



**EUROPEAN COMMISSION**

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

**C2 - Management of scientific committees ; scientific co-operation and networks**

**SCIENTIFIC COMMITTEE ON PLANTS**

**SCP/REPT/035 –17 December 2002**

**MINUTES OF THE 35<sup>th</sup> MEETING  
OF THE SCIENTIFIC COMMITTEE ON PLANTS  
BRUSSELS, 23 October 2002**

## **ATTENDANCE LIST**

### **Members**

Prof. H. V. DAVIES  
Dr. M.-P. DELCOUR-FIRQUET  
Prof. A. R. HARDY (Chairman)  
Prof. S. O. KARENLAMPI  
Mr. H. KOEPP  
Dr. H. A. KUIPER  
Prof. A. LESZKOWICZ  
Prof. M. MARONI (Vice-Chairman)  
Dr. O. MEYER  
Dr. A. MORETTO  
Prof. F. O' GARA (Vice-Chairman)  
Prof. E. PAPADOPOULOU-MOURKIDOU  
Prof. E. PETZINGER  
Prof. K. SAVOLAINEN  
Prof. J. SCHIEMANN  
Prof. A. M. S. SILVA FERNANDES  
Dr. G. SPEIJERS

### **Apologies**

None

### **Invited Experts**

None

### **Commission**

Ms. M. Dunier-Thomann DG Environment  
Mr. W. Maier DG Health and Consumer Protection, E1

### **Secretariat**

Mr. H. Bruno DG Health and Consumer Protection, C2  
Ms. S. Renckens DG Health and Consumer Protection, C2  
Mr. M. Walsh DG Health and Consumer Protection, C2

## **1. Welcome and apologies**

The Chairman, Prof. Hardy opened the meeting and welcomed the members. Mr. Walsh introduced new colleagues who have either recently joined or will shortly join the secretariat of the Scientific Committee on Plants. Suzy Renckens joined on 1 October and will be working on GMO issues. Muriel Dunier-Thoman (1 November) and Henning Bruno (1 September) will be working for the SCP secretariat.

## **2. Adoption of the agenda**

After amending the agenda regarding the progress report on the Guidance Document on relevant metabolites (point 6.4) the agenda was adopted.  
(Doc. SCP/AGENDA/035-final)

## **3. Declaration of interests by Members**

None.

## **4. Adoption of the minutes**

### **4.1 Adoption of the minutes of the 34<sup>th</sup> Plenary Meeting (18 July 2002)**

After minor editorial changes, the draft minutes were approved and are available as Document SCP/REPT/034-Final at:

[http://europa.eu.int/comm/food/fs/sc/scp/out135\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out135_en.pdf)

### **4.2 Matters arising**

None

## **5. Adoption of opinions**

### **5.1 Draft opinion on fenthion**

Following a detailed exchange of views on the tabled document (SCP/FENTHION-BIS/002 Rev 8-1 of 20 October 2002) the Committee postponed the adoption of the opinion.

The Commission requested the Committee to comment on two issues. The first question concerns the relevance of any new data and arguments related to the risk assessment for birds provided by the rapporteur Member State with respect to the intended bait use in citrus and olives. Mr Koepp introduced the new data, explained the rationale and the conclusions of the evaluation provided in the tabled document.

Following an exchange of views it was agreed that the opinion should be amended to reflect the points raised.

The second question requested the Committee to reconsider its previous assessment in the light of new toxicological data which have been provided. After consideration of these data, the Committee concluded that the new mutagenicity data do not change the previous opinion, i.e. the mutagenic properties of fenthion are not of concern. Also, the new data on delayed neurotoxicity do not indicate any potential risk. The opinion will be amended to take into account the new data.

After a further discussion in the Working Group 'Environment' the opinion on fenthion will be tabled for adoption in the Plenary meeting on 17 December.

## **5.2 Draft guidance document on the setting of Acceptable Operator Exposure Levels (AOEL).**

The Commission requested the Committee to comment on the draft Guidance document which had been prepared in collaboration with experts of Member States. It is intended to use the document to facilitate decision-making on the inclusion of active substances in Annex 1 to Council Directive 91/414/EEC.

With reference to the new versions of the draft opinion tabled for the meeting (SCP/GUIDE-AOEL/002 Rev 4 of 23 October 2002) Prof. Maroni introduced the opinion. After a short exchange of views, especially on the biological threshold and the issue of use of human data the Committee adopted the opinion.

The main conclusions of the Committee included:

- The Committee recommends a reconsideration of the concept of bystander, its appropriate exposure scenarios and the adequacy of applying the AOEL to this subpopulation.
- The Committee agrees with the approach taken on the assessment factors.
- Agreeing that human data are most useful because they provide reassurance on the extrapolation process, the Committee stresses that human data should be used in the context of the entire toxicological profile of the PPP under consideration.
- The Committee is of the opinion that biological thresholds always exist, even if they are sometimes not detectable.
- The Committee recommends the concept of margin of safety to be explained in more detail.
- As the AOEL is meant to cover a one day exposure, the Committee does not see the need for an acute AOEL since high, peak-like exposures are to be considered as accidental conditions which are not covered by operator exposure modelling under Good Agricultural practice.

The opinion is available as SCP/GUIDE-AOEL/002- Final:

[http://europa.eu.int/comm/food/fs/sc/scp/out136\\_ppp\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out136_ppp_en.pdf)

## **6. Progress Report on dossiers referred to the Scientific Committee on Plants**

### **6.1 Guidance paper for the assessment of active substances in rice**

The Chairman informed the Committee that a draft document is available from the rapporteur Mr. Koepf, which will be discussed at the next meeting of the Working Group 'Environment' on 8 November.

### **6.2 Atrazine/Simazine**

The questions addressed to the Committee concern the potential of residues to leach into groundwater and have accordingly been referred to the Working Group 'Environment'. The Chairman informed the Committee on the ongoing discussions in the scientific journals concerning possible endocrine disruption effects on amphibians caused by low levels of exposure to atrazine. The opinion is scheduled for adoption at the January Plenary Meeting.

### **6.3 Focus surface water scenario**

The Chairman informed the Committee that Andrée Carter has been appointed Rapporteur with a view to a possible adoption of the opinion at the Plenary meeting in December.

### **6.4 Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion**

Prof. Maroni informed the Committee that due to time constraints no discussion has taken place during the last meeting of the Working Group 'Toxicology' but that a 2-day meeting (28/29 November) would take place. It is intended to seek adoption of the opinion in the Plenary meeting in December.

## **7. New PPP related dossiers to be referred to the SCP**

### **7.1 Isoxaflutole**

Isoxaflutole is a new active substance in the context of Directive 91/414/EEC. The evaluation report has been prepared by the Netherlands as rapporteur Member State and the substance has been peer review with Member State experts and discussed with the 15 Member States in the Working Group 'Plant Protection Products (evaluation) of the Standing Committee of the Food Chain and Animal Health. The Scientific Committee on

Plants already issued an opinion on 18 May 1999<sup>1</sup> on environmental and toxicological issues.

The Committee is now being consulted regarding the potential of groundwater contamination of the metabolite RPA 203328 exceeding the limit of 0.1 µg/L with the following questions:

- (1) Given the variability in the DT50/DT90 from field and laboratory, can the Scientific Committee on Plants comment on the appropriate DT50/DT90 to be used in the FOCUS model scenarios?
- (2) Would the newly submitted data on metabolite RPA 203328 cause the Scientific Committee on Plants to change its conclusion expressed in its opinion 1999 with respect to the environmental and toxicological safety of that metabolite, also in the light of the last draft (rev 7b) of the relevant metabolite guidance document ?

The Committee referred question 1 to the WG Environment and question 2 to the WG Toxicology to prepare a draft opinion.

## **8. GMO dossiers**

### **8.1 Draft guidance document – progress report**

Prof. Hardy informed the Committee on the progress on the ‘Preliminary guidance document on the information needed for the risk assessment of genetically modified plants and derived food and feed’ drafted by the Joint SCF/SCP/SCAN working group. Comments received from interested parties will be considered during two working group meetings: Prof. Davies has agreed to act as Rapporteur for the molecular and environmental aspects and Dr. Kuiper as Rapporteur for the toxicological and nutritional issues. The opinion will be adopted by Scientific Steering Committee since the guidance document concerns issues relating to the work of several Scientific Committees.

## **9. Other Business**

- 9.1** Prof. Schiemann and Prof. O’Gara reported on their participation in the 7<sup>th</sup> International Symposium on genetically modified organisms in Beijing, China. A summary report will be made available to the SCP members.

## **10. Future Meetings of the Plenary**

30 January 2003

20 March 2003

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<sup>1</sup> [http://europa.eu.int/comm/food/fs/sc/scp/out40\\_en.html](http://europa.eu.int/comm/food/fs/sc/scp/out40_en.html)

7 May 2003

Prof. Maroni informed on the future Meetings of the Working Group 'Toxicology' which will be held on:

15 January 2003 (tentative if needed)

29 January 2003

13 February 2003 (tentative if needed)

19 March 2003

1 April 2003 (tentative if needed)

6 May 2003