REPORT OF EFSA

Public consultation on the existing Guidance Document on Persistence in Soil

Prepared by PPR Unit

(Question No EFSA-Q-2007-184)

Issued on 26 Jan 2009

Contents

This compilation contains the comments received via the electronic form after the public consultation which closed at March 25th, 2008. This compilation contains the comments received regarding the existing Guidance Document on Persistence in Soil. Comments received with respect to Draft project plan for the revision of the guidance document are published in a separate table.
Duplicated comments received from the same contributor appear only once and comments submitted by individuals on personal capacity are published anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization.
A report on the outcome of the public consultation is published on the EFSA website:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681377888.htm

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

Contributor	Section	Comment
Pesticides Safety Directorate	1.0 General comments	In general, it is considered that much of the detail and guidance contained within rev. 8 of the guidance document is still valid and does not require extensive revision. The main areas that need to be updated are a) Chapter 3, section "Methods for calculation of DT50/90 values" to reflect the FOCUS Degradation Kinetics guidance document b) to ensure that references to data requirements, "trigger values" and "unless" clauses reflect any agreed changes as a result of revision of Directive 91/414/EEC c) take account of the latest PPR opinion on choice of Q10 for effect of temperature on degradation rate.
Swedish Chemicals Agency	1.0 General comments	We welcome a revision of the current Guidance Document on Persistence in Soil (9188/VI/ rev. 8, 12.07.2000). The document has become obsolete. Therefore, at this point in time, we do not think that merely a revision is appropriate but rather (as already suggested by the new project plan) a new guidance document with focus not on "persistence" but on "exposure assessment in soil", hence a slightly different topic. There is only little practical guidance in the old document, and most of it has been superseded by other guidance documents (mainly the FOCUS reports). During development of the old guidance document views were diverging among experts on how to define "persistence" - as an intrinsic property of certain chemicals to resist degradation (in the general environment) or as a measure of duration of exposure in a very local environment (e.g., a treated field). Possibly, this lack of shared understanding of problem formulation resulted in the vagueness of the old guidance document. After finalisation of the old guidance document, the Stockholm Convention on Persistent Organic Pollutants (POPs) was adopted and ratified, and the Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants was established. The Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market now includes criteria related to persistence and bioaccumulation. The concerns related to persistence (in the wider sense) are addressed by these documents and the measures they provide. We therefore believe that it is appropriate to focus the new guidance document on the practical methods for risk assessment for local soil compartments.
Federal Environment Agency (German UBA)	2.0 Persistence	The trigger values have been defined using SFO degradation kinetics. Please discuss if new trigger values must be defined for biphasic (non-SFO) degradation kinetics with lower DT50 values. If not, please ensure that always both DT50 and DT90 trigger values are mentioned in the guidance document.

Contributor	Section	Comment
Federal Environment Agency (German UBA)	2.0 Persistence	Please update the definition of persistence, especially in consistence with other existing guidelines. Should loss processes reduce the persistence characteristic of a substance or should in such a case all compartments be assessed? Please add a definition of accumulation.
INIA	2.0 Persistence	please, update this section according the state of the art of the different aspects analysed.
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	Please define if the Walker correction and the Arrhenius equation (Q10 value) is applicable for biphasic (non-SFO) kinetic models.
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	Please define a check list for PECsoil (like the “CTB checklist” in case of GW modelling) in which cases a field dissipation or field accumulation study may be used on member state level for the authorisation for a plant protection product.
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	Please define which soil parameter (e.g. pH, oc%, CEC, clay%, etc.) must be covered in which value range to identify a particular contribution of each soil parameter on the degradation behaviour of the active substance and relevant metabolites.
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	Please define which level of detection is acceptable for a field dissipation and a field accumulation study.
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	Please define in which cases non-European field studies are acceptable (soil type, climate type, etc.)
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	The section on determination coefficient r2 should be erased and replaced by the section 6.3 “assessment of goodness of fit” in FOCUS Deg.kin. 2006

Contributor	Section	Comment
Federal Environment Agency (German UBA)	3.0 Determination of DT50/DT90 and influential factors	It is more than obvious that in particular the technical issues in section 3 have become outdated due to the release of FOCUS kinetics.
Swedish Chemicals Agency	3.0 Determination of DT50/DT90 and influential factors	In the second paragraph, it is recommended to base the decision for the conductance of field studies on the worst case degradation value from laboratory studies (unless it can be justified to disregard individual results). This guidance needs to be repeated in the new guidance document, because we do not think it is given elsewhere.
INIA	3.1 Criteria for conducting field dissipation studies	3.1 Criteria for conducting field dissipation studies It is stated in 9188/VI/97 rev. 8 guidance document that field studies have to be conducted in these cases where the worst case DT50 lab (SFO, 20ºC and pF2.0-2.5) > 60d or Dt50 lab (SFO, 10ºC and pF2.0-2.5) > 90d, when PPP is intended to be used in cold climatic conditions, unless there is a justification to discard individual results''. Here guidance is needed for: - the application of trigger values for DT50 lab when the kinetics used in the estimation are different from SFO, since the concept of DT50 value in SFO kinetics differs from that in a non-linear model (Biol. Fertil Soils (2001) 33: 558-564). See also comments on section 3.3.2 (No guidance is given in FOCUS degradation kinetic guidance document. - the application of the 'unless clause'. The FOCUS degradation kinetic guidance document (FOCUS DK) refers to experimental artefacts but there is not guidance on how to identify them.
INIA	3.2 Guidance for conducting laboratory and field dissipation studies	A summary of the current guidelines available for conducting lab and field studies in table format is desirable (including field accumulation studies).
INIA	3.3.1 General recommendations	This section should be updated considering the recommendations of FOCUS DK

Contributor	Section	Comment
INIA	3.3.2 Special aspects of laboratory studies	1.- The section should be updated taking into account the Opinion of the EFSA PPR Scientific Panel on Q10 value.I 2.- It would be appropriate to analyse if Arrhenius'' and Walker''s equations can be used for kinetics different to SFO. Arrhenius equation is usually used for chemical and enzimatic reactions rates whereas Gustafson model depends on parameters a and ß parameters; HS and DFOP kinetics have a break point; and the logistic model depends on the microbial growth rate.
INIA	3.3.3 Special aspects of field dissipation studies	1.- Guidance on the evaluation of the quality of field dissipation data for modelling should be included. Several indications are given in FOCUS DK (section 9.1), however there is not information on how to manage ageing residues. 2.- Clear guidance on how to use DT50f in modelling should be stated. Currently two approaches are proposed: I) normalization of DT50f. it is based on Arrhenius'' and Walker''s equations (Are they applicable for kinetics different from SFO?). An analysis of the suitability of this approach is desirable II) switch off of : i. subroutines other than degradation that allow the separate simulation of individual dissipation processes ii. subroutines describing t^o and moisture dependance of degradationin scenarios within one climatic region. 3.- Clear guidance on how to use DT50f in modelling should be stated when the kinetics are different from SFO.
INIA	3.4 Use of data from other geographical areas	1.- The extrapolations from US to European agroclimatic conditions are usually very difficult during the Peer Review. Under our understanding the information from US field studies can be only used in order to support the conclusions of the evaluation of the EU dossier.
Federal Environment Agency (German UBA)	4.0 Determination of the soil accumulation potential	The section is rather vague in wording and should be completely rewritten in a new GD. In particular, one error must be corrected: “With regard to the assessment of effects of persistent substances on terrestrial organisms, the extrapolation of the upper limits of the resulting ‘saw-teeth’-curve is of interest. The peak represents the exposure pattern that is relevant for toxicity testing as well as for the TER calculations.” (End of first bullet point.) In fact, the upper limits of the saw-teeth curve describe a situation in which the yearly applied rate of a pesticide is instantaneously distributed over the whole depth of the soil layer considered for accumulation (e.g., 20 cm for arable fields). This is a virtual figure with no relevance for the risk assessment. The actual level to consider is the sum of background plateau (before yearly application) and standard PECsoil for the top layer.

Contributor	Section	Comment
INIA	4.0 Determination of the soil accumulation potential	- Three approaches are summarised in the guidance document: I.- A simple model calculation assuming 1st order kinetics. it should be updated considering the last version of FOCUS Guidance document on degradation kinetics . In this guidance document, simple PECsoil models are proposed for no SFO kinetics. This should be considered as a first Tier. II.- Accumulation field study to calculate plateau and to study the possible phytotoxicity. In the proposal of the project plan one of the objectives is to define the role of these study. It should be mentioned that directive 95/36/EC clearly states that accumulation field studies should be conducted when no reliable information can be provided by a model. Therefore, they are considered as higher tier studies. III.- Integrated studies of exposure (determination of plateau) and ecotox. Up to now the only ecotox higher tier studies are the litter bag study and the earthworm field study. Litterbag study cannot be considered as integrated study because the application rate used during the test depends on the PECsoil calculated in the fate section. With regard to earthworm field study, it should be taken into account that soil food webs and species composition vary with geography and climate. Guidance to conduct integrated studies are still needed and desirable.
Pesticides Safety Directorate	4.0 Determination of the soil accumulation potential	Chapter 4 of the document is the area likely to require major revision given the proposals contained in the work plan. The general recommendations as to need to estimate potential for soil accumulation remain extant. However, agreed and more detailed methodology for performance of calculations are required. Proposals for development of such calculations are contained in the work plan, and we have provided separate comments on this document.
Swedish Chemicals Agency	4.0 Determination of the soil accumulation potential	In the 5th paragraph, there is guidance provided on what value (upper/lower value of saw teeth curve) to use for what purpose. This kind of recommendation needs to be included in the new guidance document.

Contributor	Section	Comment
Federal Environment Agency (German UBA)	5.0 Plateau concentration versus unacceptable residues, effects and impact	This section mainly consists of cross-references, many of which are now outdated. It is obvious that a respective chapter in a new GD has to be written from scratch. For example: Unacceptable residues in succeeding crops: Update references: OECD guidance doc 502 and 504 Unacceptable phytotoxic effects on succeeding crops: Update references and clarification on the national level and reference to EPPO is considered the most approriate way to handle this subject in the frame of this document
Pesticides Safety Directorate	5.0 Plateau concentration versus unacceptable residues, effects and impact	Chapter 5 regarding unacceptable effects ought to reflect current state of play with respect to other guidance documents and revision of ecotoxicological data requirements.
INIA	5.1 Unacceptable residues in succeeding crops	1.- New guidelines regarding to phytotoxicity have been recently published: OECD 504 and EPPO PP1/207 (2). Please, update this section taking into account the state of the art. 2.- It is desirable to include guidance on how to link the two sections.
INIA	5.2 Unacceptable phytotoxic effects on succeeding crops	1.- New guidelines have been recently published: e.g EPPO PP1/135 (3). Please, update this section taking into account the state of the art. 2.- It is desirable to include guidance on how to link the two sections.
INIA	5.3.1 Groundwater	Clear guidance on how to derive appropriate degradation data for modelling in cases with clear deviation from SFO kinetics is desirable.
INIA	5.3.2 Surface water	Although for runoff and drainage loadings, the data of 20 consecutive years of pesticide application are considered, concerns arise on how to manage the accumulation in surface waters, since TOXSWA only calculate the PECsw for a given year.
INIA	5.3.3 Air	Please, update the impact on the air according to the state of the art Guidance on this aspect is desearible.

Contributor	Section	Comment
INIA	5.3.4 Impact on non-target species	1.- Currently, there is not available an guideline for conducting integrated studies of exposure (determination of plateau) and ecotox. A state of the art with respect this aspect is desearible. It should be taken into account that soil food webs and species composition vary with geography and climate.
Federal Environment Agency (German UBA)	6.0 Non-extractable residues	See the corresponding comment to section 1.4, line 249ff of the Project Plan. The assumption that “the small fractions likely to be released from bound residues are likely to have no additional significance from the regulatory view point” may require reconsideration by updating the scientific basis of that statement. Substantial research has been published in that area since the pertinent SCP opinion in 1999. The current approach for addressing high amounts of bound residues is based on the assumption that adverse effects would become visible after several years of consecutive use of a pesticide at the same site under constant environmental conditions. However, considerations on the possible formation mechanisms for bound residues might also suggest that release of such residues could be caused by changes in environmental conditions (pH, redox potential), e.g. due to a change in agricultural management.
INIA	6.0 Non-extractable residues	Progress towards significance of non-extractable residues has to be revised. A comprehensive evaluation should be done, and a guidance on how to comply with uniform principles needs to be included.
Pesticides Safety Directorate	6.0 Non-extractable residues	Chapter 6 on non-extractable residues ought to remain. It may be worth some minor revision to emphasis the fact that the implication of the ''unless'' statement relating to non-extractable residues is that risk as a result of accumulation of non-extractable residues must be addressed. Recent experience indicates that this may not be well understood, given that it is relatively uncommon for the ''unless'' statement on non-extractable residues to be triggered. An update of additional work, e.g. PSD sponsored work from the University of Lancaster, may be desirable, but to our knowledge, the state of play in terms of understanding the significance of non-extractable residues with respect to pesticide regulation has not advanced appreciably.