

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees ; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON PLANTS

SCP/REPT/037-Final

MINUTES OF THE 37th MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS **BRUSSELS, 30 January 2003**

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. A. LESZKOWICZ

Prof. M. MARONI (Vice-Chairman)

Dr. O. MEYER Dr. A. MORETTO

Prof. F. O' GARA (Vice-Chairman)

Prof. E. PAPADOPOULOU

Prof. E. PETZINGER Prof. J. SCHIEMANN

Prof. A. M. S. SILVA FERNANDES

Dr. G. SPEIJERS

Apologies

Prof. K. SAVOLAINEN

Commission

Mr. B. DRUKKER DG Health and Consumer Protection E1

Ms. A. KLAUK DG Environment C3

Secretariat

Mr. M. WALSH DG Health and Consumer Protection, C2

Ms. M. DUNIER-THOMANN EFSA Mr. H. BRUNO EFSA Ms S. RENCKENS EFSA

1. Welcome and apologies

The Chairman, Prof. Hardy opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted (Document SCP/AGENDA/037¹).

3. Declaration of interests by Members

None.

4. Adoption of the minutes

4.1 Adoption of the minutes of the 36th Plenary Meeting SCP (17 December 2002)

The draft minutes were approved and are available as Document SCP/REPT/036-Final at: http://europa.eu.int/comm/food/fs/sc/scp/out141_en.pdf

4.2 Matters arising

None

5. Adoption of opinions:

5.1 Opinion on the guidance document on environmental risk assessments of active substances used on rice

The Scientific Committee on Plants was asked its opinion on the Guidance Document SANCO/1090/2000.

The Committee highlighted that three areas related to the proposed modelling framework are of specific concern in the guidance document. Some assumptions made in the establishment of the Step 1, particularly the environmental concentrations PEC² estimation procedures have to be reconsidered and scientifically justified; more information should also be provided in the Steps 2 and 3. Moreover, it is recommended that the scientific validity and regulatory consistency of the stepwise procedure should be checked and demonstrated through Case Studies or through illustrations with hypothetical products. Other issues of concern include exposure to non-target terrestrial compartments adjacent to rice paddies.

The Committee does not support, the proposed data requirements for avian testing, since there is no indication or scientific justification as to which of the proposed or rejected test species would be a better surrogate for the different species exposed in the paddies.

¹http://europa.eu.int/comm/food/fs/sc/scp/agenda/agenda10_en.pdf

² PEC: Predicted Environmental Concentration

The Committee is also of the opinion that the argument for using TER³ triggers in rice, which are different from those used for other crops, has no scientific justification.

Prof.A. Silva Fernandes expressed some reservations on a few points of Cha. II (p. 5-7).

The opinion was adopted by the Committee.

6.2 Opinion on atrazine

The Commission requested the SCP an opinion on the two following questions:

- 1: Can the Committee comment on the approach taken by the Rapporteur for the calculation of predicted environmental concentrations (PEC) in groundwater?
- 2: Does the Committee agree that the available monitoring data show that in large areas, application of atrazine under the intended conditions (i.e. max. 0.75~kg a.s. / ha in northern Member States and max. 1.0~kg a.s. /ha in southern Member States on maize and sorghum in spring) will not result in concentrations of the active substance or its breakdown products in excess to $0.1~\mu g/L$ in groundwater?

In discussing this opinion the Committee noted that it was asked to consider the breakdown products together with the active ingredient and not according to the guidance document on relevant metabolites. The Committee would like to point out that the opinion was given only in response to the questions addressed to it.

The Committee's comments on question 1 consisted of an assessment of the input parameters that describe the sorption and transformation of atrazine and its metabolites in soil for calculations of the environmental concentrations (PEC) in groundwater. The Committee considered the half-lives used for atrazine based on the results of field studies unsound and did not accept the reported first and higher tier calculations of the PEC of atrazine and its metabolites in groundwater.

In the opinion on question 2, the Committee considered available evidence from lysimeter studies, European field monitoring studies and of monitoring studies at regional scale (France, Greece, Spain and Portugal) and decided that the reports of these studies justified the sampling strategy insufficiently. The Committee considered the resulting interpretation problems on studies very serious. The Committee concluded that the available monitoring data does not demonstrate that concentrations of the active substance or its breakdown products will not exceed 0.1 µg/l in groundwater.

The Committee adopted the opinion.

6.3 Opinion on simazine

The Committee was asked its opinion on the same two questions as for atrazine.

In the opinion on question 1 the Committee explained why it does not accept the increased sorption coefficients used and the shorter half-life of simazine (based on measurements in two soils only. The Committee also did not accepted the reported first and higher tier calculations of the environmental concentrations (PEC) in groundwater.

³ TER: Toxicity Exposure Ratio

In its opinion on question 2, the Committee considered the available evidence from one lysimeter study and of monitoring studies but was unable to interpret this result because the reported rainfall was improbably high.

The Committee did not agree that available monitoring data demonstrate that concentrations of the active substance or its breakdown products will not exceed $0.1\mu g/l$ in groundwater. The Committee adopted the opinion.

6.4 Opinion on isoxaflutole

The Commission asked the SCP its opinion on the two following questions:

- 1: Given the variability in the DT_{50}/DT_{90} from field and laboratory, can the SCP comment on the appropriate DT_{50}/DT_{90}^4 to be used in the FOCUS model scenarios?
- 2: Would the newly submitted data on metabolite RPA203328 cause the Committee to change its conclusion expressed in its opinion adopted on 18 May 1999 with respect to the environmental and toxicological safety of the metabolite, also in the light of the last draft (revision 7b) of the relevant metabolite guidance document?

On question 1, the Committee considered that the field DT_{50} of the metabolite RPA203328 used for the FOCUS scenario calculations was underestimated and insufficiently justified. The procedure should be more conservative with respect to the estimated field DT_{50} for transformation.

On question 2, the Committee concluded that there was no need for the Committee to change its evaluation of the ecotoxicological properties of the metabolite RPA 203328. The Committee has reassessed the toxicological risk of this metabolite in light of the available data and of the draft guidance document on relevant metabolites in groundwater and has concluded that this metabolite is not toxicologically relevant under the considered scenario of exposure (groundwater). Therefore, the Committee did not see the need to change its conclusion expressed in the opinion adopted on 18 May 1999 (SCP/ISOXA/012 Final). The opinion was adopted by the Committee.

6.4 Uniform principle (Annex VI B) on micro-organisms

The working document establishing Annex VI B (Uniform Principle) to Council Directive 91/414/EEC on the placing of plant protection products on the market, concerning products containing micro-organisms (SANCO/108/2002 14.01.2002) and the amended draft (prepared at the WG Tox./Microbiol on 17-18 April 2002) were discussed.

The Committee highlighted its main concerns in its opinion and recommended that the document should be revised to provide more meaningful information and guidance on how to implement the Uniform Principle for the micro-organisms at Member State level.

The opinion was adopted by the Committee.

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⁴ DT₅₀/DT₉₀ period required for 50%/90% dissipation.

8. Other business

8.1 GMO: adventitious presence of GM seeds in conventional seeds

In the context of its policy discussions regarding the issue of co-existence of genetically modified, conventional and organic crops the Commission has asked the Committee whether there was a need to update its opinion concerning the adventitious presence of GM seeds in conventional seeds (Opinion adopted by the Committee on 7 March 2001), in the light of new scientific evidence.

The Committee stated that there is no significant new scientific evidence to give reasons for the need to update its opinion from 2001. Since the likelihood and the extent that undesired genes are present in harvested agricultural crops depend on the agricultural practice, a detailed science-based prediction is not possible. Instead, a "Best agricultural practice to avoid/reduce the adventitious presence of GM material in non-GM material" should be worked out urgently. Management practices to guarantee the purity of agricultural products are well established in seed as well agricultural production. Thresholds are common in agriculture. The application of established management practices to avoid or reduce undesired genes in agricultural products will be useful. Additional measures may be defined, if necessary. The management plan should include all steps from seed production to processing, including cultivation, harvest, transport and storage.

8.2 Last SCP meeting, next scientific panel

Mr C. Berlinguier, Head of Unit DG SANCO D, on behalf of Mr Coleman, Director General of DG SANCO, thanked the members of the Committee for their fruitful collaboration during the last 3 years and possibly 6 years for some of the members. The Chairman T. Hardy and M. Walsh (DG SANCO C) also thanked the Committee members for their contribution to the success of the SCP, which has adopted over 100 opinions during its mandate.

The SCP will be replaced by a new scientific panel on "Plant health, plant protection products and their residues", around May 2003, when the selection of the applicants to the call for expression of interest will be completed.