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/033 - Final
19 July 2002

MINUTES OF THE 33rd MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 24 April 2001

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.	M. MARONI	
Prof.	E. PAPADOPOULOU	
Prof.	K. SAVOLAINEN	
Prof.	J. SCHIEMANN	
Dr.	T. SHERRATT	
Dr.	G. SPEIJERS	

Apologies

Dr.	H. A. KUIPER	
Prof.	A. LESZKOWICZ	
Dr.	O. MEYER	
Dr.	A. MORETTO	
Prof.	F. O' GARA	(Vice-Chairman)
Prof.	E. PETZINGER	
Prof.	A. M. S. SILVA FERNANDES	

Invited Experts

Dr A Hart
Dr A C Fanetti

Commission

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

Secretariat

Mr.	M. WALSH	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/033)

3. Declaration of interests by Members

One declaration was made and noted.

4. Adoption of the minutes

4.1 Adoption of the minutes of the Thirty 32nd Plenary Meeting (31 January 2002)

The draft minutes were approved and are available as Document SCP/REPT/032-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out124_en.pdf

4.2 Matters arising

None

5. Adoption of opinions

5.1 Draft guidance document on dermal absorption

Following a short exchange of views the Committee adopted the opinion.

The Commission requested the Committee to comment on the draft Guidance document which had been prepared in collaboration with experts from Member States.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.

The main conclusions of the Committee included:

- *In vitro* human skin data alone would be sufficient to determine dermal absorption to be used in risk assessment.
- When only rat skin is available a conservative approach should be used by assuming that human skin absorption would be equal to rat skin absorption.
- The Committee supported the recommendations made regarding the use of OECD guidelines.
- In the cases of *in vitro* and *in vivo* testing, the Committee commented on how to deal with the compound found in the skin.
- The Committee endorsed the default values of 100% and 10% but rejected the use of dermal absorption between 10 and 100%. It found that insufficient justification was provided for the assumption that dermal absorption could never exceed oral absorption.

The opinion is available as SCP/GUIDE-DERM/-Final:

http://europa.eu.int/comm/food/fs/sc/scp/out126_ppp_en.pdf

5.2 Draft guidance document on risk assessment of Birds and Mammals

Following a detailed exchange of views the Committee adopted the opinion.

Germany had prepared the draft guidance document in collaboration with experts from other Member States. It is intended to use the document to facilitate the decision-making on the inclusion of active substances in Annex 1 to Council Directive 91/414/EEC. The Commission requested the Committee to respond to three specific questions and to make any other comments it considered appropriate. In its opinion the Committee responded to the three questions referred to it and also provided detailed and extensive comments on the document in section 2 of its opinion.

The main conclusions of the Committee included:

- Rice scenarios and forestry should be added as separate categories.
- A section on the assessment of granular pesticides should be added.
- The indicated species were considered relevant but the Committee was of the opinion that applicants must ensure that the most relevant species are selected on a case-by-case basis.
- All assumptions must be justified.
- Whilst the Committee acknowledged that there is a lack of evidence for frequent direct impacts of pesticides on birds and mammal populations, it is not possible at present to quantify how protective the proposed procedures would be.
- The Committee does not agree that the residue per unit dose values in the draft Guidance document to be appropriate for estimating pesticide residues on insects. It recommends that research is need to provide a more robust approach.
- The Committee is of the opinion that it is not possible at present to identify simple criteria to eliminate in Tier 1 those seed treatments posing a low long-term risk to wild animals and birds.

The opinion is available as SCP/GUIDE-B&M/002-Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out125_ppp_en.pdf

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

6.1 Draft guidance document on the setting of an Acute Reference Dose

Professor Maroni, as Chairman of the Toxicology WG, outlined progress with the preparation of this opinion. He informed the Committee that it should be ready for adoption at the next Plenary Meeting.

6.2 FOCUS surface water scenario

Prof. Hardy reiterated the statement he made to the Committee at the January Plenary meeting that work remained interrupted pending receipt by the Committee of the final report from the FOCUS working group as well as the comments from the Member States.

6.3 Mesotrione and Indoxacarb

Professor Maroni informed that Committee that work on these dossiers was in progress and involved a number of complex scientific issues. However he was optimistic that both opinion would be ready for adoption at the July Plenary Meeting.

6.4 Vinclozolin

Professor Hardy explained that he expected that this opinion would be ready for adoption at the July meeting.

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

7.1 Uniform principle (UP) for evaluation and authorisation of plant protection products containing micro-organisms

The Secretariat explained the background to the request for the opinion of the Committee. Council Directive 97/59/EC laid down Uniform Principles for the evaluation and authorisation of chemical plant protection products and the Commission was now requesting the SCP's opinion on an analogous document for the evaluation and authorisation of plant protection products containing micro-organisms. Sweden had prepared it with the assistance of other Member States.

Professor Hardy explained that he had chaired on 17 April the first meeting of the working group, which would be responsible for the preparation of the draft opinion on the document. He explained that he and the vice-chairmen had decided to consolidate the two original working groups that dealt with previous opinions on micro-organisms for reasons of coherence and efficiency. He indicated that it was the intention to have the opinion ready for adoption at the July meeting but this would depend on pressure of work.

7.2 Flusilazole

The Secretariat introduced the dossier to the Committee as follows:

Flusilazole has an inhibitory effects on the aromatase and therefore may interfere with the reproductive functions in aquatic organisms. The Rapporteur Member State concluded that an early life stage study in fish is a sufficiently sensitive study in this case to predict reproductive effects of flusilazole.

Flusilazole is also persistent in soil having a DT50 > 60 days and DT90 > 365 days (soil dissipation studies with German soils)**.** Nevertheless it does not accumulate and its concentration following recommended treatment rate will reach a plateau concentration around 0.1 mg/kg.

Questions to the SCP:

1. Can the Committee comment on the conclusion of the Rapporteur, whether in the specific case of flusilazole, that the proposed NOEC for long term effects on fish is adequate to ensure a sufficient protection of fish from adverse effects on reproduction. The Committee is also requested to provide a general comment on the comparative sensitivity of the early life stage test vs. the full fish life cycle study.

2. Can the Committee comment on the potential impact of flusilazole on organic matter decomposition under the intended use conditions?

The Chairman referred the questions to the Environmental Risk Assessment Working Group.

7.3 Method for Koc determination

The Secretariat presented the request for opinion to the Committee. He explained that during the ongoing peer review of active substances member states experts on environmental fate have identified a problem.
For test substances which degrade rapidly in water the Batch Equilibrium Adsorption method (OECD method 106) which is proposed in Annex II point 7.1.2 of Directive 91/414/EEC appears to be unsuitable due to instability of the test substance under the study conditions. Where the accuracy of the adsorption method is low due, for example, to instability of the test substance, as shown by significant deviation of the Freundlich coefficient, alternative methods may be better suited to determine the Koc constant. Possible alternative methods identified by the experts at the peer review were:

- the derivation of Koc from soil column studies
- the derivation of Koc from soil TLC studies
- the provision of data using an HPLC method

Question to the SCP
Can the Committee comment on the validity of these alternative methods for the derivation of the Koc constant? Can the Committee further provide its opinion concerning possible criteria that should trigger the use of alternative methods (e.g. a DT_{50} in water below a certain value) and on which alternative method is considered preferable?
The Chairman referred the questions to the Environmental Risk Assessment Working Group.

7.4 Fenthion

The secretariat presented the questions and explained the background to the Committee.

In its original opinion (1998)[1], the SCP identified several issues of concern as regards the risk to bees and non-target arthropods, the risk to aquatic organisms and the risk to birds.

Additional data were submitted to the Rapporteur Member State who evaluated the data.

The Rapporteur Member State (MS) carried out a risk assessment for aquatic organisms where it is concluded that "the bait application of fenthion for in olives and citrus at a rate of 75 g a.s./ha is safe for the aquatic environment". The conclusion did not raise specific comment from MS".

As regard the risk to birds, the SCP concluded in its original opinion that:
- A semi-field study to determine acute risk under field conditions was missing,
- no data on reproductive effects at sublethal dose were available,
- the issue of secondary poisoning was not addressed.

In its original opinion, the Committee concluded that, "*health concerns of fenthion relate to its acute toxicity. Therefore long-term effects do not play a crucial role in the overall risk assessment. Delayed neurotoxicity deserves further investigation which may modify the current risk assessment*".

The Committee identified some shortcomings in the mutagenicity data package, but was not concerns about the mutagenicity profile of fenthion (carcinogenicity study and 2 generation reproductive study were all negative).

Additional data were submitted and evaluated by the RMS.

[1] http://europa.eu.int/comm/food/fs/sc/scp/out22_en.html

In its opinion the Committee is expected to:
1) comment on the issue of delayed neurotoxicity (taking into account the intended uses), 2) address the issue raised by some member states (Belgium, France, UK) concerning the clastogenic properties of fenthion (can a threshold be established?) taking into account the new mutagenicity study provided by the notifier and the assessment of the RMS (2002).

Question 1

Considering the intended uses (bait uses in citrus and olives) does the Committee consider that the additional toxicological information alters its previous assessment?

Question 2

As regard the risk to birds, can the Committee comment on the relevance of the new data and arguments present by the Rapporteur Member State regarding the intended uses?

The Chairman referred the questions respectively to the Toxicological and Environmental Risk Assessment Working Groups.

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

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

Prof. Davies informed the Committee that the response from the Notifier to the questions raised on 28 March 2001 had been received on 19 April 2002. He indicated that it would be examined in the Joint Working Group on GMs on 28 May and that the opinion should be ready for adoption for the SCP Plenary of 18 July.

9. Other Business

Request for clarifications regarding the "Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds".

When the Committee prepared the above opinion it had only access to a draft report of the European Science and Technology Observatory (ESTO)/ Institute for Prospective Technological Studies (IPTS). Since the final report had recently become available, the Commission requested the Committee to check if the final document necessitated any amendments to the above mentioned opinion. The Committee confirmed that the conclusion of the SCP were still valid in the light of the final IPTS/ESTO study.

Date of the next meeting: 13 June 2002