



European Food Safety Authority

MINUTES OF THE 5TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION PRODUCTS AND THEIR RESIDUES HELD IN BRUSSELS ON 11 MAY 2004

(adopted by written procedure on 10 June 2004)

AGENDA

Items

1. Welcome, apologies for absence
2. Adoption of the agenda
3. Adoption of the opinion on daminozide
4. Discussion on the draft opinion on dinocap
5. Discussion on the draft opinion on alachlor
6. Discussion on the draft opinions on FOCUS surface water and FOCUS groundwater
7. State of the art on the draft opinion on methamidophos
8. Feedback from discussions in the meetings of the Working Groups Gentox and Exposure assessment of the Scientific Committee
9. Presentation of the future EFSA expert service
10. Miscellaneous
 - EFSA call 2004 for new experts
 - Annual declaration of interest
 - Various scientific information
 - Preparation of the meetings in Milano and Parma in September 2004.

PARTICIPANTS

Members of the PPR Panel

Mr. J. BOESTEN, A. BOOBIS, A. HARDY (Chair), A. HART, H. KOEPP, R. LUTTIK, Mrs. K. MACHERA, Mr. M. MARONI, D. Mc GREGOR, O. MEYER, A. MORETTO, E. PETZINGER, K. SAVOLAINEN, A. SCHAEFFER, W. STEURBAUT and Mrs C. VLEMINCKX.

Apologies for absence

Mrs. E. PAPADOPOULOU-MOURKIDOU, Mrs. D. TSIPI-STEFANITSI.

EFSA

Mrs. M. DUNIER-THOMANN, C. LAURENT (Scientific co-ordinators) and Mrs M. MESNAOUI (Administrative secretary).

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants, apologies for absence had been received from two members.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. ADOPTION OF THE OPINION ON DAMINOZIDE

The Chairman gave the floor to the Rapporteur of the question who presented the final draft opinion prepared in the Toxicology Working Group (WG) and highlighted the scientific uncertainties that still remain after this in depth evaluation, uncertainties which are clearly expressed in the opinion. Some minor changes were made to clarify the text, and the opinion was adopted with unanimity. The scientific secretariat will circulate the final version to all members for a final editorial check before publication on the EFSA website, a French and German summary will also be available.

4. DISCUSSION ON THE DRAFT OPINION ON DINOCAP

Two questions were asked by the Commission, the first one on “oculotoxicity” and the second on dermal absorption.

The Rapporteur for the first question explained that the mechanism of toxicity is still unclear. Moreover studies have been performed with several isomers that may have lead to different breakdown products. The determination of primary or secondary retinopathy is still under consideration. The studies provided on accumulation and metabolism do not permit any definitive conclusions to be drawn, eye effects have been observed in 3 different species: dog (retinopathy), rabbit and duckling (cataracts). The draft opinion concludes that the submitted data do not permit the effects in the dog to be irrelevant to man.

The Rapporteur for the second question on dermal absorption explained that a number of *in vivo* (mouse, rabbit and monkey) and *in vitro* (mouse and human) studies on dermal absorption have been reviewed. An appropriate value for dermal absorption could be derived by using the kinetic data from the mouse study and the *in vitro* comparative data with mouse and human skin; the data on rabbit dermal absorption are supportive of the mouse data. The quality and findings of the *in vivo* mouse and monkey studies were discussed in depth.

The final discussion will take place on 28th June at the next Toxicology WG for an adoption foreseen on 30th June at the next plenary meeting.

5. DISCUSSION ON THE DRAFT OPINION ON ALACHLOR

The Rapporteur for the two questions in toxicology, requested by the Commission, gave a brief presentation on the preliminary draft opinion especially on the first question on nasal turbinates. Three reproducible neoplasia endpoints have been observed in rats: stomach, thyroid and nasal turbinates. The Member States accepted during the evaluation that the first two are driven by a non-genotoxic mechanism. The situation is less clear for the nasal turbinates for which a genotoxic, as well as a non-genotoxic mechanism could be possible. The situation is very complex, species differences in metabolic pathways and specific sensitivity of rat nasal tissue might contribute to explain why the production of nasal turbinate tumours incidence is restricted to rats and not found in others species such as mouse. The evaluation is at an early stage for the second question and characterizations have to be undertaken for several metabolites.

The next discussion will take place on 29th June at the Toxicology WG.

6. DISCUSSION ON THE DRAFT OPINIONS ON FOCUS SURFACE WATER AND FOCUS GROUNDWATER

Two requests to the PPR Panel on the FOCUS models have arisen as self-tasking questions from the EFSA Risk Assessment of the Peer review Programme (PRAPeR). The two draft opinions are at an early stage of discussion within the Environment WG. Both the Rapporteurs highlighted the need for additional expertise especially in the fields of modelling and formulation.

It was agreed that *ad hoc* experts will be invited by the secretariat to attend the next Environment WG to be held on 2nd June.

7. STATE OF THE ART ON THE DRAFT OPINIONS ON METHAMIDOPHOS

Two questions were requested by the Commission, one in ecotoxicology (birds and mammals) and one in toxicology on dermal absorption.

The Rapporteur of the first question on birds and mammals introduced the evaluation which will focus on four key field studies, particularly their quality and relevance. Some data will be presented graphically in order to show how uncertainties may affect the results and therefore their implications for risk assessment.

The Rapporteur of the second question presented a preliminary evaluation regarding the dermal absorption and the exposure safety. The main confounder identified in all four evaluated studies is the position of the radioactive label in the molecule. When ¹⁴CH₃-S labelled methamidophos is tested, volatile metabolites are formed and the main one is the unstable compound methyl mercaptan, which was not effectively retained in the trap systems used.

It was agreed that two *ad hoc* experts will be invited to attend the next Ecotoxicology Working Group to be held on 10th June.

The Toxicology WG will discuss the toxicology question and draft opinion on 29th June.

8. FEEDBACK FROM DISCUSSIONS IN THE MEETINGS OF THE WORKING GROUPS GENTOX AND EXPOSURE ASSESSMENT OF THE SCIENTIFIC COMMITTEE

D. McGregor, as the representative of the PPR Panel, gave feedback from the Gentox WG meeting held on 26-27 April 2004. Scientists with different backgrounds belong to this working group with the objective to draft background documents related to genotoxicity and cancer. Some subjects are already under consideration such as: determination of threshold; genetic toxicity testing in cancer risk assessment, comparison of the animal dose-response relationship and margin of exposure.

A. Hart gave feedback on the Exposure WG meetings, the fourth of which was held on 7 May 2004.

Tasks the WG is working on include:

- a. proposals to the SC for procedures for the exposure group, EFSA specialists and outside experts to support non-standard or difficult exposure assessments by EFSA panels,
- b. annotated inventory of existing guidelines for exposure assessment in different areas (e.g. pesticides, contaminants, flavourings etc.),
- c. proposals for ways to improve access to data on food consumption, including definition of harmonised set of major food types (based on a modified version of the European Food Group list),
- d. proposals for ways to improve access to data on occurrence (concentrations),
- e. development of a working document on uncertainties in exposure assessment and approaches for dealing with them.

9. PRESENTATION ON THE FUTURE EFSA SCIENTIFIC EXPERT SERVICE

M. Maroni highlighted the huge amount of time required by the preparation of an opinion by the Panel and expressed his wishes to find a way to improve this situation in the future.

H. Koeter, the EFSA Head of Science, acknowledged this concern and outlined the progress towards the establishment of the scientific expert service (SES)

within EFSA which, with the future recruitment of “in house” scientists, will help the EFSA Panels, among other tasks. EFSA is willing to adopt any strategies that may reduce the workload of the Panel experts. As it will take a while before those experts are in place, EFSA in the meantime will establish criteria to prioritize the incoming questions according to the available resources.

10. MISCELLANEOUS

- EFSA call 2004 for new experts**

The selection procedure of three new experts for the PPR Panel is in progress, a short list will be sent first to the EFSA Advisory Forum for consultation by the end of May (copy to the Management Board) and the final list will be approved by the MB on 22th June. The name of the new experts will be given to the Panel members at the next Plenary.

- Annual declaration of interest**

The annual declaration of interests, signed in May 2003, were renewed. The Head of the Legal Affairs, A. Cuvillier answered questions on the document “Guidance of declaration of interests”. The new annual declarations will be put on the EFSA web site.

- Various scientific information**

M. Maroni announced the setting up of a “European Master degree in risk assessment and risk analysis”. This course supported by the EU Socrates Programme of the European Commission will start in September 2004, involving the Universities of Milano, Surrey and Utrecht.

An announcement was made by the Chairman on the 5th joint CSL/JIFSAN Symposium : “Novel applications of analytical methods in food safety” to be held in the UK at York 30 June-2 July 2004.

- Preparation of the meetings in Milano and Parma in September 2004**

The Toxicology Working Group will meet in Milano on 13th September at the Milano University (10h-17h) before transferring to Parma for the PPR Panel plenary from 14th (starting 9h) to 15th September mid-day. The Environment WG will follow on in Parma until 16th September mid-day.

The meetings in Parma will take place in a Hotel downtown and shuttles will be provided in principle to and from Milano airports. The secretariat will send more detailed information to Panel members in June.

Next plenary meeting will be held on **30th June** (starting at 9h).

