Minutes of the Twenty sixth meeting - Brussels, 25 April 2001

(Adopted by the Committee on 7 June 2001)

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, Dr. O. MEYER, Prof. E. PAPADOPOULOU, Prof. E. PETZINGER, Prof. K. SAVOLAINEN, Prof. J. SCHIEMANN, Prof. A. M. S. SILVA FERNANDES, Dr. G. SPEIJERS

Apologies
Dr. A. MORETTO, Prof. F. O' GARA (Vice-Chairman), Dr. T. SHERRATT

Invited Experts
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Commission
Ms. M. DUNIER-THOMANN Environment, Mr. W. MAIER Health and Consumer Protection, E1, Mr. C. EDMUNDS Health and Consumer Protection, E1

Secretariat
Mr. M. WALSH Health and Consumer Protection, C2, Mr. J. FERRIERE Health and Consumer Protection, C2

1. Welcome and apologies

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

2. Adoption of the agenda

The agenda was adopted. (Doc. SCP/AGENDA/026-rev3)

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 Twenty Fifth Plenary Meeting and matters arising (7 March 2001)

4.1 Adoption of the minutes of the Twenty Fifth Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/025-Final.

4.2 Matters arising

Prof. Hardy, chairman of the Committee, informed the Committee that as agreed at the previous meeting, he sent a letter to the Commission services, requesting clarification as to the Commission's expectation where plant protection product dossiers are referred without questions. Prof. Hardy informed the Committee that the Commission services replied to his letter explaining that the Committee concerns were under consideration and that the Committee will be informed on the Commission position in due course. Prof. Hardy suggested that in the mean time, the Committee deals with 'no question dossier' as it has done so far, which was agreed.

5. Progress report on the following plant protection product dossiers referred to the Scientific Committee on Plants

5.1 2,4-D

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

The Committee was requested to respond to the following question: Can the Committee comment on the adequate animal model to be used for the derivation of the ADI (Acceptable Daily Intake) and the AOEL (Acceptable Operator Exposure Level)?

The Committee expressed the opinion, that in the case of 2,4-D, mice and rats appear to be the preferable species to be used for human risk assessment.

The opinion is available as document SCP/2,4-D/002-Final at:

http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out101_ppp_en.pdf

5.2 Famoxadone

Prof. Hardy, chairman of the ENV WG, informed the Committee that the evaluation of questions 1 and 2 is now completed.

Prof. Maroni, chairman of the TOX WG, informed the Committee, that given the high specificity of the question related to the eye effects observed in a dog study, the working group felt necessary to call upon an ad hoc expert in cataracts in laboratory animals. The progress of the TOX WG on this question will depend on the availability of the expert identified by the working group members. Prof. Maroni informed the Committee that the opinion on question 4 (relating to operator exposure) is ongoing and is expected to be completed for the next plenary meeting.

5.3 Flufenacet

Mr. Koepp, member of the ENV WG, reported the progress made on the opinion on question 1 dealing with the relevance of metabolites M2 and M4. He stressed that the group will not carry out a detailed evaluation for all metabolites produced by the substance but will only check whether their respective relevance with respect to the different environmental

compartments has been adequately addressed and make cross reference to earlier SCP opinions where the methodology for addressing the relevance of metabolites is detailed.

Prof. Maroni informed the Committee that one of the metabolites covered by the question was also found in the treated plants, and therefore may be present in food. A discussion followed on whether the relevance with respect to the dietary assessment of such a metabolite should also be addressed. The Committee agreed that it understands the question on the relevance of metabolites M2 and M4 as relevance for soil water including ground water contamination but not for the presence in the plants. However, it was agreed that in the opinion the Committee will note the presence of M4 in plants and the eventual shortcomings in the dietary risk assessment.

5.4 Flumioxazin

Following an exchange of views, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers three questions.

In the first one, the Committee was requested to comment on the test used to assess the effect of flumioxazin on Lemna. The Committee considers that the test used is not appropriate because it does not simulate the main expected exposure scenario (spray drift). In addition, the provided test does not give insight into the exposure/effect relationship for either surface runoff or drift because of the addition of a sediment layer in the water vessels (which lowers the concentration in the water layer) and because of the measurements carried out during the test did not quantify the concentration of flumioxazin.

The second question dealt with the test protocol used to assess the effect of flumioxazin on earthworms. The Committee concludes that the test protocol used to assess the effect on earthworms is adequate in view of the proposed uses and that the use of a natural clay/clay loam soil to replace the kaolin clay is considered to be an acceptable deviation from the described protocol in this case **.**

In question 3, the Committee had to response to the following question: Are the developmental effects seen in animal studies of relevance to humans?

The Committee expressed the opinion that amongst the effects observed, only the ventricular septal defects are important and considered to be relevant for humans. However, the Committee considers that the data are sufficient to support the establishment of a NOEL (No Observed Effect Level) for the developmental effects.

The opinion is available as document SCP/FLUMIO/002-Final

5.5 Imazosulfuron

Following an exchange of view, the Committee adopted the opinion subject to some minor textual amendments. In its opinion, the Committee answers the following question: "Can the Committee comment on the relevance of the metabolite IPSN due to its presence in soil and water?'

To respond to this question, the Committee carried out a detail assessment of the relevance of IPSN applying the principles and approaches published in its earlier opinion on the Guidance

document on relevant metabolites adopted on 30 November 2000. (http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out82_ppp_en.pdf). The Committee intends the opinion on imazosulfuron to be used as an example for future reference to address the relevance of metabolites in soil and water.

In the opinion, the Committee concludes that:

- no significant health risk is likely to arise from IPSN in ground water;
- existing studies provide an adequate margin of safety regarding the risks from IPSN to soil micro-organisms, aquatic invertebrates and fish, and the acute risks to earthworms;
- further information is required to assess other risks from IPSN, to ground-dwelling predatory arthropods, soil macro-organisms, higher aquatic plants and sediment-dwelling organisms, and also the chronic risks to earthworms;

The Committee considers that there is a concern about risks to non-target plants from the parent molecule and/or its metabolites including IPSN. In addition, the Committee expresses the opinion that the risk to birds and mammals from metabolites present in or on potential feed items should be fully assessed.

Finally, the Committee notes that other metabolites were formed in some studies sometimes at levels comparable to IPSN and considers that ecological and toxicological risks from these metabolites should be addressed as well.

The opinion is available as document SCP/IMAZO/002-Final

5.6 Ethoxysulfuron

Prof. Hardy, chairman of the ENV WG informed the Committee that the question submitted to the Committee is under consideration by the ENV WG. The rapporteur, Dr. Forbes, has submitted a draft opinion which is under discussion.

5.7 Prosulfuron

Prof. Hardy, chairman of the ENV WG, informed the Committee that the evaluation of question 1 is now completed. As regard question 2, Prof. Maroni, chairman of the TOX WG, informed that the evaluation is on-going. An early draft opinion which was submitted by the rapporteur, Prof. Petzinger, was discussed at the TOX WG meeting of 24 April. Further discussion will take place at the next meeting of the working group.

5.8 Ferric phosphate

This new active substance had been referred to the Committee without any question for response. Following an exchange of views the Committee noted the documentation submitted and decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex VI (Uniform Principles) of Directive 91/414/EEC.

5.9 Iprodione

This dossier was referred to the Committee at the precedent plenary meeting. The evaluation is on-going. Discussion of draft opinions is scheduled at the next ENV WG meeting (on 15 May) and at the next TOX WG meeting (on 16 and 17 May).

6. Request for opinion on the following plant protection products referred to the SCP

The secretariat of the Committee introduced 5 new dossiers concerning active substance evaluation referred to the Committee.

6.1 Florasulam

This dossier was referred to the Committee with the following questions:

- 1. Can the Committee comment on the relevance of metabolites ASTCA and DFP-ASTCA?
- 2. Is it correct to establish an acute reference dose (ARfD) based on the neurotoxicity?

Dr. Carter, expert of the ENV WG, has been appointed rapporteur for question 1 whereas Dr. Moretto will report on question 2.

6.2 Thifensulfuron-methyl

This dossier was referred to the Committee without specific question.

6.3 *Pseudomonas chlororaphis*

At the 22nd plenary meeting (22 September 2000, see minutes, the Committee decided to suspend the evaluation of *Pseudomonas chlororaphis* because of the identification of a data gap. Addenda to the monograph have now been submitted and the evaluation can be resumed.

The questions referred to the Committee are the following:

- 1) Is the issue of residue levels in food and feed adequately addressed, in relation to the safety requirements of Article 5 of Council Directive 91/414/EEC?
- 2) Given the absence of models for assessing operator exposure for microbial pesticides - has this issue been adequately addressed in relation to Article 5 of Council Directive 91/414/EEC?
- 3) With regard to possible hazard to humans, is a tiered approach adequate and should repeated dosing be part of the primary (tier 1) data set?
- 4) Is the toxicological safety of the antibiotic metabolites of *Pseudomonas chlororaphis* adequately addressed?
- 5) It is known that certain health problems can arise from working with microbial pesticides e.g. allergies developed when glasshouse workers were exposed to attenuated strains of tobacco mosaic virus (TMV). Would a post authorisation requirement to monitor the health of workers (blood testing etc.) be a prudent measure? If so, what measures would the Committee recommend?
- 6) The genus *Pseudomonas* also contains important pathogens for human e.g. *Pseudomonas aeruginosa* which can establish in open wounds. There is one

documented case where *Pseudomonas chlororaphis* was found in the wound of a soldier. Does this finding give rise to any concerns for human safety?

The Committee agreed that the questions would be best addressed by the working group on toxicology, but microbiologists should be involved in the evaluation. A special meeting of the TOX WG, where microbiologists will be invited, is scheduled on 28 June.

6.4 Fosthiazate

The Committee is requested to answer the following questions:

- 1. Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?
- 2. Can the Committee confirm that the risk to soil dwelling organisms has been adequately addressed?
- 3. Can the Committee confirm that a safe use with respect to birds and mammals exists?
- 4. Does the Committee consider that there is sufficient information available on the risk of organophosphate-induced delayed polyneuropathy (OPIDPN) in humans following severe intoxication incidents to confirm that there is a safe use, or whether further *in vitro* tests of relative inhibitory potency of the individual isomers of fosthiazate for acetylcholinesterase (AChE) and neuropathy target esterase (NTE) in hen and human tissues are required?

Prof. Hardy, chairman of the ENV WG, informed the Committee that the following experts have been appointed rapporteurs, respectively for questions 1, 2 and 3: Dr. Boesten, Dr. Sherratt and Dr. Luttik.

Prof. Maroni, chairman of the TOX WG, informed the Committee that Dr. Moretto will report on question 4.

6.5 Iprovalicarb

On 7 March, the Committee adopted an opinion on iprovalicarb (see minutes of the 25th plenary meeting at http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out100_en.pdf).

Given that in the opinion, the SCP stated that the relevance to humans of the tumours observed in rats following iprovalicarb treatment cannot be ruled out, the Commission services request the Committee to now respond the following question:

"Does the Committee consider that a sufficient margin of safety exists having regard to the human exposure likely to arise from the intended uses?"

Prof. Maroni, chairman of the TOX WG, informed the Committee that Dr. McGregor, expert of the TOX WG and the TOX(CARC) WG, has been appointed rapporteur for that question. A first discussion is scheduled to take place at the next meeting of the working group on carcinogenicity on 16 May.

7. Progress report and exchange of views on GM plant dossiers referred to the SCP

7.1 Starch potato from Amylogen (Notification C/SE/96/3501)

Prof. Davies informed the Committee that a meeting with the notifier took place on 28 March. Following the meeting, the notifier agreed to carry out more Western blot tests on different plants and different GM lines in order to demonstrate that polypeptides not found in conventional lines are also not present in the GM lines. The evaluation of the Committee is therefore suspended until the notifier submits new data.

7.2 "Guidance document to facilitate notifiers in the preparation of GM plants dossiers for consideration by the SCP"

Prof. Hardy and Prof. Kuiper, respectively chairman of the SCP and chairman of the "draft group on the guidance document" informed the Committee that this group met on 19 April. At this meeting it was agreed to prepare a document the aim of which is to guide notifiers which apply for an authorisation for a GMO release and subsequently for a GM food authorisation.

5 subgroups were established to draft a document to cover the following items:

- Guidance for the molecular characterisation of the construct;
- Guidance for the establishment of substantial equivalence;
- Guidance for performing the safety assessment;
- Guidance for performing the nutritional assessment;
- Guidance for performing the environmental assessment.

Since the opinion will fall under the remit of three scientific committees (Scientific Committee on Food, Scientific Committee on Animal Nutrition and Scientific Committee on Plants), it should in principle be adopted by the Scientific Steering Committee (SSC). Prof. Hardy, informed the Committee that this issue will be raised at a subsequent SSC meeting.

8. Exchange of views on the harmonisation of risk assessment exercise

Prof. Hardy informed the Committee that a task force on harmonisation of risk assessment was established under the auspices of the Scientific Steering Committee. Following an exchange of views on this matter, it was agreed that the SCP would endeavour to comply with the common format for the expression of risk assessment, defined by the task force.

Prof. Hardy stressed the importance for the SCP to participate to the different work groups on risk assessment established by the task force and requested the members to reflect on their possible membership to one of these work groups.

9. Other business

Date of the next meeting: 7 June 2001