

Minutes of the 23rd meeting - Brussels, 30 November 2000

ATTENDANCE LIST

Members

Prof. H. V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Prof. A. R. HARDY (Chairman), Prof. S. O. KARENLAMPI, Mr. H. KOEPP, Dr. H. A. KUIPER, Prof. M. MARONI (Vice-Chairman), Dr. A. MORETTO, Prof. F O' GARA (Vice-Chairman), Prof. E. PAPADOPOULOU, Prof. E. PETZINGER, Prof. J. SCHIEMANN, Dr. T. SHERRATT, Prof. A. M. S. SILVA FERNANDES, Dr. G. SPEIJERS

Apologies

Prof. A. LESZKOWICZ, Dr. O. MEYER, Prof. K. SAVOLAINEN

Invited Experts

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Commission

Ms. M. DUNIER-THOMANN Environment, Mr V. MATZEIT Environment, Mr W. MAIER Health and Consumer Protection, E1

Secretariat

Mr. M. WALSH Health and Consumer Protection, C3, Mr. J. FERRIERE Health and Consumer Protection, C3, Ms. S. VAN IMPE Health and Consumer Protection, C3

1. Welcome and apologies

Michael Walsh, Scientific Secretary of the SCP opened the meeting and welcomed the new members.

2. Adoption of the agenda

The agenda was adopted.

(Doc. SCP/AGENDA/023-Rev. 3)

3. Introduction by the Commission services

Michael Walsh gave an overview of the Commission policy in the field of scientific advice and its future development in relation to the Commission draft proposal on food law (COM(2000)716). He outlined the main responsibilities of the SCP and the role of the Scientific Steering Committee. All members introduced themselves, highlighting their main fields of expertise and areas of interest.

4. Election of a Chairman and two Vice-Chairmen

Prof. Maroni and Prof. Silva Fernandes proposed Prof. Hardy to be chairman of the Committee. Prof. Hardy accepted to be candidate. No other member stands for chairmanship

of the Committee. Prof. Hardy was elected Chairman of the Scientific Committee of Plants at unanimity (15 votes in favour).

Prof. Silva Fernandes and Prof. Davies proposed Prof. O'Gara to be first vice-Chairman of the Committee. Prof. O'Gara accepted to be candidate. No other member stands for vice chairmanship of the Committee. Prof. O'Gara was elected vice-Chairman of the Scientific Committee of Plants at unanimity (15 votes in favour).

Mr. Koepp and Dr. Moretto proposed Prof. Maroni to be second vice-Chairman of the Committee. Prof. Maroni accepted to be candidate. No other member stands for vice chairmanship of the Committee. Prof. Maroni was elected vice-Chairman of the Scientific Committee of Plants at unanimity (15 votes in favour).

5. Declarations of interest, annual declarations of interest and confidentiality

Michael Walsh briefed the members on the rules of the declaration of interests of SCP members and the declaration of confidentiality. He drew the Committee's attention to the importance the Commission attaches to the questions of 7th annual declaration of interests of members.

6. Rules of procedures

The rules of procedure adopted by the SCP under its first mandate were handed out to all SCP members. It was proposed to adopt them as the rules of procedures of the SCP under its second mandate, which was accepted by all the members.

7. Working programme

Michael Walsh made a short presentation on the current working programme that the new Committee will have to deal with.

Wolf Maier, from DG SANCO E1 (plant health legislation) gave an overview of the forthcoming questions to be referred to the SCP. These includes questions related to application for inclusion of active substances in annex I to Directive 91/414/EEC (about 10 active substances currently being at an advance stage of the Community peer reviewed programme) but also related to new or revised guidance documents currently being prepared by the Commission services. A document on the "state of the main works with regard to the implementation of Directive 91/414" is available on the Commission (SANCO) web site. This document is updated approximately every 2 months and gives an overview (including references) on the state of activities related to the implementation of Directive 91/414/EEC.

Committee members highlighted that it would be useful for the Committee to have feed-back on the use of its opinions. Mr. Maier agreed that efforts should be made to do so regularly.

8. Structure and composition of Working Groups

The Committee agreed on the structure of the permanent working groups, i.e. working group on toxicity (TOX WG), working group on environmental assessment (ENV WG), and working group on genetically modified organisms (GMO WG). It was agreed that the TOX

WG would be supplemented with relevant invited experts to deal with specialised questions on carcinogenicity, development toxicology, etc.

Other specialised and temporary *ad hoc* working groups will be established when needed.

The participation of Committee members to the working groups is given in the appendix attached to this report.

9. Meeting schedule for 2001: adoption of dates for plenary sessions

The meetings for 2001 were scheduled as follow:

25 - 26 January,
6 - 7 March,
24 - 25 April,
6 - 7 June,
19 - 20 July,
26 - 27 September,
7 - 8 November,
19 - 20 December.

The first day will in principle be dedicated to working group meetings and the second day to SCP plenary meeting. Dates for further meetings of working groups will be established when needed by the working groups themselves.

10. Matters arising from the twenty second plenary meeting (22 September 2000)

The minutes of the twenty second plenary meeting were adopted by written procedure by the members of the SCP under the first mandate. They are available as Document SCP/REPT/022-Final at [click here](#)

11. Progress report on guidance document submitted to the SCP for opinion: relevant metabolites

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee discusses general aspects of the draft guidance document of the Commission on relevant metabolites and provides detail comments on some of the section of the document.

The opinion is available as document [SCP/GUIDE-METAB/002-Final](#)

12. Progress report on the following plant protection product dossiers referred to the Scientific Committee on Plants

12.1 *Ampelomyces quisqualis*

The draft opinion was introduced to the Committee for discussion, in which a majority opinion was expressed and a minority opinion expected to be expressed.

The Committee agreed in principle with the draft opinion but decided that the opinion should be adopted formally by written procedure once the minority opinion was included.

12.2 *Paecilomyces fumosoroseus*

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers four questions.

The first question relates to the safety of residue levels in food and feed. The Committee concludes that in the view of the biological properties and the mode of use of this product, it is of the opinion that the safety requirements with respect to residues in food and feed has been adequately addressed by the Commission Peer Review Programme.

The second question deals with the assessment of operator exposure. The Committee concludes that despite the absence of specific validated methods to assess exposure to micro-organisms, the information available indicates the presence of a sufficient margin of safety for operators, bystanders and agricultural workers in the intended uses of *P. fumosoroseus*.

With respect to the third question, the Committee expresses the opinion that in general repeated dosing should be part of the primary dossier, but this could be omitted provided that adequate justification can be offered. In the specific case of *P. fumosoroseus* the SCP is of the opinion that repeated dosing is not necessary to assess hazard to humans.

In the fourth question, the Committee was asked whether post-authorisation requirements to monitor possible allergic reaction should be considered. The Committee concludes that monitoring of the health of producers and users would certainly be a prudent measure.

The opinion is available as document SCP/PAECIL/002-Final at:

[click here](#)

12.3 Flupyr sulfuron-methyl

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers two questions.

In the first question, the Committee confirms that on the basis of the newly submitted data by the notifier, it is now possible to conclude that no significant long term risks to earthworms are likely to arise from the use of flupyr sulfuron-methyl at the recommended treatment rate.

With respect to the second question, the SCP is of the opinion that use scenarios exist which pose no unacceptable risk from drinking water derived from groundwater.

The opinion is available as document SCP/FLUPYR/002-Final at:

[click here](#)

12.4 Pymetrozine

Prof. Maroni informed the Committee that the notifier submitted the reports of three studies. Dr. Speijers was appointed rapporteur to deal with question 1 and draw up a draft opinion. Dr. Moretto prepared a draft opinion on question 2.

The two questions are expected to be addressed at a subsequent meeting of the TOX WG early 2001.

12.5 Cyclanilide

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers two questions and raised a specific issue.

The Committee responses to question 1 is that it does not consider the effects of cyclanilide on the thymus and spleen observed in animal studies relevant for the assessment of the risk in humans.

Likewise, in question 2, the Committee does not consider that the data available indicative of reproductive toxicity potential of cyclanilide to humans.

Finally, the Committee observed that the DT₅₀ value of 2.5 days for the soil metabolite 2,4-dichloroaniline is not consistent with the experimental results as summarised by the Rapporteur Member State and therefore recommends that the estimation procedure for this half-life is re-evaluated.

The opinion is available as document SCP/CYCLAN/002-Final at:

[click here](#)

12.6 Sulfosulfuron

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers to three questions and raised two specific issues.

In question 1, the Committee deals with carcinogenicity assessment of sulfosulfuron. The Committee concludes that the lesions observed in a rat study do not predict carcinogenic hazard to humans.

In question 2, the Committee was asked whether it would be appropriate to establish an acute reference dose (ARfD) for sulfosulfuron. The Committee expresses the opinion that this is not deemed necessary.

With respect to question 3, the Committee concludes that despite the persistence of metabolites in the soil, no significant long term risks to earthworms are likely to arise at the recommended rate of use (20 g a.s/ha, once per year).

Finally, the SCP identified two issues of concerns. The first one relates to the observation of three unidentified metabolisms, the relevance of which does not seem to have been adequately addressed. In addition, the Committee had noticed that drain flow calculations for a UK clay

loam soil using a leaching model have indicated risk for sensitive aquatic plants which does not seem to have been addressed by the Rapporteur Member State.

The opinion is available as document SCP/SULFO /002-Final at:

[click here](#)

12.7 Carfentrazone ethyl

Prof. Hardy, chairman of the ENV WG, informed the Committee that the notifier has submitted a significant amount of new data. These data are going to be evaluated by the ENV WG and the TOX WG.

12.8 2,4-D

Prof. Maroni chairman of the TOX WG informed the Committee that the draft opinion submitted by Dr. Moretto has not been discussed yet. This will be on the agenda of the subsequent TOX WG meeting.

12.9 Quinoxifen

Prof. Hardy chairman of the ENV WG, informed the Committee that this dossier was not dealt with at the ENV WG of 14 November. Dr. Sherratt has been appointed as a rapporteur to deal with the ecotoxicity profile of the substance.

This item will be on the agenda of a subsequent meeting of the ENV WG.

12.10 Benomyl

12.11 Carbendazim

12.12 Thiophanate-methyl

Prof. Maroni, chairman of the TOX (CARC) WG updated the Committee on the progress on these three dossiers. Prof. Maroni informed the Committee that Dr. Pfeil, responsible in the Rapporteur Member State for the monographs of the three substances (carcinogenicity sections) attended the meeting and briefed the WG group. The experience was reported to be very fruitful and will be repeated when desirable.

Dr. McGregor, rapporteur for these three substances, has drawn up a draft opinion, which will be discussed at the next meeting of the CARC WG.

12.13 Flurtamone

Prof. Hardy and Prof. Maroni, respectively chairman of the ENV WG and chairman of the TOX WG, informed the Committee the new information is currently being evaluated.

It will be on the agenda of the next ENV WG (14 December) and TOX WG (12 January) with the aim of finalising a draft opinion to be considered for adoption at the next Plenary meeting.

12.14 Azibenzolar-S-methyl

This active substance has been referred to the Committee without any specific question. The Committee will carry out an overall assessment of the dossier.

12.15 *Pseudomonas chlororaphis*

The evaluation will resume after the addendum to the monograph prepared by the Rapporteur Member States is available and will be referred again to the SCP in due course.

13. Requests for opinions on the following plant protection products dossiers referred to the SCP

13.1a Glyphosate

13.1b Glyphosate-trimesium

Glyphosate and glyphosate trimesium are two related existing active substances in the context of Directive 91/414/EEC. Both are referred to the SCP without specific questions.

The Committee will carry out an overall assessment of these dossiers.

13.2 Iprovalicarb

Iprovalicarb is a new active substance in the context of Directive 91/414/EEC.

The following two questions are addressed to the Committee:

1. Can the Committee comment on the acceptability of the risk of metabolite PMPA on earthworms?
2. Can the Committee comment on the relevance to human of the occurrence of rare tumours in rats at high doses?

Dr. Sherratt was appointed rapporteur for question 1 and Prof. Galli, member of the TOX WG (CARC), rapporteur for question 2.

13.3 Cyhalofop-butyl

Cyhalofop-butyl is a new active substance in the context of Directive 91/414/EEC.

The following two questions are addressed to the Committee:

1. Can the Committee confirm that a use exists which is acceptable for aquatic organisms and for non-target arthropods?
2. Can the Committee confirm that the operator exposure has been sufficiently addressed?

Dr. Forbes, member of the ENV WG and Dr. Moretto were appointed rapporteur, respectively for questions 1 and 2.

14. Progress report and exchange of views on plant GMO dossiers

Prof. O'Gara, Chairman of the WG on GMO, updated the Committee on the GMO dossiers.

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

Response to the questions (SCP/GMO/269) referred to the notifier on 20 July 2000 is still awaited.

14.2 Oilseed rape from Hoechst Schering AgrEvo GmbH with tolerance to glufosinate ammonium (Notification C/DE/98/6)

Following an exchange of view on the draft opinion, it was concluded that Dr. Kuiper would finalise the opinion for an adoption by written procedure.

14.3 Genetically modified insect tolerant (Bt-11) maize from Novartis Seeds SA (Notification C/F/96/05-10).

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments.

The Committee is of the opinion that there is no evidence to indicate that the placing on the market for cultivation purposes of maize line *Bt-11* and varieties derived from this line by conventional crossing with maize lines other than genetically modified ones, is likely to cause adverse effects on human health and the environment

The opinion is available as document SCP/GMO/231-Final: [click here](#)

14.4 "Guidance document to facilitate notifiers in the preparation of Plant GMO Dossiers for consideration by the SCP" (Doc. SCP/GMO/103).

Prof O'Gara informed the Committee that this document was virtually complete but that it would be examined by the newly constituted GMO WG which will deal with both the GM aspects of work under Directive 90/220/EEC and the Novel Food legislation. The next meeting of the WG is scheduled on 1 February 2001.

15. Invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize Line T25 notified by AgrEvo France (now Aventis CropScience, Notification C/F/95/12-07)

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments.

After an examination of the information submitted by the Austrian authorities, the Committee concludes that it does not provide new scientific information to change the original risk assessment carried out on the AgrEvo (now Aventis CropScience) maize line T25.

The opinion is available as document SCP/GMO/289-Final: [click here](#)

17. Other business

Date of next meeting: The next meeting will take place on 26 January 2001.

APPENDIX

Involvement of SCP member in specialised working groups

SCP Members	TOX WG	ENV WG	GMO WG
Prof. H. V. DAVIES			X
Dr. M.-P. DELCOUR-FIRQUET	X		X
Prof. A. R. HARDY		X	X
Prof. S. O. KARENLAMPI			X
Mr. H. KOEPP		X	(X)
Dr. H. A. KUIPER	(X)		X
Prof. M. MARONI	X		
Dr. A. MORETTO	X		
Prof. F O' GARA			X
Prof. E. PAPADOPOULOU		X	
Prof. E. PETZINGER	X		
Prof. J. SCHIEMANN			X
Dr. T. SHERRATT		X	(X)
Prof. A. M. S. SILVA FERNANDES	X	X	(X)
Dr. G. SPEIJERS	X		X
Prof. A. LESZKOWICZ	X	X	
Dr. O. MEYER	X		
Prof. K. SAVOLAINEN	X		

X = Full involvement of the member in the working group.

(X) = Case by case involvement of the member in the working group.