Minutes of the Sixteenth Meeting of the Scientific Committee on Plants - Brussels, 28 October 1999

ATTENDANCE LIST

Members

Prof. H.V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Dr. R. HANS, 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), Prof. E. RODRIGUEZ-CEREZO, Dr. G. SPEIJERS

Apologies

Prof. A.R. HARDY (Chairman), Prof. A.M.S. SILVA FERNANDES

Invited Experts

Mr. H. KOEPP, Dr. O. MEYER

Secretariat

Mr M. WALSH, Ms S. VAN IMPE, Health and Consumer Protection, B2

1. Welcome, Apologies and Introductory Remarks

In the absence of the Chairman, Vice-Chairman Professor F. O' Gara opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted. (Doc. SCP/AGENDA/016-Rev. 2)

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. Adoption of the minutes of the Fifteenth Plenary Meeting and matters arising (24 September 1999)

4.1 Adoption of the minutes of the Fifteenth Plenary Meeting

The <u>draft minutes</u> were approved.

5. Exchange of views on and possible adoption of the draft residue opinion on chronic risk assessment

The Rapporteur R. Hans reminded the Committee of the context of the draft report by drawing attention to the terms of reference it has established at its third plenary meeting. She outlined the content of the report which had been prepared with the help of the Residue WG.

Following an exchange of views the Committee decided to defer adoption of the report pending a widening of the terms of reference of the opinion to include a greater emphasis on the dietary data to be used in dietary risk assessments and the nature of the risk involved (chronic, semi-chronic, acute). The Committee was of the opinion that the Scientific Committee for Food should be associated with such an opinion and that the matter should be raised in the Scientific Steering Committee considering the multi-disciplinary nature of the task.

6. Endocrine disruption - Adequacy of current testing of plant protection products in the context of Directive 91/414/EEC

Exchange of views on the draft opinion prepared following the WG meeting of 7 October 1999

M. Maroni reported on the outcome of the WG meeting which had been attended by SCP members M. Maroni (Chairman), H. Kuiper, M.-P. Delcour, and invited experts O. Meyer, G. Joermann and H. Koeter. Following an exchange of views the Committee agreed the thrust of the draft opinion and requested the Rapporteur to lightly amend the text in preparation for adoption at the next Plenary meeting in December.

7. Progress report on the following plant protection products dossiers referred to the Scientific Committee on Plants

7.1 Vinclozolin

The Committee adopted the report on the reproductive effects of vinclozolin which is available as document SCP/VINCLO/019-Final

Supplementary questions - Ecotoxicological aspects

H. Koepp reported on the discussions which had taken place in the Environmental Assessment WG on 27 October. He informed the meeting that the WG would examine the first drafts at its meeting scheduled for 8 December and that the draft opinion would be ready for consideration by the Plenary Meeting of 28 January.

7.2 *Lambda*-cyhalothrin

M. Maroni agreed to prepare a short report on the common question regarding the appropriate dietary risk assessment to be applied to each of the pyrethroids. This will deal with which active substances require an acute risk assessment and the relevant studies and toxicological endpoints for derivation of an acute reference dose (ArfD). R. Hans agreed to amend the draft opinion to reflect the agreed approach.

The Secretariat reported that the WG to deal with the bridging studies required to extrapolate from unresolved isomeric mix to a resolved isomer active substance will take place 25 November.

H. Koepp reported on progress in the Environmental WG which had met on 27 October. He informed the Committee that the WG had difficulty in reconciling the requirements of the Uniform Principles of Directive 91/414/EEC with regard to beneficial arthropods and the

subsequent population recovery ability. Furthermore he noted that the WG felt it necessary to address in the opinion major factors influencing arthropod population recovery, and if/how they could be applied in risk mitigation.

7.3 Esfenvalerate

The same dietary issue risk assessment issue reported above for lambda-cyhalothrin also applies to esfenvalerate as well as the issue of bridging.

- M. Maroni reported that the carcinogenicity WG would be convened on 16 December. He also reported that the mechanistic study for the testicular tumours had been submitted since the last Plenary Meeting but that it does not establish a mechanism.
- M. Maroni reported on progress with the draft opinion on skin absorption.
- H. Koepp reported that progress on environmental evaluations was as for lambda-cyhalothrin and these will be further considered at the Environmental WG meeting of 8 December

7.4 Cyfluthrin

Dietary risk assessment as for other pyrethroids.

Resolution of bridging study issue as for other pyrethroids.

H. Koepp reported that progress on environmental evaluations was as for lambda-cyhalothrin and these will be further considered at the Environmental WG meeting of 8 December.

7.5 Beta-cyfluthrin

As for cyfluthrin.

7.6 Bentazone

H.-G. Nolting gave a progress report on the preparation of the opinion. Following an exchange of views it was decided to review the conclusions of the environmental fate part of the opinion. The draft opinion will be submitted to the December Plenary for adoption.

7.7 Diquat

H. Koepp reported on progress with questions 1, 2 and 3 dealing respectively with bird reproduction, persistence in soil and aquatic uses. He reported that these parts of the opinion have been completed. M. Maroni reported on progress with the question concerning operator exposure arising from non-professional uses and indicated that a quantitative risk assessment was difficult due to the absence of a suitable model but he agreed to finalise the opinion on the basis of available data. R. Hans reported that insufficient data were available to permit the performance of a dietary risk assessment. The Secretariat undertook to investigate the availability of additional data.

7.8 Metsulfuron

H. Koepp reported that the Environmental Assessment WG held its first exchange of views at its meeting of 27 October. The WG is awaiting the availability of new studies on soil metabolites which was originally foreseen for November 1999.

7.9 Triasulfuron

No progress to report since referral of the dossier to Committee at the fourteenth plenary meeting.

7.10 Flupyrsulfuron

No progress to report since referral of the dossier to Committee at the fourteenth plenary meeting.

8. Progress report and exchange of views on Genetically Modified Organisms dossiers

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

The GMO WG had examined the dossier in detail at its meeting held on 27 October 1999. H Davies reported on the outcome of the meeting. The Committee supported the proposal from the WG to request the notifier to supply firm evidence rather than a statement of opinion that a particular gene would not express itself at the protein/polypeptide level in the modified plant.

8.2 Oilseed rape from Hoechst Schering AgrEvo GmbH with tolerance to glufosinate ammonium (Notification C/DE/98/06)

J J Leguay reported on the examination carried out in the WG on 27 October. Following an exchange of views the Committee agreed to seek clarifications from the notifier with respect to the genetic characterisation of the modification, toxicology, substantial equivalence and environmental aspects.

8.3 Genetically modified insect tolerant (Bt-11) maize from Novartis Seeds SA (Notification C/F/96/05-10)

The dossier had not been circulated to Members. The Committee appointed H. Davies as the lead rapporteur.

8.4 Conventionally derived crosses between approved genetically modified maize lines t25 and MON810 from Pioneer Overseas Corp. (Notification C/NL/98/08)

The Committee examined the first drafts and decided to seek clarifications from the notifier regarding the genetic construct and on the submitted substantial equivalence data. The Committee will resume its examination on receipt of the necessary data.

8.5 Genetically modified maize (*Zea mays*) line GA21 from Monsanto, with tolerance to glyphosate herbicide (Reference C/ES/98/01).

The Commission referred the following question to the Committee:

"The relevant Scientific Committees are asked to consider whether there is any reason to believe that the placing on the market of the maize, for use as any other maize, is likely to cause any adverse effects on human health and the environment within the scope of Directive 90/220/EEC"

The Committee was informed that the dossier would be circulated in due course to members.

The Committee decided to appoint F. O' Gara as rapporteur for biotechnology aspect and overall co-ordinator of the dossier.

9. Other business

Date of next meeting:

The next meeting of the Committee will take place on 2 December 1999.