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/029
8 November 2001

MINUTES OF THE TWENTY NINTH MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 27 September 2001

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ATTENDANCE LIST

Members

Prof.	H. V. DAVIES	
Dr.	M-P. DELCOUR-FIRQUET	
Prof.	A. R. HARDY	(Chairman)
Prof.	S. O. KARENLAMPI	
Mr.	H. KOEPP	
Prof.	A. LESZKOWICZ	
Prof.	M. MARONI	
Dr.	O. MEYER	
Prof.	E. PAPADOPOULOU	
Prof.	K. SAVOLAINEN	
Prof.	J. SCHIEMANN	
Dr.	T. SHERRATT	
Prof.	A. M. S. SILVA FERNANDES	
Dr.	G. SPEIJERS	

Apologies

Dr.	H. A. KUIPER	
Dr.	A. MORETTO	
Prof.	F. O' GARA	(Vice-Chairman)
Prof.	E. PETZINGER	

Invited Experts

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Commission

Dr.	M. DUNIER-THOMANN	Environment
Dr.	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/029)

3. Declaration of interests by Members

No declaration was made.

4. Adoption of the minutes of the Twenty eighth Plenary Meeting (27 September) and matters arising

4.1 Adoption of the minutes of the Twenty eighth Meeting

The draft minutes were approved and are available as Document SCP/REPT/028 at:
http://europa.eu.int/comm/food/fs/sc/scp/out111_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 Florasulam

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

Two questions where referred to the SCP. In the first one, the Committee was requested to comment on the relevance of two environmental metabolites (ASTCA and DFP-ASTCA). The Committee concluded that neither of the metabolites appears to cause a concern with respect to human exposure via drinking water derived from groundwater and to soil and aquatic organisms. However, the Committee noted that in some agricultural scenarios the groundwater concentration of the metabolites may be higher than that used by the Committee in the assessment (based on PELMO modelling). As regard ecotoxicity assessment, the Committee based its appraisal on a statement from the notifier which reports data showing no toxicity to soil and aquatic organisms. These data were not assessed neither by the Rapporteur Member State (RMS) nor the SCP. The Committee recommends these data be assessed by the RMS.

In question 2, the Committee was asked whether it is correct to establish an acute reference dose (ARfD) based on neurotoxicity. The Committee expressed the opinion that in the case of florasulam the allocation of an ARfD is not needed because no unequivocal neurotoxic end-point was identified.

The opinion is available as document SCP/FLORAS/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out113_ppp_en.pdf

5.2 Flufenacet

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

The Committee was requested to respond to two questions. In the first one, the Committee was asked whether it was satisfied that the relevance of two metabolites (M2 and M4) has been sufficiently addressed. The Committee understood the question as related to potential residues in soil and water including groundwater since the two metabolites were those positively identified in all lysimeter studies. As regard terrestrial and aquatic exotoxicology, the Committee considers that insufficient information is available to confirm that the relevance of M2 and M4 has been fully addressed. However, the Committee carried out its own risk assessment which indicates that the risks to non-target aquatic organisms is likely to be acceptable for M2 and M4. The Committee noted that there are seven other environmental metabolites for which the risk to non-target organisms has not been addressed and that the ecotoxicity data for the M9 metabolite indicates that there may be a chronic risk to aquatic organism but this has not been considered.

As regard human exposure via drinking water, the Committee concluded that no unacceptable risks are expected.

During the exchange of view, Prof. Silva Fernandes highlighted that although no health risk are expected from exposure of human via drinking water, groundwater contamination by M2 may in certain circumstances be unusually high (up to 30 µg/L).

Question 2 dealt with the assessment of operator exposure. The Committee expressed the opinion that that operator risk assessment has been adequately addressed. The Committee noted that the formulation has a sensitising potential which should receive proper attention.

The opinion is available as document SCP/FLUFEN/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out112_ppp_en.pdf

5.3 Fosthiazate

Mr. Koepp updated the Committee with respect to questions 1 and 2 the evaluation of which is completed. Question 3 relates to risk for birds and mammals resulting from exposure to granules of fosthiazate and is still under consideration by the ENV WG.

5.4 Iprovalicarb (bis)

Dr. Meyer outlined the main issues discussed by the TOX WG at the meeting of 26 September. The group recognised that there is an overall need to establish a definition for "Margin of Safety", since there is no such accepted definition. With respect the specific case of iprovalicarb, Dr. Meyer informed the Committee that the two new genotoxicity

studies recently submitted by the notifier have been evaluated. . Based on these new data, the group is now confident that the substance is not DNA reactive. Dr. McGregor, the rapporteur, will provide a revised draft opinion for the next meeting of the working group on toxicology on October 10. Prof. Maroni informed the Committee that a draft text should be ready for adoption by the SCP at the plenary meeting of November.

5.5 Propineb

Mr. Koepp informed the Committee that the evaluation for question 1 dealing with exposure of birds to propineb and its metabolite PTU is almost completed.

Dr. Meyer outlined the main issue under discussion in the working group on toxicology assessment. The assessment of the group is now at an advanced stage and is expected to be completed soon.

Prof. Hardy concluded that a draft opinion might be ready for adoption by the Committee at the November plenary meeting.

5.6 Iprodione

Mr. Koepp outlined the issues discussed by the ENV WG with respect to question 1 relating to the predicted environmental concentrations of the active substance and its metabolites in groundwater. He informed the Committee that the assessment of the group is now almost completed.

Prof. Maroni, chairman of the TOX WG informed the Committee that following the background information provided by Dr. Maier from DG Health and Consumer Protection at the previous meeting, Dr. Fait, the rapporteur, was now preparing a draft opinion on question 2 which is expected to be available at the next meeting of the working group on toxicology assessment.

5.7 *Pseudomonas chlororaphis*

Prof. Maroni informed the Committee that no progress has been made on that dossier since the July Plenary meeting. He confirmed that a special one day meeting to address the pending issues of that dossier will take place on October 9.

5.8 Paraquat

Questions 1 and 2 deal with toxicology issues. Prof. Savolainen has submitted a working document which was shortly discussed at the TOX WG meeting of 26 September. Following the discussion, Prof. Savolainen will provide a revised text that will be discussed at a subsequent meeting of the working group on toxicology assessment.

Dr. Sherratt informed the Committee that the evaluation of question 3 dealing with the risk of paraquat to soil dwelling organisms is finalised. Mr. Koepp informed the Committee that the assessment of question 4 relating to risks to birds and hares, has been completed as well.

5.9 Fenarimol

Mr. Koepp outlined the main issues discussed by the ENV WG. He informed the Committee that a draft opinion is at an advanced stage and should be ready for adoption at the plenary meeting of November.

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

The secretariat of the Committee introduced two requests for opinions on draft technical guidance documents and one new dossier concerning the re-evaluation of an active substance (diquat).

6.1 Opinion on draft guidance document on setting of an Acute Reference Dose

The Commission would like the SCP to comment on the draft guidance document for the setting of an Acute Reference Dose (document 7199/VI/99 rev. 5, dated 5 July 2001).

Prof. Maroni informed the Committee that Dr. Moretto was appointed rapporteur for that question.

6.2 Opinion on draft guidance document on dermal absorption

The Commission would like the SCP to comment on the draft guidance document on dermal absorption (document Sanco/222/2000 rev. 4, dated 11 April 2001).

Prof. Maroni informed the Committee that the working group on toxicology assessment considers it would be useful to involve extra expertise in the group to deal with the question.

6.3 Diquat (bis)

The Committee expressed an opinion on specific questions relating to the evaluation of diquat in the context of Directive 91/414/EEC in April 2000[1]. In this opinion, the Committee considered that the supplied data indicate a very high risk to the aquatic environment. The Committee recognised that options for risk reduction exist, but no data were submitted to demonstrate that they would be sufficiently effective to render the aquatic uses acceptable.

Now, the notifier has provided additional information on certain aquatic uses of diquat, which were evaluated by the Rapporteur Member State. The rapporteur now considers that the body of evidence available supports the conclusion that acceptable use of diquat in the aquatic environment is possible. The Commission would like the Committee to comment on this conclusion.

[1] http://europa.eu.int/comm/food/fs/sc/scp/out64_ppp_en.pdf.

Prof. Hardy, chairman of the ENV WG, informed the Committee that Dr. Forbes has been appointed rapporteur to deal with that question. The first discussion is scheduled at the next ENV WG on November 24.

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. Davies commented on his draft assessment of the new data submitted last July by the notifier. He informed the Committee that he will await the comments of other molecular biologists from the joint GM/NF WG before preparing a draft opinion, which will be discussed at the following working group on GMOs.

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

Prof. Hardy informed the Committee that the GM/NF WG meets on 28 September. On 15th of October, a special meeting with the rapporteurs of each sub-working group will be organised to prepare a consolidated draft guidance document.

7.3 New question referred to the Committee

The Secretariat introduced a new question relating to the invocation by the UK of article 16 of Council Directive 90/220/EEC.

Dr. Schiemann was appointed rapporteur to prepare a draft opinion. The aim is to convey a draft opinion for adoption by the Committee at the November Plenary meeting.

8. Exchange of view on the progress report of the task force on Harmonisation of Risk Assessment

Prof. Hardy reminded the Committee about the on-going work of the task force from the Scientific Steering Committee on harmonisation of risk assessment. Prof. O'Gara is the SCP representative member of Task force. Dr. Sherratt is member of the sub-group on environmental risk assessment while Prof. Savolainen volunteered to be member of the sub-group "risk assessment as applied to chemical and physical agents".

Following the discussions, Prof. Hardy informed the Committee that he will report back to the Scientific Steering Committee the position of the SCP with respect to current draft text submitted by the Task Force.

9. Other Business

8.1 Dr. Maier informed the Committee of the forthcoming request for opinions to be referred to the Committee soon**:**

- Request for opinion on the Draft guidance document on setting operator exposure; Dr. Maier informed the Committee that there is no urgency to deal with that guidance document.
- Request for opinion on the FOCUS draft surface water scenario; Dr. Maier stressed the urgency of that forthcoming request. The aim of the Commission is to have this

scenario available to applicants in 2003 for use in the 3rd phase of the current review programme of Directive 91/414/ECC. He informed the Committee that the Draft report should be available early December and will be referred to the Committee for opinion as soon as available with high priority. He highlighted that in order to meet the Commission goal, the opinion of the Committee would be needed early March 2002.

Prof. Hardy agreed to deal with the dossier with high priority and informed Dr. Maier that the Committee will endeavour to have the opinion adopted at the plenary meeting of 14 March in order to meet the deadline set by DG Health and Consumer Protection.

Dr. Dunier, from DG Environment informed the Committed that a new version of the draft guidance document on the relevance of metabolites has been prepared by the Commission services. Since the revised text is now quite different from the one reviewed by the SCP in 2000, it might also be referred to the Committee for an opinion.

8.2 Special SCP workshop on 25 – 26 October:

Prof. Hardy recalled the discussion of the July Plenary meeting on the suitability of holding a special meeting of the SCP to take stock of the Committee achievements in its four years of existence but also to reflect on its future in relation with the forthcoming creation of the European Food Authority.

The aim of the meeting is to provide a report to the Commission on the Committee's view on where the Committee stands, on the main scientific issues that were considered by the SCP, identified potential emerging issues and research needed. Prof. Hardy urged all Committee members to endeavour to participate to that special workshop.

Date of the next regular Plenary meeting: 8 November