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Outcome of the Public Consultation on the Draft Project Plan for the Revision of the Guidance Document Persistence in Soil

Prepared by the PPR Unit

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Background

EFSA's Panel on Plant Protection Products and their Residues (PPR Panel) performed a public consultation on the existing Guidance Document on Persistence in Soil (SANCO 9188_VI_97), under Council Directive 91/414/EEC, as well as on the draft project plan for the revision of this Guidance Document (GD)[1]. The draft project plan, prepared by EFSA's PPR Panel, together with the existing Guidance Document was published on 29th January 2008 for public consultation until 25th March 2008.

The intention of the revision of this GD is to provide notifiers and Member States with guidance on environmental fate and behaviour of pesticides in soil in the context of the review of active substances notified for inclusion in Annex I of Directive 91/414/EEC, as well as for review of plant protection products for national registrations in Member States.

Comments received[2]

At the deadline, EFSA had received 34 comments on the existing Guidance Document on Persistence in soil from 4 interested parties (see table 1).

Table 1: Comments received on the existing Guidance Document

Source	Number of comments
UBA (Federal Environment Agency), Germany	12
Pesticide Safety Directorate, UK	4
INIA, Spain	15
Swedish Chemical Agency, Sweden	3

[1] See http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681377888.htm

[2] 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.

Regarding the draft project plan, EFSA received 124 comments from 12 interested parties (national authorities, industry and industrial associations, and consultants; see table 2).

Table 2: Comments received on the draft project plan for the revision

Source	Number of comments
UBA (Federal Environment Agency), Germany	25
Pesticide Safety Directorate, UK	24
Environmental Protection Agency, Denmark	13
INIA, Spain	12
Swedish Chemical Agency, Sweden	11
Ctgb (Board for the Authorisation of Plant Protection Products and Biocides), The Netherlands	7
Finnish Environment Institute, Finland	5
Austrian Agency for Health and Food Safety (AGES), Austria	1
BASF, Germany	14
ECPA (European Crop Protection Association), Belgium	3
Consultants (SCC, Germany and Enviresearch, UK)	9

All comments received were scrutinized and subsequently tabulated with reference to the author(s) and the section of the draft opinion to which the comment referred. Duplicate comments received from the same contributor appear only once in the table and comments submitted by individuals on a personal capacity are listed anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization. The tables of all comments are published – without reference to individual names – as separate documents on the EFSA web site for closed public consultations.

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

Screening and evaluation of the comments received[3]

The main issues addressed are summarized below. Comments will not be answered individually.

1. Comments requesting the new Guidance Document to be kept simple

The wish to keep the Guidance Document as simple as possible was expressed by several interested parties. They proposed including triggers and decision trees, as well as to divide the document into one part on the scientific background and one directly applicable part.

These aspects will be taken into account during the revision and the document will be divided into a scientific and practical part.

[3] Please note that the European Food Safety Authority may have considered some comments to be outside the instructions provided for in the terms of use of the public consultation.

2. Comments regarding the proposed use of pore water concentrations

The use of pore water concentrations or concentration in total soil as metric for exposure is still discussed controversially. Several comments addressed this topic, emphasising especially the need to review whether the current approach (using concentration in total soil) is insufficient and to prove whether pore water is the scientifically more sound approach and if it will really improve risk assessment.

A scientific opinion by the ecotoxicological sub-working group on this topic was adopted on 10th December 2009, where more detailed information can be found.

3. Comments suggesting to include guidance for exposure assessment in ecotoxicological experiments

The draft project plan was restricted to exposure assessment in the field. The wish to include guidance also on exposure assessment in ecotoxicological tests was expressed. This is deemed necessary in order to link effects observed in laboratory tests to exposure.

It is recognised that guidance on exposure assessment in ecotoxicological tests is needed. However, this is impossible within the 24-month period available for developing this guidance document. This guidance will be developed in the context of the future revision of the Guidance Document SANCO/10329/2002 (Terrestrial Ecotoxicology).

4. Comments addressing software needs

Several comments were received relating to the need to provide user-friendly software tools, in order to cope with possible new PEC calculations needed.

The request for the development of specialised software might be addressed in a separate project with focus on user-friendly software.

5. Comments on the proposed tiered approach

Several comments were received asking to keep the current first tier as it was in the existing guidance document, since it is considered as sufficient but simple. A wish to have a 3rd tier only for very specific cases and refinements and to introduce more details in the 2nd tier was expressed.

The proposal will be considered in the Fate sub-working group. The working group will develop a first simple tier considering the current first tier. However, the Fate group could not find a guidance document that describes this first tier and has to base its knowledge of the current first tier on examples of first-tier calculations. In general the intention is to develop first the second tier, and once this is defined, to develop the lower (simple) tier. A “no-tillage” option (e.g. mixing depth of 1 cm) will be included in the 1st tier in order to make a consistent tiered approach possible.

6. Comments suggesting to consider biphasic behaviour in all tiers

The need to consider biphasic kinetics of $DegT_{50}$ in all tiers was expressed.

The guidance to be developed will be able to handle biphasic field dissipation patterns both in the first and the second tier.

7. Comments on neglecting spatial variability in estimation of PEC

Spatial variability and uncertainties in estimation of PECs were addressed in several comments. Uncertainties should be considered and guidance was requested to be included on how to address uncertainties.

The need for inclusion of spatial variability (SV) was re-discussed in the Ecotoxicology sub-working group and the project plan (June 2008) adapted as follows:

> *"…The assessment procedure will not account for the random spatial variability within individual fields because this level of detail is currently not relevant for the risk assessment schemes regarding ecotoxicology effects. However, if within a field significantly different PEC_{soil} values could be expected as a consequence of systematic variability, e.g. for olive orchard plants in rows, this might lead to reconsideration of the ecotoxicological risk assessment schemes…."*

8. Comments regarding tillage

Several comments regarding tillage were received. Apart from "no-tillage" and "tillage", it was also proposed to include a "minimum or reduced tillage" approach. It was proposed to have as default a "no-tillage" condition in the first tier. Also effects of tillage on biological activity might need to be considered.

"No-tillage" will also be included in the 1st tier in order to achieve a consistent tiered approach. The role of different extents of tillage (no, reduced or conventional tillage) will be considered.

9. Choice of organisms

Microorganisms, nematodes and other relevant organisms for considering the relevance of pore water concentrations or concentration in total soil as metric of exposure concentration also had to be included.

The Ecotoxicology sub-working group will widen the selection of organisms for their review of scientific evidence; e.g. nematodes will be considered. Please refer to the scientific opinion adopted on 10th December 2008 (Question N° EFSA-Q-2008-429).

10. Development of scenarios

Some comments addressed the number of possible exposure scenarios (which might be too many). There were doubts if those new scenarios would be able to improve the prediction of risks. There is an agreement to include soil and climatic data, but a limited number of scenarios with clear guidance on their usage would be preferred.

The definition of scenarios will be based on scientific evidence, but certainly also practicability will be taken into consideration and the number of scenarios will be limited as already stated in the project plan.

11. Develop not only first tier for seed treatments and other specific applications

In the project plan a development of a first tier scenario for seed treatments and ridged potato fields was foreseen. A focus on first tier only is considered to be insufficient.

It will be discussed in the Fate sub-working group to which extent it will be possible to give more details on a tier 2 level. As proposed in the project plan, some recommendations will be included.

12. Request for more guidance regarding field studies

Several comments addressed different aspects of the use of field studies in the risk assessment, particularly because there are no OECD guidelines available. Especially the use of soil accumulation studies and field DegT50 values were mentioned.

The Working Groups are aware of this request and plan to provide more guidance on the use of these studies in risk assessment in the revised GD.

13. Models and scenarios should be validated

There is a common understanding that a full validation of the scenarios will not be possible as stated in the project plan. However, the wish to carry out some form of validation to try to give the model and its associated scenarios credibility was raised.

Testing of the selected models against field data is not part of this particular project. EFSA finds validation of the risk assessment methodology relevant and will consider the possibility of such validation outside the revision of the guidance as this activity is considered time and resource intensive.

14. Consider seed treatments, fumigation and other applications not only in the first tier

It was expressed that this is a topic where guidance is clearly needed since the assumption of crop interception of a significant proportion of sprayed PPP may lead in some cases to underestimation of the long term PEC_{soil}, when the vegetation with pesticide residues is incorporated into the soil after the growth season.

An attempt will be made to develop tier-1 calculation procedures for seed treatments separately. For fumigation and other applications this will be discussed again and considered in the Fate sub-working group. However, higher tier scenarios for these type of applications will not be developed within the 24-month time frame of the workgroup.

15. Proposal to consider PBTs, POPs cut-off criteria

It was proposed to discuss the impact of cut-off criteria for PBTs and POPs, since this is of major importance, e.g. for soil accumulation studies.

These aspects were excluded in the Terms of References (19th November 2007) and in the project plan, since this issue is of general importance not only for the soil compartment and

should be addressed in a more appropriate forum. Furthermore, the hazard cut-off criteria belongs to risk management decision and is thus outside the remit of EFSA.

16. Proposal to consider bound residues

The need to scientifically review potential releases from bound residues in order to decide on how to consider them was raised.

As stated in the Terms of References (19th November 2007) and the project plan, this is beyond the scope of this WG since it would not be possible to perform a sound scientific review in parallel to the other tasks within the given time frame. This topic might be addressed in a future PPR WG.

17. Consider the link to other Directives and Guidance Documents

It was proposed to consider ongoing updates of regulations, directives and guidance documents as well as to consider overlapping issues, e.g the Water Framework Directive.

Both sub-working groups are aware of this background. The revision of the GD on Persistence in Soil is clearly linked to other GDs, e.g. the GD on Terrestrial Ecotoxicology (SANCO/10329/2002), which will also be revised soon, taking into account the findings from the current revision. The WG has also considered developments in other directives and regulations in other areas.

18. Relevance of proposed Time Weighted Average (TWA) values

The project plan proposed to include TWA at 7, 14, 28, 56, 180 and 365 d. Doubts were raised if the time horizons were chosen correctly, since 1 year might be insufficient for persistent compounds, and if TWA is really relevant for terrestrial risk assessment also related to the tests systems used.

The relevance of exposure times for TWA values has to be assessed before a decision can be made. The Fate sub-working group will start with scenarios on both peak and TWA concentrations. The moments in time for which the exposure is calculated, will be kept flexible (to cover all foreseeable potential future needs). Later on, based on the types of Ecotoxicologically Relevant Concentrations (ERC) chosen, the tiered exposure flow charts will be developed. In the scenarios, the simulation time will be in the order of tens of years to cover the accumulation of persistent compounds.

Incorporation of comments in the opinion

The two sets of comments from the public consultation (on the existing Guidance Document as well as on the draft project plan) were all discussed by the EFSA Working Group on Persistence in Soil in its two sub-working groups at a dedicated meeting and will be considered further throughout the revision of the Guidance Document. Comments received were very appropriate and of high value for the PPR Panel and the Working Group on Persistence in Soil.

References:

EC (European Commission), 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final.

EC (European Commission), 2000. Guidance Document on Persistence in Soil under Council Directive 91/414/EEC. SANCO/9188VI/1997 rev 8 of 12 July 2000.

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. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902285834.htm