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/031-Final
31 January 2002

MINUTES OF THE THIRTY FIRST MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 20 December

(Adopted on 31 January 2002)

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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	
Dr.	H. A. KUIPER	
Prof.	A. LESZKOWICZ	
Prof.	M. MARONI	
Dr.	O. MEYER	
Dr.	A. MORETTO	
Prof.	F. O' GARA	(Vice-Chairman)
Prof.	E. PETZINGER	
Prof.	J. SCHIEMANN	
Dr.	T. SHERRATT	
Prof.	A. M. S. SILVA FERNANDES	
Dr.	G. SPEIJERS	

Apologies

Prof.	E. PAPADOPOULOU	
Prof.	K. SAVOLAINEN	

Invited Experts

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Commission

Ms.	M. DUNIER-THOMANN	Environment
Ms.	S. PICCOLI	

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/031)

3. Declaration of interests by Members

No declaration was made.

4. Adoption of the minutes of the Thirtieth Plenary Meeting (8 November) and matters arising

4.1 Adoption of the minutes of the Thirtieth Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/030-Final at: http://europa.eu.int/comm/food/fs/sc/scp/out117_en.pdf

4.2 Matters arising

None

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

5.1 Fosthiazate

Following an exchange of view the Committee adopted the opinion.

Four questions were referred to the SCP. In the first, the Commission asked the Committee whether it could confirm that use scenarios exist which pose no unacceptable risk to groundwater. The Committee could not confirm that such a scenario exist. Calculation for FOCUS scenarios made by the Committee showed that for one out of nine FOCUS scenarios a concentration below 0.1 µg/L is expected for the parent substance. With respect to metabolites, the Committee is of the opinion that there is insufficient information on the leaching characteristics of five soil metabolites to determine their contribution to groundwater risk.

In the opinion on question 2, the SCP noted that the single study that was conducted to evaluate effects of the active substance on the breeding performance of beetles, reported a significant reduction in the number of surviving offspring. Therefore the Committee recommends that the implications of this result be evaluated in more details. The SCP is aware that additional information exists but it was not submitted to the Committee. It also noted that the risks posed by the metabolites to soil organisms have not been addressed.

Question 3 deals with the risk to birds of granule formulation of fosthiazate. In its opinion, the Committee investigated the various possible routes of exposure. The Committee notes that the incorporation efficiency is critical to achieve TER < cut off values, but no information was provided as to where in Europe such required level of incorporation will be achieved by farmers. In different scenarios, the assessment of the Committee, based on different assumptions, showed that TER might fall below the regulatory cut-off values.

In question 4, the Committee was asked whether it considers that there is sufficient information available on the risk of organophosphate-induced delayed polyneuropathy (OPIDP) in humans following severe intoxication incidents to confirm that there is a safe use, or whether further *in vitro* tests of relative inhibitory potency of the individual isomers of fosthiazate for acetylcholinesterase (AChE) and neuropathy target esterase (NTE) in hen and human tissues are required? The Committee is of the opinion that there is not sufficient information available on the risk of OPIDP in humans following severe intoxication incidents with fosthiazate and that NTE (neuropathy target esterase) inhibition by fosthiazate and its isomers has not been adequately assessed.

The opinion is available as SCP/FOSTHIAZ/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out121_ppp_en.pdf

5.2 Diquat

Following an exchange of view the Committee adopted the opinion.

One additional question was referred to the SCP following the opinion adopted in April 2000[1]. The Committee looked at the additional documents provided. The conclusion is that the additional information does not substantially modify the original opinion.

The opinion is available as SCP/DIQUAT-BIS/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out118_ppp_en.pdf

5.3 Paraquat

Following an exchange of view the Committee adopted the opinion.

Four questions were referred to the Committee. In question 1, the Committee was requested to comment on the relevance for consumers and operators of the ocular and pulmonary changes, which were observed in the long-term rat study? The Committee expressed the opinion that the pulmonary lesions observed in animals after paraquat oral treatment are the critical effect. However, such an effect is not expected to occur under the exposure conditions that can take place in occupational settings or for consumers, when paraquat is used as a plant protection product as recommended. As regard the ocular lesions observed in the long-term rat study, the Committee is of the opinion that the effects of paraquat on the eye, observed in rats and not in other species, are not relevant to the risk assessment for operators and consumers.

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

In question 2, the Committee was requested to comment on the risk for operators, taking into particular account potential inhalatory and dermal exposure. The SCP concluded that when paraquat is used as a plant protection product as recommended under prescribed good working practices, its use does not pose any significant health risk for the operators. The SCP is of the opinion that the NOAELs[2] based on pulmonary effects observed in dogs should represent the basis to set short-term or medium-long-term AOELs[3].

As regard question 3, the Committee is satisfied from the data presented that if paraquat is used at recommended field rates, it is unlikely to pose a significant risk to soil-dwelling organisms. However, it noted that the litter bag study was conducted at too high a dose rate to allow a reliable assessment of the likely effects of paraquat on the rate of organic matter decomposition under field conditions. Given this uncertainty and the persistence of paraquat in soil, the SCP feels that a more detailed appraisal should be provided on the likely effects of paraquat on the rate of degradation of organic material in soil

In question 4, the Committee was requested to comment on the risk assessment to reproducing birds and hares. The Committee concluded that the available data demonstrate a hazard from paraquat to avian embryos, but that the information is not adequate for an assessment of risk. Tests with paraquat involving more realistic exposures are needed. As regard hares, the Committee concluded that paraquat could be expected to cause lethal and sublethal effects for hares. However, the available data are inadequate to estimate the proportion of hares affected.

The opinion is available as SCP/PARAQ/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out119_ppp_en.pdf

5.4 Iprodione

Prof. Maroni updated the Committee on the progress of the working group on toxicological assessment.

5.5 *Pseudomonas chlororaphis*

Following an exchange of view the Committee adopted the opinion.

Pseudomonas chlororaphis is a bacterium which may be used as a plant protection product and is the first bacteria assessed in the context of Directive 91/414/EEC. Six questions were referred to the Committee.

In question 1, the Committee was asked to consider whether the issue of residue levels in food and feed has been adequately addressed. The Committee concludes that in the absence of sustained colonisation, the number of *P. chlororaphis* associated with the harvested grain as well as the concentration of any metabolites produced would be very low. Therefore it is of the opinion that there is no cause for concern and that the issue of residues has been adequately addressed.

[2] No Observed Adverse Effect Levels.
[3] Acceptable Operator Exposure Levels.

Question 2 relates to the assessment of risk to operators. The Committee is of the opinion the operator exposure to *Pseudomonas chlororaphis* formulations has been adequately addressed notwithstanding the absence of models for assessing operator exposure for microbial pesticides.

In question 3, the Committee was asked whether a tiered approach is adequate to address hazard to human and whether repeated dosing be part of the primary (tier 1) data set?

As already expressed in other opinions, the Committee considers that repeated dosing should in general be part of the primary data set, but repeated dosing can be omitted provided that adequate justification can be offered based on the biological properties of the micro-organism. In the specific case of *Pseudomonas chlororaphis*, and in the light of the results of the available studies, the SCP is of the opinion that repeated dosing is not necessary to assess hazard to humans.

Question 4 dealt with the safety assessment of the antibiotic metabolites of *Pseudomonas chlororaphis.* The Committee noted that the toxicological information so far available on the putative antibiotic metabolites of *Pseudomonas chlororaphis* is limited. Although the SCP concluded that more studies would be needed for a more complete assessment of the mutagenicity potential of DDR, the potential for human exposure to DDR as well as to other possible antibiotic metabolites is so low that, even in the absence of further information, the Committee is of the opinion that no major concern exists for consumer and operator safety.

As regard question 5 concerning the possible allergenic reaction to the bacteria, the Committee concluded that although the probability of occurrence of allergic reactions on agricultural exposure to *Pseudomonas chlororaphis* is likely to be very low, the possibility of their occurrence cannot be totally excluded. Confirmation of lack of allergenic potential can only be obtained by a direct systematic observation on a significant number of exposed operators.

Question 6 referred to the Committee was: “The genus Pseudomonas also contains important pathogens for human e.g. *Pseudomonas aeruginosa*, which can establish in open wounds. There is one documented case where *Pseudomonas chlororaphis* was found in the wound of a soldier. Does this finding give rise to any concerns for human safety?” The Committee expresses the opinion that there is no cause for concern for human safety with regard to wound infection.

The opinion is available as SCP/PSEUDOM/002-Final at
http://europa.eu.int/comm/food/fs/sc/scp/out120_ppp_en.pdf

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

Prof. Maroni, chairman of the working group on toxicology assessment, informed the Committee that the draft guidance document is currently under consideration by the working group.

5.7 Draft guidance document on dermal absorption

Prof. Maroni informed the Committee that a special two-day meeting dedicated to the evaluation of this document is scheduled on 15 and 16 January. *Ad hoc* experts in dermal absorption have been invited to this special meeting. The working group will endeavour to finalise a draft opinion for a possible adoption at the SCP plenary meeting of 14 March.

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

The secretariat of the Committee introduced three new dossiers concerning the evaluation of active substances referred to the Committee and one request for opinion on two guidance documents.

6.1 Mesotrione

Mesotrione is a new active substance in the context of Directive 91/414/EEC. It has been referred to the Committee with the following two questions:

1. Can the Committee comment on the suitability of the rat as an animal model for the extrapolation of the toxicological properties of mesotrione in humans?

2. Can the onset of adverse effects in target organs (in animal models as well as humans) be linked to a certain threshold concentration of tyrosine in plasma? Can the Committee give an estimate of such a threshold concentration in humans?

Prof. Maroni informed the Committee that Prof. Galli has been appointed rapporteur for the two questions.

6.2 Indoxacarb

Indoxacarb is a new active substance in the context of Directive 91/414/EEC. It has been referred to the Committee with the following two questions:

1. Can the Committee comment on the NOEL for effects on red blood cells in rats?

2. The Committee is requested to comment on the adequate basis for the derivation of an Acute Reference Dose for indoxacarb.

Prof. Maroni informed the Committee that Dr. Moretto has been appointed rapporteur for the two questions.

6.3 Vinclozolin

Vinclozolin is an existing active substance in the context of Directive 91/414/EEC. The Committee has already been consulted twice on the evaluation of this active substance (Opinion of the SCP adopted 28 October 1999[4] related to reproductive toxicity of

[4] http://europa.eu.int/comm/food/fs/sc/scp/out52_en.html

vinclozolin and Opinion of the SCP adopted 20 March 2000[5] related to the risk assessment for birds and mammals).

The Committee is now requested to respond the following questions:

1. Does the Committee consider that the effects observed in the fish life cycle study with fathead minnow are of biological and ecological significance?

2. Can the Committee comment on the No Observed Effect Concentration (NOEC) suggested by the Rapporteur Member State (50 μg/L from the 28 day rainbow trout study) with regard to its validity to protect fish from effects on reproduction?

Prof. Hardy, chairman of the working group on environmental assessment, informed the Committee that Prof. Forbes has been appointed rapporteur for the two questions.

6.4 Draft guidance document on risk assessment of Birds and Mammals

The Commission drafted a Guidance document for the risk assessment for Birds and Mammals. The Committee's opinion is requested on the overall document.

In addition, the Committee is requested to respond three specific questions:

1. Are the generic indicator species and scenarios selected for the Tier 1 ecologically and agronomically relevant and protective, while at the same time their use will not trigger an excessive number of refined risk assessments?

2. Is the residue per unit dose for insects appropriate?

3. With regard to long-term risk from seed treatments to birds and mammals: Could there be more simple criteria identified, which might be applicable in Tier 1 to eliminate low risk substances? (e.g. NOEL (reproduction) > 1000 ppm, logPow < 3, and DT_{50} from seed < 4 days)?

Prof. Hardy informed the Committee that Dr. Hart, Mr Koepp and Dr. Sherratt have been appointed rapporteurs for the opinion.

6.5 Draft report on FOCUS surface water scenarios.

At the 29th plenary meeting 27 September 2001[6], Dr. Maier from DG Health and Consumer Protection informed the Committee that an opinion of the SCP on the draft report on FOCUS surface water scenarios will be requested and highlighted the urgency of the request. The request for an opinion was received on 14 December by the Secretariat.

Prof. Hardy informed the Committee that Dr. Carter has been appointed rapporteur for the opinion. The first exchange of views on the draft report is tabled at the working group

[5] http://europa.eu.int/comm/food/fs/sc/scp/out62_ppp_en.pdf
[6] Minutes of the 29th plenary meeting: http://europa.eu.int/comm/food/fs/sc/scp/out114_en.pdf

meeting of 9 January. The Committee will endeavour to adopt the opinion at the plenary meeting of March.

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)

The secretariat informed the Committee that the request for additional information was sent to the notifier which acknowledged receipt of the request and will shortly indicate the date for the delivery of the requested information.

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

Prof. Davies updated the Committee on the progress of the joint working group on GMOs, GM food and GM feed.

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

The draft report prepared by Prof. Davies was discussed. Following the exchange of view, Prof. Hardy chairman of the Committee agreed to revise the text for the following meeting.

9. Dates for 2002 SCP plenary meetings (January to July)

31 January, 14 March, 24 April, 13 June, 18 July.

10. Other Business

Date of the next meeting: 31 January