



**MINUTES OF THE 20th PLENARY MEETING OF THE SCIENTIFIC PANEL
ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

held in Parma on 5-6 September 2006

(adopted by written procedure on 4 October 2006)

#	Agenda
1.	Welcome speech by the Executive Director C. Geslain-Lanéelle
2.	Adoption of the agenda, apologies for absence, declaration of interests
3.	Presentation of the draft opinion on the safety of aldicarb MRLs
4.	Presentation of the draft opinion on the Guidance Document on FOCUS landscape and mitigation
5.	Presentation of the updating of the Guidance Document on risk assessment for birds and mammals
6.	<p>Presentation of the new requests to the Panel:</p> <ul style="list-style-type: none">○ two requests from the Commission for opinions on the revision of Annexes II and III:<ul style="list-style-type: none">1. toxicological and metabolism studies2. fate and behaviour in the environment○ request from the Commission for opinion on the acute dietary exposure of pesticide residues in fruit and vegetables○ self-tasking question on cumulative risk assessment of pesticides in human health and related EFSA colloquium
7.	<p>Miscellaneous:</p> <ul style="list-style-type: none">○ feedback from request to member states on revising and developing Guidance Documents○ feedback from Scientific Committee:<ul style="list-style-type: none">- state of the art on the draft opinion on uncertainties in dietary exposure assessment- creation of a WG on the welfare of experimental animals○ information on Article 36○ feedback from 6th EFSA colloquium on risk-benefit analysis of Foods



PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CULLERES, Mr. J. BOESTEN, 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. M. LIESS, Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MUELLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA and Ms. C. VLEMINCKX.

APOLOGIES

Ms. S. MICHAELIDOU-CANNA, X. PAVARD (DG SANCO E 03)

EFSA

Ms. C. GESLAIN-LANEELLE, Executive Director

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

Ms. J. KLEINER, present at item 7.

The Chairman started the meeting with a silent tribute to Professor Marco MARONI, our colleague and former Panel member, who passed away on 29 June 2006.

1. WELCOME SPEECH BY THE EXECUTIVE DIRECTOR

The Executive Director Ms. C. GESLAIN-LANEELLE welcomed the participants, stressed the importance of the Panel members' work for EFSA and expressed her gratitude. She welcomed the decision to create a PLH Panel, which deals with the plant health issues, thus enabling the PPR Panel to concentrate on the questions related to plant protection products and their residues. She further expressed her concerns about the foreseen time reduction for EFSA to deal with the risk assessment within the new pesticide regulation in discussion in Council and Parliament. She will discuss this issue with the Finish Council Presidency on 8 September.

Ms. C. GESLAIN-LANEELLE highlighted the importance of the EFSA priorities raised by the Management Board, especially the scientific cooperation and networking with Member States. She also emphasised that she will always be available for discussions with the chairman on requests from the Panel and signalled her understanding of the disappointment about the lack of decision so far from the Management Board on an increase in indemnities.



The Chairman stressed that it is important for the Panel members to have their work recognized; he highlighted the high degree of commitment and the enormous workload and expressed the wish that this should be much better appreciated by the EFSA management than in the past.

2. ADOPTION OF THE AGENDA, DECLARATION OF INTERESTS

The agenda was adopted without any changes.

Some Panel members declared an interest on the new questions (participations and activities in working groups, chairmanships, etc.), however, none of those were considered as a conflict of interest.

3. PRESENTATION OF THE DRAFT OPINION ON THE SAFETY OF ALDICARB MRLs

The rapporteur presented the draft opinion (revision 2) including comments from Members of the Working Group Toxicology/Residue and highlighted the specific contributions of two members of the Panel. The rapporteur also briefly summarized the discussion at the Working Group meeting on 4/5 September, such as on the general structure of the opinion, on probabilistic versus deterministic risk assessment, on the possibility to use the European food consumption database currently under development within EFSA, the variability factor to be used for the calculation, and processing factors and how they will be used in the opinion. The draft also contains a chapter reviewing the toxicology of aldicarb (and its relevant metabolites) to ensure that the calculations are based on up-to date toxicological information, including the correct acute reference dose, and will address uncertainties in the risk assessment.

The Panel discussed the draft opinion, in particular the issue of variability factors. It was recalled that the question was on the safety of the MRLs and that this should be better reflected.

The rapporteur will provide a new draft and the EFSA secretariat will circulate it, asking for final comments by 10 October. This will give the Working Group Toxicology the opportunity to finalize the opinion for adoption at the next Plenary meeting on 17/18 October 2006.

4. PRESENTATION OF THE DRAFT OPINION ON THE GUIDANCE DOCUMENT ON FOCUS LANDSCAPE AND MITIGATION

EFSA's PRAPeR Unit requested an opinion on a question concerning 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 the Panel could identify from an examination of the document.

The rapporteur gave an overview of the work done so far, including the results of the first Working Group meeting on 22 June 2006 and the suggested structure of the opinion. A draft opinion (revision 2) will be discussed in the Working Group on 6 Sept 2006, involving colleagues from the PRAPeR team.

The adoption of the opinion is foreseen during the PPR Panel's Plenary meeting mid December 2006.

5. 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 references and nominated a rapporteur. A first WG meeting took place on 22 June 2006. The EFSA Secretariat arranged a public consultation on the EFSA website, open from 17 July until 22 September.

The rapporteur gave a short outline of a plan on how to revise the Guidance Document. The Panel members identified a number of specific difficulties: how to deal with risk management issues, involvement of regulators/competent authorities, involvement of a limited number of industry representatives with specific expertise.

Panel members raised concerns about the huge workload compared to the usual questions, and the EFSA Secretariat explained the scope for outsourcing a certain work package within a restricted call for tender.

The next WG (7 Sept 2006) will analyse the key areas of science that need to be addressed, discuss the principles on which to proceed, discuss difficulties and possible solutions, whom to invite to the WGs, and elaborate for the Plenary meeting in October a framework on how to further operate. The outcome of the public consultation will be considered.

6. PRESENTATION OF THE NEW REQUESTS TO THE PANEL

- **Two requests from the Commission for opinions on the revision of Annexes II and III of Directive 91/414 :**
 - *toxicological and metabolism studies*
 - *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. The revision process

involves also 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 94/79/EC (toxicological and metabolism studies) and Directive 95/36/EC (fate and behaviour in the environment). With regard to these Directives, the Commission has prepared Working Documents (respectively 10482 and 10481) containing the now proposed data requirements. The texts have been drafted in collaboration with national experts under the coordination of the Competent Authorities respectively France and The Netherlands and have been subject to extensive consultation with Member States and industry, whose comments have been taken into account.

The EFSA secretariat presented the two questions, which are requests to 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.

For the toxicological and metabolism studies a first discussion had already taken place within a Working Group meeting, where its members found the terms of reference and the related deadline of 31 January 2007 acceptable. A rapporteur had been designated, several ad-hoc experts identified, and a work plan established. The rapporteur will prepare a first draft for the next plenary meeting.

The question on fate and behaviour in the environment will be discussed for the first time in a Working Group meeting on 6 September 2006.

The opinions should be delivered by end of January 2007.

- **Request from the Commission for opinion on the acute dietary exposure of pesticide residues in fruit and vegetables**

The EFSA secretariat presented the question. The chairman of the Working Group Tox/Residues summarized the discussion at the Tox/Residue Working Group meeting on 4-5 September, in particular regarding some clarifications with a Commission representative on the terms of reference and the agreement on the deadline (adoption foreseen at the plenary meeting on 8/9 March 2007, but an advanced draft is requested by the Commission by the end of February). The designated rapporteur then presented the work plan, including a list of potential ad hoc experts. The Panel members discussed the approach presented by the rapporteur. It was highlighted that the use of HR or MRL has been one of the concerns triggering the question and that the opinion should take this into consideration. It was agreed that the main discussion and decisions on the general outcome need to take place at the plenary meeting at the end of January in order to ensure that an advanced draft can be presented to the Commission by the end of February. The rapporteur will prepare a first progress report for the next plenary meeting and the secretariat will put the presentation from the rapporteur on the work plan on the EFSA extranet.

- **Self-tasking question on cumulative risk assessment of pesticides in human health and related EFSA colloquium**

The background of the question and the draft terms of references, as agreed by the Working Group Tox/Residue during its meeting on 4/5 September 2007, were presented by the EFSA secretariat; the chairman of the Working Group then summarized the discussion that had taken place at the Working Group meeting. The EFSA secretariat informed the PPR Panel about the upcoming colloquium on “Cumulative Risk Assessment of Pesticides to Human Health: The way forward”, and it was decided that the opinion would be based as a starting point on that EFSA colloquium, taking place on 28/29 November 2006 in Parma. All Panel Members will be invited to the above mentioned EFSA Colloquium, two are also member of the Steering Committee which will meet on 6 September to prepare the scientific programme. In the meantime the Toxicology Working Group would start reflecting on ad hoc experts to invite, as well as on the general structure of the opinion.

The PPR Panel agreed the terms of reference and the deadline for adopting of the opinion by the plenary meeting early July 2007. The volunteer rapporteur was confirmed, he will present the general structure of the opinion at the next plenary meeting.

7. MISCELLANEOUS

- **Feedback from request to member states on revising and developing Guidance Documents**

The EFSA Secretariat gave a short overview on the replies received from some Member States 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. This priority list and work programme for the Panel will be discussed at the next plenary.

- **Feedback from Scientific Committee**

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

- *State of the art on the draft opinion on uncertainties in dietary exposure assessment*

Mr. A. HART, as representative of the PPR Panel in the WG Exposure, explained that the draft of the opinion on guidance for dealing with uncertainties in dietary exposure assessment, circulated to the Panel, will be revised and circulated; the adoption should be in November.

- *Creation of a WG on the welfare of experimental animals*

The Panel found interests to participate, not only from the toxicological but also from the ecotoxicological side; Mr.O. MEYER will be the PPR representative in that WG.



- *New WG on scientific aspects of transparency in RA*

Ms. J. KLEINER gave a short explanation of the establishment of this WG and asked the PPR Panel to send a representative to the group. Mr. A. HART will be the PPR representative in that WG.

- **Information on Article 36 of EFSA Regulation 178/2002**

The EFSA Secretariat shortly summarised the background and the tasks to be entrusted in future under Article 36. It will provide a possibility to finance outsourcing (e.g. parts of the work to be done on guidance documents) with a restricted call for tender. The list of organisations proposed by MS still has to be approved at the Management Board meeting in December 2006, this new financial tool should be put in place in 2007.

- **Feedback from 6th EFSA colloquium on risk-benefit analysis of Foods**

Ms. J. KLEINER gave a short summary on this colloquium that took place in July 2006 in Tabiano/Italy, some Panel members were invited. The outcome should be published on the web by end of 2006. The Scientific Committee will have to decide on the follow up.

The 21st PPR Panel Plenary meeting will take place on **18-19 October 2006** in Parma, starting at 14h.