PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

58TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 20/21 JUNE 2012

(ADOPTED BY WRITTEN PROCEDURE ON 18 JULY 2012)

#	Items
1.	Opening, apologies for absence
2.	Adoption of the draft agenda
3.	Declarations of interest
4.	Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
5.	Opinions on the 2009 report of the FOCUS Groundwater working group
6.	Opinion addressing the state of the science on risk-assessment for non-target terrestrial plants
7.	Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment
8.	Guidance on the use of probabilistic methodology for modelling dietary exposure to pesticide residues
9.	Feed-back from the Scientific Committee and its working groups
10.	Guidance on aquatic ecotoxicology
11.	Miscellaneous
12.	Achievements of the 2009-2012 PPR Panel and future challenges

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), Mr A. HART, Ms K. HIRSCH-ERNST, Ms S. HOUGAARD BENNEKOU, Mr M. KLEIN, Mr R. LUTTIK, Ms K. MACHERA, Ms B. OSSENDORP, Ms A. PETERSEN, Ms Y. PICO`, Mr P. SOUSA, Mr W. STEURBAUT, Ms A. STROMBERG, Ms M. TASHEVA, Mr T. VAN DER LINDEN, Ms C. VLEMINCKX

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

EFSA: Mr P. BERGMAN

Apologies

Ms J. HOUINS-ROULET (DG SANCO)

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the Panel members.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted without change.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[1] and the Decision of the Executive Director implementing this Policy[2], EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest (ODoI) at the beginning of the meeting, please refer to Annexes I and II.

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

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

The Chair of the WG gave an update about the progress on the opinion. At the last WG meeting, concerns about the applicability of the agreed template for grouping and the possible future impact of the opinion in an MRL setting were discussed. It was made clear that the latter issue involves risk management and is therefore not within the scope of the mandate. The WG is delayed by about 3 months in the elaboration of cumulative assessment groups for the organ and system toxicities not covered by the outsourced activities.

The secretariat informed the Panel about the status of the call for tender regarding the elaboration of cumulative assessment groups for liver toxicity, neurotoxicity and reproductive and developmental toxicity.

The Secretariat also informed the Panel about the communication from the European Commission to the Council, dated 31 May 2012, regarding the combination effects of chemicals and chemical mixtures.

The request of the Panel for an extension of the deadline for the adoption of the opinion is still under consideration by EFSA.

5. OPINIONS ON THE 2009 REPORT OF THE FOCUS GROUNDWATER WORKING GROUP

The Chair of the WG informed the Panel about the request from the Commission for two separate opinions on the FOCUS groundwater report for assessing potential movement of active substances and their metabolites to groundwater in the EU (2009). The WG met on the 19/20 June 2012.

The Panel agreed to ask EFSA to invite a scientist with particular knowledge of the FOCUS (2009) ground-water WG report as a hearing expert to contribute to the work of the WG.

6. OPINION ADDRESSING THE STATE OF THE SCIENCE ON RISK-ASSESSMENT FOR NON-TARGET TERRESTRIAL PLANTS

The Chair of the WG on Risk Assessment for non-target terrestrial plants gave an update on the progress and current status in the WG. The WG met in June 2012 and made substantial progress in finalising some chapters of the draft opinion. The need to find out more on the status of population modelling for terrestrial plants was identified, since in order to check compliance with the protection goals, effects detected in experiments on individual plants need to be extrapolated to population level effects. The WG will hold a webconference in October. The WG will aim at meeting more frequently next year to present a complete draft opinion by the beginning of 2014.

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

The Chair of the WG introduced the latest version of the draft opinion. This draft opinion contained the amendments that have been made based on extensive comments from two Panel members (who

offered, during the last Plenary, an in-depth peer review of the draft document) and further changes made on the basis of discussions at the WG meeting that took place prior to the meeting. Major changes in content have been made in the chapters on uncertainties and isomer assessment. During the Plenary, discussions took place about the necessity of including some paragraphs on the applicability of TTC to substances having low-dose effects and in particular endocrine disruptors. After agreement on further changes, the opinion was adopted by the PPR Panel.

8. GUIDANCE ON THE USE OF PROBABILISTIC METHODOLOGY FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES

The Chair of the WG informed the Panel about the latest changes in the draft guidance resulting from the discussions during the last meetings of the WG in May and June. The Panel agreed with these changes and adopted the guidance.

9. FEED-BACK FROM THE SCIENTIFIC COMMITTEE AND ITS WORKING GROUPS

The Chair informed the Panel about the adoption of the opinion of the scientific committee on threshold of toxicological concern and on the report he made to the Scientific Committee on the activities and achievements of the PPR Panel in 2009-2012.

10. GUIDANCE ON AQUATIC ECOTOXICOLOGY

A first complete draft of the Guidance on tiered risk assessment for aquatic organisms in edge-of-field surface waters was provided to the Panel before the meeting. Since the WG Aquatic Ecotoxicology had a meeting directly before the plenary, a revised draft was presented during the plenary meeting. The main issues in each chapter were highlighted. Several chapters have been finalised; the remaining chapters are under revision and intended to be finalised by autumn 2012.

The secretariat reported that the proposals agreed by the Panel in December 2011 are still under consideration by EFSA (extension of the deadline, additional mandate for an opinion on the evaluation of the FOCUS surface water step 3 scenarios and additional mandate for an opinion on overarching principles in the environmental risk assessment of pesticides in the context of the revision of the GDs on Aquatic and Tererstrial Ecotoxicology).

11. MISCELLANEOUS

Mr Per Bergman, Director of the Scientific evaluation of Regulated Products Directorate, expressed his gratitude to the Panel for the activities completed within the last 3 years.

The secretariat informed the Panel about the announcement of the EFSA scientific conference "Challenging boundaries in risk assessment – sharing experiences" which will take place on 7 and 8 November 2012 and on the progress made regarding the article on the Risk Assessment of Plant Protection Products to be published in the special 10th anniversary issue of the EFSA journal.

The Secretariat informed the Panel of the positive outcome of the pilot project on the attendance of observers to which the PPR Panel took part.

12. ACHIEVEMENTS OF THE 2009-2012 PPR PANEL AND FUTURE CHALLENGES

The Chair and the Secretariat presented an overview of the major achievements in 2009-2012 and an outlook on future activities in all areas of the PPR Panel. An exchange of views took place after this presentation.

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Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

In his ADoI Prof. Schäffer declared the following interest: membership of the management board of the Research Institute for Environmental Risk Analysis and Assessment (GAIAC, Germany). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the above interest was deemed to represent a conflict of interest.
This resulted in it being impossible for the expert to be present at the 58th plenary meeting of the PPR Panel.

Annex II

INTERESTS AND ACTIONS RESULTING FROM THE ORAL DECLARATIONS OF INTERESTS

With regard to this meeting, Dr. Hart declared the following interest: On 11 June, he attended the first meeting of a new ILSI-Europe Expert Group on 'Effectiveness of Exposure Mitigation Options' which is an initiative of the ILSI-Europe Task Force on Process-Related Compounds and Natural Toxins. This first meeting discussed the workplan for the new initiative, including the selection of case studies on process-related compounds and natural toxins. Dr Hart attended as a substitute for a colleague who was unavailable. It is not yet certain whether Dr Hart will attend future meetings of this group.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the above interest was not deemed to represent a conflict of interest for the expert concerned.