Minutes of the 24th meeting - Brussels, 26 January 2001

ATTENDANCE LIST

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

Apologies
Prof. M. MARONI (Vice-Chairman), Dr. A. MORETTO, Dr. H. A. KUIPER

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

1. Welcome and apologies

The Chairman, Professor Hardy opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted.
(Doc. SCP/AGENDA/024-rev1)

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 Twenty Third Plenary Meeting and matters arising (30 November 2000)

4.1 Adoption of the minutes of the Twenty Third Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/023-Final

4.2 Matters arising

None.

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

5.1 *Ampelomyces quisqualis*

The adoption by written procedure of a draft opinion has not been possible and the Committee decided to reopen the discussion. Following an exchange of view, the Committee found a unanimous agreement and requested the secretariat to prepare a revised text to be adopted at the next meeting.

5.2 Carfentrazone-ethyl

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

The Committee had been asked to response to the following question: "Can the Committee comment on the relevance for humans of the elevated levels of specific porphyrins detected in test animals?"

In its opinion, the Committee considers that the elevated levels of porphyrins detected in test animals are relevant for humans and that the NOEL [1] established on the basis of pigment deposit in tissues and mild hepatotoxicity is considered appropriate.

In addition during the evaluation of the dossier, the SCP identified an issue of concern. The Committee noted that in a lysimeter study approximately 19-26 % of the radio- activity leached and that three unknown polar compounds were detected, each at average concentrations greater than 0.1 µg/l *(equivalents*) in the first year. On request, the notifier provided additional information on the three unidentified metabolites and a risk assessment.

On the basis of the additional data submitted, the Committee is confident that the three unidentified metabolites (two of which have been identified at a late stage by the notifier) will not cause an unacceptable ecotoxicological or toxicological risk via the groundwater. In its opinion, the Committee draws attention to the fact that its assessment is based on a limited range of uses which does not cover all the intended uses and which in addition are not representative of Community worst case scenarios.

The opinion is available as document SCP/CARFEN/002-FINAL

5.3 Pymetrozine

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

The Committee was requested to respond to two questions.

The first one requested the Committee to give its opinion on the significance of the changes in serum sodium levels observed in the long-term and carcinogenicity study in rats and whether these should be considered as an adverse effect in the context of deriving an Acceptable Daily Intake (ADI).

The Committee concluded that the changes in serum sodium and chloride levels should not be considered adverse in the context of deriving an ADI.

In the second question, the Committee was asked to give an opinion on the significance of effects seen in the acute neurotoxicity study and whether these should be considered as an adverse effect in the context of estimating an Acute Reference Dose (ARfD).

The Committee considers that the effects were compound related and as such should be considered in the context of estimating an Acute Reference Dose. However, the reversibility of effects, the dose-response curve, the mode of administration and the lack of neurotoxic effects in the 13 week dietary study in rats at doses up to 201 mg/kg body weight per day (3000 ppm) should be taken into account when deriving the Acute Reference Dose.

The opinion is available as document SCP/PYMET/002-FINAL

5.4 2,4-D

Dr. Meyer, updated the Committee on the state of the discussion with respect to this dossier. Further discussion will take place at the following TOX WG meeting on 6 March.

5.5 Quinoxyfen

Mr. Koepp, rapporteur for the dossier updated the Committee on the state of discussion. The Committee was informed that Dr. Kula, expert in soil breakdown studies was invited at the meeting of 10 January to provide update information to the working group on leaf litter studies.

Following the meeting of 10 January, Mr. Koepp will revise the draft opinion on quinoxyfen. The revised text will be discussed at the following ENV WG in the view of bringing a draft opinion to the Committee for adoption at the plenary of March.

5.6 Benomyl

Dr. Meyer, updated the Committee on the state of the discussion with respect to the dossier. It is envisaged that a draft opinion will be finalised at the CARC WG meeting of 27 February.

5.7 Carbendazim

See section 5.6 Benomyl

5.8 Thiophanate-methyl

See section 5.6 Benomyl

5.9 Flurtamone

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

The Committee expressed an opinion in 1998 when several areas of concerns were identified. Additional information was submitted to the Committee to respond to the Committee concerns.

For its second opinion, the Committee was requested to answer the following questions:

1. Do the soil metabolites of flurtamone, particularly 3-trifluoromethylbenzoic acid (TFMBA), represent a risk for contamination of groundwater?

On the basis of the information submitted, the Committee concluded that use scenarios exist for flurtamone which pose no unacceptable risk to groundwater with respect to leaching of the metabolite TFMBA **.**

2. In the light of the new information submitted by the notifier, can the Committee confirm that trifluoroacetic acid (TFAA) does not represent an unacceptable risk to groundwater?

Based on the new data supplied, the Committee concluded that the observed leaching of TFAA does not represent an unacceptable risk to aquatic organisms via groundwater. With respect to the risk to drinking water derived from groundwater, the Committee considered that the information submitted is insufficient for a full assessment of the metabolite TFAA **.**

The opinion is available as document SCP/FLURT/018-FINAL

5.10 Acibenzolar-S-methyl

Rapporteurs from the ENV WG and the TOX WG were appointed to review the monograph and the ECCO documents. These evaluations will be discussed at the ENV WG meeting of 14 February and the TOX WG meeting of 6 March.

5.11 Glyphosate / glyphosate trimesium

Rapporteurs from the ENV WG and the TOX WG were appointed to review the monograph and the ECCO documents. These evaluations will be discussed at the ENV WG meeting of 14 February and the TOX WG meeting of 6 March.

5.12 Iprovalicarb

Dr. Sherratt, rapporteur for the environmental question, updated the Committee with the state of the discussion with respect to question. A draft opinion is expected to be finalised at the next ENV WG meetings.

Dr. Meyer, updated the Committee on the state of progress with respect to question 2. He reported that a discussion took place at the CARC WG meeting of December and that Prof. Galli had been appointed Raporteur who will prepare a draft opinion for examination at the CARC WG meeting of 27 February.

Prof. Hardy, chairman of the Committee concluded that a draft opinion is expected to be available for an adoption at the next Plenary meeting.

5.13 Cyhalofop-butyl

Mr. Koepp, updated the Committee on the state of the discussion with respect to question 1. A draft opinion is expected to be finalised at the ENV WG meetings of February (scheduled on 14 and 27).

Dr. Meyer, updated the Committee on the state of the discussion with respect to question 2 dealing with operator exposure. A draft opinion on the question has been prepared by Dr. Moretto and discussed at the working group meeting. The text has been agreed by the WG and is considered to be ready for referral to the Committee after minor editing.

The chairman concluded that a draft opinion is expected to be available for an adoption at the next Plenary meeting.

6. Request for opinion on the following plant protection products referred to the SCP

The secretariat of the Committee introduced five new dossiers referred to the Committee concerning the evaluation of active substances.

6.1 Famoxadone

Rapporteurs were appointed to deal with each question.

The following questions are addressed to the Committee:

1. The Committee is requested to comment whether the long-term risk to *Daphnia*, in particular in relation to metabolites, has been sufficiently addressed.
Rapporteurs: Dr. Carter and Dr. Forbes.

2. Can the Committee confirm that the risk from the metabolites IN-KZ007 and IN-JS940, to earthworms, has been sufficiently addressed?
Rapporteurs: Dr. Carter and Dr. Sherratt.

3. Can the Committee comment on the relevance of the eyes effect observed in the 12 months dog study to man? Should mechanistic study on eyes be required?
Rapporteur: Dr. Delcour-Firquet.

4. Can the Committee confirm that the operator exposure has been sufficiently addressed?
Rapporteur: Dr. Moretto.

Prof. Hardy, pointed out that with respect to question 2, data were still missing. The Committee agreed to defer the evaluation of famoxadone dossier until the Rapporteur Member State submits an evaluation of the new earthworms ecotoxicity studies (addendum to the draft evaluation report).

6.2 Flufenacet

Rapporteurs were appointed to deal with each question.

The following questions are addressed to the Committee:

1. Is the Committee satisfied that the relevance of metabolites M2 and M4 has been sufficiently addressed?
Rapporteurs: Dr. Carter, Mr. Koepp, Dr. Speijers

2. Can the Committee confirm that the operator exposure has been sufficiently addressed?
Rapporteur: Dr. Fait

6.3 Flumioxazine

Rapporteurs were appointed to deal with each question.

The following questions are addressed to the Committee:

1. Can the Committee confirm that the test protocol used to assess the effect on *Lemna* is adequate in view of the proposed uses?
Rapporteur: Dr. Luttik.

2. Can the Committee confirm that the test protocol used to assess the effect on earthworms is adequate in view of the proposed uses?
Rapporteur: Dr. Luttik.

3. Are the development effects seen in animal studies of relevance to human?
Rapporteur: Dr. Meyer

6.4 Imazosulfuron

Rapporteurs were appointed to deal with the question.

The following question is addressed to the Committee:

"Can the Committee comment on the relevance of the metabolite ISPN due to its presence in soil and water?"
Rapporteurs: Drs. Boesten, Hart and Mr. Koepp.

6.5 Pyraflufen-ethyl

Rapporteurs were appointed to deal with the question.

The following question is addressed to the Committee:

"In the context of the proposed uses, can the Committee comment on the risk of ground water contamination in particular in relation to metabolite E1?"
Rapporteurs: Dr. Boesten, Dr. Luttik, Prof. Savolainen.

8 Progress report and exchange of views on GM plant dossiers referred to the SCP

8.1 Adventitious presence of GM seeds in conventional seeds.

Prof. Hardy informed the Committee that a special *ad hoc* working group has been established to deal with questions related to the adventitious presence of GM seeds in conventional seeds referred to the Committee.

The following questions have been submitted by DG SANCO:

1. As a threshold of 1% was established for the adventitious presence of (authorized) genetically modified material in food and food ingredients in respect of labelling under Commission Regulation N° 49/2000, we would like, on the basis of the considerations developed in the background point b) to propose the following thresholds for the adventitious presence of GM seeds covered by an authorisation under part C of Directive 90/220/EEC:

- 0.3% in the case of cross-pollinating crops,
- 0.5% in the case of self-pollinating crops and vegetatively propagated crops.

Do you find any error or difficulty in our reasoning?

If so, what other threshold(s) would be justified?

2. We would like, on the basis of the considerations developed in the background point c) to propose that no GM plants of the same species or of a closely related species have been grown in the field used for the production of seed of a non-GM variety in the previous

- five years in the case of small seeded Leguminosae (fodder plants), oil and fibre plants,

- two years in the case of plants other than those under the previous point.

Do you find any error or difficulty in our reasoning?

If so, what other time spans would be justified?

3. As GM seeds not covered by an authorisation under part C of Directive 90/220/EEC should not be present in conventional plant varieties and if it is justified that GM seeds covered by an authorisation under part C of the said Directive should not exceed a threshold of 0.3% in the case of cross-pollinating species, we would like, on the basis of the considerations developed in the background point d) to propose:

- the doubling of the minimum distances currently applicable under the existing EU seed legislation for the isolation of the crop for the production of seed of cross-pollinating species in respect of neighbouring sources of pollen of GM plants which may result in undesirable foreign pollination.

Do you find any error or difficulty in our reasoning?

If so, what other minimum distances would be justified?

The special *ad hoc* WG, chaired by Prof. Hardy, met on 16 and 17 January. Prof. Davies was appointed rapporteur for the dossier. A draft opinion is currently under preparation and the intention is that the opinion will be adopted at the Plenary meeting of 7 March.

8.2 Starch potato from Amylogen (Notification C/SE/96/3501)

The Secretariat informed the Committee that the notifier intends to submit new data soon. This will be examined by the newly established joint SCP/SCF/SCAN working group on GMOs and novel food ("Joint GMO WG"), which will meet for the first time on 1 February.

8.3 "Guidance document to facilitate notifiers in the preparation of GM plants dossiers for consideration by the SCP"

Prof. O'Gara, informed the Committee that the draft documents was almost finalised and will be examined by the Joint GMO/Novel food WG on 1 February.

9. Introduction to CIRCA SCP web site

The Secretariat of the Committee made a presentation of the Commission password protected web site (CIRCA) currently being developed for the SCP with the aim of streamlining the management of the SCP documentation.

The Committee members were enthusiastic about the presentation and agreed to test it during the period of time before the next plenary meeting. Report of the test will be made at the plenary meeting of March.

10. Other business

Date of the next meeting: 7 March 2001.

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[1] No Observed Effect Level.