

# Minutes of the Seventeenth Meeting of the Scientific Committee on Plants - Brussels, 2 December 1999

## *ATTENDANCE LIST*

### *Members*

Prof. H. V. DAVIES, Dr. M.-P. DELCOUR-FIRQUET, Dr. R. HANS, Prof. A. R. HARDY (Chairman), Prof. S. O. KARENLAMPI, Dr. H. A. KUIPER, Dr. J. J. LEGUAY, Prof. M. MARONI (Vice-Chairman), Prof. F O' GARA (Vice-Chairman), Prof. A. M. S. SILVA FERNANDES, Dr. G. SPEIJERS

### *Apologies*

Dr. H. G. NOLTING, Prof. E. RODRIGUEZ CEREZO

### *Invited Experts*

Dr. O. MEYER

### *Apologies*

Mr H. KOEPP

### *Commission*

Mrs M. DE SOLA Health and Consumer Protection B2, Mr V. MATZEIT Environment E1, Mr G. VAN DEN EEDE Joint Research Centre

### *Secretariat*

Mr M. WALSH Health and Consumer Protection, B2, Mrs F. DRION 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/017-Rev. 1)

## **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 Sixteenth Plenary Meeting and matters arising (28 October 1999)**

[http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out53\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out53_en.pdf)

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

The draft minutes were approved and are available as Document SCP/REPT/016 -Final)

#### **4.2 Matters arising**

- The Chairman (who had been absent from the previous meeting) indicated, with reference to item 5 of the report on residues in food, that he supported the conclusion that a better co-ordination was needed between the SCs. In the ensuing exchange of views, members cited other areas of common concern to SCs which included acute dietary assessment for GMOs, risk arising from the ingestion of contaminants relating to the work of the CSTEE. Attention was also drawn to inconsistencies of approach in dealing with residues in plants and animals products. The Chairman confirmed that he would raise the matter at the next meeting of the SSC.

- M. Maroni drew the Committee's attention to the uneven flow of plant protection products work to the Committee which resulted in peaks and troughs in the work-load of the Committee. The Chairman referred to the imminent heavy workload for the Committee which would result from the deadlines established under Directive 91/414/EEC and the draft second review regulation. The Secretariat informed the Committee that the Commission Services had examined possible means of avoiding an excessive workload reaching the Committee. These included a recognition that cases would arise where no issues would be identified which required questions to the SCP. In such cases, the relevant review documentation would be submitted to the Committee for information and the period between meetings allowed for the Committee to react. The Committee agreed with the proposal but on the clear understanding that the absence of comment from the Committee could not be inferred to imply a formal endorsement by the Committee. Absence of comment should be interpreted as only an indication of the existence of no obvious reasons necessitating comment. The Chairman concluded by stating that the Committee was conscious of the importance of avoiding unnecessary delays and that its intervention should concentrate in adding value to the evaluative procedure.

#### **5. Exchange of views on the assessment of the acute toxicological risk posed by plant protection products residues**

M. Maroni, in his capacity as Chairman of the Toxicology WG, explained the background to the initiative to prepare a stand-alone opinion giving guidance on when an acute dietary risk assessment would be necessary. He explained that the Commission has referred such a question for each of the pyrethroid insecticides referred to the SCP and that the most efficient approach for the Committee would be to prepare a single opinion addressing this question. Moreover, the opinion would serve to provide guidance for future similar cases.

In an exchange of view, the Committee endorsed the approach taken by the Toxicology WG but suggested that further consideration be given to indicating the relationship between the draft opinion and the work of other international fora, such as, the JMPR. It was agreed that the opinion should be finalised for adoption at the next Plenary Meeting in January.

#### **6. Endocrine disruption - Adequacy of current testing of plant protection products in the context of Directive 91/414/EEC**

##### **Exchange of views on and possible adoption of the draft opinion**

[http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out55\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out55_en.pdf)

The opinion concluded that endocrine disruption need not be considered as of great concern for the assessment of plant protection products currently carried out under Directive 91/414/EEC. The current process of evaluation, if conducted with specific attention to this issue, already permits a rather comprehensive appreciation of the ED-related toxicological risk for mammals and man. Ecotoxicological risks arising from ED generally can be captured by the current assessment scheme, although for some species (in particular invertebrates) the test programme is not yet satisfactory.

Further refinement of the protocols in use for the toxicological testing of the active substances of Plant Protection Products was considered to be desirable by SCP in the near future. The SCP considered it appropriate to await the conclusion of the ongoing ED test guideline-update and development programme by OECD before recommending to the EU to undertake specific actions aimed at introducing supplementary testing in the Annex 2 of the Directive 91/414/EEC.

## **7. Progress report on the following plant protection products dossiers referred to the Scientific Committee on Plants (excluding environmental aspects):**

### **Pyrethroids**

M. Maroni informed the Committee that the meeting on the issue of the bridging studies required to extrapolate from unresolved isomer mixes to a resolved isomer active substance had taken place as planned on 25<sup>th</sup> November. The Committee will prepare a stand-alone document on this issue.

#### **7.1 *Lambda*-cyhalothrin**

M. Maroni indicated that on completion of the acute risk assessment opinion (Item 5 of this report), no outstanding toxicological issues remain. A. Hardy informed the meeting that there was no progress to report on the environmental questions as the Environmental WG had not met since the last Plenary Meeting but would meet on 8 December.

The intention is to adopt the opinion at the January Plenary Meeting.

#### **7.2 Esfenvalerate**

M. Maroni confirmed that the Carcinogenicity WG would meet on 16 December.

He also informed the Committee that following the meeting on isomers (see above) of 25<sup>th</sup> November, clarifications has been sought from the notifier on the rationale used for the extrapolation from fenvalerate to esfenvalerate. He also reported on progress on dealing with the question on the conflicting results from the skin penetration studies. The dietary question would be dealt with in the same fashion as for the other pyrethroids. The environmental questions would be further addressed on 8 December.

It is expected that the opinion will be adopted at the March Plenary Meeting.

#### **7.3 Cyfluthrin**

M. Maroni reported that the dietary risk assessment question would be dealt with as for the other pyrethroids. The environmental issues would be addressed further on 8 December.

#### **7.4 Beta-cyfluthrin**

As for cyfluthrin.

#### **7.5 Bentazone**

Following an exchange of views the Committee adopted the opinion which is available as Document SCP/BENTA/002-Final

*[http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out54\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out54_en.pdf)*

The opinion concluded that use scenarios could exist which would pose no unacceptable risks to groundwater.

The modelling scenarios and lysimeter/field studies presented by the notifier do not represent the full range of soil, climate and physico-chemical properties of the active substance. This is particularly relevant for the existing use on rice.

It is recommended that risk assessments should be conducted at Member State level, in particular regarding use in rice cultivation. Member States should assess leaching potential in vulnerable locations to determine whether the revised GAP i.e. reduced application rates and timing of application can achieve the desired result.

#### **7.6 Diquat**

As no new data had become available to permit the performance of a full dietary risk assessment, the Committee agreed with R. Hans' revised draft opinion. M. Maroni reported that he would prepare a draft opinion on operator exposure for amateur use by mid-January.

The intention is to adopt the opinion at the January Plenary Meeting.

### **8. Progress report and exchange of views on Plant Genetically Modified Organisms dossiers**

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

H. Davies reported on of the most recent information provided by the notifier in response to clarifications sought by the Committee. The Committee was not satisfied with the extent of the responses received and provided a situation report to the Commission on progress with the dossier.

#### **8.2 Oilseed rape from Hoechst Schering AgrEvo GmbH with tolerance to glufosinate ammonium (Notification C/DE/98/06)**

It was reported that the Committee was still awaiting a response from the notifier on the clarifications it sought from the notifier at its Plenary Meeting on 28 October.

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

The Committee noted that the dossier had been circulated to members. H. Davies was appointed as overall co-ordinator for the dossier.

**8.4 Conventionally derived crosses between approved genetically modified maize lines t25 and MON810 from Pioneer Overseas Corp. (Notification C/NL/98/08)**

The Committee was still awaiting a response from the notifier on the clarifications it sought at its Plenary Meeting on 28 October. The notifier had indicated that a response would be forthcoming by mid-January.

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

It was confirmed that the dossier had now been circulated to members

**9. Other business**

**Date of next meeting:**

The next meeting of the Committee will take place on 28 January 2000.