



**MINUTES OF THE 23rd PLENARY MEETING OF THE SCIENTIFIC PANEL
ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

held in Parma on 13-14 December 2006

(adopted by written procedure on 10 January 2007)

	Items
1.	Adoption of the agenda, apologies for absence, declaration of interests
2.	Adoption of the opinion on the Guidance Document on FOCUS landscape and mitigation
3.	Presentation of the state of the art of the revision of the Guidance Document on risk assessment for birds and mammals
4.	Presentation of the draft opinion on the revision of Annexes II and III: fate and behaviour in the environment
5.	Presentation of the draft opinion on the revision of Annexes II and III: ecotoxicological studies
6.	Presentation of the draft opinion on the revision of Annexes II and III: toxicological and metabolism studies
7.	Presentation of the draft opinion on the acute dietary exposure of pesticide residues in fruit and vegetables
8.	Feed-back from the EFSA colloquium on cumulative risk assessment of pesticides in human health
9.	Presentation of the state of the art of the draft opinion on MRL for dieldrin
10.	Presentation of the state of the art of the draft opinion on the acute reference dose for imazalil
11.	Miscellaneous: <ul style="list-style-type: none">○ Feed-back from the Scientific Committee○ Workplan 2007



PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CULLERES, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BOOBIS (Vice-chair, chaired on 14 December), Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman on 13 December), Mr. A. HART, Mr. H. KOEPP, Mr. M. LIESS, Mr. R. LUTTIK, Mr. O. MEYER, Ms. S. MICHAELIDOU-CANNA, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MUELLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms. C. VLEMINCKX.

EFSA

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

European Commission

X. PAVARD (DG SANCO O3)

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

The agenda was adopted without any changes. One Panel member declared a new interest.

2. ADOPTION OF THE OPINION ON THE GUIDANCE DOCUMENT ON FOCUS LANDSCAPE AND MITIGATION

EFSA's PRAPeR Unit requested an opinion on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment (SANCO/10422/2005, version 1.0, May 2005). The opinion includes an assessment on the state-of-the-art in the fields of environmental science and agronomic technology; the scientific robustness of the proposed effect of mitigation measures on the reduction of exposure of surface waters to pesticides; the applicability of the procedures proposed to incorporate the consideration of mitigation measures in the risk assessment performed in the context of Council Directive 91/414/EEC and any other issues, mistakes, bias and recommendations for its improvement the Panel could identify from an examination of the document. WG meetings took place on 22 June 2006, 6 September 2006, 17-18 October 2006, 21-22 November 2006 and 12-13 December 2006.

The rapporteur gave an overview of the discussions on the advanced draft of the opinion during the WG Fate preceding the Plenary, focussing in particular on issues concerning run off and the level of protection. He guided the Panel members through the whole document and highlighted those parts that have undergone considerable changes compared to the last draft. The



contribution of the three *ad hoc* experts with very specific expertise on run off, drainage and spray drift to this opinion was acknowledged. The participants went through the draft opinion page by page and a series of modifications both editorial and to adjust the meaning were discussed and agreed. The PPR Panel then adopted the opinion. This final version of the opinion will be circulated by the EFSA secretariat for final editorial check before 8 January 2007. The Panel expressed its thanks to the rapporteur and the three *ad hoc* experts.

3. 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 the 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, open from 17 July until 22 September. WG meetings took place on 22 June, 7 September, 19-20 October 2006 and 23-24 November 2006. A 1st Core Working Group meeting took place in Cologne (Germany) on 6-7 December 2006, to which one representative from both, MS and industry had been invited, as well as two *ad hoc* experts.

The rapporteur gave a short presentation on the outcome of the core WG meeting in Cologne and the creation of different subgroups for particular topics like residues in insects, focal species, avoidance and metabolism, etc. Further, the need for input from toxicologists was explained (e.g. dermal exposure, avoidance and metabolism). The mechanisms for dermal penetration need to be understood in order to decide how to use it in risk assessment. The toxicologists among the Panel members are asked to provide either direct input or suggest an appropriate *ad hoc* expert for cooperation. Meetings for specific sub Working Group meetings are scheduled for 17-18 January 2007, 17-19 January 2007 and 22-23 January 2007. The 2nd core Working Group meeting is scheduled for end of February 2007 (to be confirmed). 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.

4. PRESENTATION OF THE DRAFT OPINION ON THE REVISION OF ANNEXES II AND III: FATE AND BEHAVIOUR IN THE ENVIRONMENT

For the revision of the Annex II and III-Fate and behaviour, the Commission requested the PPR Panel to provide an opinion on the Working Document (SANCO 10481), which contains the revised data requirements for authorisation of active substances and plant protection products in the framework of Council Directive 91/414/EEC with regard to fate and behaviour in the environment. The PPR Panel is asked to provide any observations and/or possible recommendations on the draft data requirements, in particular to verify that (i) 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 (ii) the extent of its applicability with respect to the risk assessment of plant protection products.



Working Group meetings took place on 6 September 2006, 17-18 October 2006, 21-22 November 2006 and 12-13 December 2006. The rapporteur summarised the progress made with this draft opinion. He gave an overview on the general comments that will be made on the Working Document (SANCO 10481) and the recommendations that will be given. He highlighted critical points and outlined which issues still need discussions. A general discussion followed on how draft guidelines, i.e. guidelines that are not finalised and agreed upon within the scientific community, should be referenced and used.

All further comments on the draft opinion and contributions with regard to the open issues should be submitted to the rapporteur and to the EFSA Secretariat by 7 January 2007. Based on these comments the rapporteur will elaborate a new draft to be circulated by mid January 2007. The adoption of the opinion is foreseen during the Plenary meeting on 31 January–1 February 2007.

5. PRESENTATION OF THE DRAFT OPINION ON THE REVISION OF ANNEXES II AND III: ECOTOXICOLOGICAL STUDIES

The Commission is also 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 is requested to provide observations and/or possible recommendations on the draft data requirements, 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 its 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 2006 and 23-24 November 2006. The next meeting will take place on 14-15 December 2006.

The rapporteur gave a presentation on the state of the art of the draft opinion, the current data requirements with regards to ecotoxicological studies and suggested further data requirements. Cooperation with the WG that is drafting the opinion on Annex II & III-Toxicology is necessary with regard to questions on acute oral toxicity (e.g. endpoints). Three *ad hoc* experts for terrestrial organisms and amphibians have already contributed to the opinion and further contributions and cooperation are requested (e.g. for pollinators). A general discussion on triggers that are currently in the guideline is necessary. For the discussion of sediment organisms, exposure patterns etc. cooperation with the Fate WG is necessary.

The PPR Panel aims to adopt this opinion during its Plenary meeting in March 2007.

6. Presentation of the draft opinion on the revision of Annexes II and III: toxicological and metabolism studies



The rapporteur presented the draft opinion, which has the same structure as the previous opinions on other parts of Annex II and III of Council Directive 91/414/EEC. The Working Group has discussed the issue at two meetings in October and November, and will have two more meetings before scheduled adoption. General comments which were presented and subsequently discussed were (1) the right balance between prescription and flexibility in such a document (*e.g.* flexibility needed if no validated methods are available, not necessarily all pesticides require the entire set of toxicology studies), (2) the importance of the international context (*e.g.* if OECD protocols exist that are fit for purpose, these should be mentioned as alternatives), among other things, to avoid unnecessary use of animals, (3) the need to consider the newest developments in science (*e.g.* tiered approaches to testing, work of other organizations), (4) exposure assessment for operators/residents/bystanders/workers (*e.g.* new guidelines may be needed), (5) the use of human data (*e.g.* in particular whether such studies should be used only for confirmation of information, or to change uncertainty factors) and (6) when and how to report historical data.

Regarding oral acute toxicity, the Working Group Toxicology did liaise earlier with ecotoxicologists from the Panel to ensure a maximum of consistency between this opinion and the opinion on the ecotoxicology part of Annex II and III. The Working Group ecotoxicology will discuss the text proposal made by the Toxicology Working group and propose modifications if appropriate.

The Panel reiterated its intention to extend the common glossary as started under the previous opinions on revision of Annex II and III. This opinion is scheduled for adoption on 31 January 2007.

7. Presentation of the draft opinion on the acute dietary exposure of pesticide residues in fruit and vegetables

The rapporteur presented the current state of the discussion in the Working Group Residues and stressed again the difficulty to finalise this very complex and complicated opinion within the given timeframe. The Panel discussed again on how to best address the terms of reference and stated that indeed the Panel's opinion is sought on two different issues. The Panel discussed and agreed the approach as well as the timetable with planned adoption in early March with an advanced draft end of February.

8. Feed-back from the EFSA colloquium on cumulative risk assessment of pesticides in human health

The chairman informed the Panel members about the outcome of the colloquium, which took place on 28/29 November in Parma. It has been a very useful meeting with about 100 representatives from EU and non-EU countries where aspects of both toxicology and exposure were discussed in 4 break-out groups. The colloquium will be a very valuable source for the self-tasked opinion on cumulative risk assessment.

The Working Groups Toxicology and Residues will both work on this opinion, with the Working Group Toxicology having the lead. The Working Group Residues has proposed at its meeting on 12/13 December to include the calculation of an example into the opinion. This will be discussed by the Working Group Toxicology at its next meeting, including a possible proposal on which group of pesticides could be used.

9. Presentation of the state of the art of the draft opinion on MRL for dieldrin

The rapporteur presented the state of the discussion in the Working Group. The Working Group Residues will have the lead for this opinion, but the Working Group Toxicology will be involved in assessing whether the setting of an Acute Reference Dose is appropriate. The rapporteur asked all Panel members to provide monitoring data for dieldrin in foodstuffs to the Residue Working Group if available, and also expressed its intention to use the GEMS database if relevant. The Working Group Residues aims at finalizing this opinion before summer thus before the deadline in September given by the Commission. It was recalled that as dieldrin is not supported by any company, the retrieving of data, in particular in the area of toxicology, may be difficult.

10. Presentation of the state of the art of the draft opinion on the acute reference dose for imazalil

The rapporteur informed the members that several studies on the toxicology of imazalil have been received and that the Working Group Toxicology will start its discussion at its next meeting. The adoption is foreseen for the March plenary meeting as the Commission has asked for an urgent response.

11. Miscellaneous

• Feedback from Scientific Committee

A new request from all Panel members to EFSA to reconsider the delay by the Management Board to consider any increase of the per diem/daily allowance and other reimbursements (such as airport parking tickets) will be discussed with the Executive Director at the next Scientific Committee on 14-15 December.

The chairman informed the Panel about the latest developments relating to ongoing activities within the Working Groups of the Scientific Committee.

The secretariat informed the Panel that the proceedings of the GENTOX conference are now published on the EFSA web.

- *WG exposure*



The adoption of the opinion on uncertainties in dietary exposure assessment is foreseen for 14 December plenary meeting.

- *WG on the welfare of experimental animals*

Mr. O. MEYER informed the Panel that no WG had taken place since the last plenary, and the next WG is in February 2007. The intention is to make an inventory of data and testing requirements for the different areas covered by the Panels represented.

- *WG benchmark dose*

A Working Group will take place next week.

- **Demo from IT department of the new Extranet**

The consultant from the IT department gave a second presentation of the new EFSAnet to Panel members who were unable to attend the last Plenary meeting. The new EFSAnet will replace the current one on 8 January.

- **Workplan 2007**

A new self tasking question will be launched in principle on 1 February on the Guidance Document FOCUS in air.

The discussion on the possible preparation of the next Guidance Document by the Panel in toxicology was forwarded to the Toxicology WG, to be held on 15 December.

The 24th PPR Panel Plenary meeting will take place on **31 January-1 February 2007** in Parma, starting at 14h.