

Minutes of the ninth meeting of the SCP, Brussels, 10 November 1998

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. 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

Invited

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

Commission

Mr C. EDMUNDS (DG VI/B/2.1), Mr D. BOSWORTH (DG XI/E/2) , Mr Ch. DECKART (DG XXIV/B/1), Mrs M. DE SOLA (DG XXIV/B/2), Mr G. VAN DEN EEDE (JCR)

Secretariat

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

1. Welcome, Apologies and Introductory Remarks

Mrs de Solà opened the meeting and welcomed the members.

She reminded members that following the resignation of Prof. A. Silva Fernandes as Chairman of the Committee, it was necessary to elect a new Chairman.

Prof. F O' Gara nominated Prof. A. Hardy who was seconded by Prof. M. Maroni and Dr. H. Kuiper.

Prof. A. Hardy was elected by unanimity.

In accepting his nomination as Chairman, Prof. A. Hardy thanked the members for their confidence in him and acknowledged the former Chairman Prof. A. Silva Fernandes for his work over the last year.

2. Adoption of the agenda

The agenda was adopted (Doc. SCP/AGENDA/009-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 Eighth Plenary Meeting and matters arising (2 October 1998)

4.1 Adoption of the minutes of the eighth Plenary Meeting

The draft minutes were approved with some minor textual amendments. The report is available as Document No. SCP/REPT/008-Final of 17 November 1998.

4.2 Review of the Committee's working practices.

The Chairman indicated that he would reflect and consult on this issue and requested the Secretariat to include the point on the December Plenary Meeting agenda.

4.3 Comments of the Scientific Steering Committee (SSC) GMOs

The Committee renewed the invitation it had extended to Professor Pascal, Chairman of the SSC to address the Committee with regard to his views on the evaluation of plant GMs. The Secretariat explained that the Director General of DG XXIV has recently expressed his satisfaction with the opinions on GMOs. Mrs de Solà referred to the ongoing reflections in the SSC on GMOs and indicated that the Chairman of the SCP, in his capacity as both a member of the SSC and its GMO WG, would be in a position to represent the views of the SCP. In an exchange of views, the Committee suggested that the multi-disciplinary representation of the plant GMO WG should be enhanced, in the light of nearly one year of operation, with a view to improving representation of the other relevant SCs, particularly the SC for Food.

4.4 Workshop on data requirements for Microorganisms to be used as plant protection products (Stockholm 24-28 October 1998).

Prof. F O' Gara briefly explained the background to the workshop: the Swedish Authorities had been requested by the Commission services to revise the draft data requirements for carrying out risk assessment on micro-organisms in the context of Directive 91/414/EEC on the placing of plant protection products on the market. The objective of the meeting was to achieve further consensus and agreement on the scientific basis for the data requirements. Representatives of Member States, Canada, Switzerland, Norway and United States had attended the workshop and from the SCP, Prof. F. O' Gara and the Committee Secretary.

Prof. F. O' Gara reported that he had presented to the workshop the SCP opinion of 2 October 1998 and that the consensus of the workshop was similar to that of the SCP. The intention is that the Swedish Authorities will take into account the outcome of the workshop when revising the draft data requirements which are expected to be available by March 1999.

4.5 Follow-up to the SCP opinion (Doc SCP/GMO/044-Final) on the GM potato notified by AVEBE

At the Chairman's request, the Secretary outlined developments since the adoption of the opinion at the SCP Plenary of 2 October. In particular, he explained the background to the deviation in this case from the normal practice of publishing the full content of opinions of the Committee on the Internet. Mrs de Solà explained the legal aspects of the principle of confidentiality as they apply to Directive 90/220/EEC. The Committee regretted that its

opinion was published without including the main scientific details underlying its conclusions.

4.6 Risk Communication

In an exchange of views on possible means for improving risk communication, the Committee recognised that it has a role in risk communication, particularly in ensuring that its opinions are written clearly. In this context, the Committee decided that it was unnecessary at present to include an 'Executive Summary' systematically in its opinions but that it would in future place greater emphasis on the 'Overall Assessment' sections of its opinions.

The Committee whilst recognising its role in risk communication advised the Commission services that greater attention should be given to this important and difficult aspect of scientific advice.

4.7 Requests for information from SCP Members.

Several members sought clarification on the appropriate way of dealing with contacts from sources external to the Committee (Press, notifiers etc). It was agreed that in order to avoid any possible confusion, such contacts should in principle be referred to the Secretariat.

5. Establishment of SCP meeting schedule for 1999.

The Committee fixed the dates for the next eight Plenary Meetings. In order to maximise availability of members for Plenary Meeting, the Committee decided to update its meeting schedule thereafter on a three month rolling basis. The agreed list of dates is as follows:

Meetings scheduled for 1999

3-4 February

3-4 March

17-18 May

14-15 June

15-16 July

23-24 September

27-28 October

1-2 December

6. 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 (Doc. SCP/RESI/041).

The Committee considered the draft opinion prepared by Prof. F. Führ, which he had submitted immediately prior to his resignation from the SCP. The Committee conveyed its thanks to Prof. F. Führ for the difficult task he had carried out due to the lack of data in the literature. Several Committee members were of the opinion that the relationship between plant protection product use and mycotoxins merited further work. Moreover, it was felt that the relationship between the elimination or strong reduction in the use of plant protection

products and the presence of heavy metals would be influenced by the quality of the fertilising materials used. For example, animal waste could contain high levels of copper. It was also recognised that residues of copper in fruit and vegetables could arise from the use of copper-based fungicides in both conventional and even organically grown produce.

It was decided to form a working group comprising Dr. G. Speijers, Prof. A. Silva Fernandes, Dr. M.-P. Delcour and Dr. H. Kuiper with Dr. G. Speijers acting as overall co-ordinator. The WG would finalise its consultation by 9 December with a view to circulating a revised draft opinion for adoption at the December Plenary Meeting.

7. Plant Protection Products Active Substances

Isoxaflutole, aldicarb, flurtamone, azimsulfuron and spiroxamine

The Chairman requested a progress report on each active substance.

7.1 Isoxaflutole

The Secretary informed the meeting that questions on development toxicology and carcinogenicity had been considered respectively at WGs held on 30th and 22nd of July. The draft report on development toxicology was available and that for carcinogenicity was still pending.

Dr. H. G. Nolting reported on the outcome of the environmental WG of 5th November comprising Prof. A. Hardy (Chairman), Dr. H. G. Nolting, Prof. A. Silva Fernandes and invited experts Dr. J. Boesten, Dr. A. Carter, Dr. V. Forbes and Dr. T. Sherratt. He informed the meeting that it would be necessary to evaluate toxicologically the metabolite RPA 203328 in order to respond fully to the question to the Committee on its significance. It was agreed that Prof. M. Maroni would prepare an initial draft toxicological evaluation and consult with Dr. M.-P. Delcour, Dr. O. Meyer and Dr. G. Speijers.

The draft opinion would be discussed in WGs on the 17th December with a view to adoption of the opinion at the Plenary Meeting the following day.

7.2 Aldicarb

Dr. R. Hans reported on the Residue WG she had chaired on 13th October, which was attended by Prof. A. Silva Fernandes, Dr. M.-P. Delcour and invited experts Dr. S. Crossley, Dr. O. Meyer, Dr. G. Speijers, and Dr. J. Van Klaveren.

The WG had considered information supplied by the notifier in response to the clarifications it sought. Certain difficulties were evident to the WG arising from a scarcity of adequate European dietary data in order to carry out a probabilistic risk assessment and the lack of guidance to notifiers on the requirements for such dossiers. The WG decided to seek further clarifications from the notifier on the dietary data it used in the assessment for young children.

The WG agreed to meet again on 11 November.

A. Hardy reported on the Environmental WG that he had chaired on 5th November (memberships as for isoxaflutole). The content of the draft opinion had been discussed further

and Dr. A. Carter reported on progress in obtaining 'input files' or assumptions used in the fate modelling studies submitted to the Committee. It appeared that these would not be available to the WG. In the circumstances, the WG will complete its evaluation on the database available to it.

The Committee requested Prof. M. Maroni to prepare a draft response to the question on operator exposure. In response, he explained the difficulties of dealing with risk assessment for operators in the absence of a Community harmonised approach.

It was agreed that the various elements of the opinion should be prepared with a view to the adoption of the SCP opinion on 18 December.

7.3 Flurtamone

Prof. A. Hardy reported on the progress of the Environmental WG of 5th November (membership as for isoxaflutole).

He described the difficulties the WG had in dealing with the metabolite TFMBA due to a lack of relevant data. The Committee stressed that it must be supplied with all the necessary data in order to respond to questions addressed it.

Dr. J. Boesten will prepare by 27 November the initial draft evaluation on metabolite TFMBA and will also consider the metabolite TFMMA.

Dr. T. Sherratt will also prepare by 27 November the initial draft evaluation on the question on effects on beneficial non-target arthropods.

Both draft opinions will be considered at the next WG meeting of 17 December with a view to adoption of the opinion at the Plenary Meeting on 18 December.

7.4 Spiroxamine

Prof. A. Hardy reported on the progress of the Environmental WG of 5th November (membership as for isoxaflutole).

The WG identified the main area of concern as the risk to sediment dwelling organisms.

Dr. V. Forbes will prepare the initial draft evaluation by 27 November.

Prof. M. Maroni agreed to prepare a response to the question on risk to operators.

Both draft opinions will be considered at the next WG meeting of 17 December with a view to adoption of the opinion at the Plenary Meeting on 18 December.

7.5 Azimsulfuron

Prof. A. Hardy reported on the progress of the Environmental WG of 5th November (membership as for isoxaflutole).

The WG identified the main area of risk for the environment would arise from the effects on Lemna and sediment dwelling organisms. Dr. V. Forbes will prepare by 27 November the initial draft evaluation and she will also assess the risk from possible endocrine effects on the aquatic environment.

Both draft opinions will be considered at the next WG meeting of 17 December with a view to adoption of the opinion at the Plenary Meeting on 18 December.

8. Exchange of views and possible adoption of opinion on Plant GMOs

8.1 Male sterile chicory notified by Bejo-Zaden and forwarded by the Netherlands (Notification C/NL/94/25-A).

The Secretariat reported that no response had been received from the notifier in reply to the clarifications the Committee had requested in connection with the first reply the notifier had forwarded. The Committee decided to defer finalising its opinion and requested the Secretariat to contact the notifier again in order to clarify the situation. The Committee will decide on its approach in the light of the notifier's response.

8.2 AMYLOGENE genetically modified starch potato clone (EH92-527-1) with altered starch composition (Notification C/SE/96/3501)

This notification had been referred to the Committee at its meeting of 2 October 1998.

The DG XI representative informed the Committee that the dossier was still in the process of finalisation.

8.3 DEKALB maize line DBT418 tolerant to glufosinate ammonium and resistant to feeding by the European corn borer (Notification C/NL/97/17).

This notification had been referred to the Committee at its meeting of 2 October 1998.

The DG XI representative informed the Committee that the dossier was still in the process of finalisation.

8.4 Nomination of rapporteurs for products referred to in 8.2 and 8.3.

Overall co-ordination - AMYLOGENE Potato	H. Davies
Overall co-ordination - DEKALB maize	S. Karenlampi
Biotechnology	Team Leader : H. Davies Members : J.-J. Leguay, F. O' Gara, S. Karenlampi,

	E. Rodriguez
Environmental Aspects	Team Leader : A. Hardy, Members : H. Koepp and T. Sherratt M. Vighi,
Toxicology and residues	Team Leader : H. Kuiper (Leader), R.Hans, M.-P. Delcour
Feed and food aspects	Members : A. Chesson, L. Aumaitre, A. von Wright, B. Moseley and H. Kuiper

9. Exchange of views on the draft report on the plant GMO guidance document.

Prof. F O' Gara updated the meeting on the progress which had been made during the GMO WG which he had chaired on 9 November. The Committee made some further amendments to the text and requested the Secretariat to send the third revision to all members of the SCP and GMO WG for comments. The Committee will adopt the opinion at its next meeting in December.

10. Progress report on the draft protocol for monitoring of European corn borer resistance to Bt.

The Committee had for consideration the draft opinion prepared by Prof. A. Hardy. It was decided to consult experts external to the Committee before finalising the opinion. The Chairman will convey to the Secretariat the results of his consultations on the composition of the WG. The intention is to adopt the opinion at the February meeting of the Committee.

11. Aminoglycoside resistance in relation to the expression of the aadA gene

The Committee exchanged views on the discussion paper prepared by Mr G van den Eede. It was agreed that whilst the risk of transfer of antibiotic resistance with respect to the aadA gene was probably low, it was not possible to draw conclusions with respect to the wider issue of the possible transfer of antibiotic resistance genes. In the circumstances, it was considered necessary to maintain a precautionary approach. The Committee recognised the need for further research in this area.

The Chairman thanked Mr van den Eede for his excellent paper.

12. Other Business

The next meeting of the Committee will take place on 18 December 1998.