

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**47th PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES
HELD IN PARMA ON 22-23 SEPTEMBER 2010**

(ADOPTED BY WRITTEN PROCEDURE ON 29 OCTOBER 2010)

#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest.
2.	Adoption of the Scientific Opinion on development of a Soil Ecoregions concept.
3.	Adoption of the Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides
4.	Information on the revision of the Guidance Document on Persistence in Soil
5.	Information on the Guidance Document on protected crops. Presentation of the report on <i>Modelling approach to estimate emission of Plant Protection Products from protected crop systems to surface water in Mediterranean countries</i>
6.	Discussion of the Draft Opinion on Dermal Absorption for acceptance for Public Consultation
7.	Information on the draft opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
8.	Information on the Guidance Document on the probabilistic methodologies for modelling dietary exposure to pesticide residues
9.	Information on the draft opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment
10.	Miscellaneous: <ul style="list-style-type: none">• Ongoing IUCLID database procurement (Jane Richardson – AMU)• Feed-back from the Scientific Committee and its Working Groups• Research priorities task force and proposals to Commission

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PARTICIPANTS

Members of the PPR Panel

Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. T. BROCK, Mr. E. CAPRI, Mr A. HARDY (Chair), Mr A. HART (22 September only), Ms K. HIRSCH-ERNST, Ms. S. HOUGAARD BENNEKOU, Mr. M. KLEIN, Mr. R. LUTTIK, Ms. A. PETERSEN, Ms. Y. PICO` , Mr. A. SCHAEFFER, Mr. P. SOUSA (22 September only), Mr. W. STEURBAUT, Ms. A. STROMBERG, Mr. T. VAN DER LINDEN, Ms C. VLEMINCKX.

Apologies

Mr. A. MORETTO, Ms. B. OSSENDORP, Ms. M. TASHEVA.

Commission

Ms. J. HOUINS-ROULET (DG SANCO O3).

EFSA

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, Mr. M. EGSMOSE, Mr. L. MOHIMONT, Ms. K. NIENSTEDT, Mr. I. SEBESTYEN, Mr. H. STEINKELLNER, Ms. N. SUCIU (trainee), Ms. G. BOSCHETTO, Ms. A. PASQUIN, Ms. M. SODANI, Ms. J. RICKETTS.

AMU unit: Ms. J. RICARDSON (for item 10 only), Mr. O. MOSBACH-SCHULZ (for item 2 only).

1. ADOPTION OF THE AGENDA, APOLOGIES FOR ABSENCE, DECLARATIONS OF INTEREST

The agenda was adopted without changes; apologies were received from Mr. MORETTO, Ms. OSSENDORP and Ms. TASHEVA. The Chair introduced Mr. M. KLEIN (DE), the new Panel member, and welcomed Ms J.Houins-Roulet (DG SANCO).

In accordance with EFSA's policy on Declarations of Interest, EFSA screened the ADoI filled in by the Panel members invited to the meeting. No conflicts of interest related to the issues discussed in this meeting were identified during the screening process and no new interests were declared in the SDoI or at the beginning of this meeting.

2. ADOPTION OF THE SCIENTIFIC OPINION ON DEVELOPMENT OF A SOIL ECOREGIONS CONCEPT

The Panel adopted the scientific opinion. A modelling approach for defining soil ecoregions within Europe was developed to improve the realism of exposure scenarios for plant protection products. Biological information on four soil animal groups (earthworms, enchytraeids, collembolans and isopods) was used to assign each species to different life forms, representing depth horizons in which they occur. Based on information from three countries covering a North-South gradient (Finland, Germany, Portugal), species presence-absence data were modelled using pedological and climatological information. The approach could be extended to the entire EU territory, provided

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more biogeographical data are available. For an improved risk assessment of PPP it is recommended to extend exposure modelling to the litter layer. This approach would imply a refinement of the environmental risk assessment of plant protection products which needs to be discussed with risk managers. For most of the situations in Europe, the short term worst case soil depth profile for risk assessment would be litter (if present) or 0 to 1 cm depth instead of the currently used 0 to 5 cm depth. The opinion should be published by the end of October.

3. ADOPTION OF THE SCIENTIFIC OPINION ON THE DEVELOPMENT OF SPECIFIC PROTECTION GOAL OPTIONS FOR ENVIRONMENTAL RISK ASSESSMENT OF PESTICIDES

The Panel adopted the scientific opinion. In the opinion a process for defining specific protection goal (SPG) options is presented, which uses the ecosystem services approach as an overarching concept and could be used in consultation processes with risk managers and stakeholders. SPGs are defined in 6 dimensions: biological entity, attribute, magnitude of effect, temporal and geographical scale of the effect, and the degree of certainty that the specified level of effect will not be exceeded. SPG options are presented for 7 key drivers (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates), covering all ecosystem services which could potentially be affected by the use of pesticides. The Panel also emphasized the importance of a tiered approach for risk assessment, the essential linking of exposure and effect assessments in terms of spatial and temporal scales, and the relevance of ecological scenarios for appropriate pesticide risk assessments. It intends to use the presented concepts as input for the dialogue between risk managers and risk assessors during the next steps of the revision of the Ecotoxicology Guidance Documents. The opinion should be published by mid-October.

4. INFORMATION ON THE REVISION OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The Chair of the WG updated the Panel on the Opinion on the ongoing work for the revision of the GD Persistence in Soil. The Panel was informed that the draft guidance on how to use field persistence and soil accumulation studies is available for public consultation until 4 October. The WG will take the comments received from the public consultation into consideration for the finalisation of the EFSA guidance document. Rapporteurs have been identified for the guidance document.

The procurement of the validation of the draft guidance on estimating exposure of Plant Protection Products to soil organisms will be finalised in a few weeks. The report regarding the procurement on the data collection for crop interception will be finalised within the next weeks. The intention is to publish the final reports on the EFSA website when available.

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The Panel members were informed that EFSA is working with JRC (Ispra) with the intention of having relevant soil and weather maps made publicly available for use in the higher tier exposure assessment. The report on soil and weather data prepared under the Service Level Agreement between EFSA and JRC was published on the EFSA web-site in July.

5. INFORMATION ON THE GUIDANCE DOCUMENT ON PROTECTED CROPS. PRESENTATION OF THE REPORT ON MODELLING APPROACH TO ESTIMATE EMISSION OF PLANT PROTECTION PRODUCTS FROM PROTECTED CROP SYSTEMS TO SURFACE WATER IN MEDITERRANEAN COUNTRIES

The Chair of the WG gave an update on the development of the new GD on estimating emissions from the wide range of protected crop systems (green-houses and covered crops). Four new members have been invited to join the WG, which will meet again on 23/24 September

A second data collection on protected crop structures in the EU is ongoing for filling the data gaps from the first data collection. The call regarding work in the central zone is ongoing and is scheduled for finalisation in the next weeks. The data-collection for EU southern zone is scheduled for completion by the end of this year. As no candidate for the northern zone was selected, data collection will be handled internally by EFSA.

An open call for estimation/calculation of emissions of Plant Protection Products from protected crops is ongoing. The outcome of the externalised work is expected to be available by the end of the year. The external reports will be published on the EFSA website.

Ms. SUCIU presented the EFSA report on modelling approaches for estimating emissions of Plant Protection Products from protected crop systems to surface water in Mediterranean countries. The report was published in the EFSA journal and has received some interest from the outside and was cited in the AGROW crop protection news.

6. DISCUSSION OF THE DRAFT OPINION ON DERMAL ABSORPTION FOR ACCEPTANCE FOR PUBLIC CONSULTATION

Mr. STEINKELLNER gave a brief overview about the work already done within the frame of the mandate on the Revised Guidance Document on Dermal Absorption. He presented the timeline, the structure of the old and the revised guidance document, the new elements and the major changes made in the latest version of the revised GD. Then the Panel members were informed about the structure and the content of the Opinion on the science behind the revision of the guidance document on dermal absorption. The Panel discussed both documents chapterwise and a few clarifications and changes were suggested. After this discussion the Panel accepted the Opinion and the revised Guidance Document for public consultation. The documents will be posted for public consultation on the EFSA website in October for a 6-week commenting period. Liason with the OECD WG was done by EFSA staff.

The adoption of the opinion is foreseen during the Plenary meeting in January 2011.

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7. INFORMATION ON THE DRAFT OPINION ON THE IDENTIFICATION OF PESTICIDES TO BE INCLUDED IN CUMULATIVE ASSESSMENT GROUPS ON THE BASIS OF THEIR TOXICOLOGICAL PROFILE

Mr. SEBESTYÉN informed the Panel members that in the preparatory phase of this new opinion, the PPR Unit launched a call for a proposal for exploring existing pesticide data bases, Draft Assessment Reports and open literature to identify the toxicological effects and endpoints that could be the basis of cumulative risk assessment and for a proposal for cumulative assessment groups of pesticide active substances. A contract was awarded to the National Food Institute of the Technical University of Denmark and the contractor started the work in January 2010. EFSA received the Interim Report in June 2010. The evaluation of the report is in progress. The next step in this project is a teleconference in October to discuss the grouping of pesticides based on their common toxicological effects, refinement of the grouping based on the mechanism/mode of action and collection of the NOAEL for the identified specific effects. The Panel was also informed about the establishment of a new Working Group dealing with the preparation of this opinion as agreed during the previous Plenary meeting. The first meeting of this new WG will be organized on 23/24 November.

8. INFORMATION ON THE GUIDANCE DOCUMENT ON THE PROBABILISTIC METHODOLOGIES FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES

Mr. MOHIMONT summarised the outcome of the last meeting of the WG on probabilistic methodologies. A number of technical issues were discussed and some actions were agreed regarding the part of the guidance on the single substance exposure assessment. The main task regarding this part of the guidance still requesting major resources is the performance of case studies. The major points to address for cumulative exposure assessment were identified. The WG will now start working on this part of the guidance and a new public consultation will be organised in spring 2011.

In October the secretariat will circulate a draft report of the 2010 public consultation for comments and possible endorsement by the Panel through written procedure, before publication. Partly as a consequence of the public consultation, a number of issues or questions regarding risk management have been referred by EFSA to the Commission via a formal letter in order to ensure the coherence of the guidance document and the regulatory context where it will be used.

9. INFORMATION ON THE DRAFT OPINION ON THE EVALUATION OF THE TOXICOLOGICAL RELEVANCE OF METABOLITES AND DEGRADATES OF PESTICIDE ACTIVE SUBSTANCES FOR THE DIETARY RISK ASSESSMENT

The rapporteur gave a short overview on the background of the mandate, the planned timelines and the composition of the Working Group preparing the draft opinion. The Panel members were also informed that the results of the outsourced activities on TTC concept, QSAR prediction and impact

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of the metabolic processes on the toxicological properties of pesticide metabolites were incorporated in the toxicological chapters of the draft opinion. New versions of the introduction, exposure and toxicological chapters of the opinion have been discussed since the last Plenary meeting. In the meantime the refinement of the toxicological evaluation of metabolites in the case study has been performed using the Toxtree software. The next meeting of the Working Group will take place in October. New versions of the residue and toxicological chapters as well as the approach to evaluate the toxicological relevance of pesticide metabolites will be discussed during this WG meeting. The deadline for adoption of the Opinion is September 2011, as the mandate provided the Panel members with a period of 18 months after completion of the last of the three outsourced activities.

10. MISCELLANEOUS:

- **Ongoing IUCLID database procurement**

Ms. NIENSTEDT informed the Panel about the status of the ongoing project, which includes an ongoing procurement and a call for tender in the process of evaluation. The project is carried out under a mandate received recently from the European Commission.

Ms. RICHARDSON (AMU) gave an overview of the structure of the database and the software used for data entry (IUCLID).

- **Feed-back from the Scientific Committee and its Working Groups**

The Chair updated the Panel members about the last SC held mid September and in particular about the report from the task force on Endocrine Disruptors which should be published by the end of October.

- **Research priorities task force and proposals to Commission**

The Panel members were asked to propose some research priorities, discovered in the frame of the work on the opinions, to be proposed under the 7th Framework programme.

The Chair thanked Ms. NIENSTEDT for her professional work and wished her good luck for her new position at the European Commission / DG SANCO starting in December.

The next Plenary meeting will take place on **24-25 November 2010** in Parma, starting at **14h00** on 24 November.
