



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees ; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON PLANTS

SCP/REPT/032

24 April 2002

**MINUTES OF THE THIRTY SECOND MEETING
OF THE SCIENTIFIC COMMITTEE ON PLANTS
BRUSSELS, 31 January 2002**

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: B232 6/25.
Telephone: direct line (+32-2)295.77.05, switchboard 299.11.11. Fax: 295.73.32.

Internet: Michael.Walsh@cec.eu.int

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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. A. LESZKOWICZ
Dr. O. MEYER
Prof. F. O' GARA (Vice-Chairman)
Prof. E. PAPADOPOULOU
Prof. E. PETZINGER
Dr. T. SHERRATT
Dr. G. SPEIJERS

Apologies

Prof. M. MARONI
Dr. A. MORETTO
Prof. K. SAVOLAINEN
Prof. J. SCHIEMANN
Prof. A. M. S. SILVA FERNANDES

Invited Experts

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Commission

Ms. M. DUNIER-THOMANN Environment
Mr. W. MAIER Health and Consumer Protection
Ms. B. BUJARRABAL Environment

Secretariat

Mr. M. WALSH Health and Consumer Protection, C2
Mr. J. FERRIERE Health and Consumer Protection, C2

1. Welcome and apologies

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

2. Adoption of the agenda

The agenda was adopted.
(Doc. SCP/AGENDA/032-rev2)

3. Declaration of interests by Members

No declaration was made.

4. Adoption of the minutes of the Thirty first Plenary Meeting (20 December) and matters arising

4.1 Adoption of the minutes of the Thirty first Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/031-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out122_en.pdf

4.2 Matters arising

None

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

5.1 Iprodione

Following a short exchange of view, the Committee adopted the opinion.

The Commission requested the Committee to comment on two issues, which remained unresolved following the peer review of the risk assessment. The first relates to the estimation of PEC_{soil} and $PEC_{groundwater}$ made by the Rapporteur Member State (RMS). The Committee considers that sufficient information is available to estimate the PEC_{soil} of iprodione but not for the metabolite RP 30228. The Committee disagrees with the half-life used for estimation of the PEC_{soil} values and carried out its own assessment based on different assumptions. The PEC_{soil} values thus estimated by the Committee are higher than those proposed by the RMS.

As regard $PEC_{groundwater}$, the Committee disagreed with the input parameter (half-life) used by the RMS for the assessment of the leaching of iprodione or its metabolites. The assessment of the SCP shows that for soils with pH below 6, leaching at concentration levels higher than 0.1 µg/L may occur in some realistic situations.

The opinion of the Committee highlights that the revision of the PEC values may cause a need to amend the respective risk assessment.

In the second question, the Committee was requested to comment on the Acceptable Operator Exposure Level (AOEL) proposed by the peer review group. After consideration of the available data, the Committee is of the opinion that the observed tumours in rats and mice are not relevant for risk assessment in humans and therefore there is no need for an additional safety factor for carcinogenicity. The Committee considers also that there is no need for a correction factor for oral absorption, as suggested by the peer review group. Finally, the Committee is of the opinion that the NOAEL used for the setting of the AOEL should be selected from the short-term study in rats, which is supported by data from the studies in dogs.

The opinion is available as SCP/IPRODIO/002-Final at:
http://europa.eu.int/comm/food/fs/sc/scp/out123_ppp_en.pdf

5.2 Draft guidance document on the setting of an Acute Reference Dose

Dr. Meyer, member of the working group on toxicology assessment outlined the key issues under discussion in the working group. Further discussions will take place at the next working group meeting of 25-26 February where an additional ad hoc expert (Dr. van Raaij) will be invited. The working group will deal with this request with high priority as requested by the Commission.

5.3 Draft guidance document on dermal absorption

Prof. Petzinger, co-rapporteur for this dossier with Dr. Moretto, informed the Committee that a special working group on dermal absorption was organised on January 15 and 16. The working group produced an advance draft, which is currently circulated for comments. Prof. Petzinger informed the Committee that the intention of the working group is to refer a draft opinion to the plenary for adoption at the March plenary meeting.

5.4 Draft guidance document on risk assessment for Birds and Mammals

Dr. Sherratt, member of the working group on environmental assessment informed the Committee that this draft guidance document is a complex paper. He outlined the main issues under discussion in the working group on environmental assessment. Prof. Hardy informed the Committee that the intention is to refer a draft opinion to the Committee for adoption at the March plenary meeting.

5.5 FOCUS surface water scenario

Prof. Hardy informed the Committee that the working group has started to review the draft FOCUS report, which was referred to the SCP in December 2001. He informed the Committee that the draft made available to the Committee is not the final draft of the FOCUS surface water group and clearly need additional work. The Committee agreed that the working group put its work on hold and await the final draft report from the FOCUS working group as well as the comments from the Member States.

5.6 Mesotrione

Dr. Meyer informed the Committee that the working group on toxicology has not yet started to discuss this dossier. Given that priority is given to the finalisation of the

opinion on the draft guidance documents on acute reference dose and on dermal absorption, the first in-depth discussion on mesotrione issues is deferred to some meetings in April or later.

5.7 Indoxacarb

Dr. Meyer informed the Committee that the working group has not yet started to discuss this dossier. He reported that Dr. Moretto, rapporteur for this dossier, informed the working group of the complexity of the issues to be addressed. As for mesotrione, the first in-depth discussion on indoxacarb issues is deferred to some meetings in April or later.

5.8 Vinclozolin

Prof. Hardy informed the Committee that the working group on environmental assessment has postponed the discussion of this dossier. He explained that this had been done because the Commission had requested that the report on FOCUS surface water scenario and the draft guidance document on risk assessment for birds and mammals be given priority. The first discussion of vinclozolin is tabled at the working group meeting of 8 March.

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

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

The additional information requested to the notifier is still awaited.

7. Report of the special workshop (25-26 October 2001)

Following the discussion the December meeting, Prof. Hardy revised the draft report. The Committee agreed with the new text subject to minor changes. It was agreed that Prof. Hardy would send the report with a cover letter to the Scientific Steering Committee, the chair of other Scientific Committees as well as to relevant Commission services.

8. Other Business

8.1 The Committee had an exchange of views on an urgent forthcoming request to the Committee concerning the draft Commission proposal establishing uniform principles for micro-organisms used as plant protection products and how best to handle the question. The Committee agreed that the most efficient way to deal with the request was to establish a multidisciplinary working group consisting of microbiologists, toxicologist and ecologists that would be chaired by Prof. Hardy. Prof. Hardy agreed that the Committee would do its utmost to satisfy the Commission's request before the summer break.

8.2 Prof. Hardy informed the Committee that at the GM working group of 1st February, DG Environment will introduced 2 draft documents on monitoring and environmental risk assessment. The SCP may be requested to provide an opinion on these documents.

8.3 The Committee had an exchange of views on the issue of the identification of research needs for risk assessment. The Committee decided to maintain a list of items where research is needed for risk assessment and to regularly liaise with DG Research for these subjects be included in DG Research priorities.

Date of the next meeting: 24 March '02