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/030-Final
20 December 2001

MINUTES OF THE THIRTHIETH MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 8 November 2001

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ATTENDANCE LIST

Members

Prof. H. V. DAVIES
Dr. M-P. DELCOUR-FIRQUET
Mr. H. KOEPP
Prof. S. O. KARENLAMPI
Dr. H. A. KUIPER
Prof. A. LESZKOWICZ
Prof. M. MARONI
Dr. O. MEYER
Prof. E. PETZINGER
Prof. K. SAVOLAINEN
Dr. G. SPEIJERS

Apologies

Prof.	A. R. HARDY	(Chairman)
Dr.	A. MORETTO	
Prof.	F. O' GARA	(Vice-Chairman)
Prof.	E. PAPADOPOULOU	
Prof.	J. SCHIEMANN	
Dr.	T. SHERRATT	
Prof.	A. M. S. SILVA FERNANDES	

Invited Experts

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Commission

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

Secretariat

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

1. Welcome and apologies

In the absence of the Chairman, Prof. Maroni, vice Chairman, opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted.
(Doc. SCP/AGENDA/030)

3. Declaration of interests by Members

No declaration was made.

4. Adoption of the minutes of the Twenty ninth Plenary Meeting (27 September 2001) and matters arising

4.1 Adoption of the minutes of the Twenty ninth Meeting

The draft minutes were approved and are available as Document SCP/REPT/029 at:
http://europa.eu.int/comm/food/fs/sc/scp/out114_en.pdf

4.2 Matters arising

None

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

5.1 Fosthiazate

Mr. Koepp updated the Committee on the progress of the ENV WG as regard question 3 concerning risk to birds and mammals. He highlighted that no established methodology exists to assess the risk of granules to birds and mammals and therefore, the group has to established the methodology. Prof. Maroni confirmed that the assessment of other questions is finalised.

5.2 Iprovalicarb (bis)

Following an exchange of view, the Committee adopted the opinion.

On 7 March 2001, the SCP delivered an opinion on the evaluation of the new active substance iprovalicarb (SCP/IPROVA/002-final[1]). The Committee was subsequently requested to comment on whether a sufficient Margin of Safety exists having regard to the human exposure likely to arise from the intended uses?"

[1] http://europa.eu.int/comm/food/fs/sc/scp/out94_ppp_en.pdf

In its initial evaluation of iprovalicarb, the Committee concluded that the data set presented could not rule out the relevance to humans of the tumours observed in rats. Iprovalicarb acts by an unknown, but non-genotoxic mechanism that has no counterpart in mice, therefore toxicity has a threshold dose and there is a level of exposure below which the probability of adverse effects is negligible. The Committee considers that a sufficient Margin of Safety exists having regard to the consumers' exposure likely to arise from the intended use of iprovalicarb. In the case of operators, a sufficient Margin of Safety only exists when operators wear gloves.

In addition, because the term "Margin of Safety" is used in the literature with various meanings, the Committee recommends a formal definition of Margin of Safety be established.

The opinion is available as SCP/IPROVA-BIS/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out116_ppp_en.pdf

5.3 Propineb

Following an exchange of view, the Committee adopted the opinion.

Two questions were referred to the SCP. In the first one, the Committee was requested to comment on the long-term exposure assessment for birds undertaken in the review. In its assessment, the Committee has identified a number of aspects for which the risks from propineb to birds have not been adequately addressed. The Committee indicated a number of ways in which the risk assessment could be improved. The recommended approach is likely to produce lower TERs[2] that might change the outcome of the risk assessment.

In addition the Committee expressed the opinion that the long-term risk from propineb to wild mammals has not been adequately addressed. The long-term risk from the metabolite PTU (propylenethiourea) for wild mammals should also be assessed. The Committee issued a number of recommendations aimed at improving the risk assessment for birds and wild mammals.

In the second question, the Committee was requested to comment on the appropriate animal model to be used for derivation of the Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL), considering the known hyper-sensitivity of rats to goitrogenic substances. The Committee expressed the opinion that the rat is an appropriate species for the derivation of the ADI and the AOEL. Indeed, propineb, probably through its metabolite propylenethiourea, has goitrogenic effects in rats, mice and dogs, rat being the more sensitive species. However, toxicity is expressed in rats also with effects on liver and kidneys that do not appear to be linked with thyroid effects and these liver and kidney effects in rats are seen at dose levels below those at which toxicity can be observed in either mouse or dog studies.

The opinion is available as SCP/PROPINEB/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out115_ppp_en.pdf

[2] Toxicity Exposure Ratio.

5.4 Fenarimol

Following an exchange of view, the Committee adopted the opinion.

The Committee was requested to comment on the approach taken to calculate the PEC[3] in soil. The Committee disagreed with the approach taken to calculate the PEC in soil because it is exclusively based on the overall results of the field persistence studies and as a consequence ignores the influence of the loss processes at the soil surface and the results of the soil incubation studies in the laboratory. The Committee proposed an alternative approach in which (a) the fraction of the applied amount which remains exposed at the soil or plant surfaces disappears so fast that it does not contribute to the long-term accumulation, and (b) the disappearance of the remaining fraction which penetrates into the soil is derived from the laboratory studies.

The opinion is available as SCP/FENARI-BIS/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out114_ppp_en.pdf

5.5 Diquat

Mr. Koepp updated the Committee on the progress of the ENV WG with the additional question from the Commission on diquat related to the aquatic use of the substance. He informed the Committee that a draft opinion is expected to be ready for adoption at the next meeting.

5.6 Paraquat

Prof. Maroni, chairman of the working group on toxicology, updated the Committee on the progress of the working group on toxicology assessment. Further discussion will take place at the next meeting of the TOX WG on 29 November. Mr. Koepp confirmed that the evaluation of the two questions on environmental issues is completed.

5.7 Iprodione

Prof. Maroni informed the Committee that a draft opinion is now available and will be scheduled for discussion at the next meeting of the working group on toxicology assessment. Mr. Koepp confirmed that the evaluation of the question related to the PECs in soil and goundwater has been completed.

5.8 *Pseudomonas chlororaphis*

Prof. Maroni updated the Committee on the progress on the assessment of the dossier. He outlined the complexity of the issues under discussion. He informed the Committee of the working group's intention to refer a draft opinion to the Committee for adoption at the next plenary meeting.

[3] Predicted Environmental Concentration.

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

Prof. Maroni informed the Committee that the first discussion on the draft guidance document is tabled for the November meeting of the working group on toxicology.

5.10 Opinion on draft guidance document on dermal absorption

Prof. Maroni informed the Committee that the first discussion of the dossier has been deferred. He informed the Committee that the issue of dermal absorption of pesticides is very complex. In order to fully appraise the Commission draft guidance document, he feels that it will be necessary to supplement the expertise available to the working group on toxicology.

6. Progress report and exchange of views on GM plant dossiers referred to the SCP

6.1 Starch potato from Amylogene (Notification C/SE/96/3501)

Prof. Davies reported to the Committee on the assessment by the Joint WG on GMOs/Novel Food and Feed of additional data submitted by the notifier. The Committee agreed that the information was not fully satisfactory and it decided to request additional information from the company. The secretariat agreed to request the data.

6.2 UK Article 16 concerning T25 maize line

Following an exchange of view, the Committee adopted the opinion.

On the basis of the examination of the information submitted by the UK authorities, the Committee concluded that no new scientific information that would require changes to the original risk assessment carried out on the T25 maize line, was provided. The SCP considers that the issue raised in the question is related to management and not to risk assessment. The SCP is therefore unable to comment on non-scientific issues related to the co-existence of GM and non-GM crops and the wider interpretation of existing guidelines presented in this case.

The opinion is available as GMO/T25-UK /002-Final at
http://europa.eu.int/comm/food/fs/sc/scp/out110_gmo_en.pdf

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

Prof. Davies updated the Committee on the recent progress of the draft guidance document. Prof. Maroni invited all members to provide comments on the current draft.

7. Report on the special workshop of the SCP (25-26 October)

Prof. Davies informed the Committee that he prepared a draft report on the workshop the SCP held on 25-26 October. Members are invited to send their comment to Prof. Davies. The draft report will be tabled for discussion at the next plenary meeting.

8. Other Business

Dr. Maier informed the Committee on forthcoming dossiers concerning the evaluation of plant protection products to be referred to the Committee.

Date of the next meeting: 20 December 2001