

PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

33RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 17-18TH JUNE 2008

(ADOPTED BY WRITTEN PROCEDURE ON 7 JULY 2008)

Agenda

| # | Items |
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| 1. | Adoption of the agenda, apologies for absence, declaration of interest |
| 2. | Adoption of the opinion on the Guidance Document on risk assessment for birds and mammals |
| 3. | Presentation of draft opinion on the risk assessment for cumulative exposure to triazoles-contract-negotiated procedure |
| 4. | Presentation of the draft Guidance Document on persistence in soil |
| 5. | Information on the state of work on contract under Art. 36 on the Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents |
| 6. | Information on the development of a new Guidance Document on environmental exposure in greenhouses |
| 7. | Information on the work on deltamethrin |
| 8. | Information on the state of the work on procurement/grants related to Guidance Documents |
| 9. | Miscellaneous: <ul style="list-style-type: none"> • Feed-back from the Scientific Committee and Working Groups • Feed-back from the WG on the review of the efficiency of the pesticide peer-review process • Information on the new EFSA expert data base • Other items |

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Mr. A. BOOBIS, Ms. C. BOLOGNESI, Mr. A. BUCHERT (on 17th only, item 1 and 2), Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART (on 17th only, item 1 and 2), Mr. H. KÖPP, Mr. M. LIESS (on 17th only, item 1 and 2), Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO (on 18th only), Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

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Apologies

Ms. S. MICHAELIDOU-CANNA

EFSA

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, Ms. C. FÜLL, Ms. K. NIENSTEDT, Mr. M. EGSMOSE, Mr. I. SEBESTYEN, Mr. L. MOHIMONT, Ms G. BOSCHETTO, Ms. L. DE LEO.

For item 9 only: B. BERGER (SCO Unit) and H. DELUYKER (Director of SCA).

Commission

Mr. X. PAVARD (DG SANCO O3)

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

The agenda was adopted without changes, apologies were received from one member for the whole meeting, one was not attending on 17th and three were not attending on 18th June.

New annual declarations of interests had been completed electronically for the first time, and the approval by EFSA senior management was still ongoing.

2. ADOPTION OF THE OPINION ON THE SCIENCE BEHIND THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS

In summer 2006, the PPR Panel had received a request to revise the Guidance Document (GD) on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000–final of 25 September 2002).

In the course of the revision it became apparent that the task embraced several risk management issues which are not within EFSA's and the PPR Panel's remit. Therefore, the PPR Panel adopted a 2-stage approach and first prepared a Scientific Opinion on the science behind the GD on risk assessment for birds and mammals, using a modular approach.

In a second stage, a joint Working Group of representatives from EFSA, the Commission and Member States will consider the risk management issues and elaborate a revised Guidance Document on risk assessment for birds and mammals. The Commission and MS had been informed by EFSA at the Standing Committee meeting in March 2008, and welcomed the initiative and nominated representatives. The joint WG should take up its work by end of the year depending on the availability of the Commission staff.

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The work on this opinion was carried out by one Core Working Group steering the process, and 4 sub-WGs for particular issues. Altogether, about 30 people were actively involved in the work.

Transparency of the work and the involvement of stakeholders were important objectives during the whole process. Two public consultations were carried out in 2006 and 2007/08 respectively; a stakeholder consultation workshop took place in May 2007, and a meeting with Member States in December 2007.

The rapporteur gave an overview of the whole process, the current state of the draft opinion and the a few proposed changes to the draft version for adoption that had been sent out to the Panel members on 9 June 2008.

The PPR Panel considered that the submitted draft opinion on the science that would underpin the new GD on birds & mammals was an impressive piece of work, expressed its thanks to the members of all working groups involved, and adopted the opinion and its 32 Appendices. Panel members were requested to submit further editorial comments and corrections to the opinion and its Appendices to the PPR Panel Secretariat by 30 June 2008, after which it would be published.

3. PRESENTATION OF DRAFT OPINION ON THE RISK ASSESSMENT FOR CUMULATIVE EXPOSURE TO TRIAZOLES - CONTRACT-NEGOTIATED PROCEDURE.

The general opinion on Cumulative Risk Assessment (CRA) adopted on 15 April 2008 was to be followed up with a worked example of cumulative risk assessment for a group of triazole fungicides. A part of this work had been outsourced by procurement and the responsible EFSA scientific officer reported on the progress of the contracted work on the contract for the “Cumulative Exposure Assessment of some triazole Fungicides”. An interim report had been agreed at a Steering Committee meeting of 22nd April, and the technical conditions for performing the second stage of the contract were defined and agreed. The final Steering Committee for evaluation of the final report was planned for 22nd September.

A joint meeting of the Toxicology and Residue WGs had been held on 16th June. A first draft of the toxicological section has already been prepared. Tasks had been defined to progress the drafting of the opinion by the next joint meeting of Toxicology and Residue WG which would take place in September 22– 23rd. The expected date of adoption of this opinion was April 2009.

4. PRESENTATION OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The Chairman of the Fate sub WG informed the Panel about the progress of the work by the Fate sub WG which had met on the 20-21st May and would meet again on the 18-19th June. The WG had also had a specific meeting with JRC (Ispra) of the 24th April regarding soil, weather, and soil ecological data needed for the guidance revision. Then the Chairman of the Ecotoxicology sub WG (Bugs) informed the Panel

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about the progress of the work in this WG which had met on the 19-20th May and on the 16-17th June.

The PPR Panel agreed on the Terms of Reference and Background for a new self-tasked question for a new Scientific Opinion regarding the relative utility of total concentration and pore water concentration as exposure metrics in the assessment of ecotoxicological risks from pesticides and their metabolites in soil.

5. INFORMATION ON THE STATE OF WORK ON CONTRACT UNDER ART. 36 ON THE GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS

The PPR Panel had self-tasked the development of a new Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents. The information-gathering and the drafting of suggested content of the GD had been outsourced by a contract under Art. 36 of Regulation (EC) No. 178/2002. The contractors had submitted the interim report due on this contract 1 May 2008. The Rapporteur gave detailed information about the Steering group meeting held on 13th May. The Steering group accepted the interim report. The scope, data series, report, points for discussion in the opinion, and an outline structure of the opinion were presented and discussed. The questions and comments that arose during the discussion focused on the effect of formulation on dermal absorption, communication of risk, and public consultation.

6. INFORMATION ON THE DEVELOPMENT OF A NEW GUIDANCE DOCUMENT ON EMISSION FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATION GROWN UNDER COVER)

The Chairman of the WG gave an update on the (self-tasked) development of a new GD on estimating emissions from a wide range of protected crop systems (greenhouses and covered crops). The WG had met on the 21-22nd May and on the 16-17th June. A draft project plan had been further developed and was expected to be put out for comments through a public web consultation this autumn.

A meeting on data-collection was scheduled with EUROSTAT (Luxembourg) in July as it would be important to collect data on the type and abundance of protected crop systems in Europe.

7 INFORMATION ON THE WORK ON DELTAMETHRIN

The Commission had requested an opinion from EFSA on the developmental neurotoxicity of deltamethrin. The Toxicology WG of PPR Panel had started work on this opinion on 16-17th June. The Rapporteur reported that the work was now in the data collection phase. A first draft opinion would be circulated before the September meeting. The deadline for adoption was 15th December 2008.

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8. INFORMATION ON THE STATE OF WORK ON PROCUREMENT/GRANTS RELATED TO THE DEVELOPMENT OF GUIDANCE DOCUMENTS.

The EFSA scientific officer in charge reported on the outcome of the first joint meeting of the Toxicology and Residue WGs on preparing a GD on the evaluation principles of the toxicological burden related to metabolites, degradation and reaction products of pesticides. The context of this self-task activity was discussed and it was recognized that the project was mainly orientated to the introduction and discussion of new or existing toxicological tools in the process of establishing the residue definition for consumer Risk Assessment. The legal reason for the non-involvement of experts in the preparation of the call under Art. 36, recently launched, was to avoid potential conflict of interest for the institution to which the expert belongs in case they wished to tender, was explained. Members emphasised the importance of ensuring that the scope of any work undertaken on Procurements/Grants met the needs of the WG tasked with preparing the relevant GD.

The relationship between this project and the OECD Guidance on the residue definition was also clarified. The OECD Guidance document states that residues (including metabolites and degradates) of toxicological relevance should be included in the residue definition for risk assessment. The current project aims to define when a residue is toxicologically relevant. The EFSA scientific officer in charge will attend the next meeting of the OECD Residue Chemistry Expert group.

9. MISCELLANEOUS

- **Feedback from the Scientific Committee and WGs**

The Chairman informed the Panel members that the next Scientific Committee meeting would be held on 14-15th July.

WG Transparency : A draft of the opinion on transparency had been circulated in April and feedback from Panel members was requested by end of July, with adoption foreseen in September.

- **EFSA WG on the review of the efficiency of the pesticide peer review process (chapter on Guidance Documents)**

H. DELUYKER (Director of SCA) presented the remit and aim of the WG. The final document prepared by the WG would be published in the EFSA Journal this summer. Many questions were raised by the Panel members, in particular on the procedure proposed by the WG for the development and updating of Guidance Documents. Ms. C. VLEMINCK, who represents the PPR Panel, explained the latest developments. Ms. DUNIER-THOMANN will attend the last WG meeting on 1-2nd July. The 3 pages of text on Guidance Documents will be corrected by the secretariat and the draft circulated to the Panel for further amendments, with deadline 27th June. A process for priority-setting and priority-checking was needed; possible criteria could be 1) the role of the GD in the RA process (some

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GD may be more critical than others) and 2) the degree of interpretation left to risk assessors.

- **Information of the new EFSA expert database**

B. BERGER from the SCO Unit presented EFSA's new database of scientific experts that had been in place since 5th June. All ad hoc experts would now have to register before being able to be selected for a WG.

- **Timing of call for renewal of Panel members**

The call should be launched this autumn; it will close 2 months later, early 2009.

- **Feed-back from a meeting on the 'IESTI equation' organised by the Commission.**

A Panel member informed the Panel of a recent meeting organised by the Commission with MS representatives and participation of the EFSA on the IESTI equation. As a consequence of the proposals for possible amendment of the IESTI equations, the Residue WG meeting on 17th June considered the possibility of making an addendum to the IESTI opinion (adopted April 2007). Although there is potential relevance in extending the IESTI opinion, it is not yet clear whether the Commission intends to make such a request to the Panel, without which there would be no mandate for undertaking the work.

- **Calls for outsourcing work**

The PPR-Panel requested that it should be consulted to define the objectives of the calls before launching them for outsourcing work in the limit of time constraints and issues regarding potential conflict of interests.

- **Other items**

The provisional planning of PPR meetings in 2009 is on the Extranet, any conflicting workshop/congress on those dates should be signalled to the secretariat within 2 weeks.

The next **PPR Plenary meeting** will be on **23-24th September 2008 in Parma**, starting at 14h00 on 23th.