

Minutes of the thirteenth meeting of the Scientific Committee on Plants - Brussels - 18 May 1999

ATTENDANCE LIST

Members

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

Apologies

Dr. H.A. KUIPER, Prof. F O' GARA, (Vice-Chairman)

Invited Experts

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

Commission

Mr W. MAIER (DG VI/B/2.1), Mr K. TYRKKO (DG XI/E/2), Mrs M. DE SOLA (DG XXIV/B/2)

Secretariat

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

1. Welcome, Apologies and Introductory Remarks

The Chairman opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted (Doc. SCP/AGENDA/013-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 Twelfth Plenary Meeting and matters arising (4 March 1999)

4.1 Adoption of the minutes of the Twelfth Plenary Meeting

The draft minutes were approved with some minor textual amendments. The report is available as Document No. SCP/REPT/012-Final of May 18, 1999.

5. Exchange of views on the draft opinion on the relationship between the elimination or strong reduction in the use of plant protection products in the

cultivation of fruits and vegetables and the presence of mycotoxins and heavy metals

A. Hardy reported on the WG meeting which had taken place on 15 April '99 with the following membership: SCP members A. Hardy (Chairman), A. Silva Fernandes, SCF member A. Carere and invited experts D. Richard-Molard, G. Speijers and M. Thomas (apologies for absence from M.-P Delcour-Firquet, R. Hans and H. Kuiper). He reported that the structure and the content of the opinions were agreed and the section rapporteurs appointed. A further WG meeting has been scheduled for 29 June '99 to consider the draft opinion. The intention is to submit the draft opinion for adoption to the SCP Plenary of 16 July '99.

6. Plant Protection Products - active substances

Fluroxypyr, isoxaflutole and fenarimol

Status report and exchange of views on the active substance:

6.1 Fluroxypyr (Doc. SCP/FLUROX/001-Final)

The Committee adopted its opinion.

In the opinion, the Committee confirmed the conclusion of the peer-review organised by the Commission services (Directorate General for Agriculture - DGVI) that the use of fluroxypyr in autumn is not supported by the available data. The Committee also concluded that the environmental safety of two metabolites had not been completely addressed.

The opinion is available on the Internet at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out41_en.pdf

6.2 Isoxaflutole (Doc. SCP/ISOXA/012-Final)

The Committee adopted its opinion.

In the opinion, the Committee concluded that the environmental metabolites would be unlikely to pose an unacceptable risk for man. With regard to the significance of the metabolites for the environment, the Committee concluded that one of the metabolites represents a risk for contamination of ground water but it was considered acceptable, as it does not pose an unacceptable ecotoxicological risk. The Committee also identified two metabolites that are of agronomic significance due to their phytotoxicity.

In response to a question from the Commission on carcinogenic effects in rats, the Committee did not accept the statistical evaluation of the notifier and changed the NOEL from 2.0 mg/kg to 0.5 mg/kg. It reviewed the significance of these effects for man and concluded that at doses near or below the no effect levels (NOELs), both the thyroid and liver tumours have no relevance for man.

The Committee also reported the data on development effects do not raise a concern for man notwithstanding the proposed category 3 classification of the compound for development effects.

The opinion is available on the Internet as:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out40_en.pdf

6.3 Fenarimol (Doc SCP/FENARI/005-Final)

The Committee adopted its opinion and concluded as follows:

The effects of fenarimol on male fertility seen in rats had to be considered relevant for human risk assessment although man is less sensitive than rats to the effects of aromatase inhibition by fenarimol.

The effects of fenarimol on parturition in rats could be considered as not relevant for human risk assessment. It was further concluded that, apart from male-mediated reduced fertility and effects associated with delayed parturition, there was no convincing evidence for other adverse reproductive effects associated with aromatase inhibition by fenarimol.

The toxicological studies submitted for fenarimol permit to establish a reliable ADI and AOEL ¹. The SCP agrees with the proposed ADI ² of 0.01 mg/kg bw and suggests to adopt an AOEL of 0.02 mg/kg bw.

The opinion is available on the Internet at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out42_en.pdf

7. Status report and exchange of views on the preparation of an opinion on draft guidance document in the framework of the Directive 91/414/EEC

7.1 Draft Guidance Document on Aquatic Ecotoxicology

7.2 Draft Guidance Document on Terrestrial Ecotoxicology

7.3 Draft Guidance Document on Persistence in soil

A. Hardy reported on the WG meeting which had taken place on 17 May '99 with the following membership: SCP members A. Hardy (Chairman), A. Silva Fernandes, H.-G. Nolting and invited experts J. Boesten, H. Koepp, and T. Sherratt (apologies for absence A. Carter). He reported that the WG had reviewed the work prepared by the rapporteurs on documents 7.1 & 7.2 and that the WG agreed on the format for the opinions.

A further WG meeting had been scheduled for 28 June '99 to consider the three draft opinions. The intention is to submit the draft opinions for adoption to the SCP Plenary of 16 July '99.

8. Progress report and exchange of views on plant GMO dossier:

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

The Committee had received a reply from the notifier shortly before the meeting in response to the clarifications it sought from the notifier during the eleventh Plenary Meeting (4 February 1999). It was satisfied with the new information supplied by the notified but decided

that the reply raised several other minor questions that required clarification. The Committee will finalise its opinion when the clarifications are received and examined.

9. Exchange of views and possible adoption of an opinion on the requests from Member-States invoking Article 16 (Safeguard Clause) of Council Directive 90/220/EEC

9.1 Greece's decision with respect to the genetically modified oilseed rape notification C/UK/95/M5/1 (AgrEvo).

The Committee adopted its opinion and concluded as follows:

The additional data submitted by Greece did not justify the case that an unacceptable risk would arise from the importation for processing of AgrEvo herbicide tolerant (glufosinate ammonium) rape seed due to its possible crossing with related wild species. The Committee also rejected possible health implications arising from the consumption of certain related wild species should they be pollinated by escaped modified rape plants.

The opinion is available on the Internet at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out36_en.pdf

9.2 France's decision with respect to the genetically modified oilseed rape notification C/UK/95/M5/1 (AgrEvo)

The Committee adopted its opinion and concluded as follows:

The additional data submitted by France did not justify the case that an unacceptable risk would arise from the importation for processing of AgrEvo herbicide tolerant (glufosinate ammonium) rape seed due to its possible crossing with related wild species.

The opinion is available on the Internet at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out37_en.pdf

9.3 France's decision with respect to the genetically modified oilseed rape notification C/UK/94/M1/1 (PGS)

The Committee adopted its opinion and concluded as follows:

The additional data submitted by France did not justify the case that an unacceptable risk would arise from the cultivation of Plant Genetic Systems' (PGS) herbicide tolerant (glufosinate ammonium) rape seed due to its possible crossing with related wild species.

The opinion is available on the Internet at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out38_en.pdf

10. 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

10.1 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) (Doc.: XI/366/97-Rev. 4)

10.2 Draft guidance on the criteria to be investigated to determine whether a genetically modified micro-organism is suitable for inclusion in Annex IIC (Doc.: XI/367/97-Rev.4)

10.3 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 (Doc.: XI/368/97-Rev. 4)

F O' Gara, Chairman of the WG on genetically modified micro-organisms (GMMs) informed the Committee of the progress made at the WG meeting of 8 April '99. He confirmed that the draft opinion would be available for adoption at the July Plenary Meeting.

11. Other business

Date of next meeting:

The next meeting of the Committee will take place on 16 July 1999.

¹ Acceptable Operator Exposure Level

² Acceptable Daily Intake