Minutes of the Twenty fifthth meeting - Brussels, 7 March 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, Prof. M. MARONI, Dr. O. MEYER, Dr. A. MORETTO, 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
Dr. H. A. KUIPER

Invited Experts
-

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/025-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 Fourth Plenary Meeting and matters arising (26 January 2001)

4.1 Adoption of the minutes of the Twenty Fourth Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/024-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*

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, the safety requirements with respect to residues in food and feed have been adequately addressed by the Commission Peer Review Programme.

The second question deals with the assessment of operator exposure. The Committee concludes that considering the data available, it is not possible to establish a NOAEL [1] for pulmonary toxicity and therefore neither is it possible to confirm the margin of safety for inhalatory exposures in operators. Consequently, the Committee is of the opinion that the risk to operators has not been adequately addressed.

As regard question 3, the Committee expresses the opinion that in the absence of information on pulmonary toxicity, it is unable to comment on the necessity for repeated dosing by inhalation to assess hazard to humans due to absence of information on pulmonary toxicity.

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 be a prudent measure.

The opinion is available as document SCP/AMPEL/002-Final

5.2 Acibenzolar-S-methyl

This new active substance had been referred to the Committee without any question for response. Following an exchange of views the Committee noted the documentation submitted and decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex VI (Uniform Principles) of Directive 91/414/EEC.

The Committee reiterated its earlier statements that absence of comments should only be interpreted as an indication of no obvious reasons necessitating comments.

Prof. Maroni raised the question on the expectation of the Commission concerning the dossiers with no precise questions. He pointed out that so far the Committee has been expected to address specific questions by scrutinising the documentation produced by the ECCO process, the monograph prepared by rapporteur member states and where necessary the original studies directly related to the specific issues raised by the question.

The Committee confirmed that there had been no in-depth peer review of the monograph and stressed that it does not have the resources to perform such a work. It was agreed the Chairman of the Committee should write a letter to the Commission services requesting clarification as to the Commission's expectation where dossiers are referred without questions. In addition, Prof. Hardy will raise the matter of referral of unclear and insufficiently focused questions: such questions require the deployment of greater resource from the Committee that would otherwise be necessary, slow the work progress and risk that the Committee does not respond to the precise needs of the Commission.

5.3 Glyphosate / glyphosate trimesium

These existing active substances had been referred to the Committee without any question for response. Following an exchange of views the Committee decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex VI (Uniform Principles) of Directive 91/414/EEC.

The Committee reiterated its earlier statements that absence of comments should only be interpreted as an indication of no obvious reasons necessitating comments.

5.4 Quinoxyfen

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

The Committee was asked to respond to the following question: "Is there any scientific reason to suspect that the use of quinoxyfen under the proposed conditions of use would lead to accumulation in soil at such levels that an unacceptable impact on the environment would occur?"

The Committee is of the opinion that the available studies on quinoxyfen do not convincingly demonstrate acceptable impact on the environment.

In addition, the Committee further noted that in the order of 10% of the dose of quinoxyfen may volatilise after application to a crop. In view of the uncertainty in the estimated atmospheric half-life of quinoxyfen of 1.9 days, the Committee expects that measurements of this half-life will be necessary after appropriate schemes have been developed.

The opinion is available as document SCP/QUINOX/002-Final

5.5 Cyhalofop-butyl

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

The Committee was asked to respond to the following questions:

- Can the Committee confirm that a use exists which is acceptable for aquatic organisms and for non-target arthropods?

- Can the Committee confirm that the operator exposure has been sufficiently addressed?

As regard question 1, the Committee concludes that a use exist which is acceptable for aquatic organisms. With regard to non-target arthropods, the Committee considers that there are some uncertainties with regard to non-target arthropods other than bees.

With respect to the second question the Committee is of the opinion that the operator exposure to cyhalofop-butyl has been adequately addressed.

The opinion is available as document SCP/CYHALO/002-Final.

5.6 Iprovalicarb

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

The Committee was asked to respond to the following questions:

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

As regard question 1, the Committee expressed the opinion that the protocol for evaluating the effects of chronic exposure of earthworms to the parent compound did not include a sufficiently high test concentration to allow for a margin of safety, and therefore these tests are inconclusive.

Concerning the second question, the Committee is of the opinion that the data set presented does not rule out the relevance to humans of the tumours observed in rats after iprovalicarb treatment.

The opinion is available as document SCP/IPROVA/002-Final.

5.7 Benomyl/ Carbendazim / Thiophanate-methyl

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

The three substances are currently under evaluation under the ECCO peer review programme. Before the peer review is completed, the Commission requested the SCP to clarify the genotoxicity profile of the three substances.

The Committee noted that carbendazim is the biologically active substance common for the three fungicides. The Committee concluded that carcinogenicity is not a concern. Given that the known effects of these substances upon reproduction are explicable by their interaction with the microtubules of the spindle apparatus (inhibition of polymerisation of tubulin), and since multiple copies of tubulin molecules are present in proliferating cells in the presence of low concentration of the fungicides, a limited number of tubulin molecules will be affected.

However the Committee is satisfied that a clear no adverse effect level exists and that both an ADI [2] and an AOEL [3] can be derived.

The opinion is available as document SCP/BENOMY/002-Final, SCP/CARBEN/002-Final and SCP/THIOPHAN/002-Final.

5.8 2,4-D

Prof. Maroni updated the Committee on the progress made on the dossier. Following he working group meeting of 6 March Dr. Moretto will revise the draft opinion for final discussion at the next TOX WG. Adoption of the opinion is envisaged at the next plenary meeting.

5.9 Famoxadone

The secretariat informed the Committee that all information is now available (the Committee awaited an addendum to the draft assessment report which has been submitted and made available to all members and ad hoc experts). Prof. Hardy confirmed that the Committee can now proceed.

5.10 Flufenacet

Prof. Hardy and Prof. Maroni informed the Committee that this dossier is currently under evaluation by rapporteurs (see minutes of the 24th Meeting). The draft opinions will be discussed at the next meeting of the TOX WG and the ENV WG.

5.11 Flumioxazin

Prof. Hardy informed the Committee that a draft opinion on the two questions dealing with environmental issues have been prepared and is currently under consideration by the ENV WG.

Prof. Maroni informed the Committee that the rapporteur, Dr. Meyer, submitted a draft opinion on the toxicological question which will be discussed at the next meeting of the TOX WG.

5.12 Imazosulfuron

Prof Hardy informed the Committee that a draft opinion on the sole question dealing with the relevance of metabolite ISPN, has been submitted by the rapporteurs and has been discussed by the ENV WG.

The ecotoxicological assessment will be further discussed at the next meeting of this working group (3 April), while the toxicological assessment will be discussed at the TOX WG of 20 March.

5.13 Pyraflufen-ethyl

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

The Committee was asked to comment on the risk for ground water contamination in particular in relation with metabolite E1.

The Committee concludes that it is unlikely that concentrations of E1 will exceed 0.1 mg/l. There is negligible risk of groundwater contamination for the parent compound and groundwater concentrations for other metabolites are expected to be considerably lower than those estimated for E1. The Committee is of the opinion that exposure to E1 through drinking water does not pose a significant health risk for humans.

The opinion is available as document SCP/PYRAF/002-Final

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

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

6.1 Ethoxysulfuron

The Committee is requested to answer the following question:

"Can the Committee confirm that the risk to aquatic organisms has been adequately addressed?"

Prof. Hardy informed the Committee that Dr. Forbes has been appointed rapporteur to deal with this question

6.2 Prosulfuron

The Committee is requested to answer the following questions:

1. Can the Committee comment on the acceptability of the risk of metabolites M5 and CGA 349707 to sediment dwelling organisms?

2. The Committee is requested to comment on possible hormonal disruption effects on uterus and mammary glands in test animals and possible relevance to human.

Prof. Hardy and Prof. Maroni, respectively chairmen of the ENV WG and the TOX WG informed the Committee that Dr. Forbes has been appointed rapporteur on question 1 and Dr. Petzinger rapporteur on question 2.

6.3 Ferric phosphate

This dossier was referred to the Committee without specific question. Further to the discussion under items 5.2 and 5.3, Prof. Hardy suggested to defer any work on this dossier until clarification has been received from the Commission on dossiers without questions.

6.4 Iprodione

The Committee is requested to answer the following questions:

1. After a thorough assessment of all available information the RMS concluded that sufficient information is available to reliably estimate the Predicted Environmental Concentrations in soil (PEC_s) and groundwater (PEC_{gw}). Can the Committee comment on this assessment?

2. Can the Committee comment on Acceptable Operator Exposure Level (AOEL) selected?

Prof. Hardy and Prof. Maroni, respectively chairmen of the ENV WG and the TOX WG informed the Committee that Dr. Boesten has been appointed rapporteur on question 1 and Dr. Fait rapporteur on question 2.

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

7.1 Contamination of conventional seeds by GM plants

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

The Committee was asked to response to three questions.

In the first question, the Committee was requested to comment on the proposed labelling thresholds (0.3% in the case of cross-pollinating crops and 0.5% in the case of self-pollinating crops and vegetatively propagated crops) for adventitious presence of GM in conventional seeds in relation to the 1% labelling threshold for the adventitious presence of (authorised) genetically modified material in food and food ingredients.

The SCP is of the opinion that with the scientific knowledge currently available the thresholds of 0.3% for cross-pollinated crops and 0.5% for self-pollinated and vegetatively propagated crops will only be achieved under ideal seed production conditions. There will be situations where achieving these thresholds will be problematic e.g. varietal association cultivars, production of hybrid seed. Achieving the 0.3 % and the 0.5 % thresholds will become increasingly difficult as GM crop production increases in Europe. In due course the 1% threshold set by the Commission may have to be revised. The SCP is also firmly of the opinion that, in addition to the thresholds of 0.3 % or 0.5 % defined for seed used to produce the crop, farm management and commercial production practices will influence the ability to achieve a 1% threshold in food and food ingredients.

Question 2 dealt with the time span between two crops of a same species (or closely related species) in a field used for seed production of a non GM variety in order to meet the proposed 0.3 and0.5% labelling thresholds.

The Committee, after examining the available information, finds there is difficulty in the reasoning for the following two main reasons:

- the grouping in the Commission proposal is too general to address the probability of gene flow from volunteer plants in some species and varieties;
- there is a lack of clear scientific data on persistence times for some species and therefore reliance is placed on anecdotal evidence and seed production experience.

It is recommended that previous cropping requirements be addressed according to current knowledge on seed longevity genus by genus.

In question 3, the Committee was asked to comment on isolation distances of the fields used for the production of seeds of a non GM variety.

The SCP is of the opinion that with the scientific knowledge currently available the 0.3% standard for adventitious admixture in fully fertile (*Brassica napus*) oilseed rape can be achieved with currently implemented isolation distances. It is likely that current isolation distances in maize are adequate if other measures to reduce outcrossing (e.g. the use of physical or pollen barriers) are implemented. There is insufficient information to comment on isolation distances required for hybrid oilseed rape, turnip rape (*B. rapa)*, and Beta species. The SCP is also of the opinion that, in addition to isolation distances, a range of other measures currently used in seed crop management practices will influence the ability to achieve a 0.3% threshold in seed production.

In addition, the Committee commented on the issue of the zero level tolerance for unauthorised GM seed. The Committee is of the opinion that a zero level of unauthorised GM seed is unobtainable in practice.

The opinion is available as document SCP/GM-SEED-CONT/002-Final

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

Prof. O'Gara, co-chairman of the joint GMO/Novel food WG informed the Committee that the notifier submitted new data on the molecular characterisation of the GMO. The data were evaluated by the WG but were considered insufficient. It was agreed that further clarification will be sought with the notifier.

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

Prof. O'Gara, informed the Committee that a draft group has been established under the auspices of the joint SCF/SCP/SCAN GM-Novel food working group. The members of the draft group are Dr. Kuiper, Dr. Engel, Dr. Poeting, Dr. Chesson, Prof. Davies and Dr. Schiemann.

The draft group will meet for the first time on 19 April under the chairmanship of Dr. Kuiper.

8. Report on the experience on the use of CIRCA

Experience with CIRCA was reported to be successful. Some members reported minor difficulties which have been sorted out by contacting the secretariat.

Since all ad hoc experts of the ENV WG and the TOX WG have also access to CIRCA web site, it was agreed that CIRCA SCP sites should be used for the management of the documentation whenever possible.

9. Other business

Date of the next meeting: 25 April 2001.

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[1] No observed adverse effect level.

[2] Acceptable Daily Intake.

[3] Acceptable Operator Exposure Level.