

Minutes of the fifth meeting, Brussels, 18/19 May 1998

ATTENDANCE LIST

Members

Dr. M.-P. DELCOUR-FIRQUET, Prof. H. V. DAVIES , Prof. F. FUHR , Dr. R. HANS, Prof. A. R. HARDY , 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

Apologies

Prof. S. O. KARENLAMPI, Prof. A. M. S. SILVA FERNANDES (Chairman)

Invited

Mr H. Koepf

Commission

Ms M. ZETTERSTRAND (DG XI), Mr G. VAN DEN EEDE (JCR), Mr A. SCHARPE (DG VI), Mr M. GRANERO (DG XXIV)

Secretariat

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

1. Welcome, Apologies and Introductory Remarks

In the absence of A. Silva Fernandes, the first day of the meeting was chaired by M. Maroni (Vice Chairman) and the second by F. O' Gara (Vice Chairman). Prof. Maroni opened the meeting, welcomed the members and noted the apologies (see attendance list). He reported that C. L. Galli had tendered his resignation as a member of the Committee and commented that since two members had resigned from the SCP due to pressure of work (Dr Caboche had earlier resigned), it had now become urgent for the Commission to supplement the membership of the Committee.

2. Adoption of the agenda

The agenda was adopted. (Doc. SCP/AGENDA/005-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. Matters arising from the minutes of the fourth Plenary Meeting (18/19 March 1998)

The draft minutes had been approved by written procedure prior to the meeting. The report is available as Document No. SCP/REPT/004-Final of 19 March 1998.

It was noted that the names of H. Koeppe and P. Vasseur should be added to the list of attendance.

F. Fuhr noted with satisfaction the resolution of the question of the terms of reference of the SCP with respect to plant protection product evaluations and invited the Secretariat to prepare a detailed work plan for the Committee.

5. Plant Protection Products - active substances

Inclusion of active substances in Annex 1 to Directive 91/414/EEC.

5.1. Kresoxim-methyl

The Committee indicated that it intended to finalise its opinion at the its June Plenary Meeting.

5.1.1. Toxicological evaluation

M. Maroni reported on the meeting of 6 May 1998 of the working group (WG) on carcinogenicity which he chaired in the presence of other SCP members M.-P Delcour, and A. Silva Fernandes and invited experts J. Parry and R. Schulte-Hermann and G. Rice. The initial orientation of the WG was that the carcinogenic effects observed in the rat liver was as a non-genotoxic promoter with a threshold. The WG agreed to prepare its evaluation by June 15 and requested the secretariat to obtain certain additional information from the notifier.

5.1.2. Environmental fate evaluation

H.-G. Nolting reported on the meeting of 11 May 1998, which had been chaired by A. Hardy in the presence of A. Silva Fernandes and H. Koeppe. He outlined his draft evaluation on the soil leaching behaviour of metabolite 1. The Committee supported the conclusion of his evaluation i.e. that no leaching problem was evident when the up-to-date agriculture practice for the use of kresoxim-methyl on vine and pome fruit was taken into account.

5.2. Fenthion

The Committee noted the revised agricultural practice involving the application of fenthion solely as a bait treatment and commended the efforts to reduce risk through the reduced rate of use compared with previous uses.

5.2.1. Toxicological evaluation

M. Maroni reported on the meeting of 7 May 1998 of the WG on toxicology, which he chaired in the presence of other SCP members M.-P Delcour, R. Hans and A. Silva Fernandes. Following an exchange of views the Committee agreed with the content of his toxicological draft opinion and that on residues aspects of the opinion as prepared by R. Hans. M. Maroni agreed to prepare the final draft text for submission to the June Plenary meeting for adoption.

5.2.2 Environmental evaluation

H.-G. Nolting and H. Koepp presented respectively their draft evaluation on the fate and ecotoxicological aspects respectively which had been discussed at the WG meeting of 11 May. The fate evaluation indicated that no leaching of parent or metabolites was to be expected whilst the ecotoxicological risk was difficult to assess due to lack of data corresponding to the new agricultural practice.

Following an exchange of views, the Committee agreed on the orientations to be taken and requested the rapporteurs to present final draft texts to the June Plenary Meeting.

5.3. Isoxaflutole

The questions regarding this active substance concerned carcinogenicity, development toxicity and fate. The first two aspects will be addressed at specialised working groups which will take place on 23 June and 30 July. Accordingly, the Committee will adopt its opinion at its October 1 and 2 Plenary Meeting.

5.3.1. Relevance of metabolite RPA 203328

H.-G. Nolting outlined the consensus of the working group, which met on 11 May with respect to the leaching potential of the parent and metabolites. There was agreement with the conclusion in the monograph of the Rapporteur MS that no problem exists with the parent or two of the metabolites. However it was concluded that RPA 203328 could leach to a level of 2-3 µg/l but the relevance of this would need to be further studied.

6. Pesticide Residues

6.1. Questions relating to the modification of the annexes to Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC

Mr A Scharpe of DG VI outlined the content of the envisaged legislation which related to a draft directive providing for the establishment of maximum pesticide residue limits (MRLs) in agricultural products and drew attention to the risk-assessment calculations using the draft MRLs. He explained the background to the questions addressed by the Commission to the Committee. The questions were as follows:

1. General question relating to the proposed maximum residue limits (MRLs)

1.1. Do the draft maximum pesticide residue limits (MRLs) ensure adequate protection for all sections of the population including infants and young children?

2. Acephate and metamidophos

2.1. What is the maximum toxicologically acceptable maximum residue level which could be established for methamidophos in pome fruit, peaches and peppers?

3. Dithiocarbamate group of fungicides

3.1. Is it scientifically justifiable to include ziram in the dithiocarbamate intake calculations when ziram uses have not been taken into account in determining the MRLs and ziram is not included in the residue definition?

3.2. If it is justifiable, should the authorisations for the use of ziram on pome fruit and tomatoes be withdrawn in advance of the regulatory outcome of the authorisation review currently underway?

3.3. If it is not justifiable, should the authorisation/MRL position of ziram be fully reassessed, together with that of each of the other seven dithiocarbamates, when the authorisation review of all eight has been further progressed?

Following an exchange of views, the Committee referred the question, in the first instance to the Pesticide Residue WG, which had been appointed at the third Plenary Meeting under the Chairmanship of R. Hans. The WG will meet on June 16 with the intention of finalising its opinion at the July Plenary.

6.2. Questions relating to pesticide residues in manufactured food intended for infants and young children

Mr M Granero, Secretary to the Scientific Committee for Food (SCF) explained the background to the questions addressed to the SCF and to the SCP. He explained that the SCF, in its opinion of 19 September 1997 on a maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children, concluded that **'the current ADIs would give a reasonable basis for evaluation the health impact of pesticides in foods intended for infants and young children'**. It nevertheless indicated a number of limitations on the adequacy of toxicological testing regimes to identify risks to infants and young children. In this context, the Committee referred to the limitations of 'standard toxicological tests' and 'the currently used data packages'. The Committee also stated that 'a new guideline regarding developmental neuro-toxicity is being prepared within the OECD test guideline programme in order to obtain more information about these effects'.

In order to allow the Commission **to fully** understand the **scientific** implications of its advice, the SCF was asked **the following additional questions**:

1. Should a distinction be made between 'currently used data packages' and the earlier ones on which many of the current ADIs for pesticides are based? For example, would this difference be reflected in broad terms by the age of the evaluation?

2. Whether ADIs based on current data packages reflect the particular sensitivities of infants and young children to individual pesticides in foods?

3. Whether ADIs based on earlier data packages would in general reflect the particular sensitivities of infants and young children to individual pesticides in foods?

3.1. If yes, what would be the criteria to identify those pesticides where there are reasons for concern that they may pose a risk to infants and young children?

3.2. If the answer is negative or subject to doubt, how could those pesticides for which protection would not be ensured by a common limit covering the majority of substances, be identified in the absence of adequate ADIs?

4. What are the scientific criteria for determining limitations for the most toxic pesticides?

5. In the conclusions to its opinion expressed on the 19 September 1997, the Committee stated that 'The fact that infants and children have a relatively higher intake of some food items than adults should clearly be considered in the risk assessment. This is not always taken into consideration when setting MRLs'. The Committee is asked to explain the scientific implications of this statement for the setting of MRLs.

The questions addressed to the Scientific Committee on Plants were as follows:

In the case of elimination or strongly reduced use of pesticides in the cultivation of fruit and vegetables used as ingredients in foods intended for infants and young children, does the Committee consider there to be a potential for significant adverse effects related to health associated with, for example, mycotoxins and heavy metals?

In the case of the questions referred to the SCF, it was decided that SCP members R. Hans and M.-P. Delcour should participate in the SCF WG and in the case of the SCP questions, the WG should comprise F. Fuhr, M.-P. Delcour and M. Maroni as co-ordinator. It was agreed that the draft of the SCF opinion would be circulated to all SCP Members for comment by mid-June and the draft SCP opinion would be discussed at the Plenary Meeting on 23 June and be adopted at the SCP July 13/14 Plenary Meeting.

7. Genetically Modified Organisms - Plants

7.1. General observations and recommendations by Plant GMO WG

Committee members raised a number of problems they have experienced with evaluations to date and made the following recommendations for the future, which would facilitate their work:

- a) In order to expedite reviews confidential business information should be provided systematically to rapporteurs;
- b) Originals of gels etc should be provided to co-ordinators due to the frequent inadequacy of the submitted photocopies.

7.2. Possible adoption of opinions for three GMO dossier

Pioneer insect-resistant (Bt) Maize line MON 809	Notification C/F/95/12/01/B
PGS glufosinate-tolerant male sterile swede rape	Notification C/BE/96/01
AgrEvo glufosinate-tolerant swede rape	Notification C/DE/96/05

The meeting had been preceded by a preparatory meeting chaired by F. O'Gara on 12 May 1998 when the following members were present: H. Davies, A. Hardy, S. Karenlampi, H. Kuiper, J.-J. Leguay, F. O'Gara, E. Rodriguez-Cerezo, A. von Wright, A. Chesson, B. Moseley, M. Vighi, H. Koepp, G.C. Lozzia, G. Riba. Following an exchange of views the Committee decided to adopt opinions on the Pioneer Maize line Mon 809 and the PGS swede rape which are available respectively as SCP/GMO/013-Final and SCP/GMO/012. It was

decided to request a number of further clarifications from the notifier with respect to the AgrEvo swede rape with respect to the genetic construct, substantial equivalence and environment aspects.

7.3. Progress report on five GMO dossiers

The following five applications had been referred to the Committee at the previous meeting. An exchange of views had taken place at the WG meeting of 12 May 1998 (as above) and it was confirmed that members had now received the dossiers and the evaluations were in progress. Adoption of opinions will take place at the June and July Plenary Meetings.

DFL-Trifolium, Monsanto and Danisco fodder beet tolerant to glyphosate	Notification C/DK/97/01
AVEBE potato with a change in starch composition	Notification C/NL/96/10
Zeneca tomato with reduced activity of the expression of the endogenous tomato fruit PG gene	Notification C/ES/96/01
Monsanto cotton with tolerance to glyphosate	Notification C/ES/97/01
Monsanto cotton with an insecticidal activity against lepidopteran insect pests (Bt)	Notification C/ES/96/02

7.4. Bt resistance document

This document had been submitted to the Committee by the Commission during the meeting of the GMO WG, which met on 12 May.

The Committee set a deadline for transmission of comments of 30 May to the Rapporteur A. Hardy with provision for circulation of a draft opinion to members by 15 June.

7.5. GMO Guideline document

It was decided to appoint co-ordinators as follows:

Food and Feed aspects	A. Chesson
Environmental aspects	A. Hardy
Biotechnological aspects	H. Davies

The Committee agreed to review progress at the next meeting of the joint GMO WG/Plenary meeting in June.

8. Antimicrobial study

The Secretariat outlined the background to the establishment of a multi-disciplinary working group of the Scientific Steering Committee on the use of anti-microbials, which should include representation from the various relevant Scientific Committees. The problem of increased anti-microbial resistance has been identified as a potential or emerging hazard. The current uses of anti-microbials was outlined including their limited use as plant protection products and the question of the potential for gene transfer in the case of the use of antibiotic resistance markers use in plant GMOs.

The Committee decided that it would nominate Dr A. von Wright who is a member of the Scientific Committee on Animal Nutrition and of the plant GMO WG. The SCP members agreed to supply input to the WG on antimicrobials used as plant protection products.

10. Other business

The next Plenary Meeting was confirmed for 22/23 June 1998.