

31ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 12-13TH FEBRUARY 2008

(ADOPTED BY WRITTEN PROCEDURE ON 7TH MARCH 2008)

Agenda	
1.	Adoption of the agenda, apologies for absence, declaration of interest
2.	Mandate of the Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents-contract under Art. 36
3.	Presentation of the state of the revision process of the Guidance Document on risk assessment for birds and mammals
4.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
5.	Presentation of draft opinion on the risk assessment for cumulative exposure of triazoles-contract negotiated procedure
6.	Presentation of the state of revision of the Guidance Document on persistence in soil-public consultation
7.	Presentation of proposals for developing a new Guidance Document on environmental exposure in greenhouses
8.	Miscellaneous: <ul style="list-style-type: none"> • Feed-back from the Scientific Committee and Working Groups • Other items

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO (on 13th only), Mr. M. MÜLLER, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms. C. VLEMINCKX.

Apologies

Mr. A. BOOBIS, Mr. H. KOEPP, Mr. M. LIESS, Ms. S. MICHAELIDOU-CANNA and Ms. B. OSSENDORP.

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 and Ms. I. RIHANI.

Head of the Risk Assessment Department: Ms. R. MAIJALA (on 12th for item 3)

Commission

Mr. X. PAVARD (DG SANCO O3) *via tele - conference.*

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

The agenda was adopted without changes, five apologies were received, and one member attended only 13th February. There were no new declarations of interest.

The chairman Mr.T. HARDY welcomed Mr. L. MOHIMONT, the new scientific officer in the PPR Unit in charge of the Residues WG, who joined the Unit in mid January and who briefly introduced himself.

The chairman informed Panel members that the Head of the Risk Assessment Department Ms R. MAIJALA would be present for part of the afternoon.

2. MANDATE OF THE GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS UNDER ART. 36.

The Panel members were informed that the call 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” had been awarded to Pesticides Safety Directorate (PSD) from UK, and the co-contractor, University of Ghent from Belgium.

The responsible EFSA scientific officer reported on the progress of the work of the steering committee set up to monitor the work of the contractor. The Terms of Reference and the Background of the mandate for the preparation of the Guidance Document for pesticide exposure assessment for worker, operators, bystanders and residents were discussed. The Rapporteur will circulate an amended text for endorsement at the next Plenary meeting in April.

3. PRESENTATION OF THE STATE OF THE REVISION PROCESS OF THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS

The draft of the revised Guidance Document (GD) on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC was placed on EFSA’s website for public consultation between 19 November 2007 and 27 January 2008. Numerous comments were received from 14 Member States, ECPA, two consultancies and one chemical company. The EFSA Director on Risk Assessment, R. MAIJALA, reported on her decision that the PPR Panel should adopt the scientific document on the GD (the one consulted on the web) as an opinion at its Plenary Meeting in April 2008. An “user-friendly” GD should be developed on the basis of this opinion by a specific small WG consisting of representatives from EFSA, the PPR Panel, the Commission and risk managers from Member States. The MS participating in the WG “Legislation” of the Standing Committee on the Food Chain and Animal Health (SCFCAH) will be informed officially by the Head of the PPR Panel Unit of the decision during their next meeting on 13-14 March 2008 and asked to nominate risk managers for this WG.

The rapporteur gave an overview of the revision process and reported on the outcome of the 7th Core WG meeting on 6-7 February 2008 in Amsterdam, NL.

During that meeting the participants agreed a strategy for revision in the light of the new procedure for producing the GD. They agreed the structure of the opinion, taking into account the comments of stakeholders on its structure and readability. They identified key scientific issues raised in the 127 pages of comments, and agreed on how to resolve them in the revised document. They made a detailed action list for completion of the revisions in good time for the April PPR plenary meeting. The rapporteur further explained the intended modular structure of the opinion, in order to make it easier for the specific WG that will take the risk management decisions and choose one option but leave the rest of the text as it stands. Concern was expressed that this new WG might start to change the science in the modules but this is not what the Panel wants. A transparent process should be established to ensure that this does not happen and the Terms of Reference for that new specific WG should be carefully worded. The role of the Panel members attending that WG will be that of advisers and interpreters of scientific issues. The final GD will not be an EFSA product but is intended to be presented at the DG SANCO SCFCAH for endorsement.. The finalisation of the revised GD is envisaged by the end of 2008.

Given the fact that no GD will be revised/developed without dealing with RM issues, it would be a good opportunity to revisit and review the original mandate given to EFSA, to revise and create GDs.

The timeline for the remaining work for the Core WG is very demanding; the final draft of the scientific opinion, revised in the light of comments from the public consultation, will be circulated to the PPR Panel by mid March. The adoption of this scientific opinion by the PPR Panel is foreseen for 15-16 April 2008.

4. PRESENTATION OF THE DRAFT OPINION ON CUMULATIVE RISK ASSESSMENT OF PESTICIDES IN HUMAN HEALTH

The Rapporteur of the toxicology part explained the latest changes in the now advanced draft, which would be discussed further at the next Toxicology Working Group meeting 13-14th February. The main discussion points included: other sources of exposure, dose addition and synergy, types of combined actions, dose gaps in experiments between the NOAEL and LOAEL, possible effects that are not detected by the current methods, need for *ad hoc* tests and an explanation of a tiered approach. The Panel members also discussed the use of uncertainty factors, the assumption of parallel dose response curves, differences in time course of effects, physiologically based pharmacokinetics as a higher tier assessment, the applicability of EPA results on anticholinesterase compounds to the European population and similarity of metrics for the different risk assessment methods.

In the absence of the Rapporteur another member of the Working Group on residues presented the exposure part of the opinion. The Panel agreed that using the MRL level for chronic exposure assessment in the MRL setting scenario was not realistic. By analogy to the second step of the WHO guidelines for calculating the dietary intake for single compounds, it was proposed to use the STMR level for the combination pesticide/commodity of interest, although this is still constitutes a gross overestimation.

Related to the exposure to pesticides in drinking water the Panel recognized that from a theoretical point of view, it is not possible to exclude that such exposure represented a significant proportion of the toxicological reference values. This would however require the simultaneous presence of several highly toxic pesticides at the

maximum legal level which is from a practical point of view is rather unrealistic. The Panel agreed that the contribution from drinking water would not be of toxicological concern in the vast majority of cases.

The Panel agreed that the tiered approaches for toxicological characterisation and exposure assessment should be merged as far as possible, in compliance with the principle that the tiered approach should increase the degree of refinement of the risk assessment.

In order to merge the contributions of the two Working Groups on toxicology and on residues into a single consistent document and to draw appropriate recommendations and conclusions, it was decided to organise a joint meeting at the end of March in Brussels. It was further agreed to merge the introductions from the toxicological and exposure parts at the beginning of the document. Assumptions for acute intake, variability factors and other sources of uncertainty should be discussed.

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

The Panel started at the end of 2007, a self-task opinion as an example of a cumulative risk assessment using the triazole group of pesticides with a view to testing and refining the proposed methodologies. The responsible EFSA scientific officer presented a short overview of the project: the contract (negotiated procedure) for “Cumulative Exposure Assessment of some triazole fungicides” had been awarded to the Safe Foods+ Consortium, for which the lead contractor is RIKILT Institute of Food Safety, in the Netherlands. The report is due this summer and the first steering committee meeting took place in December. The Panel agreed new Members for the steering committee.

The rapporteur gave an overview of the selected toxicological end points for acute and chronic assessments as well as the lists of compounds forming the respective common assessment groups. The selected index compounds and the Relative Potency Factors (RPFs) calculated on the basis of the NOAELS of each compound were also described. The RPFs will be considered by the Toxicology WG on 13-14th February.

6. PRESENTATION OF THE STATE OF REVISION OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL- PUBLIC CONSULTATION.

The Rapporteur presented the current status of the work to revise the Guidance Document. A public web consultation on the Project Plan and the existing Guidance Document was launched on the EFSA-website on 29th January and is open for comments up till 25th March 2008. The intention is to develop a limited number of European exposure scenarios based on climatic and ecological considerations. The Rapporteurs of the 2 sub WGs (Fate and Ecotoxicology) presented updates including the expected time-line of the work of the Ecotox WG.

The two sub WG on Ecotoxicology and Fate met in December 2007 and will meet again on the 13-14th of February in separate and combined meetings.

7. PRESENTATION OF PROPOSALS FOR DEVELOPING A NEW GUIDANCE DOCUMENT ON ENVIRONMENTAL EXPOSURE IN GREENHOUSES.

A number of Member States have expressed interest in the development of new GD in this area (consultation on GD by the Director of Sciences from EFSA on 3 July 2006 *via* the Standing Committee on the Food Chain and Animal Health). Protected crops (including greenhouses) are specified in the 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). A draft Terms of Reference for developing a new GD (self-task) on developing emissions from greenhouses and protected crops was discussed in the PPR plenary meeting and rapporteurs were identified.

8. MISCELLANEOUS

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

Mr.T. HARDY gave a short update on the progress on the activities of the Scientific Committee, as the next meeting will be on 14-15th February.

Mr.T. HARDY reported on progress of the Transparency WG on 30-31st December in Parma.

Mr.O. MEYER reported on progress of work in the Working Group on animal welfare in experimental animals.

- **EFSA WG on the review of the efficiency of the pesticide peer review process**

EFSA's SCA Directorate created in November 2007 a WG with DG SANCO and MS representatives to try to identify means to improve the efficiency of the pesticide peer review process (current context of the tight deadlines for finalizing the work on the 3rd and 4th list). Ms. C.VLEMINCK, who represents the PPR Panel in this WG, explained the mandate of that WG. In January 2008, a sub WG was created dealing with the procedure on EU Guidance Documents (on risk assessment and risk management). Ms. DUNIER-THOMANN will attend the next WG on 4-5th March to explain the PPR Panel's current work plan for updating and developing GDs.

The Panel members expressed their wish to discuss this issue with the Director of SCA at the next Plenary meeting in April.

- **Follow up on the adopted opinion on acute dietary intake assessment of pesticides residues (IESTI).**

Ms M. DUNIER-THOMANN explained the work carried out by the secretariat on a possible follow up on the opinion on IESTI. At the Standing Committee-Residues in December 2007, one MS expressed the wish to have additional calculations performed and available by the next Codex Alimentarius meeting in April 2008. However this request was not agreed by the other MS and the Commission at the last Standing Committee-Residues meeting on 1st

February, consequently the question will not be raised to the Panel by the Commission. L. MOHIMONT will attend the next Standing Committee-Residues meeting in March.

- The IT Department demonstrated the software for web conferences: experts could have the opportunity to work on the same document remotely, together with their colleagues who were present in a WG meeting. This tool will be particularly useful for experts from USA and Canada (done already once by the Core WG on GD birds and mammals).
- Mr. T. HARDY informed members that he will participate in a workshop with Chairs of Panels and Commission's non food Committees planned to be held in Copenhagen 28-29th May, as a follow up to the annual meeting in Stockholm in November 2008. The subject will be harmonisation on Risk Terminology used in food safety. Mr. A. HART will also attend.

The next **PPR Plenary meeting** will be on **15-16th April 2008 in Parma**, starting at 14h00 on 15th February when two adoptions are foreseen. The chairman asked for full participation to be able to reach the quorum for adoption.