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/034 - Final
29 October 2002

MINUTES OF THE 34th MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 18 July 2002

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ATTENDANCE LIST

Members

Prof.	H. V. DAVIES	
Prof.	A. R. HARDY	(Chairman)
Prof.	S. O. KARENLAMPI	
Mr.	H. KOEPP	
Prof.	A. LESZKOWICZ	
Prof.	M. MARONI	(Vice-Chairman)
Dr.	O. MEYER	
Dr.	A. MORETTO	
Prof.	F. O' GARA	(Vice-Chairman)
Prof.	E. PAPADOPOULOU-MOURKIDOU	
Prof.	K. SAVOLAINEN	
Prof.	J. SCHIEMANN	
Dr.	T. SHERRATT	
Prof.	A. M. S. SILVA FERNANDES	
Dr.	G. SPEIJERS	

Apologies

Dr.	M-P. DELCOUR-FIRQUET
Dr.	H. A. KUIPER
Prof.	E. PETZINGER

Invited Experts

Dr A C Fanetti

Commission

Ms.	M. Dunier-Thomann	DG Environment
Mr.	W. Maier	DG Health and Consumer Protection E1
Mr	P. Wagstaffe	DG Health and Consumer Protection C2
Mr	L. Breslin	DG Research E2
Mr	B. Verachtert	DG Research E2

Secretariat

Mr.	M. WALSH	DG 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/034)

3. Declaration of interests by Members

The Chairman informed the Committee that Tom Sherratt had resigned from the SCP on taking up an appointment in Canada. He thanked Dr Sherratt for his contribution to the work of Committee and wished him success in his new career.

4. Adoption of the minutes

4.1 Adoption of the minutes of the Thirty 33rd Plenary Meeting (24 April 2002)

The draft minutes were approved and are available as Document SCP/REPT/033-Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out127_en.pdf

4.2 Matters arising

None

5. Adoption of opinions

5.1 Draft guidance document on the setting of an Acute Reference Dose (ARfD).

The Commission requested the Committee to comment on the draft Guidance document which had been prepared in collaboration with experts of Member States.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

Following an introduction from Prof Maroni and a short exchange of views the Committee adopted the opinion.

The main conclusions of the Committee included:

- The ARfD should be clearly defined on a one-day time frame and that its establishment should not be driven by considerations of the likely dietary intake.

- The Committee reaffirms its previous position[1] on the need to consider the establishment of an ARfD for all PPPs and that when this is considered unnecessary the justifications for this should be clearly stated.

- The Committee supports a stepwise approach for providing additional studies for refining the ARfD and that such studies should only be performed if the estimated acute intake is higher than the proposed ARfD.

- In order to achieve sufficient flexibility to provide a good understanding and characterisation of the relevant effect, the Committee is of the opinion that no single test guideline should be provided for studies aimed at refining an ARfD.

- The Committee agrees with the concept that only one ARfD should be derived to cover all sub-population groups.

- Human data are most useful because they provide reassurance on the extrapolation process. The Committee stresses that human data should be used in the context of the entire toxicological profile of the PPP under consideration.

The opinion is available as SCP/GUIDE-ARFD/002- Final:

http://europa.eu.int/comm/food/fs/sc/scp/out133_ppp_en.pdf

5.2 Draft opinion on indoxacarb

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

The Commission requested the Committee to comment on two issues. The first relates to the NOEL for effects on red blood cells as low level exposure in test animals resulted in effects of unclear biological significance. The Committee concluded in its opinion that the absence of reticulocytosis and the slight changes (<10%) in treated animals with values mostly within the range of normal values lead the Committee to consider that these effects are non adverse up to 40 ppm. The second question the Commission sought advice on was the derivation of the ARfD for indoxacarb. The SCP concluded that the general and non-specific signs of toxicity observed in the acute neurotoxicity study in rats can be used as a basis for the derivation of an ARfD.

The opinion is available as SCP/Indoxa/002 - Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out132_ppp_en.pdf

5.3 Draft opinion on mesotrione

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

[1] http://europa.eu.int/comm/food/fs/sc/scp/out02_ppp_en.html

The Commission requested the Committee to reply to two questions. The first dealt with the suitability of the rat as an animal model for extrapolation to man. The Committee concluded that due to similarities in tyrosine kinetics between mice and humans, the mouse can be considered a better animal model than the rat for human risk assessment purposes. In the second question the SCP was requested to comment on the possible existence of a mesotrione plasma threshold level for adverse effects on target organs. The Committee identified the critical effect as ocular toxicity mediated by increased systemic levels of tyrosine and concluded that there is a threshold of plasma tyrosine levels for the expression of ocular effects in humans.

The opinion is available as SCP/MESOTRI/002 - Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out134_ppp_en.pdf

5.4 Draft opinion on vinclozolin

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

The Committee addressed two questions in its opinion. The first question sought advice on the possible biological and ecological significance of the effects observed in the fish life-cycle study using fathead minnows. The Committee concluded that vinclozolin has potential to adversely affect reproduction in fish species but that substantial uncertainties exist in extrapolating from laboratory to field conditions. In the second question the SCP was requested to comment on the adequacy of estimated No Observed Effect Concentration to avoid adverse effects on fish reproduction. In its reply the Committee indicated that the available study was inadequate to assess reproductive effects in fish.

The opinion is available as SCP/VINCLO-TER/002 - Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out130_ppp_en.pdf

5.5 Draft opinion on flusilazole

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

Two questions were addressed to the Committee. In the first the SCP was asked to comment on the adequacy of the proposed No Observed Effect Concentration (NOEC) for long term effects on fish and also to comment on the comparative sensitivity of the early life stage versus full fish life cycle study. The Committee concluded that it cannot conclude that a NOEC based on a fish early life-stage test for a single species is necessarily adequate in this particular case since there is evidence that flusilazole may have specific effects on the fish reproductive process. The SCP considered that early life-stage tests are not designed to detect potential effects on reproduction and if there are reasons to expect such effects, a test which incorporates appropriate should be conducted.

In the second question the Committee was requested to comment on the potential impact of flusilazole on organic matter decomposition under the intended use conditions. In its reply the SCP indicated that no data were submitted to assess the impact on organic

matter decomposition. Given the persistence of flusilazole in soil and the environmental and agronomic importance of the organic matter breakdown for soil fertility, the Committee considers a risk assessment based solely on the existing data as not adequate.

The opinion is available as SCP/FLUSILAZOLE/002 - Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out131_ppp_en.pdf

5.6 Method for Koc determination

Following an exchange of views the Committee adopted the opinion.

The Committee was requested to comment on the validity of possible alternative methods for determining the organic carbon adsorption coefficient for active substances that degrade rapidly in water. In its opinion the SCP made the following recommendations:

- Determine the necessity for the use of alternative methods depending on environmental fate;
- Comments and recommendations on alternative methods;
- Recommendation for the use of alternative methods if hydrolysis half-life is less than 7 days;

The opinion is available as SCP/KOC/002 - Final at:

http://europa.eu.int/comm/food/fs/sc/scp/out128_ppp_en.pdf

6. Progress Report on dossiers referred to the Scientific Committee on Plants

6.1 Focus surface water scenario

This dossier had been referred to the Committee at the December 2001 Plenary Meeting but it was decided at the Plenary Meeting of 31 January to defer further consideration of the opinion until the Committee received the final draft report from the Focus working group.

The Chairman informed the Committee that the final draft report had now been forwarded to the Committee and that it would be examined at the Environmental WG scheduled for 13 September.

6.2 Uniform principles (UP) for the evaluation and authorisation of plant protection products containing micro-organisms

Prof. Hardy reported work on the opinion following the WG meeting of 17 April still ongoing but that adoption of the opinion would be delayed because of heavy work commitments of some members of the WG who should prepare contributions for the draft opinion.

6.3 Fenthion

Prof. Maroni reported that the question dealing with toxicological aspects had been completed and Prof. Hardy reported that the environmental aspects would be ready to allow the opinion to be adopted at the Plenary meeting in September.

7. New PPP related dossiers to be referred to the SCP

7.1 Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion

The draft guidance document had been prepared by the Commission services in co-operation with experts from Member States and industry. The Council and Commission, on the adoption of Annex VI (Directive 97/57/EC[2]) to Council Directive 91/414/EEC, recognised that due to particular conditions associated with rice cultivation the specific criteria and principles contained in Annex VI were inappropriate. The Commission undertook to develop criteria for environmental risk assessment and decision making which would address the use of plant protection products in rice cultivation.

The Commission addressed no specific question to the Committee but drew attention to the following conclusion "Aquatic organisms in rice paddy itself do not require the same level of protection as those in the non-target water bodies adjacent to the fields". The rational for this conclusion was that paddy fields become dry at certain times of the year and all aquatic life ceases. However account needs to be taken that species dwelling within the paddy may have a particular ecological function during the time there are there.

The Committee referred the document to the WG Environment to prepare a draft opinion.

7.2 Draft Guidance document on relevant metabolites

The SCP has issued an opinion[3] on the 30 November 2000 on an earlier version of the draft guidance document on relevant metabolites. Following the publication of the SCP's opinion the draft guidance document had been revised by the Commission services in co-operation with experts from Member States. The SCP is now requested to give an opinion on the revised document and respond in particular to the following questions:

(1) What is the Committee's opinion with regard to the overall level of protection for consumers, which is achieved by the proposed approach?

(2) Could the Committee comment on the appropriateness of the proposed cut-off limit to all non-relevant metabolites in groundwater?

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[2] OJ L265, 27.9.1997, p87

[3] http://europa.eu.int/comm/food/fs/sc/scp/out82_ppp_en.html

(3) Can the Committee comment on the introductory remarks for "Step 4" and provide its opinion about the alternative approach proposed by Germany (see comments)?

The Committee referred the request to the Toxicology WG for preparation of a draft opinion.

7.3 Guidance for the setting of acceptable operator exposure levels (AOELs)

The draft guidance document had been prepared by the Commission services in collaboration with experts of Member States. It was referred to the SCP for opinion without any specific question.

The Committee referred the request to the Toxicology WG for preparation of a draft opinion.

7.4 Atrazine and simazine

Atrazine and simazine are existing active substances in the context of Directive 91/414/EEC and are listed in the Regulation (EEC) No 3600/ 92[4]. The evaluation report was prepared by the United Kingdom as Rapporteur Member State (RMS) and the substances has been peer reviewed with Member State experts and discussed with the 15 Member States in the working group "Plant Protection Products - Evaluation" of the Standing Committee on Plant Health.

The main problem identified during the review relates to the leaching potential of the active substances and their breakdown products. The Rapporteur has evaluated extensive modelling data and also monitoring data from several Member States and has identified use conditions, which are unlikely to lead to a contamination of groundwater. However, a consultation of the Scientific Committee on Plants appears necessary to have an additional, independent opinion on the following questions:

The SCP is requested to respond to the following questions:

(1) Can the Committee comment on the approach taken by the Rapporteur for the calculation of predicted environmental concentrations (PEC) in groundwater?

(2) Does the Committee agree that the available monitoring data show that in large areas, application of atrazine and simazine under the intended conditions (i.e. max. 1.5 kg a.s./ ha on maize and sorghum only and in spring), will not result in concentrations of the active substances nor their breakdown products in excess to 0.1 μg/L in groundwater?

The Committee referred the document to the WG Environment to prepare a draft opinion.

[4] OJ 366, 15.12.92, p10.

8. GMO dossiers

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

Following an exchange of views the Committee adopted the opinion.

The Committee had been requested to consider whether there is any reason to believe that the placing on the market of the potato clone EH92-527-1, derived from cultivar Prevalent, for use in cultivation and starch production, is likely to cause adverse effects on human health and/or the environment.

In its opinion the SCP concluded that there is no evidence to indicate that the placing on the market of potato clone EH92-527-1, for use in cultivation and starch production is likely to cause adverse effects on human health and the environment.

The opinion is available as SCP/GMO/165-Final:

http://europa.eu.int/comm/food/fs/sc/scp/out129_gmo_en.pdf

9. Other Business

9.1 The SCP adopted an opinion on the Commission's 'Draft Guidance on Dermal Absorption on 24 April 2002[5] and agreed the following statement regarding with regard to its interpretation of 'absorbed dose' and that of OECD:

"The Committee was informed that dermal absorption testing was discussed at a recent meeting of OECD. It established some definitions for the absorbed dose *in vivo* and *in vitro*, distinguishing the absorbed dose from the absorbable dose. In its recent opinion on a guidance document on dermal absorption, the SCP included in the "absorbed dose" only the amount of substance that is truly absorbed plus the amount remaining in the dermal layers with the exclusion of the stratum corneum. OECD included in the concept of absorbable dose not only the amount of test substance present on or in the skin following washing, but also the amount remaining in the stratum corneum with the intent to adopt a slightly more conservative approach and to avoid the definition of a standard procedure to remove the stratum corneum at the end of the test. The SCP has taken note of this difference but it feels that it is unnecessary to revise the recent opinion, and is satisfied that the approach it has taken is scientifically valid.

9.2 European Food Safety Authority

Mr P. Wagstaffe present a progress report to the Committee on the European Food Authority and paying particular attention to the Authority's Scientific Committee and Scientific Panels.

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

9.3 Research and Technological Development Framework Programmes

Messrs Breslin and Verachtert spoke on Framework Six[6] and explained the new of developments of the programme compared to earlier ones. They drew particular attention to the increased focus of this programme on integrated projects and clusters of projects. The project selection process and the timing of the various actions were also explained in detail.

10. Future Meetings

30 January 2003

20 March 2003

7 May 2003

[6] http://europa.eu.int/comm/research/fp6/index_en.html