

# **Minutes of the twenty first meeting of the Scientific Committee on Plants - Brussels, 20 July 2000**

## *ATTENDANCE LIST*

### *Members*

Prof. H. V. DAVIES, Dr. R. HANS, Prof. A. R. HARDY (Chairman), Prof. S. O. KARENLAMPI, Mr H. KOEPP, Dr. O. MEYER, Dr. A. MORETTO, Prof. F O' GARA (Vice-Chairman), Prof. K. SAVOLAINEN, Prof. A. M. S. SILVA FERNANDES, Dr. G. SPEIJERS

### *Apologies*

Dr. M.-P. DELCOUR-FIRQUET, Dr. H. A. KUIPER, Dr. J. J. LEGUAY, Prof. M. MARONI (Vice-Chairman), Dr. H. G. NOLTING, Dr. T. SHERRATT

### *Invited Experts*

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### *Commission*

Mr. W. M. MAIER Health and Consumer Protection, E1, Mr. L. BRESLIN Research, B11, Mr. B. VERACHTERT Research, B11

### *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/021-Rev. 3)

## **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 Twentieth Plenary Meeting and matters arising (6 June 2000)**

### **4.1 Adoption of the minutes of the Twentieth Plenary Meeting**

The draft minutes were approved and are available as Document SCP/REPT/020-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***

A draft opinion has been prepared by the rapporteurs and will be discussed at the micro-organisms' WG <sup>1</sup> on 6 September, for possible adoption at the Plenary meeting on 22 September.

### **5.2 *Pseudomonas chlororaphis***

A draft opinion has been prepared by the rapporteurs and will be discussed at the micro-organisms' WG on 6 September.

### **5.3 *Paecilomyces fumosoroseus***

A draft opinion has been prepared by the rapporteurs and will be discussed at the micro-organisms' WG on 6 September, for possible adoption at the Plenary meeting on 22 September.

### **5.4 Ethoxysulfuron**

The draft opinion has been prepared and will be discussed at the carcinogenicity WG of 5 September, for possible adoption at the Plenary meeting on 22 September.

### **5.5 Flupyrsulfuron-methyl**

The draft opinion is planned to be finalised after the WG meeting of 4 September where the draft opinion on "relevant metabolites" will be discussed.

### **5.6 Sulfosulfuron**

Three questions have been addressed to the Committee. With respect to the first question relating to toxicology issues, information from the notifier is awaited. Subject to submission of the information by the notifier, the draft opinion on question 1 will be discussed at the WG meeting on carcinogenicity on 5 September.

The draft opinion on question 2 (relating to the necessity of establishing an acute reference dose) has been prepared and will be discussed at the Toxicology WG on 21 September.

The draft opinion on question 3 related to the possible long term effects on earthworms will be discussed at the Environment WG scheduled on the 4<sup>th</sup> of September.

The intention is to submit a draft opinion for adoption at the Plenary meeting of 22 September.

### **5.7 Carfentrazone ethyl**

One question on toxicology issue has been referred to the Committee. The SCP has raised one specific environmental issue.

Further information on three uncharacterised metabolites has been requested from the notifier. The Committee still awaits the notifier's response. The opinion of the Committee on this specific issue relating to metabolites will be finalised after the opinion on the Guidance document on relevant metabolites has been adopted (see 6.1 hereafter).

The contribution of the rapporteur on the toxicology question (Dr. M-P Delcour-Firquet) will be discussed at the relevant WG meeting of 21 September.

#### **5.8 2,4 D**

The Committee has been requested to answer to one question related to the setting of the ADI <sup>2</sup> and the NOAEL <sup>3</sup>. The first exchange of view will take place at the Toxicology WG on 21 September.

With respect to environmental issues, the Committee has completed the evaluation of the relevant part of the dossier. No outstanding environmental issue was identified.

#### **5.9 Pymetrozine**

The Committee has received the documentation. The first exchange of view will take place at the Toxicology WG of 21 September.

#### **5.10 Quinoxifen**

The Committee has been asked to answer to one question related to the possible long-term accumulation of quinoxifen in soils. The first exchange of view will take place at the Environment WG of 4 September.

#### **5.11 Cyclanilide**

The Committee is requested to answer to two toxicology questions. Two rapporteurs have been appointed respectively Dr. A. Fait (question 1) and Dr. O. Meyer (question 2). The draft opinions will be discussed at the Toxicology WG of 21 September.

#### **5.12 Fenhexamid**

No specific question was addressed to the Committee.

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 <sup>4</sup>. It was recognised that national authorisations would involve specific risk management in line with Annex VI <sup>5</sup> (Uniform Principles) of Directive 91/414/EEC.

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

### **5.13 Benomyl**

### **5.14 Carbendazim**

### **5.15 Thiophanate-methyl**

The Committee was asked to answer to one question related to the establishment of an ADI and an AOEL. The first exchange of view will take place at the WG on carcinogenicity of 5 September.

The Secretariat informed the Committee that the evaluations of these active substances had not been completed and that it was likely that further questions would be referred to the Committee in due course. Accordingly, the Committee was requested for the present to confine its evaluation to the one question.

### **5.16 Thiabendazole**

The environmental issue related to the use of thiabendazole as a post-harvest treatment (adequacy of "waste water treatment" to protect surface water) will be dealt with at the WG of 4 September, for possible adoption at the Plenary meeting of 22 September.

### **5.17 Flurtamone**

The SCP in its opinion of 18 January 1999 <sup>6</sup> expressed concern regarding the human toxicology and ecotoxicology of the soil metabolites of flurtamone. Additional data had been recently submitted to the Committee and the Environment WG considered these data at its meeting of 28 June. The WG felt that the summarised data provided insufficient detail and the full study reports were requested. These will be discussed at the WG's meeting of 4 September.

A new study on the health risk of TFAA <sup>7</sup> metabolite has been submitted by the notifier. It will be referred to the Toxicology WG, which will meet on 21 September 2000.

### **5.18 CGA 45 704**

No specific question has been addressed to the Committee. The Committee will carry out an overall evaluation of the dossier.

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

### **6.1 Draft Guidance Document on Relevant Metabolites**

The draft opinion is being prepared. It will be circulated to WG members in order to be discussed at the joint WG of the SCP/SCTEE <sup>8</sup> on 4 September.

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

The draft opinion is being prepared. It will be circulated to WG members in order to be discussed at the joint SCP/SCTEE scheduled on 4 September.

## **7. Presentation / Exchange of views on the Commission Research and Development Programme Key Action 1 Food Nutrition and Health**

The Commission (DG Research) made a presentation of its Research and Development program, in particular key Action 1 "Food Nutrition and Health". The Commission insisted on the willingness to link the actions of the R&D Commission programmes with Community policy.

In that respect, the Commission (DG Research) would welcome recommendations and/or proposals for action, from scientific committees.

Specific information was provided on on-going projects related to the safety assessment of genetically modified food crops.

## **8. Progress report and exchange of views on plant GMO dossiers**

The secretariat informed the Committee that a GMO WG meeting was held on 19 July.

Prof. F O'Gara, chairman of the GMO WG, updated the Committee on the state of play of GMO dossiers.

### **8.1. Starch potato from Amylogene (Notification C/SE/96/3501)**

Further to the Committee request, a feeding study has been submitted by the notifier. It will be evaluated and discussed at the GMO WG of 21 September.

However, the extent of the response to the questions relating to ORF4 was not fully satisfactory. The Committee agreed to refer to the notifier and request further data.

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

The responses to two of the five questions referred to the notifier on 28 October 1999 are still being awaited. The Committee expressed concerns about the delays in receiving the necessary information to complete its evaluation.

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

Further to the letter sent to the notifier on 11 May, additional data has been provided by the notifier immediately prior to the meeting. The evaluation of this new set of data will be discussed at the GMO WG on 21 September.

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

The information requested by the SCP in April 2000 was supplied and will be evaluated. The evaluation will be discussed at the GMO WG meeting on 21 September.

**9. 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)**

The Committee is requested to respond to two questions:

1. 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?
2. Does this information constitute relevant scientific information that invalidates the original risk assessment for other "Bt-products" that have been approved or are pending appraisal by the Scientific Committee?

The Secretariat requested the Committee to deal with the questions urgently and the Committee agreed. A Hardy was appointed as rapporteur. A draft opinion will be prepared and discussed at the GMO WG of 21 September. The Committee will endeavour to adopt an opinion at the Plenary meeting of 22 September.

**10. 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 Committee is asked to respond to the following question:

- "Does the information submitted by Austria constitute relevant scientific evidence, which would cause the Committee to consider that this product constitutes a risk to human health and the environment?"

The technical justification of the safeguard clause adopted by Austria has been submitted in German language. An English translation has been requested by the Committee. The Committee agreed to give a high priority to this dossier, as soon as the English version of the documentation is available.

**11. Other business**

*Revision of the "Guidance document to facilitate notifiers in the preparation of Plant GMO Dossiers for consideration by the SCP":*

A draft document will be discussed at the next GMO WG scheduled on 21 September.

**Date of next meeting:**

The next meeting of the Committee will take place on 22 September 2000.

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<sup>1</sup> Working group.

<sup>2</sup> Acceptable daily intake.

<sup>3</sup> No observed adverse effect level.

<sup>4</sup> OJ No L 230, 09.08.1991, p.1, at last amended by Directive 1999/80/EC (OJ No L 210 of 29.07.99 p. 13).

<sup>5</sup> OJ No L 265, 27.09.1997, p.87.

<sup>6</sup> [click here](#)

<sup>7</sup> Trifluoroacetic acid.

<sup>8</sup> Scientific Committee on toxicity, ecotoxicity and the environment.