

# Minutes of the Fifteenth Meeting of the Scientific Committee on Plants - Brussels, 24 September 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, Prof. M. MARONI (Vice-Chairman), Dr. H.G. NOLTING, Prof. F. O'GARA (Vice-Chairman), Prof. E. RODRIGUEZ-CEREZO, Prof. A.M.S. SILVA FERNANDES, Dr. G. SPEIJERS

### *Apologies*

Dr. H.A. KUIPER, Dr. J.J. LEGUAY

### *Invited Experts*

Mr. H. KOEPP, Dr. O. MEYER

### *Commission*

Health and Consumer Protection, B2: Mrs M. DE SOLÀ

Health and Consumer Protection, F1: Mr W.-M. MAIER, Mr C. NOLAN, Mr B. DRUKKER

Research, E2: Mr I. BENEDIKTSSON

Joint Research Centre: Mr G. VAN DEN EEDE

### *Secretariat*

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

## **1. Welcome, Apologies and Introductory Remarks**

The Chairman opened the meeting and welcomed the members.

## **2. Adoption of the agenda**

The agenda was adopted. (Doc. SCP/AGENDA/015-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. Meeting schedule for the year 2000**

The members agreed on following dates for next year's Plenary meetings. Although the Committee identified two days per meeting, it recognised that normally a one-day meeting would be sufficient.

27-28 January  
16-17 March  
4-5 May  
5-6 June  
19-20 July  
21-22 September  
9-10 November  
14-15 December

## **5. Adoption of the minutes of the Fourteenth Plenary Meeting and matters arising (16 July 1999)**

### **5.1 Adoption of the minutes of the Fourteenth Plenary Meeting**

The draft minutes were approved subject to some minor textual amendments.

## **6. Exchange of views on and possible adoption of the draft opinion on the relationship between the elimination or severe reduction in the use of plant protection products for the cultivation of fruits and vegetables and the presence of mycotoxins and heavy metals.**

The Committee had been circulated, prior to the meeting, a draft opinion which had been amended by G. Speijers in line with the suggestions agreed at the fourteenth plenary meeting. Following an exchange of views and agreement on some minor amendments, the Committee adopted the draft opinion which is available as Document SCP/RESI/063 - Final. The Chairman expressed a special thanks to the working group which prepared the initial draft and particularly thanked the invited scientists who had contributed to the preparation of the opinion.

In its opinion the Committee concluded and made the following recommendations:

### *Conclusions*

The Scientific Committee on Plants considered the available data from field studies on the influence of pesticides on the production of mycotoxins and concluded that they are equivocal. Thus there is not sufficient evidence that pesticides play a prominent and consistent role in preventing or inhibiting the production of mycotoxins by toxicogenic fungi. However, it cannot be excluded that in future fungicides will be selected on the basis that they can effectively inhibit the production of mycotoxins, since the contamination of plant crops with mycotoxins are frequently reported, which is a growing concern for risk assessors of food contaminants. Every effort should be made to avoid such contamination with mycotoxins.

### *Recommendations*

1. More research based on well designed studies is required with respect to the effects of the administration of plants protection products on prevention of plant diseases and the production of mycotoxins and or other toxicants.

2. As part of the testing of plant protection products, efficacy testing against mycotoxigenic fungi responsible for major plant diseases, such as *Fusarium* headblight, should also include the evaluation of efficacy against mycotoxin production.

3. Desirability of increased monitoring for mycotoxins in foodstuffs generally and particularly in those destined for the food of infants and young children.

## **7. Exchange of views on and possible adoption of opinions on draft guidance documents in the framework of the Directive 91/414/EEC**

### **7.1 Draft Guidance Document on Aquatic Ecotoxicology**

### **7.2 Draft Guidance Document on Terrestrial Ecotoxicology**

### **7.3 Draft Guidance Document on Persistence in soil**

The Committee adopted the opinions on the draft guidance documents. These documents will be available respectively as [SCP/GUIDE/023-Final](#), [SCP/GUIDE/024-Final](#) and [SCP/Guide/032 - Final](#)

The Committee in each of the three opinions made a number of general observations and recommendations regarding the draft guidance documents, and responded to the questions referred to it by the Commission.

## **8. Progress report on the following plant protection products dossiers referred to the Scientific Committee on Plants**

### **8.1 Vinclozolin**

In addition to the questions referred to the Committee at its July meeting, the following two questions were also referred to the Committee for opinion:

3) Which is the appropriate No Effect Concentration (NOEC) of vinclozolin in birds?

4) On the basis of the data available so far, is it possible to conclude on the risk the intended uses of the substance will pose to birds and wild mammals? Could the SCP comment on the appropriate approach for an adequate risk assessment for birds and small mammals?

The WG on toxicology had met on 23 September 1999 under the Chairmanship of M. Maroni and with SCP members M.-P. Delcour, R. Hans, A. Silva Fernandes, G. Speijers and invited experts I. Chahoud, O. Meyer and P. Peters. M. Maroni outlined the content of the draft report. It is the intention of the Committee to adopt the report on the first two questions at its next meeting. The Committee referred the two additional questions (ie 3 & 4) to the Environmental WG with the intention of adopting its opinion at its December Plenary Meeting.

### **8.2 Lambda-cyhalothrin**

a) Dietary intake question

The Committee discussed in detail the possible approaches to answering this question given that the same question has been repeated for each of the four pyrethroids submitted to the Committee for opinion. It was felt that it would be more coherent to formulate a single opinion dealing with the generic pyrethroid question and make reference to this in each of the individual opinions. With regard to this question, the Committee felt that the Commission services should implement the recommendation expressed in its opinion of 14 July 1998<sup>1</sup> that short-term dietary exposure to pesticide residues should be considered on a routine basis. The non-performance of an acute risk assessment should in each case be appropriately justified.

The Committee also discussed another point common to many pyrethroids, namely the use of studies carried out for the unresolved isomeric mix with certain bridging studies to support the resolved isomer active substance. The Committee felt that an ad hoc group of experts should investigate this and report back as soon as possible. This meeting would need to have taken place before any of the individual pyrethroids opinions could be finalised.

H. Koepp reported on progress in the Environmental WG which had met on 22 September. He informed the Committee that the environmental aspects of the opinions should be ready in time for the next Plenary Meeting in October.

### **8.3 Esfenvalerate**

The same dietary issue risk assessment issue reported above for lambda-cyhalothrin also applies to esfenvalerate as well as the issue of bridging.

M. Maroni reported on the outcome of the meeting of the toxicological WG which had discussed the question of carcinogenicity. He reported on the methods used to assess the carcinogenicity studies and the fact that the mechanistic studies for the testicular tumours had not yet been submitted to the Committee. In the circumstances it was considered impossible to advance this dossier. The secretariat was requested to investigate when the study would become available.

M. Maroni reported on progress with the draft opinion on skin absorption.

H. Koepp reported that progress on environmental evaluations was as for lambda-cyhalothrin.

### **8.4 Cyfluthrin**

Dietary risk assessment as for other pyrethroids.

Resolution of bridging study issue as for other pyrethroids.

H. Koepp reported on progress in the environmental WG. He expected the draft to be ready for the October Plenary Meeting.

### **8.5 Beta-cyfluthrin**

As for cyfluthrin.

### **8.6 Bentazone**

H.-G. Nolting gave a progress report on preparation of the opinion. Following examination of first draft in the relevant WGs, he envisaged that the opinion would be ready for adoption at the October Plenary Meeting.

### **8.7 Diquat**

M. Maroni reported on progress with his draft opinion on operator exposure assessment for amateur uses. He reported on the difficulty in making this assessment due to the lack of a suitable model to make a quantitative assessment. He undertook to pursue the matter further and to report back to the next Plenary Meeting.

R. Hans reported that the data she had been supplied with by the Commission was inadequate. The secretariat undertook to raise the matter with the relevant Commission services.

The Committee intends to have the draft opinion ready for adoption in December.

### **8.8 Metsulfuron**

Referred to the Environmental WG at the fourteenth plenary meeting.

### **8.9 Triasulfuron**

Referred to the Environmental WG at the fourteenth plenary meeting

### **8.10 Flupyr sulfuron**

The Commission referred the following questions to the Committee:

- a. Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?
- b. Can it be confirmed that the uses reviewed are acceptable for the aquatic environment and for earthworms ?

The Committee referred the questions to the Environmental WG

### **8.11 Flurtamone**

Following the questions raised in the Committee's opinion of 18 December 1998 (SCP/FLURT/004 - Final ([http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out28\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out28_en.pdf))) regarding soil metabolites, the notifier submitted additional data to the Commission. The Commission referred these data to the Committee for evaluation. The matter will be dealt with by the Environmental WG.

### **8.12 Exchange of views on possible forthcoming questions to the Committee.**

The Commission services sought the advice of the Committee on the best means to seek its advice concerning a large number of maximum pesticide residues limits (MRLs). C. Nolan of the relevant Commission services explained that his services had prepared residues proposals on some 21 pesticide active substances with varying number of MRLs. Some of these active

substances were currently before the Committee with questions relating to their toxicological properties whilst other had at an earlier date been referred to the Committee. He informed the Committee that it had been necessary to provide for very tight deadlines for possible consultation of the SCP.

In its response, the Committee questioned the appropriateness and feasibility of the seeking its opinion on hundreds of individual MRLs. It was felt that these were routine matters that did not necessarily involve a high level of scientific content. Furthermore, the Committee referred to the earlier guidance it had given on the procedures which should be followed when establishing MRLs. It suggested that it would not be efficient that the SCP would in effect have to resort to the verification of the correct application of its guidance or even duplicate the work of the Standing Committee on Plant Health. The Committee indicated that it was willing to help on these matters but that this must be requested on the basis of precise questions rather than all embracing questions as to the safety of the MRLs. The Commission representatives agreed to consider the matter further.

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

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

The Committee had referred questions to the notifier and summaries of the responses received had been forwarded to the Committee immediately prior to the meeting. The Committee was still awaiting the study reports and would finalise on receipt of these.

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

It was established that all members had now received the dossier and accordingly the Committee could start its evaluation. The Committee appointed J.-J. Leguay as the lead rapporteur. A first draft opinion will be reviewed at the October GM WG and at the October Plenary Meeting.

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

The dossier had not at the time of the meeting been circulated to Members.

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

It was established that all members had now received the dossier and accordingly the Committee could start its evaluation. The Committee appointed E. Rodriguez as the lead rapporteur. A first draft opinion will be reviewed at the October GM WG and at the October Plenary Meeting.

## **10. Exchange of views on the request from Member-State Austria invoking Article 16 (Safeguard clause) of Council Directive 90/220/EEC with regard to**

## **the Monsanto genetically modified maize (MON 810) expressing the Bt *cryIA(b)* gene - Notification C/F/95/12-02**

The Committee examined the draft report which had been examined on the previous day by the GM WG. Following an exchange of views, the Committee adopted its opinion.

The opinion is available as SCP/GMO/175 - Final  
([http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out49\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out49_en.pdf))

The summary of the opinion is as follows:

The Scientific Committee concluded that the information submitted by Austria does not constitute new significant information that was not already considered in its original risk assessment and opinion on MON810 and that the previous risk assessment stands unchanged.

The SCP also concludes that this information does not invalidate its original risk assessments for the other Bt products.

### **11. Progress report and exchange of views on the guidance documents relating to Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms**

**11.1 Draft criteria for establishing whether a genetically modified micro-organism (GMM) is safe for human health and the environment and would be suitable for inclusion into Annex IIC of Directive 90/219/EEC (amended)**

**11.2 Draft guidance on the criteria to be investigated to determine whether a genetically modified micro-organism is suitable for inclusion in Annex IIC**

**11.3 Draft guidance for risk assessment outlined in Annex III of the proposed amendment to Directive 90/219/EEC on the contained use of genetically modified micro-organisms COM(95)640**

The Committee adopted an opinion on the three draft guidance documents. It also made available to the responsible service of the Commission annotated versions of the three draft guidance documents.

### **12. Other business**

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

The next meeting of the Committee will take place on 28 October 1999.

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<sup>1</sup> Opinion of the SCP regarding Variable Pesticide Residues in Fruit and Vegetables.