MINUTES OF THE 24th PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

held in Parma on 31 January–1 February 2007

(adopted by written procedure on 21 February 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: fate and behaviour in the environment
3.	Adoption of the opinion on the revision of Annexes II and III: toxicological and metabolism studies
4.	Presentation of the draft opinion on the revision of Annexes II and III: ecotoxicology
5.	Presentation of the draft opinion on the acute reference dose for imazalil
6.	Presentation of the draft opinion on the acute dietary exposure of pesticide residues in fruit and vegetables
7.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
8.	Presentation of the draft opinion on MRL for dieldrin
9.	Presentation of the state of the art of the revision of the Guidance Document on risk assessment for birds and mammals
10.	Presentation of the new requests to the Panel
11.	Miscellaneous: o Feed-back from the Scientific Committee o Article 36

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. 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.

APOLOGIES

Mr. H. KOEPP, Mr. J. BOESTEN, and on 1 February A. MORETTO.

EFSA

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

COMMISSION

X. PAVARD (DG SANCO O3), F. ARENA, B. DRUKKER (DG SANCO D3) followed the discussion *via* audioconference.

---

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

The chairman introduced Mr. M. EGSMOSE, a new member of staff who joined the PPR Unit in mid January.

He also officially welcomed the Bulgarian member of the Panel, following the official joining of her country as an EU Member State on 1 January 2007.

The chairman reminded the Panel members of the need for them to send a letter to the Executive Director *via* the secretariat to claim for reimbursement of parking fees in airports or the exceptional use of taxis.

Some additional interests were reported, and "declaration of interest" forms were completed by all members for each new opinion.

2. ADOPTION 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, including 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 now 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 the PPR Panel to comment and provide 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, 21/22 November, 12/13 December and 31 January 2007. The rapporteur gave an overview of recent changes to the draft opinion. The structure follows the one already applied to the first three opinions on parts of Annexes II & III. Open points remaining from the last meeting (aged residues and PEC in soil pore water) have been clarified. The WG meeting of 31 January 2007 carefully considered all comments received since the last revision and completed the chapter on conclusions and recommendations as well as the summary.

The rapporteur guided the participants through the whole text. It was agreed to refer to all six Annex-parts in the introduction i.e. to add “fate and behaviour, ecotoxicological studies and toxicological and metabolism studies”. A number of editorial comments and proposals for language improvement were made. Some general clarifications were inserted.

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 for a final check by Panel members. Any comments should be sent to the EFSA Secretariat by 9 February 2007. The opinion will then be published on the EFSA web.

The Chair expressed his thanks to everybody, especially the rapporteur, the *ad hoc* expert and the staff of the fate group of the PRAPeR unit.

3. ADOPTION OF THE DRAFT OPINION ON THE REVISION OF ANNEXES II AND III: TOXICOLOGICAL AND METABOLISM STUDIES

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, Directive 94/79/EC (toxicological and metabolisms studies). With regard to this Directive, the Commission has prepared a Working Document (SANCO/10482/2006) containing the now proposed data requirements. The text has been drafted in collaboration with national experts under the coordination of the Competent Authorities of France and has been subject to extensive consultation with Member States and industry, whose comments have been taken into account. The Commission requested the PPR Panel to comment and provide possible recommendations on the draft data requirements, in particular to verify that (1) 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 (2) the extent of its applicability with respect to the risk assessment of plant protection products. Working Group meetings on this opinion took place on 4/5 September 2006, 19/20 October, 23/24 November, 14/15 December and 30/31 January 2007.

The rapporteur introduced the opinion and the most changes agreed during the last meeting of the Working Group Toxicology. The Panel members then discussed in particular the issues of

historical data, the use of human data, the risk assessment for bystanders/residents and how to ensure that the requirements on mammalian toxicity are consistent with the needs for the risk assessment of vertebrate wildlife. It was recommended that once the entire Annex II and III has been revised, an holistic check of all 6 documents should be done by the European Commission to ensure consistency.

The Panel then agreed some editorial changes for clarification and adopted the opinion.

The EFSA Secretariat will do another editorial check, especially with regard to the references and will then circulate the adopted opinion for a final check by Panel members. All comments should be sent to the EFSA Secretariat by 9 February 2007. The opinion will then be published on the EFSA web.

The Chairman expressed his thanks to the toxicologists, especially the rapporteur and the *ad hoc* experts.

4. PRESENTATION OF THE DRAFT 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 is requested to comment and provide 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, 23/24 November and 14/15 December 2006.

The rapporteur gave a presentation on the current state of the draft opinion, and unresolved questions. These are especially on the use of effect data on algal growth, where the use of a more sensitive endpoint is considered. Further, it was agreed that amphibians are a relevant group and appropriate information and recommendations will be given in the opinion. Reptiles may be relevant for southern MS, but there is hardly any relevant information available on them. The Panel members suggested checking if reptiles are more sensitive than other test organisms before including them in the data requirements. Concerning effects on biological methods for sewage treatment, the Panel is asked to provide any new information they might be aware of. The Panel further suggested making reference to the latest version of guidance documents, and if no standardised tests are available, recommends the use of the most appropriate tests until a standardised one is available. The Panel reiterated that the structure of the opinion should follow that already used in the previous opinions on other Annex parts and recommended that a holistic

check be carried out by the Commission across all opinions on the six Annex finalised revisions. With regard to the specification of the test substances, a reference to the adopted opinion on the Annex II and III: physical and chemical properties (and possibly to the toxicological studies part) should be included. Further text on endocrine endpoints will be included in the final opinion. The next WG meeting will take place on 1/2 February 2007 and the PPR Panel aims to adopt this opinion during its Plenary meeting on 7 and 8 March 2007.

5. PRESENTATION OF THE DRAFT OPINION ON THE ACUTE REFERENCE DOSE FOR IMAZALIL

The PPR Panel received a request from the European Commission to review all available toxicological information for imazalil and advise the Commission whether the setting of an acute reference dose (ARfD) is necessary and if so, at which level it should be fixed.

The rapporteur presented the draft opinion and the background to the question, including the studies that have been submitted by the notifier. The Panel then discussed NOAEL values and their implications for an ARfD for imazalil, based on the discussion in the Working Group Toxicology. It was further decided to include a sentence on general clinical experience of compounds inhibiting aromatase and whether the compound administered in the studies (free base, sulphate, nitrate) made any difference to toxicological effects.

The Panel discussed whether two acute reference doses can be proposed, one for the general population and one for women of child-bearing age, as in the exposure assessment, the different population groups could be treated differently. It was agreed that was appropriate on scientific grounds. It would however require clear risk communication to avoid confusion, in particular for enforcement activities.

6. PRESENTATION OF THE DRAFT OPINION ON THE ACUTE DIETARY EXPOSURE OF PESTICIDES RESIDUES IN FRUIT AND VEGETABLES.

The PPR Panel has received a request from the European Commission for advice on how conservative the IESTI equation is with respect to the total European population protected, the sensitivity to variation and uncertainty in each of the parameters of the IESTI mode, and how replacing the HR with other estimates of highest residues would affect the outcome of the equation.

The rapporteur presented the current state of the work and what is planned to finalize the opinion. Additional issues discussed included reasons for exceedances of the ARfD, uncertainties in the probabilistic modeling, and the importance of chosing pesticides with a representative range of exposure patterns and ARfDs.

A more complete draft will be available at the next plenary for a broader discussion. It was re-emphasized that the request of the Commission is for adoption of the opinion at the Plenary in March, as the Commission wish to discuss it with Member States at their Standing Committee to facilitate decision-making for the EU position at the next Codex Alimentarius meeting. It was

recalled in that context, that EFSA policy is not to release a draft opinion before adoption. Thus in the event that adoption is not possible on 7/8 March, the rapporteur, together with the Working Group, will prepare a synopsis, summarizing the state of the art of the opinion to send to the Commission.

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

The PRAPeR unit tasked the PPR Panel to evaluate the suitability of existing methodologies and, if appropriate, to identify of new approaches to 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 Rapporteur presented the intended structure of the opinion. As the opinion will include toxicological and exposure aspects, the Working Group Toxicology and the Working Group Residues are working together on the opinion. The PPR Panel then discussed whether to include a worked example in the opinion. It was felt that this could be particularly useful for the exposure aspect. The PPR Panel could choose a group of compounds which are already (or close to being) included in the Annex I of Directive 91/414. However, this might result in the need to extend the planned deadline, possibly to the end of the year, already agreed in a separate discussion between EFSA's PRAPeR unit and the main Panel members involved in the preparation of the opinion.

8. PRESENTATION OF THE DRAFT 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?

As this question has toxicological and exposure aspects, it is being dealt with by both the Working Group Residues and the Working Group Toxicology.

The rapporteur introduced the opinion and its background and the co-rapporteur reported back from recent discussions in the Working Group Toxicology. These evaluated several studies on the toxicity of dieldrin, and identified one study suitable for setting an ARfD.

Regarding the exposure assessment, the collection of monitoring data has so far been difficult. Although data from two different sources have been found, more work is needed on data collection.

The rapporteur re-emphasized that it is still the intention of the Working Group Residues to finalize the opinion by the summer.

9. 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 (GD) 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 2006. WG meetings took place on 22 June, 7 September, 19/20 October and 23/24 November. The first meeting of the Core Working Group 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. Further, three sub-working groups on different specific topics met in Parma on 17/18 January, 17/19 January and 22/23 January 2007.

The rapporteur gave an overview of the ongoing work in the different sub WGs. One of these sub groups discussing “focal species for the RA” met on 17/18 January 2007. Member States were asked to send information on their national focal species. Further topics within this Working Group include dead/dying insects, dehusking, PD (fraction of food type in diet), off-field vegetation, and determination of PT (time spent in the treated area). Most data on the first three issues are owned by industry.

In discussion, Panel members raised the question of how sure one can be about birds eating dead insects? This is known to occur, meaning, a worst case exists. The current assumption is that birds continue to eat their normal diet in normal quantities, even if insecticides have been used, meaning they might eat also dead insects. Another question was regarding the link between PD and PT? The current GD does not take that into consideration but there might be a dependency. This difficult issue needs further discussion within the WG.

This sub WG is also responsible for the scientific organisation of a workshop on ”focal species and ecological parameters” to be held in May 2007 in Valencia (Spain, participation by invitation only). This workshop will bring together representatives from all Member States and some representatives from industry, as well as bird and mammal risk assessors. The main goals are to inform Member States on the state of the art of the GD and to come to a conclusion with regard to the use of focal species in Risk Assessment. A first announcement was circulated shortly before the end of 2006. The official invitations will be sent in February 2007. The sub WG will meet again on 14/15 March 2007 in Valencia (Spain).

A second sub WG deals with “residues in food items” (insects and others) and met on 22/23 January 2007. One of the goals is to create a generic table for default Residue Unit Dose values for different categories of insects (soil dwelling, canopy, flying). One of the obstacles here is also that most data are owned by industry. Further topics discussed in that sub WG are residues in vegetation, MAF (Multiple Application Factors) and degradation times. The next meeting for this sub WG is planned for May 2007.

The third sub WG deals with “modelling approaches and routes of non-dietary exposure”; the WG met on 17/19 January 2007. They reviewed an empirical model predicting avian mortality from the application rate, LD_{50} and K_{OW} for a pesticide. A decision has to be made whether this model can be used in Risk Assessment or not. The second topic concerns the review of a theoretical model of avoidance, metabolism and the feeding rate. The PPR opinion on pirimicarb and a Syngenta adaptation of it were discussed. A series of actions has been agreed among the participants to evaluate the model and its potential use. The next sub WG meeting will take place on 16-18 April 2007 in Parma.

The core Working Group will next meet on 28 February–1 March 2007 in Amsterdam (The Netherlands) to consolidate the first results and information and discuss further steps.

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

10. PRESENTATION OF NEW REQUESTS TO THE PANEL

Two new requests tasking from EFSA were presented: on FOCUS air and on on the default value for Q10 used to describe the temperature effect on transformation rates of pesticides in soil.

- FOCUS air:

An opinion is requested to 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 intention of the Commission and Member States in preparing this Guidance Document was that the exposure assessments should be used to address the data requirements 7.2.2 (annex II) and 9.3 (annex III) of Directive 91/414 EEC as laid out in directive 95/36 EC (the current data requirements). The proposal for the new fate and behaviour data requirements references this report as the guidance to be used for addressing the annex points regarding fate in air. It will be a self-tasking question from EFSA’s PRAPeR Unit to the Panel.

The rapporteur of the opinion gave an overview of the outcome and the results of the first Working Group meeting held on the 30 January 2007. The opinion should include an assessment of the state-of the art in the field of pesticides in air; the scientific robustness of the proposed assessment of exposure and the communication of the risk assessment procedures and hazard characterisation proposed. Further it should consider whether the proposed cut-off values, in particular for short range transport exposure, are appropriate for its intended use.

The adoption of the Opinion is foreseen during the PPR Panel’s meeting at the beginning of July 2007.

- Default value for Q10:

The chairman explained the context of this request due to additional data that have become available since adoption of the opinion Q-2005-058 published on 8 February 2006 (EFSA Journal (2005) 322, 1-40). He summarized the discussions of the first Working Group meeting on the 30 January 2007. It should be considered whether the database on which the proposed default for Q10 of 2.8 for temperature correction of DT50 values from soil degradation studies still reflects the current scientific state of the art or should be updated in view of additional data identified by the European Crop Protection Association and any other relevant data that have emerged since. This will be a PPR Panel self-tasking question and a rapporteur was agreed.

The adoption of the opinion is foreseen during the PPR Panel's meeting at the beginning of July 2007.

11. MISCELLANEOUS

Feed-back from Scientific Committee:

The chairman informed Panel members about a discussion within EFSA to develop a policy that in exceptional cases could feed input from Senior EFSA management into opinions before finalisation. Communication on opinions *via* press releases is linked to this new policy.

-WG Emerging risks: The EFSA Secretariat informed the Panel that a paper has been circulated from the Scientific Committee with the intention of identifying and collecting information on possible emerging risks from each EFSA Panel. The intention is to develop EFSA's capacity to identify emerging risks in agreement with Article 34 of Regulation No 178/2002 (Food Law). The Panels members should send their input before the 9 February 2007.

-WG on Transparency: the chairman, reported on the WG meeting held on the 30 January 2006. The first part of the guidance was endorsed on 11 April 2006, and the second part intends to convert the procedures into more operational guidance for improving the transparency of the EFSA Risk-Assessments. The opinion should be available by the end of the year.

-WG on Welfare of Experimental Animals: Mr. O. MEYER, representative of the PPR Panel, mentioned that the intended meeting in February had been postponed till March 2007. The now adopted opinion on Toxicology on the revision of Annexes II and III to Directive 91/414/EEC will be sent to the WG to be added as an appendix to their opinion.

-WG on Benchmark Dose: Mr. A. BOOBIS representative of the PPR Panel, informed the Panel about the last WG meeting held on 18/19 December 2006. The WG was working on the applicability of using this approach and the potential outcome. The next meeting will be in March 2007.

The EFSA secretariat informed the Panel that the opinion on "Uncertainties in Dietary Exposure Assessment" has been published and can be found on the EFSA-website. The Scientific Committee has asked all Panels to consider the conclusion of the opinion on board and to systematically address uncertainty in preparing their own opinions.

Other topics:

Article 36: The EFSA secretariat informed the Panel that the list of competent organisations under Article 36 para 2 of Council Regulation 178/2002 has now been adopted by the EFSA Management Board. This is a list of EU scientific organisations, designated by Member States, which may assist the authority with its mission, either individually or in networks. This will allow EFSA in 2007 to provide grants on certain tasks to externalise *via* a call for co-financing activities to institutions on this list. The list is active and new institutions that fulfil the requirements may be proposed by their Member State and added to the list (e.g. new Member States BU and RO).

The PPR secretariat intends to use this new financial tool to collect data and start the work for development of a new Guidance Document on the assessment of health risks from exposure to pesticides in operators and bystanders, as requested by Member States as a top priority.

The updated time-table for adoption of ongoing opinions was presented by the EFSA secretariat.

The EFSA Secretariat will make all presentations given at the Plenary available to Panel members on the EFSA Extranet under the “PPR library” folder.

The next Plenary meeting will be held on **7-8 March 2007** in Parma (starting 14h). Four WG meetings will take place before the plenary meeting and one after.