



**MINUTES OF THE 25th PLENARY MEETING OF THE SCIENTIFIC PANEL
ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

held in Parma on 7– 8 March 2007

(adopted by written procedure on 28 March 2007)

#	Agenda
1.	Adoption of the agenda, apologies for absence, declaration of interests
2.	Adoption of the opinion on the revision of Annexes II and III: ecotoxicology
3.	Adoption of the opinion on the acute reference dose for imazalil
4.	Presentation of the opinion on the acute dietary exposure of pesticide residues in fruit and vegetables
5.	Presentation of the draft opinion on MRL for dieldrin
6.	Presentation of the draft opinion of the revision of the Guidance Document on risk assessment for birds and mammals
7.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
8.	Presentation of the draft opinion on FOCUS air and the state of the art on the new request on the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil
9.	Presentation of the future requests to the Panel <ul style="list-style-type: none">○ From Commission○ Self-tasking on Guidance Document (Art. 36)
10.	Miscellaneous <ul style="list-style-type: none">○ Feed-back from the Scientific Committee○ Feed-back from annual meeting DG RTD/EFSA○ EFSA web site

PARTICIPANTS

Members of the PPR Panel

Ms. C. BOLOGNESI, Mr. A. BOOBIS (on 7th March only), Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. H. KÖPP, Mr. M. LIESS, Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms. C. VLEMINCKX.

APOLOGIES



Ms. S. MICHAELIDOU-CANNA, Mr. J. BOESTEN and Mr. D. BARCELLO-CUILLERES.

EFSA

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, Ms. C. FÜLL, Mr. B. BERGER, Mr. M. EGSMOSE, Ms. PERCIVALDI and Ms. G. BOSCHETTO.

COMMISSION

X. PAVARD (DG SANCO O3)

B. DRUKKER (DG SANCO D3) followed the discussion on Item 4 *via* audioconference on 8th March morning.

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

The agenda was adopted. No interest was declared.

2. ADOPTION OF THE OPINION ON THE REVISION OF ANNEXES II AND III: ECOTOXICOLOGICAL STUDIES

The Commission is revising the data requirements (Part A of Annexes II and III) for active substances and plant protection products, Directive 96/12/EC (ecotoxicological studies). With regard to that Directive, the Commission has prepared a Working Document (SANCO 10483) containing the now proposed data requirements. The PPR Panel was requested to provide observations and/or possible recommendations on the draft data requirements, and in particular to verify that the methodology and the approaches presented in the draft data requirements are in line with the state of the art in the relevant field and the extent of their applicability with respect to the risk assessment of plant protection products.

The Terms of reference were agreed during the 21st Plenary meeting on 18-19 October 2006 and Working Group meetings took place on 19-20 October, 23-24 November, 14-15 December 2006, 1-2 February and 6-7 March 2007.

An advanced draft of the opinion had been send to all Panel members on 20 February 2007. The Ecotox WG on 6-7 March dealt with comments received since then and with the remaining open issues. The participants also finalised the conclusions and recommendations and elaborated a summary.

The rapporteur gave a presentation on the main topics that were addressed in this opinion. The participants then discussed the few remaining open points (for example, the shortcomings of the avian short-term dietary studies). The PPR Panel recommends including a statement in the opinion, which makes very clear that these studies should be only be considered for a particular range for compounds.



The participants discussed the conclusions and recommendations in depth and suggested some improvements and changes. With these changes the PPR Panel adopted this opinion. The EFSA Secretariat will do another editorial check, especially with regard to the references and will then circulate the adopted opinion to Panel members for a final check before publication on EFSA's website.

The Chairman expressed his thanks to everybody working on this opinion.

The Communication Department should prepare a web story on the 6 opinions adopted. It was suggested that opinions should be highlighted by the Commission at the next meeting of the DG SANCO Standing Committee after they are adopted.

3. ADOPTION OF THE OPINION ON THE ACUTE REFERENCE DOSE FOR IMAZALIL (ARfD)

The PPR Panel has been asked by the European Commission to review all available toxicological information for imazalil and advise the Commission whether the setting of an ARfD is necessary and if so, at which level it should be fixed. The Working Group Toxicology has discussed this question at four Toxicology Working Groups.

The rapporteur presented the current draft, including a brief background on the question with some additional clarifications on the history of the risk assessments of imazalil and also summarized the different studies which have been evaluated by the Working Group. Panel members proposed some editorial changes, including the addition of some references. The Panel noted that the reference point for the derivation of the ARfD, based on an NOAEL (No Observed Adverse Effect Level) for reproductive toxicity was supported by a benchmark dose calculation.

With the proposed changes the PPR Panel adopted this opinion. The EFSA Secretariat will do another editorial check, and will then circulate the adopted opinion for a final check among the Panel members before publication.

The Chairman thanked everybody who had contributed to this opinion.

4. PRESENTATION OF THE DRAFT OPINION ON THE ACUTE DIETARY EXPOSURE TO PESTICIDE RESIDUES IN FRUIT AND VEGETABLES

The Commission has asked the PPR Panel: (1) How conservative is the IESTI equation with respect to the percentage of the total European population protected? (2) What is the sensitivity - in terms of probability of exceeding the ARfD - to variation and uncertainty in each of the parameters of the IESTI model? and (3) How does replacing HR with other estimates of highest residues e.g. the MRL (determined either using the EU method –Rber, Rmax-, or an alternative statistical method such as the lognormal distribution recently proposed by NAFTA) affect the outcome of the equation?

The Working Group has discussed this opinion at its meeting on 6/7 March and proposes that the Panel discuss the current draft opinion with a view to adopting the opinion at the next meeting in

April. In order to provide input to the discussion between Member States and the Commission on the issue, the Chairman has agreed with EFSA's senior management that at this stage a statement should be issued and sent to the Commission. Adoption in April will ensure that the opinion can be tabled as a room document at the Codex Alimentarius meeting in May in Beijing (China). A member of the PPR Panel attending that meeting could present the outcome of the opinion.

The rapporteur summarized briefly the state of the discussion on the opinion in the Working Group Residues, followed by a discussion of a draft statement prepared by that Working Group.

Some clarifications, including the addition of sentences to improve the text, were agreed. It was proposed to include calculations not only of the frequency with which the ArfD might be exceeded, but also of the frequency with which it might be exceeded by specified factors (e.g. tenfold). The Panel also discussed the conclusions of the draft statement, in particular the meaning of the "total European Population" in the context of the question against "individual exposure", as well as how NAFTA MRLs compare to EU MRLs.

The statement was adopted and will then be sent to the Commission.

The Panel appreciated the huge work carried out by the Working Group, in particular by the *ad hoc* experts, and asked the Working Group and the rapporteur to prepare a final draft for discussion and adoption in April.

5. PRESENTATION OF THE DRAFT ON OPINION ON MRL FOR DIELDRIN

The PPR Panel has received a question from the Commission about (1) whether it is appropriate, from the available toxicological data, to establish an acute reference dose (ARfD) for dieldrin and if so what ARfD should be established, (2) whether a newly proposed MRL will lead to an exceedance of that ARfD and the TDI, taking into account all foodstuffs in which dieldrin can be found, (3) what percentage of consumers are likely to exceed the TDI? and (4) what are the toxicological consequences of exposure exceeding the ARfD and TDI?

The Working Groups Residues and Toxicology are working on different aspects of this question. The co-rapporteur (part Toxicology) presented the recent discussion of the opinion in the Toxicology Working Group. This Working Group has concluded at its last meeting that an ARfD for dieldrin will be necessary, and also provisionally agreed on a value, based on the information available. However, several issues remain to be clarified, and an additional systematic literature search will be carried out.

The rapporteur (part Residues) presented the results from IESTI/TMDI calculations carried out by the Working Group, using EFSA's food consumption database. Consumption data for fish – not included in EFSA's database - were taken from other sources (some national information, WHO diet). There are national, but no international MRL values for dieldrin in fish.

The next step will be to carry out calculations with monitoring data. Remaining issues to be clarified are whether there are additional monitoring data that could be used, how to deal with



results below the reporting level in monitoring programs, and how much the dieldrin intake from courgettes (the commodity originally raising concern) actually adds to the total dieldrin intake.

6. PRESENTATION OF THE STATE OF THE ART OF THE REVISION OF THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS

The PPR Panel received a request to revise the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000–final of 25 September 2002). The EFSA Secretariat arranged a public consultation on the EFSA website, in summer 2006. Four WG meetings took place on 22 June, 7 September, 19-20 October and 23-24 November 2006. Core Working Group meetings took place in Cologne (Germany) on 6-7 December 2006 and in Amsterdam on 28 February to 1 March 2007. Further, meetings of three sub-Working Groups on different specific topics took place in Parma on 17-18, 17-19 and 22-23 January 2007, and another one will follow on 14-15 March 2007 in Valencia (Spain).

The rapporteur gave a brief but comprehensive overview on the ongoing work and especially the outcome of the 2nd Core WG meeting (28 Feb.–1 March). During that meeting the planned workshop in May was discussed in depth, its agenda further elaborated and tasks distributed. An outline of the revised GD was discussed, especially how it should look like and who should take over which task. Two new topics were identified: granules and long term risk assessment for birds. With regard to granules, a request for a discussion paper had been sent to respective experts. For the discussion of long term risk assessment a new sub WG will be created. Further, a questionnaire was addressed to pesticide competent authorities in Member States and to product safety/regulatory affairs managers in industry. The aim of this questionnaire is to seek views on the appropriate scope for the revised Guidance Document. It does not address the question of the level of protection or degree of conservatism of risk assessment, as there will be a separate consultation on this topic at a later stage. The next meetings will take place as follows:

- sub WG “focal species and ecological parameters” 14-15 March 2007 in Valencia (Spain)
- sub WG “modelling approaches” 16-17 April 2007 in Parma
- sub WG “long term RA” 18-19 April 2007 in Parma.
- 3rd Core Working Group meeting 17-18 April 2007 in Parma
- sub WG “residues in food items” in May 2007.

The Working Group should aim for an advanced draft in September 2007, which could then undergo a public consultation on the web, followed by the adoption of the final Guidance Document before the end of 2007.

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



The PRAPeR unit asked the PPR Panel to evaluate the suitability of existing methodologies and, if appropriate, to identify new approaches for assessing cumulative and synergistic risks from pesticides to human health in relation to setting MRLs for those pesticides in the framework of Regulation (EC) No. 336/2995.

The EFSA secretariat informed the PPR Panel members about the possibility of outsourcing a project under a procurement procedure to support the Working Group in elaborating an example to accompany the opinion. The Panel welcomed this possibility, and the next Working Group Residues will discuss it.

8. PRESENTATION OF THE DRAFT OPINION ON FOCUS AIR AND THE STATE OF THE ART ON THE NEW REQUEST ON THE DEFAULT Q10 VALUE USED TO DESCRIBE THE TEMPERATURE EFFECT ON TRANSFORMATION RATES OF PESTICIDES IN SOIL.

- Default value Q10:

The Terms of Reference were adopted at the 24th PPR Plenary meeting (31 January/1 February 2007) for establishing a default Q10 value in the light of the additional information. It was agreed at the Working Group meeting on the 6th March to evaluate the new studies from the PRAPeR unit in addition to studies identified from a search in the open literature carried out by EFSA and provided by ECPA. The Working Group will invite *ad hoc* experts to its next meeting in April. The adoption of the opinion is scheduled for the PPR Panel meeting on 3/4 July 2007.

- FOCUS air:

A self-tasking question from EFSA PRAPeR Unit to the Panel asked for comment on the Final Report of the FOCUS Working group on: "Pesticides in air: Considerations for exposure assessment" (SANCO/10553/2006 draft 1 of 13 July 2006). The Terms of Reference were adopted at the 24th PPR Plenary meeting. The working group met on the 7th March and developed questions and issues to be addressed for the next Working Group meeting in April. The adoption of this opinion is foreseen during the PPR Panel meeting on 3/4 July 2007.

9. PRESENTATION OF FUTURE REQUESTS TO THE PANEL

- From Commission

The Commission informed the Panel about a new question in preparation concerning the metabolites and/or impurities of tritosulfuron. The Commission will provide the Terms of reference to the PPR panel before the next PPR plenary meeting in April.

- Self-tasking on Guidance Documents (Art. 36)

The EFSA secretariat informed the PPR Panel members about the possibility of launching before the summer a project under Article 36 para. 2 of Council Regulation 178/2002 to initiate the



preparation of a Guidance Document on operator, worker, bystander and resident risk assessment. A first draft of a technical annex has been prepared by the secretariat. The project will deal with exposure assessment as requested by Member States in the consultation undertaken by the secretariat in October 2006. A more in-depth discussion will take place at the next Plenary meeting.

10. MISCELLANEOUS

- **Feed back from the Scientific Committee:**

The Chairman reported that all Panel chairs had been invited to meetings with the Management Board to present the work of their Panel. The Chairman of the PPR Panel will participate in the meeting on 19 December 2007.

- **Feed-back from annual meeting DG RTD/EFSA:**

The annual meeting took place on 28 Feb.-1 March 2007, when five officers from Directorate E visited EFSA. The work-plan for the 7th Framework Programme was presented and a number of topics were discussed in the calls for 2007 and projects for 2008 of interest to EFSA. Members were informed that P. Venturi was recently replaced by J-F Maljean for projects concerning pesticides, and the secretariat has contacted him.

- **EFSA web site**

The Communication Department together with the PRAPeR and PPR Units have prepared a new web page on the EFSA work on pesticides which will be soon available under "In Focus".

The next **PPR Plenary meeting** will be on **18-19 April 2007 starting at 14h.**

The PPR Plenary meeting scheduled for 30-31 May 2007 will be cancelled as no opinions are planned for adoption and to allow more time for the Working Group meetings in a smaller week (Whit Monday).