MINUTES OF THE 28th PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Held in Parma on 11-12 September 2007 (adopted by written procedure on 28 September 2007)

#	Agenda
1.	Adoption of the agenda, apologies for absence, declaration of interest
2.	Adoption of the opinion on MRL for dieldrin
3.	Presentation of the draft opinion on the new request on the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil
4.	State of revision of the Guidance Document on risk assessment for birds and mammals
5.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
6.	Presentation of the draft opinion on tritosulfuron
7.	Presentation of the draft opinion on buprofezin
8.	Follow up on the work plan for updating and developing Guidance Documents, new question expected
9.	Miscellaneous: • Feed-back from the Scientific Committee • Strategy on how to reply to comments on opinions

PARTICIPANTS

Members of the PPR Panel

Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BOOBIS (Vice chairman), Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HART, Mr. H. KÖPP, Mr. R. LUTTIK, Mr. O. MEYER, Ms. S. MICHAELIDOU-CANNA, Mr. M. MONTFORTS, Mr. A. MORETTO (only 12th September), Mr. M. MÜLLER, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms. C. VLEMINCKX.

Apologies

Mr. D. BARCELLO-CUILLERES, Mr. A. HARDY, Mr. M. LIESS, Ms. B. OSSENDORP and Mr. X. PAVARD (DG SANCO O3).

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 5 to 7.

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

The agenda was adopted without changes, four apologies were received, including from the chairman, the meeting was chaired by the vice chairman A. BOOBIS. No new declaration of interest was done.

2. ADOPTION 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 exposures exceeding the ARfD and PTDI?

A new draft had been circulated for comments to all PPR Panel members before the meeting. Based on the comments received, a final draft had been prepared during the meeting of the Working Group before the meeting of the PPR Panel. The rapporteur and the co-rapporteur presented this current draft opinion, which had two parts, one on the MRL/exposure and the other on the toxicology of dieldrin.

The PPR Panel then discussed the final draft. Some editorial changes as well as rearrangements and deletions in the summary, the main body of the text, and some figures and figure captions were agreed with a view to improving clarity and ensuring consistent terminology (*i.a*. PTDI *versus* TDI, zucchini and courgette being synonyms, food of animal origin/fish) and the understandability of the opinion. Issues of particular relevance in the discussion were (1) how to present the ratio between dieldrin and photodieldrin, the safety factor used in the toxicological assessment and the possible role of photodieldrin, (2) the variability factor used in the IESTI equation, as dieldrin is no longer used as a pesticide but is rather an environmental contaminant, (3) the acute toxicity of “free” dieldrin to the CNS, (4) the distinction between the exposure of a consumer group and the potential exposures of individuals within that group, and how to best explain this in the context of this opinion, (5) the limitations of the available data on food consumption for some Member States and consumer groups, (6) the use of data received from France (formally notified French database on infants and toddlers and new French consumption data for children), (7) the list of uncertainties affecting the opinion, in particular the uncertainties in deriving an ARfD due to limitations of the data, (8) the issue of how to deal with residues below the LOQ (limit of quantification), and the need to better consider the requirements of risk assessment when setting those limits, and (9) the relevance of hepatic tumors in mice to human risk in the context of this opinion. The PPR Panel also expressed the view that the opinion is likely to overestimate the risk rather than underestimate it.

The PPR Panel adopted the opinion, acknowledged the work of the rapporteur, the co-rapporteur and the Working Group, including the ad-hoc experts, and emphasized the complexity of the question, as the terms of reference extended to all foodstuffs where dieldrin can be found, while data are very limited. The last version will be circulated for a final editorial check before publication.

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

The Rapporteur provided an update of the ongoing opinion. The Working Group, which met on 10-11th September, is evaluating the additional references from the open literature search by EFSA, new studies available from the PRAPeR Unit and papers provided by ECPA using

the established selection criteria. A database has been developed containing about 100 studies on about 50 compounds. The Working Group will meet again on the 23-24 October to evaluate the data and develop the opinion further. The opinion is now targeted for adoption in December.

4. State of 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. Five Core Working Group meetings took place between December 2006 and September 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 state of the revision of the GD. The WG has elaborated a table with about 20 different crop scenarios and a considerable number of bird and mammal species that occur in crops in Europe to carry out tier-2 risk assessments (RA). The tier-2-RA takes various parameters into account, e.g. the food intake rate (FIR), body weight, single or mixed diets etc. From this tier-2-table a simpler table has been derived to carry out the RA for the first tier. If a substance leads to a TER of <10 and hence fails in tier 1, calculations for all species in tier 2 have to be carried out (for the relevant scenarios) taking into account LD_{50}, application rate and the number of applications. If a substance also fails tier 2, the notifier will be asked to submit additional information, e.g. on the time a species spends in the treated field or providing results of population modelling.

A table with residue unit doses (RUD) for different food items that are needed for calculating the exposure in the first and second tier has been elaborated as well. The RA for acute scenarios is always based on the LD_{50}. For long term scenarios the Core WG proposes a phase specific approach and has elaborated a table with a list of endpoints from current avian toxicity tests used to represent pesticide effects of concern to reproduction potential during different phases of the reproductive cycle and the comparable exposure measures for use in calculating Toxicity Exposure Ratios.

The Core WG also presented first tier assessment methods. The current approach is to calculate the toxicity/exposure ratio (TER) and use this for acute and long term RA for birds and mammals. This approach is based on a theoretical estimate of a dietary intake; however, it ignores all other possible (non-dietary) routes of exposure. To overcome these shortcomings of the current approach the Core WG is considering three different options to develop a new approach for acute risks to birds. These options include (i) the use of field studies to derive an empirical model using the best predictors of bird mortality in the field, (ii) the use of field studies to “calibrate” the existing dietary exposure model, and (iii) the use of dietary exposure models without calibration. By the end of 2007 stakeholders will also be consulted on one or more of these options in a web consultation.

The Core Working Group will submit an advanced draft for discussion to the Plenary meeting on 24-25th October. The adoption of the revised GD by the PPR Panel is now foreseen for spring 2008.

5. 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 of the toxicology part briefly informed the plenary about the status of the part on the toxicological aspects, including the discussion at the last Working Group Toxicology on the selection of triazoles as an illustrative case study, and in particular the difficulties of identifying which compounds should belong in a common mode of action group.

The Working Group Residues will start to work on the exposure part at the October meeting. Three ad-hoc experts have been contacted and agreed to participate in preparing that part of the opinion. The EFSA secretariat informed the plenary that a call for tender (negotiated procedure) to carry out an exposure assessment for triazoles as an example has been launched. This will be a new self-tasked opinion separate from the first one.

6. PRESENTATION OF THE DRAFT OPINION ON TRITOSULFURON

The rapporteur gave a brief overview on a question from the Commission, regarding the toxicological relevance of the soil and ground water metabolite TBSA of tritosulfuron. The revised version of the draft opinion had already been circulated and would be the basis for discussion during the WG Toxicology to be held on 12-13 September.

The next revision of the draft opinion on tritosulfuron will be discussed during the meeting of the Toxicology Working Group in November 2007 (in Brussels). The adoption of the tritosulfuron opinion should be possible in principle at the Plenary meeting in December 2007, thus before the negotiated deadline.

7. PRESENTATION OF THE DRAFT OPINION ON BUPROFEZIN.

The rapporteur gave a brief overview on a self-tasked question regarding the genotoxic and carcinogenic potential of buprofezin in the context of the human risk assessment. The first draft version of the opinion had been circulated. The first thorough discussion on the draft opinion on buprofezin will take place during the WG Toxicology on 12-13th September. The adoption of this opinion is envisaged for December 2007.

8. FOLLOW UP ON THE WORK PLAN FOR UPDATING AND DEVELOPING GUIDANCE DOCUMENTS, NEW QUESTION EXPECTED

M. DUNIER-THOMANN gave a short feedback on her presentation to the Member States at the DG SANCO's Standing Committee on the Food Chain and Animal Health-Section: Plant Protection Products on 12-13 July 2007, regarding the priorities for developing and updating existing EU Guidance Documents in risk assessment by the PPR Panel. Only two MS had questions.

The state of the art for new developments in autumn is the following:

- The deadline for submitting 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" is now over, thus the selection procedure will start very soon.

- A Panel member presented the various steps planned for updating the GD on persistence in soil (SANCO 9188/VI/97 of 12 July 2000), and this will be discussed in more detail by the Fate WG on 12-13th September.

- The start of the updating of the guidance document on terrestrial risk assessment should be delayed due to the postponement of the finalisation of the GD on birds and mammals, which requires a large effort from the ecotoxicologists of the Panel and the ad hoc experts involved, as well as the EFSA secretariat.

9. MISCELLANEOUS

- Feed-back from the Scientific Committee

The chairman reported briefly the progress of on the activities in the various WGs of the Scientific Committee in which PPR-Panel members are involved. For the Working Group on use of the Benchmark Dose Approach in Risk Assessment a paper has been produced and submitted to the Scientific Committee for comments. The work of the Risk-Benefit Assessment of Foods and the Animal Welfare Working Groups is ongoing. For the Animal Welfare Working Group an inventory is being prepared to provide an overview of where animal studies are used.

For the WG on emerging risks, a paper concerning Strategies for building EFSA's capability for identifying and evaluating Emerging Risks available for comments (the Annex V was circulated again for comments). The next Scientific Committee meeting will take place on 17-18 September.

- Strategy on how to reply to comments on opinions

A procedure was presented for dealing with enquiries or comments on published opinions from the PPR-Panel prepared by T. HARDY.

- Forum 5th EFSA Anniversary "From safe food to healthy diets" on 20-21 November 2007 in Brussels.

Three Panel members will attend the Forum - two will be speakers- about 400 participants are expected.

The next **PPR Plenary meeting** will be on **24-25 October 2007**, starting at 14h**.**

N.B.: The PPR Plenary meeting 11-12 December 2007 will be extended to **1 ½ days** as 3 adoptions are foreseen, starting at 14h on 11 and finishing at 18h on 12 December.