

Minutes of the twenty second meeting of the Scientific Committee on Plants - Brussels, 22 September 2000

ATTENDANCE LIST

Members

Prof. H. V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Dr. R. HANS, Prof. A. R. HARDY (Chairman), Prof. S. O. KARENLAMPI, Mr H. KOEPP, Dr. H. A. KUIPER, Prof. M. MARONI (Vice-Chairman), Dr. O. MEYER, Prof. F O' GARA (Vice-Chairman), Dr. T. SHERRATT, Prof. A. M. S. SILVA FERNANDES

Apologies

Dr. J. J. LEGUAY, Dr. A. MORETTO, Dr. H. G. NOLTING, Prof. K. SAVOLAINEN, Dr. G. SPEIJERS

Invited Experts

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Commission

Ms. M. DUNIER-THOMANN Environment

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, Apologies and Introductory Remarks

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

2. Adoption of the agenda

The agenda was adopted.

(Doc. SCP/AGENDA/022-Rev. 4)

(http://ec.europa.eu/food/sci-com/scp_en)

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 First Plenary Meeting and matters arising (20 July 2000)

4.1 Adoption of the minutes of the Twenty First Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/021-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 draft opinion was submitted to the Committee and was extensively discussed. On the basis of the discussion, the Committee agrees that the part related to toxicology issue needed to be refined. Prof. Maroni and Dr. Meyer were appointed to revise the draft opinion for discussion at the subsequent meeting of the working group on toxicology and a possible adoption by the Committee at the next Plenary meeting.

5.2 *Pseudomonas chlororaphis*

New data relating to the evaluation of the metabolites produced by the organisms have been submitted by the notifier to the Rapporteur Member State (Sweden). The Committee decided to suspend the evaluation of this active substance and wait for an addendum to the Monograph to be submitted.

5.3 *Paecilomyces fumosoroseus*

The draft opinion was submitted to the Committee and was extensively discussed. On the basis of the discussion, the Committee agrees that some parts related to the toxicology evaluation needed to be refined. Prof. Maroni was appointed to revise the draft text for discussion at the subsequent meeting of the working group on toxicology and a possible adoption by the Committee at the next Plenary meeting.

5.4 Ethoxysulfuron

Following an exchange of views the Committee adopted the preliminary opinion subject to some minor textual amendments. In its opinion the Committee answered one question from the Commission. The Commission requested the Committee to carry out a preliminary evaluation of the substance in order to address possible carcinogenicity properties of the substance.

The Committee concluded that the increase in uterine tumour incidence in rats is considered of no relevance to human risk as it occurred only at a high dose causing marked general toxicity. In addition, no carcinogenic effect was found in male rats, nor in male and female mice and no evidence for genotoxicity was found. For endocrine responsive tissues of rats, only ovary and uterus weight were decreased in a reproduction study, but without histological abnormalities and at clearly toxic doses. For these reasons no additional mechanistic studies are deemed necessary.

5.5 Flupyr-sulfuron-methyl

Prof. Hardy, Chairman of the Environment WG reported that the draft opinion was well advanced and its completion was dependent on the adoption of the draft Guidance Document on Relevant Metabolites.

5.6 Sulfosulfuron

The questions referred to the Committee dealt with toxicology: question 1 is a carcinogenicity issue and question 2 relates to the necessity to establishing an acute reference dose (ARfD). Prof. Maroni, Chairman of the Toxicology and Carcinogenicity WGs, reported that the draft opinion on the two questions was well advanced. The carcinogenicity WG had examined the matter on 5 September and will finalise its examination at its meeting of 6 November.

With respect to the question on ARfD, Prof. Maroni informed the Committee, that the question was discussed at the meeting of the Toxicology WG of 21 September and will be re-examined at the Toxicology WG of 9 November.

Prof. Hardy, Chairman of the Environment WG reported that the draft opinion on the ecotoxicity issue raised by the Committee was well advanced. The rapporteur Dr. Sherratt, will edit the draft opinion for discussion at the next Environment WG meeting.

5.7 Carfentrazone ethyl

The draft opinion on the single question on the relevance for humans of elevated porphyrins detected in test animals is now completed. The Committee still has to address the specific issue of the relevance of the three uncharacterised metabolites.

Mr. Koepf was appointed to address the environmental relevance of the metabolites, while Prof. Silva Fernandes will be dealing with the toxicology profile of these metabolites. The Secretariat was requested to contact the notifier about the response to the Committee's questions of 11 May 2000.

Further discussions will take place at the next meetings of the working groups on toxicology and on environmental issues.

5.8 2,4 D

Prof. Maroni, Chairman of the Toxicology WG, informed the Committee that Dr. Moretto has been appointed to prepare a draft opinion. Dr. Moretto is currently evaluating the data submitted by the notifier as well as the public data. The first exchange of view will take place at the next Toxicology WG meeting.

5.9 Pymetrozine

Two toxicology questions have been addressed to the Committee, one dealing with the setting of the ADI (Acceptable Daily Intake) and one with the establishment of an ARfD. Prof. Maroni, Chairman of the toxicology WG, informed the Committee, that he has been appointed to prepare a draft opinion on the ADI issue while Dr. Moretto will report on the ARfD question.

5.10 Quinoxyfen

Prof. Hardy, Chairman of the Environment WG, informed the Committee that the first exchange of view took place at the WG meeting of 4 September. The WG decided to refer to the notifier to request further data. Mr. Koepp and Dr. Boesten have been appointed to draft an opinion respectively on ecotoxicity issue and on the fate and behaviour issue.

5.11 Cyclanilide

Prof. Maroni, Chairman of the Toxicity WG, informed the Committee that due to the workload the WG at the meeting of 21 September the discussion on cyclanilide was postponed to the subsequent meeting of the WG.

5.12 Benomyl

5.13 Carbendazim

5.14 Thiophanate-methyl

Prof. Maroni, Chairman of the carcinogenicity WG, informed the Committee that the first exchange of view on these three substances took place at the WG meeting of 5 September.

Professors Parry and Savolainen have been appointed to respectively prepare a working document on the mutagenicity aspects and a working document on the carcinogenicity/reproductive aspects. These documents will be discussed at the WG meeting planned for 6 November.

5.15 Thiabendazole

Following an exchange of views the Committee adopted the opinion subject to some minor textual amendments. In its opinion the Committee answered one question from the Commission, related to potential environmental risk associated with the post-harvest use of this active substance.

The Committee concluded that providing that appropriate mitigation measures are implemented, post-harvest use of thiabendazole will not pose an unacceptable risk to the aquatic environment.

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out74_ppp_en.pdf

5.16 Flurtamone

Prof. Maroni, Chairman of the Toxicology WG, informed the Committee that the first exchange of view on the new data on the metabolite TFAA (trifluoro-acetic acid) took place at the WG meeting of 21 September. Members of the Toxicology WG have been requested to evaluate the new data submitted by the notifier. The question will be addressed at a future meeting of the WG on toxicology.

Prof. Hardy, Chairman of the Environment WG, informed the Committee, that the issue of the metabolite TFMBA is in progress. New soil study data, showing different results from the 1998 lysimeter study submitted at the time of the first evaluation, have been submitted. Dr. Sherratt and Dr Carter have been appointed to evaluate the new data.

5.17 CGA 45 704 (azibenzolar-methyl)

No specific question has been referred to the Committee.

Due to the workload, the Committee has not been able to start the overall evaluation of this substance. This can only be done after opinions on substances currently dealt with by the Committee would have been adopted.

6. Progress reports on guidance documents submitted to the SCP for opinion

6.1 Draft Guidance Document on Relevant Metabolites

Prof. Hardy, Chairman of the joint Environment/Toxicology WG, invited Mr. Koepp, rapporteur for this dossier to introduce the draft opinion to the Committee.

Following an extensive exchange of view, the Committee agreed that a revised text should be circulated to all Committee members and *ad hoc* working groups. It is the intention to adopt the opinion at the next Plenary Meeting.

6.2 FOCUS groundwater scenarios in the EU plant protection products review process

Following an exchange of view, the Committee approved the [draft opinion](#), subject to some minor textual amendments.

7. 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.

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

Following the Plenary meeting of 20 July 200, further questions were addressed to the notifier. The Committee is still awaiting the requested outstanding data.

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

Following the WG meeting of 21 September it was agreed to refer to request further data from the notifier to establish the substantial equivalence of the GM rape seeds and enable the Committee to finalise its opinion.

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

The Chairman of the GM WG Professor O' Gara informed the Committee that new data relating to the Bt11 event were presented in July at a conference held in Baltimore (Iowa, USA) and that these data may confirm the substantial equivalence of the Bt11 lines with conventional maize. It was agreed to refer to the notifier to request a copy of the data to finalise the opinion.

7.4 Genetically modified maize (*Zea mays*) line GA21, with tolerance to glyphosate herbicide from Monsanto (Notification C/ES/98/01)

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

The Committee was asked to consider whether there is any scientific reason to believe that the placing on the market of genetically modified maize (*Zea mays*) line GA21 tolerant to glyphosate herbicide with the purpose to be used as any other maize is likely to cause any adverse effects on human health and the environment.

The Committee, after examining the information and data provided in the dossier and using available background knowledge underpinning the areas concerned, considers that there is no evidence to indicate that the placing on the market of the modified maize line (*Zea mays* GA21) with tolerance to glyphosate herbicide is likely to cause any adverse effects on human health and the environment. [Click here](#)

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

The draft document prepared by the GMO working group was introduced to the Committee. After a brief exchange of view, it was agreed that Dr. Kuiper will revise the document, in accordance with the outcome of the discussion. The document will be adopted as a recommendation from the Scientific Committee on Plants.

8. Invocation by Germany of Article 16 of Council Directive 90/220/EEC regarding a genetically modified Bt-maize line CG 00256-176 notified by Ciba-Geigy (now Novartis, Notification C/F/94/11-03)

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

The Committee was asked to consider the following questions:

- Does the information submitted by Germany constitute relevant scientific evidence, which would cause the Committee to consider that this product constitutes a risk to human health and the environment?
- Does this information constitute relevant scientific information that invalidates the original risk assessments for the other Bt-products that have been approved or are pending approval under the provisions of Directive 90/220/EEC following appraisal by the Scientific Committee?

Following an extensive exchange of view, the Committee agreed to circulate a [revised text](#), which will be circulated to all Committee members for adoption by written procedure. The Committee concluded that, following its examination of the scientific information provided by the German Competent Authority, these do not alter the original risk assessments carried out on the Ciba-Geigy (now Novartis) Bt-maize Line CG 00256-176. The Committee also considers that the information does not invalidate the original risk assessments made for the other Bt-products, which have been approved or are pending approval after evaluation by the SCP.

9. 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, Notification C/F/95/12-07)

The English translation of the documentation supporting the Austrian invocation was transmitted to the Committee. Prof. Hardy was appointed to prepare a draft opinion, which will be discussed at the next GMO WG meeting. The Committee will endeavour to adopt an opinion at the next Plenary meeting.

10. Other business

Date of next meeting:

The next meeting will take place on 30 November 2000 under the new mandate of the Committee.