

Minutes of the eleventh meeting of the SCP, Brussels, 4 February 1999

ATTENDANCE LIST

Members

Prof. H. V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Prof. A. R. HARDY (Chairman), 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

Apologies

Dr. R. HANS

Invited Experts

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

Commission

Mr C. EDMUNDS (DG VI/B/2.1), Mr V. MATZEIT (DG XI/E/2), Mrs M. LJUNGSTROM (DG XI/E/2), Mrs M. DE SOLA (DG XXIV/B/2), Mr G. VAN DEN EEDE (JCR)

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

(Doc. SCP/AGENDA/011-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. Adoption of the minutes of the Tenth Plenary Meeting and matters arising (18 December 1998)

4.1 Adoption of the minutes of the Tenth Plenary Meeting

The draft minutes were approved with some minor textual amendments. The report is available as Document No. SCP/REPT/010-Final of February 4, 1998.

4.2 Matters arising.

The Chairman informed the Committee that he had drawn the attention of the Scientific Steering Committee (SSC) to the SCP's GMO Guidance document. The SSC felt that the document represented a valuable contribution to transparency of the SCP's work on plant GMs. The Committee reiterated its wish for receipt of feedback on the document.

5. Adoption of 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

G. Speijers introduced his draft opinion to the Committee. It dealt with the relationship between severe reduction in the use of plant protection products and the levels of mycotoxins and inherent toxicants. It also dealt to a lesser extent with the possible increase in uptake of heavy metals by plants.

Following an exchange of views, Dr. Speijers agreed to review his draft opinion in the light of written comments from members. The Committee will review further the draft opinion at its next meeting on the 4th of March. Adoption of the opinion is planned for the May Plenary Meeting of the Committee.

6. Plant Protection Products - active substances

Azimsulfuron, isoxaflutole, fenarimol

6.1 Azimsulfuron

Following a short exchange of views the Committee adopted its opinion, which is available as Document SCP/AZIM/001-Final.

6.2 Isoxaflutole

- Development effects - the Committee decided that, in addition to the developmental studies in rats and rabbits, which it had already reviewed, it should also review the 2-generation study in rats in order to respond fully to the question it had been addressed. O. Meyer agreed to review the study and report back to the next meeting.

- Relevance of metabolites - this section was agreed.

- Carcinogenicity - report from rapporteur still pending.

6.3 Fenarimol

The secretariat reported that the rapporteur will submit his report for consideration at the next Plenary meeting.

7. Progress report and exchange of views on plant GMO dossiers:

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

F. O' Gara, the Chairman of the Plant GM WG reported on the outcome of the meeting of 3 February. Before finalising its opinion the Committee decided to seek clarifications from the notifier on the following points:

- Molecular biology of the GM plant;
- By-products;
- Toxicity testing;
- Substantial equivalence;
- Non-target organism testing.

7.2 Herbicide tolerant and Bt resistant maize by Dekalb (Notification C/NL/97/17).

The meeting also received a report on the outcome of the previous day's WG discussions. It was also decided to seek a number of clarifications from the notifier which were on the following points:

- Molecular biology of the GM plant;
- Substantial equivalence.

8. Requests from Member-States invoking Article 16 (Safeguard clause) of Council Directive 90/220/EEC:

First exchange of views on:

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

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

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

The Committee had received immediately prior to the meeting requests for opinions on the scientific justification contained in three above-mentioned invocations of the safeguard clause of Directive 90/220/EEC.

The Committee had a first exchange of views and requested A. Hardy and H. Koepf to prepare draft opinions.

9. Examination and possible adoption of the opinion on the draft protocol for the monitoring of European corn borer resistance to Bt.

A. Hardy presented the draft opinion which he had prepared following the meeting of the WG comprising invited experts R. Albajes, N. Birch, D. Bourguet, R. Cannon, G. C. Lozzia, G. Riba and T. Sherratt, which he chaired on 13 January 1999. He stressed the clear difference in the situation in Europe compared to the US in terms of the area of the Bt modified grown. He also drew attention to the need for further research to be carried out in the Community. Following an exchange of views, it was agreed that members should submit their comments in writing in order to facilitate preparation of the final draft.

10. First exchange of views on 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)

The Commission had referred the three above-mentioned draft guideline documents to the Committee, which concerned Directive 90/219/EEC on the contained use of genetically modified micro-organisms. The documents concerned the classification of micro-organisms, environment risk assessment, microbial ecology, gene transfer and toxicology. F. O' Gara agreed to chair the WG, which would be responsible for preparing the draft opinions.

11. Other Business

Date of next meeting:

The next meeting of the Committee will take place on 4 March 1999.