the 'bound' residue may be released by a variety of processes and become potentially bioavailable. It is the opinion of the SCP that the fractions of bound residue which are released are low and any concern over their ecotoxicology or effect on succeeding crops should have been addressed during studies required under Annex II and III for the active substance and relevant metabolites. The small fractions released from bound residues therefore have no significance from a regulatory view point. The SCP therefore believes that it is not necessary to discuss the issue of bound residues in detail in the guidance document and there should be no additional study requirements provided that appropriate and satisfactory long-term tests have been carried out.

2. Observations and recommendations of the SCP to other issues

The guidance document should be reviewed/revised regularly. The following areas are currently likely to require more detailed guidance in the near future:

- Calculation of PEC's for soil (water, sediment and air are also required) e.g. Kloskowski **et al** (in press);

- Calculation of the formation and degradation of metabolites;

- Interpretation of inverse modelling data and other available data to determine the impact of soil temperature and moisture on degradation time with particular respect to colder climates;

- Accounting for changes in bioavailability over time;

- The use of standard methodologies to determine the most appropriate rate constant.

The SCP supports the need for a guidance document on Persistence in Soil but is of the opinion that there is scope for improved presentation, greater clarity and attention to the scientific justification of the specific guidance provided. There also appears to be general confusion over the definitions of and differences between, persistence and non-extractable /bound residues. A number of comments from member states and others state that there should be an upper limit for persistence. The SCP believes that arbitrary cut off points have no scientific validity and the environmental and agricultural significance of persistence should be assessed as outlined in the current guideline. The SCP considers that a determination coefficient (r^2) of >0.7 is not a reliable indicator of either accuracy or fit of a degradation curve. A coefficient as low as 0.71 could indicate that the data are variable and/or that degradation does not proceed via first order kinetics thus incorrect assessments and extrapolation could be made. If this simplistic approach is maintained it is suggested that a higher determination coefficient of 0.85-0.9 is used. Equations to calculate DT50/90 from first order kinetics or biphasic degradation are not clearly presented in this chapter. Consideration should be given to the presentation of a stepwise procedure starting with simple first order degradation and then proceeding to more complex kinetics. A full assessment of all factors which influence dissipation rates should be considered including volatilisation, photolysis and leaching in order to describe the behaviour of the plant protection product. It would be useful to provide guidance with respect to depth of core sampling in field dissipation studies. The SCP considers that core samples taken to determine dissipation rates should not be taken below 50 cm depth.

Residue data from deeper layers are most relevant to leaching. The SCP proposes that a stepwise procedure be adopted for assessing field dissipation whereby an initial study should be made using bare soil plots and applying the formulated product at a typical time of year for its intended use. If resulting data give cause for concern then the notifier could make a case to justify the assessment of field dissipation rates under more realistic conditions with crop present in order to determine the effect of interception and other processes influenced by the presence of a crop such as photolysis and volatilisation on field dissipation rates. The determination of the field dissipation rate is clearly influenced by the initial concentration and supporting data should justify choice of concentration used together with relevant information such as, volatilisation, photolysis and accuracy of the application method. The SCP disagrees with the guidance document which states that 'field dissipation studies will always be conducted in European countries' and believes that if it can be demonstrated that dissipation data generated outside of Europe is comparable to soil/climatic and agricultural conditions within Europe it should be accepted as part of the data submission. The guidance document states that 'persistent substances give rise to long-term exposure of organisms in the environment'. This statement does not take into account the bioavailability of the persistent substance to non-target organisms or succeeding crops. Reference to the guidance document on terrestrial ecotoxicology should be made in this chapter. Summary papers concerning the FOCUS ground and surface water scenarios will shortly be available and these should be referenced.

6. Acknowledgements

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Professor A. Hardy (Chairperson), and Committee Members Dr. H. G. Nolting and Prof. A. Silva Fernandes and invited experts Drs. V. Forbes, J. Boesten, A. Carter and T. Sherratt and Mr H. Koep.

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[1] **OJ L 230, 19. 8. 1991, p.1.**

[2] **Forum for the Co-ordination of Pesticide Fate Models and their Use**

[3] **Predicted environmental concentration**

[4] **Disappearance time for first 50%/90% of compound**

[5] **Organic carbon adsorption coefficient**