27th PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Meeting date **3-4 July 2007**
Time **14h-18h (3 July) / 9h-13h (4 July)**
Venue **EFSA, DUS building D Room 0/002**
Largo Palli Natale 5/A, 43100 Parma, Italy

Draft agenda

#	Items
1.	Adoption of the agenda, apologies for absence, annual renewal of declaration of interests
2.	Adoption of the opinion on the FOCUS air report
3.	Presentation of the draft opinion on the new request on default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil
4.	Presentation of the revision of the Guidance Document on risk assessment for birds and mammals
5.	Presentation of the opinion on MRL for dieldrin
6.	Discussion on the work plan for updating and developing Guidance Documents
7.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
8.	Presentation on the new questions: • from Commission on tritosulfuron • self-task on buprofezin
9.	Miscellaneous: • Feed-back from the Scientific Committee • Information from Finance Department • How to deal with comments concerning adopted opinions

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BOOBIS (only 4th July), Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON (only 4th July), 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

EFSA

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

PRAPeR: Ms. M. TIRAMANI for item 8, Finances: Ms. M. VARHO for item 9.

Commission

Mr. X. PAVARD (DG SANCO O3)

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

The agenda was adopted without changes. The EFSA Secretariat explained the new forms for the Annual Declarations of Interest (ADoI) prepared by EFSA's Legal Department. It was recommended to Panel members to detail all their interests (belonging to national authorities, international or EU bodies, etc) as exhaustively as possible. The new forms are quite different from the former ones; therefore the PPR Secretariat will forward all concerns, needs for clarification, ideas for improvement etc. to EFSA's Legal Unit.

The new colleague in the PPR Secretariat, Mr. Istvan SEBESTYEN (toxicologist from Hungary) was welcomed by the chairman.

2. ADOPTION OF THE OPINION ON THE FOCUS AIR REPORT

The Rapporteur for the FOCUS Air opinion presented the outcome and the main conclusions of the opinion. The FOCUS air Working Group had met on the 2nd of July to consider and include comments from PPR Panel members. The opinion will be circulated to the PPR Panel to receive final editorial comments before the 12th of July. The opinion was adopted at the meeting and will soon be published on the EFSA web-site.

The chairman thanked the Panel members and the *ad hoc* experts for their contribution to the opinion.

3. PRESENTATION OF THE DRAFT OPINION ON THE NEW REQUEST ON DEFAULT Q10 VALUE USED TO DESCRIBE THE TEMPERATURE EFFECT ON TRANSFORMATION RATES OF PESTICIDES IN SOIL

The Rapporteur of the Q10 Working Group (WG) provided an update on the ongoing opinion. The WG is evaluating the additional references from the open literature search by EFSA, new studies available from the PRAPeR Unit and papers provided by ECPA. The WG will meet again on the 4th and 5th of July in order to discuss the statistical analysis of the data and to develop the opinion further. The opinion is targeted for adoption on 24-25 October 2007.

4. PRESENTATION OF THE REVISION OF THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS

The PPR Panel had 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). Subsequently, the EFSA Secretariat arranged a public consultation on the EFSA website, in summer 2006, and four WG meetings took place between June and November 2006. Core Working Group meetings took place in Cologne (Germany) on 6-7 December 2006, in Amsterdam on 28 February to 1 March 2007, in Parma on 17-18 April, and in Parma on 2-3 July 2007. In addition, eight meetings of four different sub-Working Groups on specific topics took place in 2007. A workshop with Member States and industry on focal species and ecological parameters was held from 8-11 May 2007 in Valencia/Spain.

The rapporteur gave a comprehensive overview of the ongoing work in the Core WG and the work of the different sub WGs “Focal species”, “Residues in food items”, “Modelling” and “Long term Risk Assessment”. The PPR Panel discussed the further timeline for the finalisation of the GD based on two proposals made by the Core WG. Although the Panel recognised the desire of EFSA senior management for rapid completion, they considered that the current timeline leading to adoption of the GD in December was unrealistic. The chairman will give further explanation of this during his presentation of the work of the Panel to the Management Board on 13th December 2007. The Core WG is asking for an extension of the deadline of six weeks, i.e. with submission of an advanced draft to the PPR Panel Plenary meeting in October 2007. A new working plan with precise deadlines will now be elaborated and sent out to the participants in all WGs.

The PPR Panel emphasised that one year for the revision of a complete GD was an extremely challenging timeline. It should be borne in mind that this task previously took 3-4 times longer under the European Commission’s auspices. Also, it should be considered that Commission and Member States have been using the existing GD for several years in spite of the problems they had with it. If these problems could have been solved simply and quickly, they might have chosen to do so. That this did not happen underlines the Panel’s observation that the issues to be solved are in fact scientifically complex and difficult. The Panel wished to produce a GD that was scientifically sound and not to fall back on existing and partly incorrect positions simply because of time constraints. It was emphasised that the workload relating to the revision of a GD should be considered the equivalent of at least 5-6 opinions.

The Panel members agreed to extend the deadline and to submit an advanced draft for discussion to the Plenary meeting in October 2007. A public consultation on the web will then take place by the end of 2007. The adoption by the PPR Panel will probably take place in February 2008.

5. PRESENTATION OF THE OPINION ON MRL FOR DIELDRIN

The PPR Panel had 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 would lead to an exceedance of that ARfD or of the PTDI, taking into account all foodstuffs in which dieldrin can be found, (3) what percentage of consumers are likely to exceed the PTDI, and (4) what are the toxicological consequences of exposure exceeding the ARfD and PTDI?

The rapporteurs presented the current draft opinion, which has two parts, one on the MRL/exposure and the other on the toxicology of dieldrin. A new draft was circulated for comments to all PPR Panel members before the meeting. The part of the question linked to the MRL was then discussed at the Working Group Residues on 2-3 July; the toxicological aspect will be discussed at the Toxicology Working Group following the Plenary meeting.

The rapporteur thanked the PPR Plenary for all comments received. The Plenary then discussed the entire draft opinion. Main discussion items were: (1) the safety factor to be used in the setting of the ARfD for dieldrin and the uncertainties in setting that ARfD, (2) how best to clarify the view of the Panel on the studies used by some Member States in setting an ARfD, (3) how "background levels" of dieldrin should be addressed in the opinion (to be further discussed at the Toxicology Working Group), (4) how to word the final conclusions on acute exposure, (5) which concentration levels should be used for dieldrin in the different commodities for the exposure assessment1, (6) whether calculations with different assumptions should be carried out, (7) how to specify clearly the uncertainties of the exposure assessment due to the lack of an agreed methodology in the case of banned plant protection products, (8) the data used and the general conclusions on question 3, and (9) whether the PTDI needs to be re-evaluated/refined.

The rapporteur will circulate a new draft inviting PPR Panel members to provide final comments. The PPR Panel will probably adopt the opinion at its Plenary on 11-12 December.

6. DISCUSSION ON THE WORK PLAN FOR UPDATING AND DEVELOPING GUIDANCE DOCUMENTS

M. DUNIER-THOMANN presented a proposal for priorities in the Panel's future work programme concerning updating the existing Guidance Documents and developing new ones, based on the list proposed by Member States after consultation in summer 2006 and March 2007. The EFSA Executive Director urged that work start on some of them as soon as possible, and therefore that financial tools be used to outsource parts of the work to alleviate the work load of the Panel. The two financial tools for outsourcing were explained (grant agreement under Art. 36 and procurement) and illustrated by examples. One was the ongoing call for proposals under Article 36 of European Parliament and Council Regulation N° 178/2002 for the "Preliminary work in view to develop the GD for pesticides exposure assessment for workers, operators, bystanders and residents" (the deadline for applicants to submit proposals is 7/9/2007). When using calls for tender under the Article 36 procedure the intention is to facilitate the Panel's work in delivering the preparatory work and collecting available information that will be used by the WG to develop a GD. Several Panel members emphasised that any draft or report submitted by contractors should then be subject to thorough review and revision (if necessary) to ensure that the final guidance document is indeed the product of the Panel. It is also desirable to include public consultations both at the start (to help define the scope of revision) and at then end (to consult on the draft).

[1] As dieldrin is banned in most countries of the world, the residues result from environmental contamination and not from agricultural application. The methodology used for the risk assessment for authorised plant protection products is not suitable and no established methodology is currently available. Monitoring data are too limited to provide a solid basis for the exposure assessment, they can however be used as an indication.

Panel members stated that the supporting information (technical annexes of the call) on a GD required preparatory work by the relevant experts of the Panel together with the secretariat to prioritise the issues that should be tackled by the applicant. The final responsibility for the GD lay within the Panel. Therefore, at least 1-2 meetings were necessary to clearly define the work expected from the consultant. The Panel would wish to spend more scientific effort and time for the revision and/or creation of a scientific GD, a commitment that is clearly not comparable with the time spent on one opinion.

Panel members also stated that any outsourced work would need to be closely followed and steered by a sufficient number of Panel members, to ensure that adoption of the GD by the Panel is possible without major revisions of the outsourced work.

Panel members expressed concern about the proposed timeline. If time is allowed to prepare a specification, time for tendering, time for the contract to be done, time for review and finalisation by the Panel, and at least the public consultation on the draft (the initial consultation could take place outside the timeline), then one year is not sufficient.

A clear prioritisation of the necessary work has to be made. The list of GD to be revised and/or created and the proposed prioritisation by MS should be accepted without a sound justification, similar to the other questions addressed to the Panel. Further, the work has to be clearly restricted to the remit of the Panel. When the Panel adopts a GD, it endorses the whole document. Therefore, the Panel would have to look at all parts of a GD also where for some GD a partial revision might be sufficient from the clients' point of view.

The existing guidance documents contain a lot of risk management components, as risk assessment and risk management are almost inseparably intertwined. Therefore it is necessary that they are developed together with Member States' representatives. It was also recalled that guidance documents are also developed in other fora, such as OECD, WHO, JMPR and others.

The Fate WG had discussed during its meeting the various steps and possible timing for starting to update and develop two guidance documents in the autumn.

The guidance documents for aquatic risk assessment (RA) and for terrestrial RA both have components of ecotoxicology and fate. This means that more than one rapporteur is necessary to cover the whole GD. Since work is already underway to update and elaborate guidance documents in the fate area, and the GD on birds and mammals still requiring a large effort, all available Panel resources are currently committed. Hence, it was agreed that starting the work for a GD on aquatic ecotoxicology would not be feasible in 2007.

The chairman will give feedback in the Scientific Committee (9-10th July) on the views and concerns of the PPR Panel with regard to this work.

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

To support EFSA in carrying out cumulative risk assessments in the future, the PPR Panel has self-tasked an opinion 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 rapporteur presented the current draft, including the discussion at the last Working Group Toxicology on the relevant terminology, work done and methodologies developed by other bodies, the different types of combined actions, and the identification of key steps to define a common mode of action.

An example of a cumulative risk assessment of some selected triazoles – which will be a separate document - is planned to demonstrate how such a cumulative risk assessment might be conducted. Adoption of the opinion is planned for 11-12 December 2007.

8. PRESENTATION ON THE NEW QUESTIONS

- Question from Commission on tritosulfuron

The rapporteur gave a brief but comprehensive overview on a question regarding the toxicological relevance of the soil and ground water metabolite TBSA of tritosulfuron. The results of toxicological studies with TBSA were explained. The first draft of an opinion had been already circulated and would be the basis for discussion during the WG Toxicology on 4-5 July.

The next revision of the draft opinion of tritosulfuron will be discussed during the meeting of the Toxicology Working Group in September 2007. Adoption of the tritosulfuron opinion is planned for the Plenary meeting in February 2008, as this deadline was negotiated and agreed with the Commission.

- Self-task question on buprofezin

Ms. M. TIRAMANI from the PRAPeR unit presented the background to a question on buprofezin. Finland (Rapporteur Member State) had finalised the DAR, and identified a data gap on genotoxicity. The RMS had requested further data from the notifier to clarify the *in vitro* and *in vivo* genotoxicity of buprofezin; and new studies were submitted in September 2006. A PRAPeR toxicology meeting had evaluated the carcinogenicity study and decided to forward a question to the PPR Panel. The Panel members accepted the Terms of Reference. A rapporteur was identified who agreed to prepare a first draft. The adoption of this opinion is envisaged for December 2007.

9. MISCELLANEOUS

- Feed-back from the Scientific Committee

The Chairman reported the progress of various WGs (Animal cloning, welfare of experimental animals, emerging risks, botanical, risk benefit and transparency). Details are available in the minutes of the last Scientific Committee meeting.

- Information from Finance Department

M. VARHO gave an update on recent developments concerning reimbursements for experts and answered questions. The efficiency of the Finance Department was acknowledged by the Panel members.

- How to deal with comments concerning adopted opinions

EFSA had received questions and comments in 2007 from ECPA concerning the following opinions in the area of ecotoxicology:

- acute and chronic risk to aquatic organisms
- aquatic RA for the evaluation of dimoxystrobin
- Annex II & III: ecotoxicological studies

The PPR Panel discussed whether to provide a specific response to every single comment.

The Panel considered it important to have a clear strategy on how to deal in general with requests concerning opinions. The chairman together with the EFSA secretariat will develop a general strategy on how to react on such requests. It will be submitted to the September Plenary meeting. Such a strategy should allow the Panel the freedom to react on a case by case basis, and also the freedom to acknowledge a comment but not to further respond if this is considered appropriate.

Regarding the comments from ECPA on the opinion on "Annex II and III: ecotoxicological studies", the Panel felt that further work on data requirements lies now within the responsibility of the EU Commission and the Member States

In this context it was mentioned that it is a common criticism that EFSA opinions are not peer reviewed. It was pointed out that the number of experts involved in agreeing an opinion constituted a form of peer review as does discussion at meetings of Member States. The possibility of internal and external peer review of documents and opinions is now being considered within EFSA.

The next **PPR Plenary meeting** will be on **11-12 September 2007, starting at 14h.**

N.B.: **The Plenary meeting on 24-25th October was confirmed.**