



**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/028-Final  
27 September 2001**

**MINUTES OF THE TWENTY EIGHTH MEETING  
OF THE SCIENTIFIC COMMITTEE ON PLANTS  
BRUSSELS, 20 July 2001**

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## **ATTENDANCE LIST**

### **Members**

Prof. A. R. HARDY (Chairman)  
Mr. H. KOEPP  
Dr. H. A. KUIPER  
Prof. A. LESZKOWICZ  
Prof. M. MARONI  
Dr. O. MEYER  
Dr. A. MORETTO  
Prof. E. PAPADOPOULOU  
Prof. E. PETZINGER  
Dr. T. SHERRATT  
Prof. A. M. S. SILVA FERNANDES  
Dr. G. SPEIJERS

### **Apologies**

Prof. H. V. DAVIES  
Dr. M-P. DELCOUR-FIRQUET  
Prof. S. O. KARENLAMPI  
Prof. F. O' GARA (Vice-Chairman)  
Prof. K. SAVOLAINEN  
Prof. J. SCHIEMANN

### **Invited Experts**

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### **Commission**

Ms. M. DUNIER-THOMANN Environment  
Mr. W. MAIER Health and Consumer Protection

### **Secretariat**

Mr. M. WALSH Health and Consumer Protection, C2  
Mr. J. FERRIERE Health and Consumer Protection, C2

**1. Welcome and apologies**

The Chairman, Prof. Hardy opened the meeting and welcomed the members.

**2. Adoption of the agenda**

The agenda was adopted.  
(Doc. SCP/AGENDA/028)

**3. Declaration of interests by Members**

No declaration was made.

**4. Adoption of the minutes of the Twenty Seventh Plenary Meeting (7 June 2001) and matters arising**

**4.1 Adoption of the minutes of the Twenty Seventh Plenary Meeting**

The draft minutes were approved and are available as Document SCP/REPT/027 at:  
[http://europa.eu.int/comm/food/fs/sc/scp/out107\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out107_en.pdf)

**4.2 Matters arising**

None

**5. Progress report on the following plant protection product dossiers referred to the Scientific Committee on Plants**

**5.1 Famoxadone**

Following an exchange of view, the Committee adopted the opinion subject to some minor textual changes.

Famoxadone was referred to the Committee with the following questions:

- 1) The Committee is requested to comment whether the long-term risk to Daphnia, in particular in relation to metabolites, has been sufficiently addressed.
- 2) Can the Committee confirm that the risk from the metabolites IN-KZ007 and IN-JS940, to earthworms, has been sufficiently addressed?
- 3) Can the Committee comment on the relevance of the eye effects observed in the 12 month dog study to human? Should mechanistic study on eyes be required?
- 3) Can the Committee confirm that the operator exposure has been sufficiently addressed?

With respect to question 1, the Committee concludes that the long-term risk to Daphnia of famoxadone and its metabolites has been sufficiently addressed. The Committee notes that famoxadone is acutely toxic to fish and Daphnia and therefore substantial risk mitigation measures would be necessary to prevent unacceptable acute effects of famoxadone from occurring in aquatic organisms.

As for the risk of metabolites IN-KZ007 and IN-JS940 to earthworms, the Committee considers that these metabolites are unlikely to present an acute risk to earthworms. However the Committee has been unable to evaluate the likely chronic risks of famoxadone or its metabolites to earthworms since no long-term sub-lethal test was performed. The Committee notes that famoxadone can be applied up to 12 times per season and therefore according to the Guidance Document on Terrestrial Ecotoxicology of the European Commission (document 2021/VI/98-rev7, 08 July 2000, [http://europa.eu.int/comm/food/fs/ph\\_ps/pro/wrkdoc/wrkdoc09\\_en.pdf](http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkdoc/wrkdoc09_en.pdf)), a sub-lethal test should be provided.

Questions 3 and 4 dealt with toxicological issues. With respect to question 3, the Committee is of the opinion that the eye effect of famoxadone in dogs is to be considered relevant for humans. A more complete understanding of the mechanism of action of famoxadone on the eyes in the various species would be needed to revise this opinion. Consequently, in its response to question 4, the Committee concludes that the risk to operator has not been adequately assessed and needs to be reassessed using the AOEL (Acceptable Operator Exposure Level) derived from the NOAEL (No Observed Adverse Effect Level) based on cataracts induction in dogs.

The opinion is available as document SCP/FAMOX/002-Final at:  
[http://europa.eu.int/comm/food/fs/sc/scp/out110\\_ppp\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out110_ppp_en.pdf)

## **5.2 Florasulam**

Mr. Koepp updated the Committee with the progress of the ENV WG on question 1 related to metabolites. The evaluation is currently ongoing and is expected to be finalised at the next meeting of the working group on environmental assessment in September.

Prof. Maroni, chairman of the TOX WG confirmed that the evaluation of question 2 has been finalised while the evaluation of question 1 dealing with the toxicological relevance of some metabolites has been almost completed.

## **5.3 Propineb**

Mr. Koepp informed the Committee on the progress made by the ENV WG with respect to question 1 related to risk of propineb to birds. The assessment of the WG is expected to be completed at the next ENV WG of 12 September. Prof. Hardy mentioned that the opinion on question 1 might become a reference on the approach to be used for the assessment of risk to birds.

As for question 2, Prof. Maroni informed the Committee that a draft evaluation was submitted by the rapporteur Dr. McGregor and discussed at the working group on toxicology on 19 July. Following this discussion, it was felt necessary to go back to the original report of a number of studies. Further discussions will take place at the next working group on toxicology scheduled on 26 September.

## **5.4 Flufenacet**

Question 1 on flufenacet deals with the assessment of the relevance of two metabolites. Mr. Koepp updated the Committee on the progress of the work of the ENV WG. He

stressed that flufenacet degrades in a number of metabolites, which makes the overall assessment quite complex. The toxicological relevance of the two metabolites, with regard to groundwater contamination, is considered by the TOX WG.

Prof. Maroni informed the Committee that the evaluation of question 2 related to the assessment of the risk to operators was completed at the working group on toxicology of 19 July.

## **5.5 Fosthiazate**

Mr Koepp informed the Committee that the evaluation of the metabolite issues in relation with groundwater contamination is almost completed. Dr. Sherratt, rapporteur for question 2, outlined the issues discussed and informed the Committee that the evaluation is almost finalised as well.

Question 3 deals with the possible risk to birds and mammals of granular formulate of fosthiazate. Mr. Koepp outlined the progress of the ENV WG on that question. Further discussions will take place at the next meeting of the working group on environmental assessment.

Dr. Moretto, rapporteur for question 4, confirmed Prof. Maroni statement at the previous meeting that the evaluation is now completed.

## **5.6 Iprovalicarb**

Prof. Maroni updated the Committee on the state of play with respect to the question put to the Committee following the publication of the opinion on iprovalicarb adopted in March 2001. Further discussions are tabled at the next meeting of the working group on toxicology in September.

## **5.7 Iprodione**

Mr. Koepp informed the Committee that the ENV WG has recently completed the evaluation of question 1 related to predicted environmental concentrations of iprodione in soil and water.

Prof. Maroni outlined the main issues under discussion at the TOX WG. He explained that the question is quite broad and relates to the setting of the AOEL (Acceptable Operator Exposure Level). He reiterates that unfocused questions are both difficult to address and time consuming and that in future the Committee would appreciate if the Commission would make clear the scientific issue to be addressed.

Dr. Maier, from DG Health and Consumer Protection, explained that in this case, the Commission services are looking for advice on which end points to be used for derivation of the AOEL. More specifically, the issue is whether an AOEL can be derived from a carcinogenicity end-point.

Prof. Hardy stated that as a general rule, it would be extremely useful if the Commission services could provide a written background to the questions put to the Committee.

## **5.8 *Pseudomonas chlororaphis***

Prof. Maroni informed the Committee that a special meeting was held on 27 June to discuss this active substance. He outlined the complexity of the questions to be addressed by the Committee, which dealt with a micro-organism producing chemical substances. Further to the June meeting, Dr. Moretto was appointed overall rapporteur to produce a draft opinion highlighting the issues which need further discussion. The intention is to circulate the document in advance of the next meeting of the working group on micro-pesticides scheduled on 9 October.

## **5.9 Paraquat**

Prof. Maroni informed the Committee that rapporteurs have been appointed (see minutes of the 27<sup>th</sup> plenary meeting, [http://europa.eu.int/comm/food/fs/sc/scp/out107\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out107_en.pdf)) and that the first discussion is scheduled at the next TOX WG on 26 September.

Dr. Sherratt outlined the issues under discussion related to question 3 dealing with potential long-term effects to soil dwelling organisms.

With respect to question 4 relating to the risk that paraquat use might pose to reproducing birds and hares, Mr. Koepf updated the Committee on the on-going discussion in the ENV WG.

## **6. Request for opinion on the following plant protection products referred to the SCP**

The secretariat of the Committee introduced a new dossier concerning the evaluation of an active substance.

### **6.1 Fenarimol**

This dossier was referred to the Committee with the following question:  
“Can the Committee comment on the approach taken to calculate Predicted Environmental Concentration (PEC) in soil?”

Dr. Maier provided a short background on the origin of the question to the Committee.

Prof. Hardy, chairman of the ENV WG, informed the Committee that Dr. Boesten has been appointed rapporteur to deal with that question.

## **7. Progress report and exchange of views on GM plant dossiers referred to the SCP**

### **7.1 Starch potato from Amylogene (Notification C/SE/96/3501)**

Prof. Hardy informed the Committee that the notifier has submitted new data. The new data will be evaluated by the experts in molecular biology of the joint SCF/SCP/SCAN WG at the next working meeting on 28 September

## **7.2 Guidance document on the evaluation of GM plants, novel food and novel feed.**

The secretariat updated the Committee on the progress of the joint working group on this item. He informed the Committee of the intention to organise a special meeting in October with the rapporteurs of each sub-group and edit a draft text that would then be published on the internet for comments from stakeholders. The document will be subsequently revised in the light of the comments and finalised.

## **7.3 Revision of opinion SCP/GMO/289-Final on the invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize line T25 notified by AgrEvo France and of opinion SCP/GMO/006-Final regarding the submission for placing on the market of glufosinate tolerant corn (*Zea mays*) transformation event T25 by AgrEvo (notification C/F/95/12/07)**

Following some comments sent to the secretariat of the Committee, it appeared that in the two opinions SCP/GMO/289-Final on the invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize line T25 notified by AgrEvo France<sup>1</sup> and opinion SCP/GMO/006-Final regarding the submission for placing on the market of glufosinate tolerant corn (*Zea mays*) transformation event T25 by AgrEvo (notification C/F/95/12/07)<sup>2</sup>, some wording was ambiguous. The Committee decided to revise the two documents in order to clarify the text.

The revised texts (documents SCP/GMO/299-final and SCP/GMO/300-final) are adopted by the Committee and will be published on the internet indicating that they will replace the two previous versions, which will be later on remove from the SCP web site. The Committee made clear that the conclusions of the risk assessment remain unchanged.

The documents are available as documents SCP/GMO/299-Final and SCP/GMO/300-Final respectively at the following URLs:

[http://europa.eu.int/comm/food/fs/sc/scp/out108\\_gmo\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out108_gmo_en.pdf) and  
[http://europa.eu.int/comm/food/fs/sc/scp/out109\\_gmo\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out109_gmo_en.pdf)

## **8. Dates of Plenary meetings for the first half of year 2002**

The Committee set the dates for its plenary meetings during the first half of 2002 as follow: 31 January, 14 March, 24 April, 13 June and 18 July.

## **9. Exchange of views on the progress report of the Task Force on harmonisation of risk assessment**

The Committee had a brief exchange of views on the reports of the meetings of the steering committee task force on risk assessment harmonisation. Prof. Hardy suggested that all Committee members reflect on the two reports (documents SC/HRATF/001 and 002) for an in-depth discussion at the September plenary meeting.

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<sup>1</sup> [http://europa.eu.int/comm/food/fs/sc/scp/out85\\_gmo\\_en.html](http://europa.eu.int/comm/food/fs/sc/scp/out85_gmo_en.html)

<sup>2</sup> [http://europa.eu.int/comm/food/fs/sc/scp/out04\\_en.html](http://europa.eu.int/comm/food/fs/sc/scp/out04_en.html)

## **10. Other business**

- 10.1** Prof. Hardy informed the Committee that he recently gave different speeches presenting the Scientific Committee on Plants, its remit and activities, the most recent one being at a conference in Brussels organised by the European Crop Protection Association.

He reminded that the SCP has existed for four years and suggested that the Committee should take stock of the work carried out during the period, review its activities with the aim to identifying its key achievements and possible horizontal emerging issues or areas where specific research is needed. In addition, Prof. Hardy stressed that in the view of the creation of the European Food Authority, foreseen in 2002, the role of the Committee is likely to change. Therefore, he suggested the Committee reflects and looks at its future.

Prof. Hardy suggested the Committee held a special meeting to focus on the main issues the SCP has dealt with during the last four years and on those the Committee will need to look at in the future. The meeting is scheduled on 25 and 26 October.

- 10.2** On June 7 at the previous plenary meeting, the Committee recognised that there were clear difficulties to carry out a risk assessment of metabolites of PPP from the toxicological and ecotoxicological points of view. Prof. Hardy informed the Committee that he raised this issue at the most recent Scientific Steering Committee meeting (SSC). He suggested to the SSC that it organise a workshop where the issue of the assessment of metabolites could be extensively discussed between scientists, regulators and other stakeholders. The Chairman of the Scientific Committee on Toxicity, Ecotoxicity and Environment supported this idea. Thus, it is proposed that some members of the SCP work out of a framework proposal to be sent to the Commission for financing such a workshop.
- 10.3** Dr. Kuiper informed the Committee that the Commission (DG Research) will organise a workshop in Brussels on 9 October to re-launch the process of GMO approval in the Community and that he will attend that meeting.

**Date of the next meeting:** 27 September 2001