

# **Minutes of the Twentieth Meeting of the Scientific Committee on Plants - Brussels, 6 June 2000**

## ***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. M. MARONI (Vice-Chairman), Dr. O. MEYER, Dr. A. MORETTO, Dr. H. G. NOLTING, Prof. K. SAVOLAINEN, Dr. T. SHERRATT, Prof. A. M. S. SILVA FERNANDES

### ***Apologies***

Dr. R. HANS, Dr. J. J. LEGUAY, Prof. F O' GARA (Vice-Chairman), Dr. G. SPEIJERS

### ***Invited Experts***

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### ***Commission***

Mrs. M. DE SOLA Health and Consumer Protection, B2, Mr. D. PETTAUER Health and Consumer Protection, B3

### ***Secretariat***

Mr. M. WALSH Health and Consumer Protection, B2, Ms. S. VAN IMPE Health and Consumer Protection, B2

## **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/020-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 Nineteenth Plenary Meeting and matters arising (17 March 2000)**

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

The draft minutes were approved and are available as Document SCP/REPT/019-Final.

### **4.2 Matters arising**

None.

## **5. Progress report (including possible adoption of certain opinions) on the following plant protection product dossiers referred to the Scientific Committee on Plants**

### **5.1 *Ampelomyces quisqualis***

The Secretariat reported that the Working Group meeting scheduled for 28 March had taken place. Following an exchange of views, rapporteurs were appointed to prepare contributions to the various questions for examination at the WG of 27 June.

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

Following an exchange of views at the WG of 28 March it was decided to seek certain clarifications from the Notifier. The questions related to a metabolite produced by the micro-organism and the extent of operator exposure. The WG will continue its examination as soon as the data is received.

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

Following an exchange of views at the WG of 28 March it was decided to seek certain clarifications from the Notifier. The questions related to the extent of operator exposure. The WG will continue its examination as soon as it receives the required information.

### **5.4 Ethoxysulfuron**

M. Maroni, Chairman of the Toxicology WG reported the draft opinion prepared by P. Wester had been examined on 23 May 2000. The draft opinion will be considered at the Plenary Meeting of 20 July.

### **5.5 Flupyr-sulfuron-methyl**

A Hardy, Chairman of the Environment WG reported that the draft opinion was well advanced. The Committee decided, since the draft opinion involved consideration of metabolites, to defer adoption of the opinion until the SCP has issued its opinion on the draft Guidance Document on Relevant Metabolites. The WG will return to the draft opinion at its next WG meeting of 4 September.

### **5.6 Sulfosulfuron**

The questions referred to the Committee dealt with carcinogenicity, necessity to establish an acute reference dose and possible effects on earthworms. M. Maroni, Chairman of the Toxicology WG reported that the WG, which met on 23 May, had referred questions of clarification to the notifier. If the response is received in time, these will be examined at the WG meeting scheduled for 5 September. He also reported that K. Savolainen had been appointed to prepare the draft opinion on the necessity for establishing an acute reference dose. A Hardy, Chairman of the Environment WG reported that T. Sherratt would evaluate the recently available study on possible long-term effects on earthworms. This would be considered at the Environment WG of 4 September.

### **5.7 Carfentrazone ethyl**

A single question had been referred to the Committee on the relevance for humans of elevated porphyrins detected in test animals. It was satisfied with the draft opinion on porphyrins, subject to some minor amendments. However, the Committee sought clarification from the notifier regarding the relevance of three uncharacterised metabolites  $>0.1\mu\text{g} / \text{l}$  in soil leachate. The Committee decided to defer adoption of its opinion until it had issued its opinion on the draft Guidance Document on Relevant Metabolites.

## **5.8 Pyridate**

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

In its response to a question on establishment of the Acceptable Operator Exposure Level (AOEL) for pyridate the Committee concluded that the three generation study in rats was suitable for the estimation of the AOEL for pyridate. In the absence of a mechanistic explanation of the observed effects on organ weights, and in the absence of data to predict the relevance of similar effects to humans, it is justified to use the NOAEL of 3.6 mg/kg bw/day, based on decreased thyroid weight and increased kidney weight for AOEL setting.

## **5.9 Amitrole**

Following an exchange of views the Committee adopted the opinion subject to some minor textual amendments. In its opinion the Committee answered two questions from the Commission.

### **Question 1**

Can the Committee confirm that for amitrole, the appropriate study for the estimation of the AOEL is the dermal 28-day study? If not, which study would the Committee propose?

### **Opinion**

Due to the toxicological properties of amitrole, the NOAEL<sup>1</sup> of 100 mg/kg bw/day observed in the dermal 28-day study in rats can be used for the derivation of AOEL, taking into consideration an estimated skin absorption rate of 0.1-1 %.

### **Question 2**

Can the Committee comment on the relevance for man of the thyroid tumours found in rodents?

### **Opinion**

The thyroid tumours found in rats after long-term amitrole treatment appear to be of little or no relevance for humans. The thyroid carcinogenic effect of amitrole appears to be mediated through thyroid-pituitary disruption to which humans are less sensitive than rodents.

## **5.10 Warfarin**

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.

## **Question**

The Committee is requested to comment on the acceptability of using clinical data generated following repeated warfarin use as an anti-coagulant in human medicine for establishing an Acceptable Daily Intake (ADI) and an Acceptable Operator Exposure Level (AOEL).

## **Opinion**

The SCP is of the opinion that it is not necessary to allocate an ADI for warfarin. However, data available from the extensive clinical use of warfarin as an anticoagulant may confidently be expected to support the establishment of an ADI, should this be considered necessary. An AOEL can likewise be established based on human data, taking into account that in rats about 15% of the applied dose is absorbed through the skin.

## **Note Agenda items 5.11 to 5.21**

It had not been possible to circulate the monographs prior to the meeting for agenda items 5.11 to 5.21 due to the workload involved. M. Maroni referred to his statement made at the Seventeenth SCP Plenary Meeting where he drew attention to the fluctuations in the plant protection product work reaching the Committee. He stated that it was regrettable that the Commission was unable to circulate in a timely fashion the complete documentation and that unfortunately this could lead to delays in expressing opinions.

### **5.11 Pymetrozine**

#### ***Terms of Reference:***

- 1) Can the Committee give its opinion on the significance of the changes in serum sodium levels and should these be considered as an adverse effect in the context of estimating an ADI?
- 2) Can the Committee give its opinion on the significance of effects seen in the acute neurotoxicity study and should these be considered as an adverse effect in the context of estimating an acute reference dose?

### **5.12 Quinoxifen**

#### ***Terms of Reference:***

The properties of quinoxifen in soil raised some concerns about its potential to accumulate in soils. However, 5 year accumulation studies in various locations (south and north of France and Germany and UK) showed no trend for accumulation in soil and only a slight accumulation to a plateau of the metabolite 3-hydroxyquinoxifen.

1) Is there any scientific reason to suspect that the use of quinoxifen under the proposed conditions of use would lead to accumulation in soil at such levels that an unacceptable impact on the environment would occur?

### **5.13 Cyclanilide**

#### ***Terms of Reference:***

- 1) Does the SCP consider the effects on the mouse immune system to be of any relevance for man?
- 2) Does the SCP consider the teratological effects observed in the rabbit study to be of any relevance to man?

#### **5.14 Fenhexamid**

No question has been referred to the Committee

#### **5.15 Benomyl**

#### **5.16 Carbendazim**

#### **5.17 Thiophanate-methyl**

##### ***Terms of Reference:***

1) Can the Committee comment on the advisability of establishing an Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) having regard particularly to the results of mutagenicity, carcinogenicity and reproductive data for the active substance.

#### **5.18 Thiabendazole**

##### ***Terms of Reference:***

1) Can the Committee comment on the potential environmental risk associated with the use of thiabendazole and can it confirm that the proposed risk mitigation measures (waste water treatment) are adequate to protect surface waters?

#### **5.19 CGA254704**

No question has been referred to the Committee

#### **5.20 Flurtamone**

In its opinion 18 December 1998 <sup>2</sup>, the SCP concluded that the metabolite trifluoroacetic acid (TFAA) represents a risk for contamination of ground water but in the absence of mammalian toxicology data, the Committee was unable to evaluate the health risk.

The Committee has now been submitted the data to allow it to evaluate the health risk of TFAA.

#### **5.21 2,4-Dichlorophenoxy Acetic Acid (2,4D)**

##### ***Terms of Reference:***

1) Can the Committee comment on the adequate animal model to be used for the derivation of the ADI and the AOEL?

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

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

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

Due to the relevance of these documents to chemicals generally it had been decided to include members of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). The members of the WG are as follows:

- A. Hardy (Chairman),
- SCP members: MP Delcour, R. Hans, H. Koepp, M. Maroni, O. Meyer, A. Moretto, H\_G Nolting, K. Savolainen, T. Sherratt, A. Silva Fernandes, and
- CTEE Members: E. Dybing, C. Lambre, J. Rueff, MS Salkinoja-Salonen, JV Tarazona, M. Vighi and invited experts J. Boesten, A. Carter and V. Forbes.

It was reported that the Environment WG had examined the documents on 19 May and that a joint Environmental / Toxicology WG would meet on 28 June to examine the documents.

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

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

The Secretariat reported that the Commission services had decided to refer the question to the Notifier as agreed at the SCP Plenary of 2 December 1999. The question was transmitted to the Notifier on 6 March and concerned certain molecular biology aspects considered necessary to carry out the risk assessment. A response from the notifier is still awaited.

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

The Committee had referred five questions to the notifier on 28 October 1999. It had received responses on 27 January 2000 to three of the five questions it had raised. The Notifier responded partially on 3 May 2000 to the remaining two questions but indicated that the full response will be forthcoming in due course.

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

The Committee had received from the Notifier the additional detail on substantial equivalence that it had requested. Following an exchange of views it was decided that the data should be examined in detail for the next Plenary Meeting in July.

### **7.4 Conventionally derived crosses between approved genetically modified maize lines T25 and MON810 from Pioneer Overseas Corp. (Notification C/NL/98/08).**

The Committee examined the draft opinion and adopted its opinion. In its opinion it supported the proposed authorisation of the placing of grains, conventionally derived from crossing

T25xMON810, on the market with the restriction that the grain must not be used for cultivation.

The opinion is available as [Document SCP/GMO/195 - Final](#)

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

No progress could be reported as the Committee was still awaiting the substantial equivalence data on a site-by-site basis rather than as supplied (pooled). In addition the issue of data confidentiality for the requested molecular biology data was still being resolved.

## **9. Other business**

### **Date of next meeting:**

The next meeting of the Committee will take place on 20 July 2000.

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<sup>1</sup> **No Observed Adverse Effect Level**

<sup>2</sup> [http://ec.europa.eu/food/sci-com/scp\\_en](http://ec.europa.eu/food/sci-com/scp_en)