

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**50th PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES
HELD IN PARMA ON 16-17 MARCH 2011**

(ADOPTED BY WRITTEN PROCEDURE ON 15 APRIL 2011)

| # | Items |
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| 1. | Adoption of the agenda, apologies for absence, declarations of interest. |
| 2. | Information on the draft Guidance Document and draft Opinion on Dermal Absorption. |
| 3. | Information on the draft GD on the use of probabilistic methodologies for modelling dietary exposure to pesticide residues. |
| 4. | Information on the draft Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment. |
| 5. | Information on the draft Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile. |
| 6. | Information on revision of the GD persistence in soil. |
| 7. | Information on the draft GD on emissions from protected crop systems. |
| 8. | Information on the revision of the GDs on Aquatic and Terrestrial Ecotoxicology. |
| 9. | Dissimilar mode of action in cumulative risk assessment of pesticide residues. |
| 10. | Non-dietary cumulative risk assessment. |
| 11. | Request of the EU Commission for providing opinions on the report of the FOCUS Groundwater working group (FOCUS, 2009) |
| 12. | Miscellaneous: <ul style="list-style-type: none"> - Feed-back from the Scientific Committee and its Working Groups. - Pesticide Steering Committee of 22 and 23 March. - Risk assessment of isomer mixtures. - Changes in the PPR Panel. - Reorganisation in EFSA. - News from the EU Commission. |

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PARTICIPANTS

Members of the PPR Panel

Mr J. BOESTEN, Ms C. BOLOGNESI, Mr T. BROCK, Mr E. CAPRI, Mr A. HARDY (Chair), Ms K. HIRSCH-ERNST, Ms S. HOUGAARD BENNEKOU, Mr M. KLEIN, Mr R. LUTTIK, Ms Y. PICO, Mr A. SCHAEFFER, Mr P. SOUSA, Mr W. STEURBAUT, Ms A. STROMBERG, Ms M. TASHEVA, Mr T. VAN DER LINDEN, Ms C. VLEMINCKX.

Apologies

Mr A. HART, Ms B. OSSENDORP, Ms A. PETERSEN

Commission

Ms J. HOUINS-ROULET (DG SANCO)

EFSA

PPR Panel secretariat: Mr L. MOHIMONT, Ms S. BOPP, Mr M. EGSMOSE, Mr I. SEBESTYEN, Mr H. STEINKELLNER, Mr F. STREISSL, Ms G. BOSCHETTO, Ms A. PASQUIN, Ms M. SODANI, Ms J. RICKETTS

1. ADOPTION OF THE AGENDA, APOLOGIES FOR ABSENCE, DECLARATIONS OF INTEREST

The agenda was adopted without changes; apologies were received from 3 participants.

In accordance with EFSA's policy on Declarations of Interest, EFSA screened the ADoI filled in by the Panel members invited to the meeting. No conflicts of interest related to the issues discussed in this meeting were identified during the screening process and no new interests were declared in the SDoI or at the beginning of this meeting.

2. INFORMATION ON THE DRAFT GUIDANCE DOCUMENT AND DRAFT OPINION ON DERMAL ABSORPTION

The PPR Panel appointed Ms HOUGAARD BENNEKOU as Chairperson for the Working Group on the Toxicology of Pesticides. This Working Group deals both with the mandate on the Opinion and with the mandate on the Guidance on dermal absorption. Mr STEINKELLNER then informed the Panel about the ongoing activities within the frame of the two mandates. After the public consultation, both the draft Opinion and the draft Guidance were updated. The responses to the individual comments have been finalised and will be inserted in the report on the public consultation that is currently being prepared. The PPR Unit is currently preparing a letter describing the main risk management elements contained in the Guidance. This letter, together with the draft Guidance, will be sent to the Commission after the next meeting of the Working Group on the Toxicology of Pesticides.

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3. INFORMATION ON THE DRAFT GD ON THE USE OF PROBABILISTIC METHODOLOGIES FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES

The Panel was informed about the outcome of the last meeting of the WG on statistical issues. The WG will now produce a new draft of the GD including specific provisions for cumulative exposure assessment. Depending on the progress achieved by the WG, this new draft will be circulated to the Panel members by mid April and submitted to the Panel for approval in view of the second public consultation which should take place in May.

4. INFORMATION ON THE DRAFT OPINION ON THE EVALUATION OF THE TOXICOLOGICAL RELEVANCE OF METABOLITES AND DEGRADATES OF PESTICIDE ACTIVE SUBSTANCES FOR THE DIETARY RISK ASSESSMENT

Before the Plenary meeting, a draft Opinion was circulated, for the first time, to the whole Panel for commenting. The rapporteurs presented the current state of the Opinion and the critical issues to be discussed further during the next WG meeting. The draft Opinion largely reflects the outcome of outsourced activities on non-testing methods for the assessment of pesticide metabolites. The Panel recommended that the elements taken from the reports of these outsourced projects should be clearly distinguished from the scientific considerations elaborated by the Panel. The Panel was informed that it might receive a request from EFSA to specifically address active substances existing as a mixture of isomers (and the issue of changes of the isomer ratios due to metabolism or degradation), as this was identified as a priority by the Pesticide Steering Committee. Adoption of the Opinion is foreseen for the meeting in June even though the project deadline is September 2011 (the deadline will be extended in case of the inclusion of the isomer questions).

5. INFORMATION ON THE DRAFT OPINION ON THE IDENTIFICATION OF PESTICIDES TO BE INCLUDED IN CUMULATIVE ASSESSMENT GROUPS ON THE BASIS OF THEIR TOXICOLOGICAL PROFILE

The preparatory activities for elaboration of the Opinion, such as the data collection and the proposals for cumulative assessment groups of pesticides, have been outsourced by Art. 36 of Regulation (EC) 178/2002. Due to a request for an extension of the deadline, the final report will be submitted by 1 April. The rapporteur informed the Panel that the 4th Coordination meeting of the project took place on 15/16 March.

The WG on Cumulative Assessment Groups of Pesticides started working in November 2010 when the workplan was agreed. Regarding the next steps in the preparation of the Opinion, a teleconference will be organized in the middle of April and a WG meeting will take place in May in order to prepare and discuss the first draft of the Opinion.

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6. INFORMATION ON REVISION OF THE GD PERSISTENCE IN SOIL

The Rapporteur gave an update on the on-going work for the revision of the GD Persistence in Soil. The WG will meet again on 17/18 March. Some Risk Management options in the Scientific Opinion “for evaluating laboratory and field dissipation studies to obtain DegT50 values of Plant Protection Products in soil” had been presented at the SCFCAH meeting in January. Based on the response from the Commission and the Member States (expected in May) an EFSA Guidance Document will be produced.

In support of the revision of the GD a scientific report on tier-1 and tier-2 scenario parameterisation and example calculations is under preparation.

As part of the JRC/EFSA cooperation, a report on JRC activities in support of the EFSA WG has been published on the EFSA website.

Mr EGSMOSE informed the Panel that a new mandate was accepted by the EFSA Executive Director on 7 February 2011. The PPR Panel is consulted, as part of the revision of the Guidance document on Persistence in Soil, to prepare a Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of substances in soil. As currently no Panel chair is eligible or available for the WG, the Panel agreed that the chairing of the WG will be carried out ad interim by the PPR secretariat. Proposals for rapporteurs and external expertise for the Opinion will be discussed at the next Plenary meeting.

7. INFORMATION ON THE DRAFT GD ON EMISSIONS FROM PROTECTED CROP SYSTEMS

The Rapporteur gave an update on the development of the new GD on estimating emissions from protected crop systems (green-houses and covered crops). The WG will meet again on 28/29 April.

The data-collection on protected crop structures and systems for EU has been completed and a database is available. The database has also proven to be useful for the PLH Panel. The Panel Chair will inform the SC of the existence of this database and invite other groups to use the database.

A procurement report for estimation/calculation of emissions of PPPs from protected crops has been submitted to EFSA for approval. The external reports will be published on the EFSA website when finalised.

A background report in support of the scientific Opinion is close to finalisation and is scheduled for completion under the current mandate.

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8. INFORMATION ON THE REVISION OF THE GDS ON AQUATIC AND TERRESTRIAL ECOTOXICOLOGY

The WG Ecotoxicological Effects had identified the need to break the revision down in a modular approach due to the complexity of the task and the different expertise needed for the different fields involved in the GD on Aquatic and Terrestrial Ecotoxicology.

For the revision of the GD on Aquatic Ecotoxicology, a sequential modular approach was proposed. An update of the mandate was requested and accepted on 16 March. The modular approach will result in 4 separate GDs with the first focusing on edge-of-field surface water risk assessment for water organisms, the second focusing on modelling approaches for effect and exposure models, the third focusing on RA for sediment organisms and the fourth on a wider spatial scale going to catchment scale level, also considering multiple use of PPPs. The PPR Panel agreed to create a new WG on Aquatic Ecotoxicology to work on the first module. Additional necessary expertise has been identified as well as respective external experts. Nomination of the WG Chair and of rapporteurs is still under consideration.

For the revision of the GD on Terrestrial Ecotoxicology, a division of the revision activity in GDs dedicated to the different organism groups was proposed. The reason for this was that different expertise is needed in the different fields of the terrestrial risk assessment. Furthermore it is expected that developing guidance will take more time in some areas than in others and also the priorities are different. For the risk assessment for bees a separate mandate is expected from the Commission. The Panel agreed to the plan of creating different working groups (bees, in-soil non-target organisms, non-target arthropods, non-target plants, modelling, amphibian/reptiles) for the update of the terrestrial Guidance Document.

9. DISSIMILAR MODE OF ACTION IN CUMULATIVE RISK ASSESSMENT OF PESTICIDE RESIDUES

Mr STEINKELLNER reported about the outsourced EFSA project carried out within the frame of an internal mandate for “investigating the state-of-science on combined actions of chemicals in food through dissimilar modes of action, and proposal for a science-based approach for performing related cumulative risk assessment”. A first coordination meeting with the consortium took place in January. The final report from the project is expected in January 2012 and will be the starting point for a PPR opinion. The draft mandate of this Opinion “on the relevance of dissimilar mode of action (response addition) and its appropriate application for cumulative risk assessment of pesticides residues in food” was prepared by EFSA and sent to the PPR Panel before the Plenary for commenting. Minor changes to the Terms of References were suggested by the PPR Panel to EFSA.

10. NON-DIETARY CUMULATIVE RISK ASSESSMENT

Mr SEBESTYEN reported on the outsourced project on collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment. The first coordination meeting took place on 10 February,

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when the detailed workplan of the consortium who was awarded this contract was discussed and commented. The first interim meeting will take place during the first week of May.

11. REQUEST OF THE EU COMMISSION FOR PROVIDING OPINIONS ON THE REPORT OF THE FOCUS GROUNDWATER WORKING GROUP (FOCUS, 2009)

Mr EGSMOSE informed the Panel about the request from the Commission for providing two separate Opinions on the FOCUS groundwater report for assessing potential movement of active substances and their metabolites to groundwater in EU.

The FOCUS groundwater report was “taken note of” by the SCFCAH in 2010 and will be used as a working document. The new software shells and tools will be released within a few weeks by the FOCUS version control group, which will allow the Report to be used by notifiers and Member States.

The first Opinion, which is more urgent, will review the scenario selection procedure and whether the new shells and tools can be released with confidence. The second Opinion will review the tiered scheme and the refined risk assessment approaches (expected deadline: within one year of acceptance of the Mandate).

The Panel had some questions regarding the Terms of References and the PPR secretariat agreed to seek clarification of the questions with the Commission before taking the task onboard.

12. MISCELLANEOUS:

- Feed-back from the Scientific Committee and its Working Groups.
The Panel Chair gave an overview of the agenda points of the last SC meeting in February, in particular regarding the EFSA policy on independence, the science strategy of EFSA, the activities on emerging risks, the activities on the food consumption database and the public consultation on nanotechnology.
The Panel was also informed on the state of the activities of the WGs on TTC, 90-days feeding trials, statistical approaches of adverse and biologically relevant effects and RA terminology.
 - Pesticide Steering Committee – 22/23 March.
The Pesticide Steering Committee will be updated about new activities or new orientation taken by the PPR Panel regarding the development or revision of guidance documents (aquatic and terrestrial ecotoxicology, persistence in soil, FOCUS groundwater).
 - Risk assessment of isomer mixtures.
The PPR Panel was also informed about a number of specific questions under preparation by EFSA on the risk assessment of active substances existing as mixtures of isomers.
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- Changes in the PPR Panel.

The PPR Panel was informed about the impact of a potential conflict of interest that was investigated by the Internal Auditor in January 2011, when EFSA noted that Professor Angelo Moretto had omitted to mention a potential conflict of interest in his Annual Declaration of Interest (ADoI) and Specific Declaration of Interest (SDoI) since July 2008. Triggering the breach of trust process, on the basis of some preliminary information regarding the nature and extent of the interest, EFSA concluded that the interest should have been declared as it was relevant and potentially leading to a conflict of interest. The procedure was halted when Professor Moretto resigned from his role as a Panel member. The Executive Director asked the Internal Auditor (David Caira), to perform a review of the scientific outputs the expert had contributed to since July 2008. Mr Caira outlined that he had been given “reasonable assurance” that none of the expert’s written contributions nor any other involvement could have led to any bias in/to any undue influence on the opinions adopted by the Panel.

Panel members expressed their appreciation for the valuable contributions Profesor Moretto had made to the work of the PPR Panel.

- Reorganisation in EFSA.

EFSA presented the main lines of the EFSA reorganisation which is planned to take place from 1 May to 31 December. The PPR and PRAPeR units will be merged into one single PESTICIDES unit.

- News from the EU Commission.

The commission informed the PPR Panel on the feed-back given by the Commission to its outputs since 2009.

- PPR Panel Opinions (6) updating previous PPR Panel Opinions on draft amendments of annexes II and III: the Commission will take these Opinions into consideration to prepare new draft proposals on data requirements by the end of 2011.
 - EFSA Guidance on the Risk Assessment for birds and mammals: the SCFCAH invited the Member States to implement the guidance in 2009.
 - PPR Panel Opinion on the laboratory and field dissipation studies: the Opinion was presented to the SCFCAH in January and a discussion of risk management options is planned to take place at the SCFCAH meeting in May 2011.
 - PPR Panel Opinion on emissions from protected crops: the Opinion was communicated to the SCFCAH in 2010.
 - PPR Panel Opinion on the exposure of operators, bystanders, workers and residents: the Opinion was communicated to the SCFCAH in 2010 and the Commission plans to create of a Commission WG in view of further developing and finalising the draft guidance.
 - PPR Panel Opinion on the cumulative risk assessment of triazole pesticides: the Opinion was communicated to the SCFCAH in 2009.
 - PPR Opinion on protection goals: the Opinion is under consideration by the Commission and is planned for discussion by the SCFCAH in May 2011.
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The next Plenary meeting will take place on 27-28 April 2011 in Parma, starting at **14h00** on 27 April.
