

Minutes of the third Meeting of the Scientific Committee on Plants, Brussels, 9-10 February 1998

ATTENDANCE LIST

Members

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

Apologies

Dr. M. CABOCHE, Prof. C. L. GALLI

Commission

M. C. NOLAN (DG XII), MME M. DE SOLA (DG XXIV/B/2), M. D. BOSWORTH (DG XI), MME P. OELKER (DG XI), M. G. VAN EEHE (JCR)

Invited Experts

M. S. CROSSLEY Pesticide Safety Directorate UK, M. D. TENNANT TAS International

Secretariat

M. M. WALSH (DG XXIV/B/2), MME S. VAN IMPE (DG XXIV/B/2)

1. Welcome, Apologies and Introductory Remarks

The Chairman welcomed the members to the meeting and noted the apologies (see attendance list).

2. Adoption of the agenda

The agenda was adopted and apologies for absence noted. (Doc. SCP/AGENDA/003)

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. Approval of the minutes of the meeting of 22 December 1997

The meeting approved the draft minutes with some minor amendments. The report is available as Document No. SCP/REPT/002 final of 11 February 1998.

5. Genetically Modified Organisms

Insect-resistant maize line MON810 notified by Monsanto (Notification C/F/95/12/02)

Glufosinate-tolerant rape notified by AgrEvo
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(Notification C/UK/95/M5/1)
Glufosinate-tolerant maize (event T25) notified by AgrEvo
(Notification C/F/95/12/07)
Insect-resistant (Bt) and glufosinate-tolerant maize notified by Novartis
(Notification C/GH/96/M4/1)

A joint session of the Plant GMO Working Group (WG) and the SCP Plenary took place on the 10th February. Non-SCP members (members of other SCs) of the WG present were as follows: M. Vighi, L.-A. Aumaitre & A. Von Wright with apologies from B. Moseley & A. Chesson. The meeting had been preceded by a preparatory meeting held on 2 and 3 February 1998 when the following members were present: H. Davies, A. Hardy, S. Karenlampi, H. Kuiper, J.-J. Leguay, F. O'Gara, E. Rodriguez-Cerezo, L.-A. Aumaitre, A. Von Wright, A. Chesson, B. Moseley, P. Vasseur and H. Koeppe.

Both working group meetings were chaired by F. O'Gara. The meeting examined in detail the draft documents which had been prepared by members. In addition to preparing the four opinions, the Committee decided to prepare in due course a document of an advisory nature for the benefit of future notifiers.

The final documents were agreed on 10 February, 1998 and are available as follows :

Doc. SCP/GMO/004-Final	Insect-resistant maize line MON810 notified by Monsanto (Notification C/F/95/12/02)
Doc. SCP/GMO/005-Final	Glufosinate-tolerant rape notified by AgrEvo (Notification C/UK/95/M5/1)
Doc. SCP/GMO/006-Final	Glufosinate-tolerant maize (event T25) notified by AgrEvo (Notification C/F/95/12/07)
Doc. SCP/GMO/008-Final	Insect-resistant (Bt) and glufosinate-tolerant maize notified by Novartis (Notification C/GH/96/M4/1)

Mrs de Sola, Head of Unit XXIV/B/2 thanked the Committee members for their prompt treatment of the four dossiers.

The Secretariat requested the WG to study the following two new dossiers:

Insect-resistant (Bt) Pioneer Maize line MON 809 (Notification C/F/95/12/01/B)

PGS glufosinate-tolerant male sterile swede rape (Notification C/BE/96/01)

It was stated that there was a possibility that an additional AgrEvo swede rape dossier (Notification C/DE/96/05) would shortly be submitted to the Committee.

It was decided to create four multi-disciplinary sub-groups with the following membership:

No	Study area	Members
1 .	Biotechnology	H. Davies, Maize line MON 809 E. Rodriguez, PGS swede rape J Lequay AgrEvo swede rape
		Members also to act as co-ordinators for their respective GMOs
2 .	Toxicology & Residues	R. Hans, H.-G. Nolting and H. Kuiper
3 .	Environment	A. Hardy, H. Koepp and P. Vasseur
4.	Food & Feed	B. Moseley, A.Chesson, A. Von Wright and L.-A. Aumaitre

The following meeting dates and deadlines were agreed:

23 February	Deadline for biotechnology evaluation and forwarding of this part of the evaluations to the food and animal feedingstuff experts
3 March	Deadline for sending sub-group 2,3 & 4 evaluations to the co-ordinators of sub-group 1
11 March	GMO WG meeting to examine the three draft documents
18/19 March	Combined GMO WG and SCP Plenary and possible adoption

6. Plant Protection Products - kresoxim methyl and azoxystrobin

The Chairman of the Plant Protection Product WG, M.Maroni, reported on the WG meeting of 4 February which examined the draft reports prepared by the members of the WG. Members of the WG present were, M. Maroni, H.-G. Nolting and P. Delcour. The Committee sought clarifications of its role and also requested that certain additional scientific data be made available before it finalised its reports.

The SCP discussed in detail the question of its role in the plant protection product evaluation procedure: greater precision was needed concerning the exact role considering that the two active substances under examination represented the first of many which would be submitted to the Committee for opinion. Concern was expressed regarding the broad scope of the Commission's questions on kresoxim methyl and azoxystrobin which could involve the Committee repeating much of the work carried out in the 'Peer Review' process as organised by the Commission. It was the opinion that such evaluation would be very resource demanding, would be a duplication of previous work and accordingly would be wasteful of scarce resources. Furthermore, it would involve the Committee in a task which it considered to be outside that which was normally expected of a Scientific Committee and would also increase unnecessarily delays in the legislative process.

The Committee sought clarification from the Commission concerning the exact role envisaged for the SCP with regard to plant protection product evaluations. The Secretariat undertook to clarify the SCP's role at its next meeting. In the meantime, the WG will endeavour to

finalise its reports on the two active substances with a view to their possible adoption at the next plenary meeting in March. This may involve, if considered necessary, holding a WG meeting on 11 March.

7. Risk Assessment for Pesticide Residues in Food

The Committee at its second Plenary Meeting had agreed to invite Mr S Crossley to give a presentation on 'Recent International Activities in the Methodology for Dietary Risk Assessment of Pesticide Residues'. Mr Crossley dealt with the following points in his presentation.

Four Joint FAO/WHO Expert Consultations.

These consultations addressed the application of risk analysis to food standards, revision of guidelines for predicting dietary intake of pesticide residues, risk management and food consumption and risk assessment of chemicals.

Estimation of Chronic Dietary Intake.

It was reported that the existing guidelines of the WHO 1989 for predicting the dietary intake of pesticide residues were being updated by that organisation in the light of experience gained from their use. It was reported that the objective was to make the guidelines more realistic by taking in account factors, such as, supervised trial median residues levels, use of monitoring and surveillance data, effects of storage and processing, catering for population sub-groups, such as, adults, children, infants. Mr Crossley presented several practical examples for estimating the dietary intake for certain foodstuffs/residue combinations.

Estimation of Acute Dietary Intake

It was stated that MRLs are based on bulked composite samples and that recent studies have indicated that residue variation between individual crop units may be high with up to a 29 fold variation reported. This variability has implications for the nature of the risk assessment which must be used for acute exposure. This involves a different data base for quantification of the residue with an acute nature in products, consideration of the food portion consumed at a single sitting and the use of an acute reference dose as opposed to an acceptable daily intake (ADI) used for chronic exposure.

Following a short exchange of views on Mr Crossley's presentation, the Committee decided to appoint a residue working group as follows:

R. Hans, Chairperson;

C Galli, P. Delcour and S. Crossley.

The Committee decided to invite the Scientific Committee on Food to nominate a member in order to ensure consistency in approach between the two committees.

The Committee agreed that the terms of reference for the WG would be as follows:

1) Review of existing international guidelines for predicting the dietary intake of pesticide residues;

2) Review of existing guidelines, including models and dietary data used, for the establishment of Community MRLs and possible proposals for their amendment;

3) Response to the question from DG VI on the possible risk of variable residues in fruit and vegetables (Doc. SCP/RESI/001 of 11 December 1997).

8. Data Requirements for micro-organisms to be used in and as plant protection products pursuant to Directive 91/414/EEC.

The Committee discussed the structure of the Committee in the context of the work which it had been requested to undertake. The Secretariat was requested to contact a number of eminent experts to support the Committee. The Secretariat will report back to the next Plenary Meeting.

9. Exchange of views and on the content and means for addressing the documents from the European Environmental Bureau on:

- Arguments for the Exclusion from Annex 1 of Directive 91/414/EEC of pesticides presently being revised

- Pesticides and Cancer Survey of Epidemiological studies

Available time did not permit an examination of M. Maroni's paper on the possible options for dealing with these reports: discussion was deferred until the next Plenary Meeting.

10. Exchange of views on the adequacy of the testing requirements to detect potential endocrine toxicity of plant protection products pursuant to Directive 91/414/EEC concerning the placing of plant protection product on the market.

Dr C. Nolan of DG XII outlined in detail the many international initiatives currently dealing with this area, such as, agreement on the creation of an international data base. He indicated that due to the extensive research input, knowledge in this area was advancing quickly although no satisfactory screening methods were yet available.

The Committee decided to create a small working group which would have a mandate to follow developments in the field of endocrine disrupting chemicals and keep the Committee informed: M. Maroni and H. Kuiper were nominated. Similarly, the Secretariat was requested to keep the Committee informed on progress on the endocrine toxicology WG of the Scientific Committee on Toxicology, Ecology and the Environment.

The Committee invited DG VI to submit updated data requirements for Directive 91/414/EEC as soon as the necessary protocols have been agreed internationally.

11. Committee Rules and Procedures

Time did not permit an exchange of views on this item: it will be included on the agenda of the next meeting.

12. Other business

The next Plenary Meeting was confirmed for 18/19 March 1998.