



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/027

23 July 2001

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**MINUTES OF THE TWENTY SEVENTH MEETING
OF THE SCIENTIFIC COMMITTEE ON PLANTS
BRUSSELS, 7 June 2001**

(adopted on 20 July 2001)

ATTENDANCE LIST

Members

Prof. H. V. DAVIES
Dr. M-P. DELCOUR-FIRQUET
Prof. A. R. HARDY (Chairman)
Prof. S. O. KARENLAMPI
Dr. H. A. KUIPER
Prof. A. LESZKOWICZ
Prof. M. MARONI (Vice-Chairman)
Dr. O. MEYER
Prof. F. O' GARA (Vice-Chairman)
Prof. E. PAPADOPOULOU
Prof. E. PETZINGER
Prof. K. SAVOLAINEN
Dr. T. SHERRATT
Prof. J. SCHIEMANN
Prof. A. M. S. SILVA FERNANDES

Apologies

Dr. A. MORETTO
Mr. H. KOEPP
Dr. G. SPEIJERS

Invited Experts

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Commission

Ms. U. FALK Environment

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/027)

3. Declaration of interests by Members

One member declared a non specific, non personal interest. The Committee concluded that the declaration was not prejudicial to the member's independence.

4. Adoption of the minutes of the Twenty Sixth Plenary Meeting (25 April 2001) and matters arising

4.1 Adoption of the minutes of the Twenty Sixth Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/026.

4.2 Matters arising

None

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

5.1 Thifensulfuron-methyl

This existing active substance had been referred to the Committee at the previous meeting without any question for response. Following an exchange of views the Committee noted the documentation submitted and decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex VI (Uniform Principles) of Directive 91/414/EEC.

5.2 Ethoxysulfuron

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

The Committee was requested to confirm whether the risk to aquatic organisms has been adequately addressed.

The conclusion of the Committee is that the assessment of the risk of ethoxysulfuron to aquatic organisms is lacking in several respects, in particular in respect of sediment dwelling organisms. In addition, the Committee noted that the assumptions for calculating

predicted environmental concentration deviate from previous rice paddy scenarios already dealt with by the SCP. As a general rule, the Committee recommends that a consistent approach be used to address the risk to aquatic organisms associated with rice paddies.

The opinion is available as document SCP/ETHOXY-bis/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out106_ppp_en.pdf

5.3 Prosulfuron

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

Prosulfuron was referred to the Committee with the following two questions:

1. Can the Committee comment on the acceptability of the risk of metabolites M5 and CGA 349707 to sediment dwelling organisms?
2. The Committee is requested to comment on possible hormonal disruption effects on uterus and mammary glands in test animals and possible relevance to humans.

With respect to question 1, the Committee is of the opinion that the risk of the two metabolites to sediment dwellers has not been adequately addressed. In addition, the Committee notes that the risk did not appear to have been assessed for other persistent metabolites which were formed in sediment water tests.

As regard the possible hormonal disruption effects of prosulfuron, the Committee considers that the mild oestrogenic effect observed at high doses in rats is not relevant for human risk assessment in the context of the intended uses of prosulfuron.

The opinion is available as document SCP/PROSULF/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out105_ppp_en.pdf

5.4 Famoxadone

Dr. Sherratt, member of ENV WG, reported the conclusion of the ENV WG on the evaluation of questions 1 and 2 which is now finalised.

Prof. Maroni, chairman of the TOX WG, informed the meeting that Prof. Vrensen has been appointed to join the TOX WG and provide some additional expertise to the group to address question 3 relating to cataracts observed in some animal studies. Prof. Maroni informed the Committee that the evaluation of questions 3 and 4 by the TOX WG is now in progress, and he expects a draft opinion to be referred to the Committee at the next plenary meeting.

5.5 Flufenacet

Dr. Sherratt updated the Committee on the evaluation of question 1 by the ENV WG and informed the Committee that the assessment is now at an advanced stage.

Prof. Maroni informed the Committee that the TOX WG was unclear about the scope of the question referred to the Committee. It was decided that the SCP's response should cover the underlying toxicological assessment for the AOEL and the assessment of

operator exposure. The Committee reiterated its earlier statement, i.e. that until a single European model is available and accepted by the regulators, all models are in principle reckons acceptable to estimate the risk to operators.

5.6 Iprodione

Iprodione was referred to the Committee with two questions. Draft assessments have been produced by the rapporteurs and are currently under consideration by the ENV WG and the TOX WG.

5.7 Iprovalicarb

This dossier was referred to the Committee at the previous plenary meeting. A draft assessment has been prepared by the rapporteur Dr. McGregor. The document will be discussed at the next meeting of the CARC WG.

5.8 Florasulam

This dossier was referred to the Committee at the last plenary meeting. Prof. Hardy, chairman of the ENV WG, informed the Committee that evaluation of question 1 is currently under consideration by the ENV WG.

Prof. Maroni informed the Committee that the evaluation of the TOX WG (question 2 and question 1, toxicological relevance of the metabolites) has been recently completed.

5.9 Fosthiazate

This dossier was referred to the Committee at the previous plenary meeting. Prof. Hardy, informed the Committee that evaluation of question 1 is under consideration by the ENV WG.

Prof. Maroni informed the Committee that the evaluation of question 4 (on a toxicology issue) is now completed.

5.10 *Pseudomonas chlororaphis*

Prof. Maroni informed the Committee that a special meeting of the working group on toxicology of microbio-pesticides is scheduled on 27 June.

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

The secretariat of the Committee introduced 2 new dossiers concerning the evaluation of active substances referred to the Committee.

6.1 Paraquat

This dossier was referred to the Committee with the following questions:

1. Can the Committee comment on the relevance for consumers and operators of the ocular and pulmonary changes, which were observed in the long-term rat study?

2. Can the Committee comment on the risk for operators, taking into particular account potential inhalatory and dermal exposure?
3. Can the Committee comment on potential long-term effects to soil dwelling organisms.
4. Can the Committee comment on the risks the intended uses might pose to reproducing birds and hares.

The following experts have been appointed rapporteurs: Prof. Savolainen, supported by Prof. Vrensen (eye experts) on questions 1 and 2, Dr. Sherratt on question 3 and Dr. Luttik on question 4.

6.2 Propineb

This dossier was referred to the Committee with the following questions:

1. Can the Committee comment on the long-term exposure assessment for birds undertaken in the review?
2. Can the Committee comment on the appropriate animal model to be used for derivation of the ADI and AOEL, considering the known hyper-sensitivity of rats to goitrogenic substances.

The following experts have been appointed rapporteurs: Dr. Luttik (question 1) and Dr. McGregor (question 2).

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

7.1 Starch potato from Amylogen (Notification C/SE/96/3501)

Prof. Davies informed the Committee that information from the notifier was still awaited. The secretariat of the SCP informed the Committee that the notifier let it know that for technical reasons, it has not been in a position to provide the requested data by the end of May as previously foreseen, but expected to be able to submit new data by the end of June.

The evaluation of the Committee will be resumed when new data will be available.

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

Dr. Kuiper updated the Committee on the work currently being done by the joint WG on GMOs, novel food and novel feed, in respect of the preparation of a guidance document for the application for release/marketing of GM plants, GM food and GM feed.

8. Other business

Prof. Maroni informed the Committee that the TOX WG identified an urgent need for clarifying the key principles for carrying out toxicological risk assessment of metabolites. Dr. Sherratt confirmed that a similar situation exists with respect to the environmental assessment of metabolites.

The Committee agrees that for environmental assessment and for toxicological assessment of metabolites, several issues need urgent clarification in particular, the rules for carrying out a quantitative risk assessment of structure and the use of the concept of threshold of toxicological concerns. The Committee reckons that given its workload and its limited resources, filling these gaps is out of its possibilities. The Committee wishes to draw the attention of the Commission on the importance of this issue of the risk assessment of metabolites.

Prof. Hardy informed the Committee that he will raise this issue, at a future Scientific Steering Committee meeting, which might consider this as an emerging issue. He suggested that the SCP drafted a document which would then be conveyed to the SSC and subsequently to the Commission services.

Date of the next meeting: 20 July 2001