

Minutes of the fourth Meeting of the Scientific Committee on Plants, Brussels, 18-19 March 1998

ATTENDANCE LIST

Members

Dr. M.-P. DELCOUR-FIRQUET, Prof. H. V. DAVIES, Dr. R. HANS, Prof. A. R. HARDY , Prof. C. L. GALLI, Prof. S. O. KARENLAMPI, Dr. H. A. KUIPER, Dr. J. J. LEGUAY , Prof. M. MARONI (Vice-Chairman) , Dr. H. G. NOLTING, Prof. F O' GARA (Vice-Chairman) , Dr. E. RODRIGUEZ-CEREZO, Prof. A. M. S. SILVA FERNANDES (Chairman)

Apologies

Dr. M. CABOCHE, Prof. F. FUHR

Commission

Ms J. KIOUSSI (DG XI), Mr A. HOEVELER (DG XII), Mr M. LEX (DG XII), Mr K. DOEHLER (DG XI), Mr G. VAN DEN EEDE JCR), Mr C. EDMUNDS (DG VI)

Secretariat

Mr M. WALSH (DG XXIV/B/2), Mr T. DASKALEROS (DG XXIV/B/2), Ms S. VAN IMPE (DG XXIV/B/2)

1. Welcome, Apologies and Introductory Remarks

The Chairman welcomed the members to the meeting and noted the apologies (see attendance list).

2. Adoption of the agenda

The agenda was adopted. (Doc. SCP/AGENDA/004-Rev. 1)

3. Declaration of interests by Members

All members present confirmed that they had no conflict of interests to report relative to the items for discussion.

4. Matters arising from the minutes of the third Plenary Meeting (9/10 February 1998)

The draft minutes had been approved by written procedure prior to the meeting. The report is available as Document No. SCP/REPT/003-Final of 19 March 1998.

5. Plant Protection Products

5.1. Role of the SCP

At its third Plenary Meeting the Committee had sought clarification from the secretariat concerning the role envisaged by the Commission for the Committee in the plant protection product evaluation process. Following further clarifications from the Secretariat, the Committee concluded that, in order to utilise its resources effectively, account must be taken of the existing structures for plant protection product evaluation both at Member State and Community levels. The Committee felt that it could contribute most effectively by complementing and adding value to existing procedures and avoiding any duplication. Accordingly, the Committee decided to adopt the following working procedure for dealing with draft proposals for inclusion of active substances in Annex 1 to Directive 91/414/EEC and for other questions concerning plant protection product active substances:

- 1) Requirement that adequate data be made available to the Committee in an appropriate form in order to facilitate the discharge of its responsibilities;
- 2) In cases of specific questions addressed to the SCP, the Committee will issue an opinion addressing the question raised, subject to 4) below;
- 3) In cases of draft Annex 1 inclusion proposals which are not accompanied by specific question(s) to the SCP, agreement of the Committee will normally be indicated in the relevant Plenary Meeting report. Should the Committee disagree with a proposal, it will issue an opinion explaining its reasoning;
- 4) The Committee will act proactively and will therefore retain the right to draft or supplement questions and issue opinions accordingly.

5.2. Inclusion of azoxystrobin in Annex 1 to Directive 91/414/EEC

Azoxystrobin had been referred to the SCP without a specific question. The Committee was satisfied that it had been provided with adequate documentation comprising the complete dossier from the notifier Zeneca, the monograph prepared by the Rapporteur Member State (Germany) and the documentation from the Peer Review Meetings involving national experts of Member States and the draft proposal from the Commission services of DG VI for inclusion of the active substance in Annex 1 to Directive 91/414/EEC. The Committee reviewed the above mentioned documentation and agreed, in the context of the uses described, with the overall conclusions and the proposal for inclusion of the azoxystrobin in Annex 1 to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex 6 (Uniform Principles) of Directive 91/414/EEC.

The Committee made the following recommendations:

- a) that notifiers and Rapporteur Member States use a consistent system for the identification of metabolites throughout the documentation in order to facilitate transparency.
- b) that study summaries should clearly describe adverse effects when establishing No Observed Adverse Effect Levels (NOAELs).
- c) that documentation supplied to the Committee should include details of updated agricultural practices.

5.3. Inclusion of kresoxim-methyl in Annex 1 to Directive 91/414/EEC

Kresoxim-methyl had been referred to the SCP without a specific question being addressed to the Committee. It was decided to prepare an opinion dealing with the carcinogenicity results in the rat and the soil leaching behaviour of metabolite 1. In the case of the latter point, the Committee sought clarification of the precise details of the proposed uses of the fungicide on cereals, pome fruit and grapes as outlined in the draft Review report.

A working group (WG) was appointed to report on the carcinogenicity of kresoxim-methyl, which will meet on 6 May 1998. The composition of the WG is as follows:

SCP Members: C. L. Galli (Chairman), M. Maroni, M.-P. Delcour, A. Silva Fernandes

Invited experts: Prof. R. Schulte-Hermann, Institut für Tumorbologie und Krebsforschung der Universität Wien;

Dr. G. Rice, International Agency for Research on Cancer (IARC), LYON;

Prof. J. Parry, University of Wales Swansea.

5.4. Inclusion of fenthion in Annex 1 to Directive 91/414/EEC

Mr Edmunds introduced the fenthion dossier on behalf of DG VI to the Committee. He referred to the outcome of the Peer Review meetings where the recommendation was for suspension of the active substance for use in plant protection product due principally to a very high and unacceptable risk to birds resulting from the aerial application, toxicity to aquatic organisms, questions regarding operator and dietary exposure and certain unresolved toxicological questions. He stated that following the evaluation of additional data it was now the intention to restrict the use of fenthion to bait applications involving spot treatment of trees where approximately 10% of one third of trees would be treated. This would be subject to the generation of certain named confirmatory studies by 31 December 2000. Mr Edmunds drew the Committee's attention to the following questions submitted by DG VI for opinion to the SCP:

- 1) Is it appropriate (and possible) to establish an ADI and an AOEL using the toxicological end point mutagenicity? If so, which safety factor should be used to ensure human and animal safety?
- 2) If not, is it correct to use the endpoint of plasma cholinesterase inhibition to establish the ADI and AOEL and which safety factor should be used to ensure human and animal safety?

Following a short exchange of views, the Committee decided to extend its evaluation to cover the overall toxicology of the active substance as it was felt that this was necessary to deal with the questions addressed to the Committee. In addition, having regard to the intrinsic properties of fenthion, it was decided to enlarge further the scope of its evaluation to cover also ecotoxicological and dietary residue aspects. The Committee appointed the following two WG for the evaluations:

- Ecotoxicology Working Group: Meeting Date 11 May 1998.
- WG Chairman: A. Hardy

- SCP Members: H. G. Nolting and A. Silva Fernandes
- Members - invited experts : H. Koepp and P. Vasseur
- Toxicology Working Group: Meeting Date 7 May 1998.
- WG Chairman: M. Maroni
- Members C. L. Galli, M.-P. Delcour and R. Hans

5.5. Inclusion of fenarimol in Annex 1 to Directive 91/414/EEC

Mr Edmunds introduced the fenarimol dossier and explained the basis of the questions DG VI would like to address to the Committee for its opinion. The questions were as follows:

- 1) How does the Scientific Committee for Plants interpret the multi-generation studies conducted in guinea pigs and rat and in particular could the aromatase inhibition of fenarimol have effects which might have been overlooked in the evaluation conducted by the Rapporteur Member State?
- 2) Do the toxicological studies submitted for this active substance permit a reliable ADI and AOEL to be established. If they do - what ADI and AOEL is recommended by the Committee?

It was decided to create a working group comprising M. Maroni (Chairman), C. L. Galli, M.-P. Delcour with relevant invited experts to be agreed with the SCP Chairman.

5.6. Inclusion of isoxaflutole in Annex 1 to Directive 91/414/EEC

Mr Edmunds introduced the isoxaflutole dossier and outlined the following questions to the Committee:

- 1) Relevance of metabolite RPA 203328
- 2) Consideration of the statistical analysis of the tumour incidence in the 2 year rat study
- 3) Foetal effects in relation to classification of the active substance.

The Committee decided to refer the carcinogenicity and reproductive questions to the specialist groups already agreed for kresoxim-methyl and fenarimol respectively. It was also decided to enlarge the scope of the environmental evaluation to include aquatic ecotoxicological in addition to the fate aspects raised by DG VI - the WG composition will be as for fenthion and will meet on 11 May 1998.

5.7. Data Requirements for micro-organisms to be used in and as plant protection products pursuant to Directive 91/414/EEC.

The Secretary reported that he had contacted the three invited experts to support the Committee in respect of this work. The WG will have the following composition:

WG Chairman	F. O'Gara
SCP Members	M.-P. Delcour, F. Führ, A. Hardy

Invited Experts	Dr. Claude Alabouvette, Professor Geneviève Defago, Professor Marco P. Nuti.
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A suitable date for a first meeting of the working group will be shortly agreed with members.

6. Progress report on addressing the documents from the European Environmental Bureau on:

- Arguments for the Exclusion from Annex 1 of Directive 91/414/EEC of pesticides presently being revised

- Pesticides and Cancer Survey of Epidemiological studies

The Committee decided that it would not be efficient to deal with the many unsubstantiated points mentioned in the document. It decided to examine the points raised with respect to imazalil which was the first plant protection product active substance included in Annex 1 to Directive 91/414/EEC. It would likewise systematically review the points for other active substances as they are referred to the Committee for opinion.

It requested the Secretariat to obtain the documentation on imazalil and circulate it to members.

- Pesticides and Cancer Survey of Epidemiological studies

The Committee discussed the possible means of addressing this document. It was very conscious of the time implications which would be involved in the preparation of a detailed response, particularly having regard to the Committee's heavy work-schedule. It was decided to raise the question again at the meeting of specialist carcinogenicity experts on 6 May in order to investigate further a possible efficient means for dealing with the question.

7. Genetically Modified Organisms - Plants

Pioneer insect-resistant (Bt) Maize line MON 809	Notification C/F/95/12/01/B
PGS glufosinate-tolerant male sterile swede rape	Notification C/BE/96/01
AgrEvo glufosinate-tolerant swede rape	Notification C/DE/96/05

The meeting had been preceded by a preparatory meeting chaired by F. O'Gara on 11 March 1998 when the following members were present: H. Davies, A. Hardy, S. Karenlampi, H. Kuiper, J-J. Leguay, F. O'Gara, E. Rodriguez-Cerezo, L.-A. Aumaitre, P. Vasseur, M. Vighi, H. Koepf, R. Hans. The WG sought in writing a number of clarifications from the notifiers which were circulated to members during the meeting. The responses were discussed and members will further study them before finalising the three opinions. The following timetable was agreed:

Agreed Deadlines	Agreed Dates
Receipt of requests by secretariat for further clarifications from notifiers	1 April 1998

Draft text contributions to co-ordinators	17 April 1998
Draft opinions for circulation to Members	7 May 1998
Plant GMO WG	12 May 1998
Joint SCP Plenary and Plant GMO WG	19 May 1998
Intended date for adoption of opinions	

Ms J. Kioussi of DG XXIV informed the Committee that the draft resistance management programme would be submitted by 20 April to the Committee for opinion. The document will be examined at the Plant GMO WG, which will meet on 12 May - two representatives from the WG of national experts who prepared the document will present it to the SCP WG. The Committee agreed to give its opinion at its May Plenary Meeting.

Ms J. Kioussi also introduced the following six new dossiers for evaluation by the Committee:

- 1) Fodder beet tolerant to glyphosate notified by DFL-Trifolium, Monsanto and Danisco and forwarded by Denmark.
- 2) Potato with a change in starch composition notified by AVEBE and forwarded by the Netherlands.
- 3) Tomato with reduced activity of the expression of the endogenous tomato fruit PG gene notified by Zeneca and forwarded by Spain.
- 4) Cotton expressing the Bt cry IA(c) gene notified by Monsanto and forwarded by Spain.
- 5) Cotton tolerant to glyphosate notified by Monsanto and forwarded by Spain.
- 6) Male sterile chicory notified by Bejo-Zaden and forwarded by the Netherlands.

It was decided to maintain its normal work practice and created four multi-disciplinary sub-groups with the following membership:

Biotechnology	Fodder Beet - F O'Gara, Tomato - S. Karenlampi 2 Cottons - J.J Leguay Potato - H. Davies Chicory - E. Rodriguez.	Members also to act as co-ordinators for their respective GMOs
Toxicology & Residues	H. Kuiper (Team Leader) R. Hans, H.-G. Nolting, and C.L Galli	
Environment	A. Hardy (Team Leader), H. Koeppe and P. Vasseur	
Food & Feed	B. Moseley, A.Chesson, A. Von Wright and L.-A. Aumaitre	

The Committee decided that preliminary drafts should reach the Secretariat by 8 May for a first exchange of views at the meeting of 19 May with the intention that opinions, with the exception of the potato opinion, should be adopted at the June SCP Plenary Meeting: the potato opinion should be adopted at the July SCP Plenary meeting.

M. M. Lex (DG XII-E-1) indicated that successive Biotechnology Research Programmes since 1986 had supported Prenormative Research on Biosafety aspects of GMOs. Some 25 MECU of funding had been provided to more than 150 laboratories in this area. The research results had been published by the Commission and these reports would be mailed to Committee members together with the Proceedings of several international Symposia.

8. Committee Rules and Procedures

Time did not permit an exchange of views on this item: it will be included on the agenda of the next meeting.

9. Other business

The next Plenary Meeting was confirmed for 18/19 May 1998.