



**MINUTES OF THE 21st PLENARY MEETING OF THE SCIENTIFIC PANEL
ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

held in Parma on 18-19 October 2006

(adopted by written procedure on 14 November 2006)

| # | Agenda |
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| 1. | Adoption of the agenda, apologies for absence, declaration of interests |
| 2. | Adoption of the draft opinion on the safety of aldicarb MRLs |
| 3. | Presentation of the draft opinion on the Guidance Document on FOCUS landscape and mitigation |
| 4. | Presentation of the updating of the revision of the Guidance Document on risk assessment for birds and mammals |
| 5. | Presentation of the draft opinion on the revision of Annexes II and III: fate and behaviour in the environment |
| 6. | Presentation of the draft opinion on the revision of Annexes II and III: toxicological and metabolism studies |
| 7. | Presentation of the work on the opinion on the acute dietary exposure of pesticide residues in fruit and vegetables |
| 8. | Presentation of the work on the opinion on cumulative risk assessment of pesticides in human health, last news on the EFSA colloquium |
| 9. | Presentation of the new requests from the Commission to the Panel |
| 10. | Miscellaneous: <ul style="list-style-type: none">○ Feedback from member states on revising and developing Guidance Documents○ Feedback from the Scientific Committee |



PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CULLERES, Ms. C. BOLOGNESI, Mr. A. BOOBIS, Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. H. KOEPP, Mr. R. LUTTIK, Ms. S. MICHAELIDOU-CANNA, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MUELLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA.

Mr. X. PAVARD (DG SANCO O3)

APOLOGIES

Mr. J. BOESTEN, Mr. M. LIESS, Mr. O. MEYER, Ms. C. VLEMINCKX.

EFSA

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

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

The agenda was adopted without any changes.

Some members declared an interest, in particular on the new questions from the Commission but no conflict of interest was reported.

2. ADOPTION OF THE DRAFT OPINION ON THE SAFETY OF ALDICARB MRLS

The rapporteur presented the current draft opinion (Revision 6) as a result of discussion at the Residues Working Group (WG) on 17-18 October. A previous version had been circulated to all Panel members and comments had been received from several of them.

The rapporteur highlighted the following issues:

1. An explanation is needed to clarify that the question did not involve consideration of the probability that an exposure at the level of the MRL would occur and that the estimation of that probability is a different question, which would require an exposure assessment using monitoring data. The Panel members discussed the issues and the best way that this could be addressed, and agreed to add a new paragraph in the summary and the conclusions/recommendations.
2. The Residues Working Group had discussed the issue of the variability factor and proposed referencing the minutes of a meeting of the respective Working Group of the Standing



Committee on the Food Chain and Animal Health, restricting the use of a variability factor of 10 (the highest variability considered by the PPR Panel) to the scenario “leafy vegetables shortly before harvest”, and hence this variability factor was not relevant to aldicarb uses. The proposed text from the rapporteur was accepted.

Some further minor modifications were also proposed and subsequently agreed. The Panel adopted the opinion with these changes. The revised version will be circulated by the EFSA secretariat with a one week deadline for final editorial comments. A press release is foreseen.

3. PRESENTATION OF THE DRAFT 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 should include 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 that the Panel could identify from an examination of the document. WG meetings took place on 22 June 2006, 6 September and 17-18 October 2006.

The rapporteur gave a comprehensive presentation of the draft opinion (Rev 3) including the outcome of the WG Fate 17-18 October 2006, to which two *ad hoc* experts had been invited. All members of the WG will provide further input to this draft and a draft revision 4 will be circulated by 7 November 2006 for comment. Rev 4 will be discussed in the WG Fate on 21-22 November 2006, when missing data as well as information on run-off and erosion, probabilistic modelling, and ecological considerations will be discussed and included. The adoption of the opinion is then foreseen during the PPR Panel's Plenary meeting on 13-14 December 2006.

4. PRESENTATION OF THE UPDATING 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) within 12 months after acceptance of the question (i.e. June 2007). The 19th PPR Plenary meeting discussed the terms of reference and nominated a rapporteur. WG meetings took place on 22 June and 7 September 2006. The EFSA Secretariat arranged a public consultation on the EFSA website, open from 17 July until 22 September, 2006.

The rapporteur gave an overview of the progress of the revision on the GD birds and mammals, of the key areas of science that need to be addressed and of the strategy on how to proceed with



the revision. The EFSA Secretariat informed the Panel members about representatives nominated from five Member States.

The Working Group meeting on 19-20 October 2006 will further discuss the specific issues and work programme and set the timeline and agenda for a meeting of the standing WG to which further experts will be invited, including a MS representative.

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

The Commission is revising the data requirements for authorisation of active substances and plant protection products in the framework of Council Directive 91/414/EEC, including Part A of Annexes II and III. The revision process has been organised in order to amend current Directives laying down the data requirements for active substances and plant protection products, particularly Directive 95/36/EC (fate and behaviour in the environment). With regard to this Directive, the Commission has prepared a Working Document (SANCO 10481) containing the proposed data requirements. The text has been drafted in collaboration with national experts under the coordination of the Competent Authorities of The Netherlands and has been subject to extensive consultation with Member States and industry, whose comments have been taken into account. The Commission requested that the PPR Panel to provide 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 and 17-18 October 2006. The rapporteur gave an overview of the document to be worked on, the task, and the outcome of the WG Fate discussions on 17-18 October. The structure for the opinion has been agreed and *ad hoc* experts have been identified. As a Rev 6 of this Working Document SANCO 10481 is available, the Panel members agreed that the opinion should refer to this last revision in agreement with the Commission services. The WG members were requested to submit further comments on the Rev 6 document by 27 October. Based on these comments the rapporteur will elaborate a first draft opinion to be circulated by 6 November 2006. The next WG Fate will take place on 21-22 November 2006 and the adoption of the opinion is foreseen by end of January 2007.

6. PRESENTATION OF THE DRAFT OPINION ON THE REVISION OF ANNEXES II AND III: TOXICOLOGICAL AND METABOLISM STUDIES

As for the previous item of the agenda, a process (Part A of Annexes II and III) has also been initiated by the Commission to amend the current Directive 94/79/EC (toxicological and metabolism studies). With regard to this Directive, the Commission has prepared a Working Document (SANCO 10482 Rev 10) containing the proposed data requirements. The text has



been drafted in collaboration with national experts under the coordination of the Competent Authorities of France.

The rapporteur presented the current draft opinion (Rev 2). The text would be further discussed at the Working Group Toxicology on 19-20 October. The importance of consistency of this opinion with previous opinions on the revision of other parts of Annex II and III (including the inclusion of a glossary) was highlighted. The use of human data will be an item of further intensive discussion. It was stressed that the Working Group should not rewrite the proposed data requirements for revision of the Annex II and III document, but rather comment on them.

The rapporteur will prepare a new draft, based on the discussion at the Working Group Toxicology on 19-20 October with Panel members and ad hoc experts, and present the progress at the next plenary meeting.

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

The rapporteur presented an updated working program (available on the extranet) and the approach to address the question as discussed at the meeting of the Working Group Residues on 17-18 October. Overall, several models will be used to simulate the necessary information on exposure. Several ad hoc experts will be involved in this opinion to ensure a broad coverage of different models available in the EU.

It was highlighted that the opinion is very complex and consequently demanding to produce within a short timeframe. Nevertheless, the intention to meet the deadline of March 2007 for adoption, with an advanced draft by end of February, was confirmed.

As a first task, the Working Group members will check Draft Assessment Reports (lists 1-3) to determine which pesticides have sufficient data for use in the calculation with the IESTI equation and the modeling.

The Working Group Residues aided by ad hoc experts will continue to work on the opinion and the rapporteur will present the progress, including a first draft, at the next plenary.

8. PRESENTATION OF THE WORK ON THE OPINION ON CUMULATIVE RISK ASSESSMENT OF PESTICIDES IN HUMAN HEALTH, LAST NEWS ON THE EFSA COLLOQUIUM

The designated chairman of the EFSA colloquium to be held in Parma on 28-29 November, presented the current status of the preparations for the colloquium on "Cumulative risk assessment of pesticides in human health: the way forward", including the draft program. One hundred participants are foreseen, and most of the rapporteurs, chairpersons and speakers who have been invited have already accepted their tasks. Draft discussion briefs have been submitted and will be discussed in the Toxicology Working Group on 19-20 October and subsequently distributed to the participants of the colloquium.



Ten members of the PPR Panel have registered and will be invited to the Colloquium.

9. PRESENTATION OF NEW REQUESTS FROM THE COMMISSION TO THE PANEL

- **Requests from the Commission for opinions on the revision of Annexes II and III of Directive 91/414: 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 text has been drafted in collaboration with national experts under the coordination of the Competent Authorities of Ireland and the United Kingdom and has been subject to extensive consultation with Member States and industry, whose comments have been taken into account.

The representative from the European Commission presented the question, which asks the PPR Panel 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 Plenary agreed on the Terms of reference and identified a rapporteur for this task. The question would be discussed for the first time in the Working Group meeting on 19-20 October 2006. The PPR Panel aims to adopt this opinion during its Plenary meeting in March 2007.

- **Request from the Commission for an opinion on dieldrin MRLs:**

A representative from the European Commission presented the question, which is based on a request from the Netherlands, on the risk that would be associated with an increase of the Maximum Residue Level (MRL) for dieldrin on courgettes. The PPR Panel discussed the proposed terms of reference and proposed different wording of the question. It was emphasized that it would be necessary to obtain the detailed risk assessment/toxicological evaluations from the UK and the Netherlands as well as the available JMPR information in order to address in particular the toxicological aspect of the question. The European Commission, will be asked to provide access to this information, and the deadline should be postponed.

The Panel agreed a rapporteur for the opinion from the Residue Working Group, who will be supported by a member from the Toxicology Working Group.

- **Future request from the Commission**

A representative from the European Commission informed the Panel about a new question being prepared on toxicology.

10. MISCELLANEOUS



- **Feedback from Member States on revising and developing Guidance Documents**

The EFSA Secretariat gave a short overview on the replies received from MS on their priorities for revising and developing Guidance Documents, as requested in July *via* the Standing Committee on the Food Chain and Animal Health in DG SANCO. The priority list compiled for both categories was discussed briefly, but due to a lack of sufficient time, a more extended discussion was scheduled for the next Plenary meeting. In the meantime the Panel members should examine the MS arguments and comments.

- **Feedback from Scientific Committee**

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

- *WG exposure*

Adoption of the opinion on uncertainties in dietary exposure assessment was postponed to the November plenary meeting.

- *WG on the welfare of experimental animals*

The new WG will start its activities on 20 November; when Mr. O. MEYER will be the PPR representative.

- *New WG on Scientific cooperation with Member States*

A new WG was created in September 2006, following the EFSA evaluation report, with the aim of improving links and collaboration with the institutions of Member States. An externalisation of part of EFSA's work will be considered.

The secretariat presented the new staff organigramme for EFSA.

The 22nd PPR Panel Plenary meeting will take place on **22-23 November 2006** in Parma, starting at 14h.