

Minutes of the fourteenth meeting of the Scientific Committee on Plants - Brussels, 16 July 1999

ATTENDANCE LIST

Members

Dr. R. HANS, Prof. S. O. KARENLAMPI, Dr. H. A. KUIPER, Prof. M. MARONI (Vice-Chairman) Prof. E. RODRIGUEZ-CEREZO, Prof. A. M. S. SILVA FERNANDES

Apologies

Prof. H. V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Prof. A. R. HARDY (Chairman), Dr. J. J. LEGUAY, Dr. H. G. NOLTING, Prof. F O' GARA (Vice-Chairman)

Invited Experts

Mr. H. KOEPP, Dr. G. SPEIJERS, Dr. O. MEYER

Commission

Mr L. SMEETS (DG VI/B/2.1)

Secretariat

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

1. Welcome, Apologies and Introductory Remarks

In the absence of the Chairman, Vice-Chairman Professor M. Maroni chaired the meeting.

2. Adoption of the agenda

The agenda was adopted. (Doc. SCP/AGENDA/014-Rev. 4)

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 Thirteenth Plenary Meeting and matters arising (18 May 1999)

4.1 Adoption of the minutes of the Thirteenth Plenary Meeting

The draft minutes were approved with some minor textual amendments. The report is available as [Document No. SCP/REPT/013-Final](#) of July 16, 1999.

5. Exchange of views and possible adoption on the draft opinion on the relationship between the elimination or severe reduction in the use of plant protection products and the presence of mycotoxins

The Committee considered the draft opinion which had been prepared by the WG which met on 29 June with the following membership: A. Hardy (Chairman), SCP members R. Hans and A. Silva Fernandes and invited experts D. Richard-Molard and M. Thomas. Following an exchange of views the Committee decided that the following points should be included:

- a) A short overview in the introduction on the toxicity of mycotoxins explaining the problems posed by these compounds;
- b) The conclusion needs to reflect the complexity of the relationship between plants and mycotoxin producing fungus;
- d) A more detailed explanation of the action of fungicides on fungi;
- e) A fuller explanation of the possible reasons for the differences between the results from field and laboratory studies on the effects of fungicides on mycotoxin production.
- f) Recommendations need to reflect the amended text.

It was agreed that G. Speijers would prepare the revised draft opinion for adoption at the next Plenary Meeting.

6. Exchange of views and possible adoption of opinions on draft guidance documents in the framework of the Directive 91/414/EEC

- Draft Guidance Document on Aquatic Ecotoxicology

- Draft Guidance Document on Terrestrial Ecotoxicology

- Draft Guidance Document on Persistence in soil

The Committee received a progress report from H. Koepp. He reported that the Environmental WG had met on 28 June and was attended by A. Hardy (Chairman), SCP members A. Silva Fernandes, H.G. Nolting, and invited experts H. Koepp, J. Boesten, A. Carter, V. Forbes and T. Sherratt. The WG had finalised its work on the aquatic and terrestrial documents but was still working on the persistence document. The Committee decided that considering the close relationship between the three opinions it was appropriate to wait until the September Plenary in order to consider the three opinions together.

7. Exchange of views on the guidance document for deriving acute reference doses (ArfDs)

The Chairman in his introduction reminded the Committee that it had previously identified dietary acute risk assessment as a priority area. In this context it had been decided to organise a WG on 11 May 1999 to examine progress in this area and to prepare an internal guidance document to facilitate future work of the Committee. The membership of the WG was R. Hans and M. Maroni (Joint Chairpersons) and SCP Members A. Silva Fernandes, M.-P. Delcour, G. Speijers and invited experts I. Dewhurst, C. Harris, Moretto, O. Meyer.

The Committee exchanged views on the document and agreed that it represented an up-to-date record of the state of the art for deriving acute reference doses. It decided not to devote further resources at this time to develop the document further to cover effects other than cholinesterase inhibition as other possible effects had to be treated on a case-by-case basis.

The Committee acknowledged the work of Drs I. Dewhurst and A. Moretto for preparing the document.

8. Exchange of views with particular reference to PPPs on the opinion adopted by the Scientific Committee on Toxicity, Ecotoxicity and the Environment on human and wildlife health effects of endocrine disrupting chemicals, with emphasis on wildlife and on ecotoxicology test methods, March 1999

The Chairman explained that the Committee had identified endocrine disruption as an area of priority for the SCP and had nominated M. Maroni and H. Kuiper to follow developments in the area. Following publication by the Scientific Committee on Toxicity, Ecotoxicity and the Environment of its opinion of endocrine disrupting chemicals, it was felt timely to use this opinion as a basis for a more in depth examination of these effects for plant protection products.

The Committee established an ad hoc WG and nominated the following members: M. Maroni (Chairman), M.-P. Delcour, H. Kuiper, O. Meyer and H. Koepp. The Committee also decided to invite a representative from OECD to participate at the first meeting of the WG which will take place on 7 October 1999.

9. Exchange of views on the Scientific Steering Committee (SSC) opinion on antimicrobial resistance adopted on 28 May 1999, with particular reference for its implications for GMOs and PPPs

S. Karenlampi who had been the SCP's representative on the SSC's antimicrobial WG outlined the content of the opinion with respect to marker genes use in genetic modifications and the use of antimicrobials as plant protection products. She pointed out that the opinion with respect to the use of marker genes coincided with the views the SCP had repeatedly expressed while she noted that the use of antimicrobials as plant protection products is low in Member States in comparison with use elsewhere.

The Committee noted the opinion and expressed its thanks to Professor Karenlampi for her work in the WG. It was also decided that the SCP did not consider it necessary to recommend any further action for the present.

10. Referral of questions to the Scientific Committee on Plants on the following plant protection products

The following questions were referred by the Commission services to the Committee:

10.1 Vinclozolin

- 1) Is there enough scientific evidence to support the assumption that reproductive effects observed in rats would not occur at significantly lower doses in humans i.e. that humans might be significantly more sensitive? In this respect the Committee is requested to comment particularly on the possible increased sensitivity of infants and children to these effects.
- 2) Are the reproductive effects of vinclozolin mediated via an acute or (sub-)chronic exposure response?

10.2 Lambda-cyhalothrin

- 1) Can the Committee comment on the appropriate dietary risk assessment to be used?
- 2) Can it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?
- 3) Can it be confirmed that the proposed risk mitigation measures are adequate to protect non-target arthropods and honey bees?

10.3 Esfenvalerate

- 1) The Committee is requested to comment on the relevance for man of the results from the two-year carcinogenic study in rats.
- 2) Does the available information on dermal absorption allow a reliable estimate to be made for man, if so, at what level?
- 3) Can the Committee comment on the appropriate dietary risk assessment to be used?
- 4) Can it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?
- 5) Can it be confirmed that the proposed risk mitigation measures are adequate to protect non-target arthropods and honey bees?

10.4 Cyfluthrin

- 1) Can the Committee comment on the appropriate dietary risk assessment to be used?
- 2) Can the Scientific Committee on Plants confirm that the available ecotoxicological data supports uses only in glasshouses and for seed treatment?

10.5 Beta-cyfluthrin

- 1) Can the Committee comment on the appropriate dietary risk assessment to be used?
- 2) Can the Scientific Committee on Plants confirm that the available ecotoxicological data supports uses only in glasshouses and for seed treatment?

10.6 Bentazone

- 1) Can the Committee comment on the assessment of the rapporteur MS on storage stability of crop samples and confirm the acceptability of the consumer dietary risk assessment?
- 2) Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?

10.7 Diquat

- 1) Can the Committee comment on the effects on bird reproduction and confirm the NOEC of 25 ppm?
- 2) Considering the slow degradation of diquat in the soil, can the Committee comment on the potential long-term effects of its use and the adequacy of the available data.
- 3) Can the Committee comment on the ecotoxicological acceptability of the aquatic uses?
- 4) Can the Committee comment on the acceptability of the operator exposure for amateur uses?

- 5) The Committee is requested to comment on the acceptability of the desiccant uses from the point of view of dietary exposure.

10.8 Metsulfuron

- 1) Can it be confirmed that the uses reviewed are acceptable for the aquatic environment?
- 2) Can it be confirmed that under the conditions investigated the substance poses no risk of groundwater contamination?
- 3) Can it be confirmed that no unacceptable impact is to be expected on non-target plants?

10.9 Triasulfuron

- 1) Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?
- 2) Can the Committee comment on the relevant metabolites for water and confirm that no unacceptable impact is to be expected for the uses reviewed on non-target aquatic organisms.

11. Progress report and exchange of views on plant GMO dossier

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

The Secretariat reported that the notifier had not yet responded to the clarifications sought by the Committee at the May Plenary Meeting.

12. Guidance document to facilitate notifiers in the preparation of Plant GMO Dossiers for consideration by the SCP

Exchange of views on the comments received from interested parties

The WG on GMOs had examined on the 17th July the responses received with respect to SCP's guidance document. The WG noted with interest the comments received but decided not to enter into a dialogue at this time given the ongoing negotiations on revising Directive 90/220/EEC including the provisions covering risk assessment.

13. Exchange of views on the request from Member-State Austria invoking Article 16 (Safeguard clause) of Council Directive 90/220/EEC with regard to the Monsanto genetically modified maize (MON 810) expressing the Bt *cryIA(b)* gene - Notification C/F/95/12-02

The Committee considered the potential activity of genetically modified Bt-maize against Monarch butterflies and other lepidopterans under European conditions. Following a first exchange of views on the matter, the Committee agreed to continue its evaluation of the submitted data and to consult extensively with other scientists working in the area. It is the intention of the Committee to express an opinion at its next Plenary Meeting scheduled for 24 September 1999.

14. Progress report and exchange of views on the guidance documents relating to Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms

14.1 Draft criteria for establishing whether a genetically modified micro-organism (GMM) is safe for human health and the environment and would be suitable for inclusion into Annex IIC of Directive 90/219/EEC (amended)

14.2 Draft guidance on the criteria to be investigated to determine whether a genetically modified micro-organism is suitable for inclusion in Annex IIC

14.3 Draft guidance for risk assessment outlined in Annex III of the proposed amendment to Directive 90/219/EEC on the contained use of genetically modified micro-organisms COM(95)640

The Committee considered the draft opinion submitted by the WG which had met on 10 May and comprised the following members: F. O'Gara (Chairman), A. von Wright (SCAN Member) and invited experts Drs A. Ledebøer, D. Stead and Professor M. Nuti.

Following an exchange of views the Committee decided to postpone adopting the draft opinion to allow further time for its consideration. Members agreed to submit their observations in writing to the Chairman of the WG.

15. Other business

Date of next meeting:

The next meeting of the Committee will take place on 24 September 1999.