

32ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 15-16TH APRIL 2008

(ADOPTED BY WRITTEN PROCEDURE ON 12 MAY 2008)

Agenda	
1.	Adoption of the agenda, apologies for absence, declaration of interest: presentation of the new electronic form.
2.	Presentation of the draft opinion on the Guidance Document on risk assessment for birds and mammals
3.	Adoption of the opinion on cumulative risk assessment of pesticides in human health
4.	Presentation of draft opinion on the risk assessment for cumulative exposure of triazoles-contract negotiated procedure
5.	Presentation of the outcome of the public consultation on the Guidance Document on persistence in soil
6.	Information on the Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents-contract under Art. 36
7.	Information on the development of a new Guidance Document regarding emission from protected crop systems (e.g. greenhouses and cultivation grown under cover)
8.	New requests from Commission and self-task (Guidance Document)
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 • INEX report • Other items

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Mr. A. BOOBIS, Ms. C. BOLOGNESI, Mr. A. BUCHERT, Mr. E. CAPRI (on 15th only) Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. H. KÖPP, Mr. M. LIESS, Mr. R. LUTTIK, Ms. S. MICHAELIDOU-CANNA, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

Apologies

Mr. O. MEYER

EFSA

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

Head of the Risk Assessment Directorate: Ms R. MAIJALA (on 15th for item 1)

E. GUISADO from IT for item 1.

Commission

Mr. X. PAVARD (DG SANCO O3) *via* teleconference.

1. ADOPTION OF THE AGENDA, APOLOGIES FOR ABSENCE, DECLARATION OF INTEREST: PRESENTATION OF THE NEW ELECTRONIC FORM

The agenda was adopted without changes, apologies were received from one member, and another attended only on the 16th April. There were no new declarations of interest.

The Head of the Risk Assessment Directorate Ms R. MAIJALA presented the new electronic form for the declaration of interest which will replace the current paper forms, the pre-filled forms will have to be checked by Panel members.

IT made a detailed presentation of the IT tools, a password will be allocated.

2. PRESENTATION OF THE DRAFT OPINION ON THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS

The public consultation on the revised Guidance Document (GD) on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC closed on the 27 Jan 2008 and the comments from 14 MS, ECPA, two consultancies and one chemical company were received and analysed. It was agreed with EFSA management in January 2008 that revision would be done in two steps: firstly, the PPR Panel would adopt a comprehensive opinion on the science behind the GD birds & mammals (for further details see minutes of 31st PPR Plenary); secondly: the "final user-friendly" GD (in which choices among the different modules from the opinion will be made) will then be developed on the basis of this opinion in a specific joint WG consisting of representatives from EFSA, the PPR Panel, Commission and risk managers from Member States which will choose between different modules in the opinion. On 13-14 March 2008, DG SANCO E3 and MS participating in the WG "Legislation" of the Standing Committee on the Food Chain and Animal Health (SCFAH) welcomed this idea and EFSA asked MS for nominations of risk managers to participate in this joint WG. Due to a heavy work load and prioritisation of tasks it will not be possible for DG SANCO E3 to invest resources in this WG before autumn 2008. In this context, Ms. DUNIER-THOMANN explained to the participants of the Standing Committee that consequently the adoption, foreseen in April, would be postponed to June to allow the PPR Panel to finalize this demanding work with less pressure.

The rapporteur gave an overview of the current status of the revision process and reported on the outcome of the 9th Core WG meeting on 14-15 April 2008. He explained the content of the five parts of the draft opinion (Introduction; Risk

assessment modules for sprayed products; other risk assessment modules and special topics; options for refinement; mitigation and references). A new chapter 2 will be added that will describe the toxicity tests, and how to deal with non-standard toxicity data, and the “greater than” values (from limit tests). It will basically contain the issues discussed in chapter 4 of the document version that was published on the EFSA website for public consultation. The specific comments on the various chapters of the draft opinion made by Panel members before and during the meeting will be taken into due consideration during the further work on the opinion.

The following time line was proposed:

- All chapters will be available on the EFSA Extranet for panel members by 25 April 2008 including most of the Appendices;
- Comments are to be sent before 20 May 2008;
- 10th (and final) Core WG meeting will be held on 3-4 June 2008 in Frankfurt/Main (Germany);
- The final draft of the opinion will be sent out to Panel members on 9 June 2008.

The responses to the stakeholder comments received during the public consultation are being finalised. This is a major task since the comments received filled 130 pages, and extends to nearly 170 pages with the responses included. All responses will be made published on the EFSA website. The adoption of the opinion by the PPR Panel is foreseen during the 33rd PPR Plenary meeting on 17-18 June 2008.

3. ADOPTION OF THE OPINION ON CUMULATIVE RISK ASSESSMENT OF PESTICIDES IN HUMAN HEALTH

The Rapporteur gave an overview of the latest changes made to the draft opinion during the WG meeting immediately before the Plenary. All comments had been addressed and discussion focused on the following items:

- Table of uncertainty and the rating of the sources of uncertainties, particularly the sampling uncertainty;
- Tiered approach and decision tree on toxicology evaluation. Currently considered as provisional, it will be refined after finishing the conazole (triazole) case study. The final tier on physiologically based pharmacokinetics (PBPK) modelling. Discussion on RPF based on BMD in context of level of protection provided. This will be addressed in the EFSA Scientific Committee opinion on the BMD approach.
- The tiered approach and decision tree for acute exposure scenario and MRL-setting scenario.
- Conclusions and recommendations. The previous chapters 7 and 8 were combined. How the margin of safety should be achieved if lower tier deterministic assessment proves satisfactory.

The following recommendations were discussed:

- New recommendation: when designing monitoring programmes consideration should be given to collection of data more representative of actual exposure to pesticides forming a Common Assessment Group in order to provide a better

basis for cumulative risk assessment. Advantage should be taken of assessments already undertaken, provided they are of sufficient quality and relevance.

- The PPR panel will use the tiered approach that has been described in this opinion in its forthcoming opinion on triazoles and will refine the procedure if necessary in the light of the results.

The Summary was reworded, and criteria by which to include compounds in a common assessment group were proposed and the most useful methods were listed.

The opinion was adopted; the final draft will be circulated to members of PPR Panel for editorial comments before publication.

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

This self-task opinion is an example of a cumulative risk assessment using the triazole group of pesticides with a view to testing and refining the proposed methodologies outlined in the above adopted opinion.

The responsible EFSA scientific officer presented a short overview of the project and an update of the ongoing work under the contract (negotiated procedure) for “Cumulative Exposure Assessment of some triazole fungicides”. The second steering committee meeting will take place next week.

The Rapporteur then presented the calculated benchmark doses and relative potency factors as agreed by the Toxicology WG before the Plenary meeting.

5. PRESENTATION OF THE OUTCOME OF THE PUBLIC CONSULTATION ON THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The public web consultation on the Project Plan and the existing Guidance Document was launched on the EFSA-website on 29th January and closed on 25 March 2008. The intention is to develop a limited number of European exposure scenarios based on climatic and ecological considerations. The Risk Managers in MSs were specifically asked for their view on the proposed spatial 90th percentile PEC_{soil}, but few MSs submitted comments.

Panel members discussed the best way to respond to the public consultation: e.g. whether to respond to individual comments or to provide general answers to more than one point.

The Chairman of the Fate sub WG informed the Panel about the status of the work in this Fate sub WG which met on the 14-15th April.

The Panel discussed in particular the relevance and desirability of developing a specific rice exposure scenario due to the particularities of the rice ecosystem, alternating flooded and dry areas during the year, crop rotation with other crops, and impact on potential surrounding wetlands. It would cover all aquatic and terrestrial aspects for this particular crop. It was pointed out that it was a recurring problem for the PRAPeR unit to evaluate dossiers for a active substance intended for use in rice as no generally accepted environmental risk assessment methodology exists today when the low tier risk assessment indicate that the environmental risk could be high.

The Panel agreed that there is a need to develop new science-based risk assessment methodology for the use of plant protection products on rice; this will be discussed further at the next Plenary meeting.

The Chairman of the Ecotox sub WG informed the Plenary about the public consultation aspects related to Ecotoxicology and the status of the work in the Ecotox Sub WG which will meet on the 16-17th April.

6. INFORMATION ON THE GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS- CONTRACT UNDER ART. 36

The EFSA scientific officer in charge gave a brief overview of the state of the outsourced work done under Article 36 of European Parliament and Council Regulation N° 178/2002 for “Preliminary work in view to develop the GD for pesticides exposure assessment for workers, operators, bystanders and residents”.

The Interim report from the Pesticides Safety Directorate (PSD) and the co-contractor, University of Ghent will be delivered by the end of April 2008. The Steering group meeting will be held on 13th May.

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

A number of Member States have expressed interest in the development of new GD in this area in a consultation on GDs by EFSA on 3 July 2006 *via* the Standing Committee on the Food Chain and Animal Health. Protected crops (including greenhouses) are specified in Directive 91/414/EEC as amended, as fields of use of both chemical and microbial products. Several active ingredients have been listed on Annex I to the Directive with reference to use in greenhouses and in one case specifying the closed hydroponic system. During the review process of the active substances of the second and third lists, concerns were raised by Member States regarding the lack of guidance for the environmental exposure assessment for crops grown under cover (protected crops).

The Chairman of the WG gave an update on the development of a new (self-task) GD on estimating emissions from the wide range of protected crop systems (greenhouses and covered crops). A draft project plan was prepared and rapporteurs were identified.

Data on the type and abundance of protected crop systems in Europe will be collected through externalisation. The WG will meet on the 16-17th April.

8. NEW REQUEST FROM COMMISSION AND SELF TASKING (GUIDANCE DOCUMENTS)

- A new question in toxicology on deltamethrin was sent by the Commission. The EFSA scientific officer in charge explained the background of the question and introduced the Terms of Reference. A Rapporteur for this opinion was proposed (to be confirmed) and the first WG will take place on 16-17th June.

- The EFSA scientific officer in charge presented the draft for a self-tasking question regarding the metrics (e.g. TC or pore water C) for the assessment of ecotoxicological effects in soil and the Panel discussed possible Terms of Reference. A rapporteur volunteered for this opinion.
- With respect to the revision of the Terrestrial Ecotoxicology GD, to be started in the near future, the EFSA scientific officer in charge presented briefly the data gaps identified in the current GD and the Panel discussed possibilities to anticipate work in these fields through external procurement.
- The EFSA scientific officer in charge presented a new self-task related to the evaluation principles of the toxicological burden of metabolites, degradation and reaction products of pesticides. In order to document this opinion preliminary work will be outsourced *via* contracts under Article 36 (in particular applicability of thresholds of toxicological concern).

9. MISCELLANEOUS

- **Feedback from the Scientific Committee and WGs**
The Chairman informed the Panel members that the next Scientific Committee meeting will be on held on 21-22nd April.
- **EFSA WG on the review of the efficiency of the pesticide peer review process**
Ms. C. VLEMINCK, who represents the PPR Panel on this WG, explained the latest developments at the last WG. Ms. DUNIER-THOMANN attended the WG on 4-5th March to explain the PPR Panel's current work plan for updating and developing risk assessment GDs.

EFSA's Scientific Cooperation Assistance (SCA) Director, chairman of this WG, will come to the next Plenary meeting to report on the progress of the WG regarding the updated list of Guidance Documents used in the Peer Review.
- **Feedback on the visit to EFSA of the ENV delegation of the European Parliament**
On 14th April a delegation of 9 persons, Members of the European Parliament Environment, Public Health and Food Safety and assistants visited EFSA. Ms. DUNIER-THOMANN gave a presentation together with PRAPeR unit colleagues. The preparation of the new Regulation on pesticides is a main concern for them. Questions were raised on various subjects in particular on the cumulative effect of pesticides and the need for risk assessment in relation to pesticides and bees was highlighted.
- **Feedback on the Standing Committee on the Food Chain and Animal Health–Pesticides Legislation DG SANCO E3 on 13th March**
Ms. DUNIER-THOMANN attended the Standing Committee; she explained to Member States and the Commission that EFSA intended to implement in the PRAPeR Peer Review, the new Q10 coefficient as described in the ad hoc Opinion adopted by the Panel in December 2007.

- **Information of the new EFSA expert database**
Item postponed to next meeting due to lack of time.
- **INEX report**
Ms R. MAIJALA presented the procedures for the internal and external (INEX) evaluation of opinions. The internal review will start in 2008, one opinion per Panel/per year will be selected at random and the quality, adequacy of the opinion *versus* the terms of references will be evaluated by senior scientific officers from units other than the PPR unit. A report for all EFSA opinions reviewed will be published. The external review will start in 2009. A discussion followed in which Panel members sought clarification and expressed their concerns.

The next **PPR Plenary meeting** will be on **17-18th June 2008 in Parma**, starting at 14h00 on 17th. The chairman asked for full participation as one major adoption is foreseen and a quorum is required.