European Food Safety Authority

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

53RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 21-22 SEPTEMBER 2011

(ADOPTED BY WRITTEN PROCEDURE ON 8 NOVEMBER 2011)

#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest.
2.	Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile.
3.	Guidance on dermal absorption.
4.	Opinion on the guidance on clustering and ranking of emissions from protected crops.
5.	Guidance on terrestrial ecotoxicology.
6.	Opinion on the science behind the development of a risk assessment of PPPs on bees (*Apis mellifera* and *Bombus spp.*)
7.	Guidance on aquatic ecotoxicology.
8.	Guidance on the use of probabilistic methodologies for modelling dietary exposure to pesticide residues.
9.	Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment.
10.	Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting PEC in soil.
11.	Opinion on dissimilar modes of action in cumulative risk assessment of pesticide residues.
12.	Opinions on the 2009 report of the FOCUS Groundwater working group.
13.	Dietary exposure assessment in EFSA.
14.	Miscellaneous: - Feed-back from the Scientific Committee and its Working Groups, including the last public consultations - Presentation of the new Audio/Web conferencing tool - Election of a vice-chair for the PPR Panel

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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 (22nd September), Ms A. PETERSEN, Ms Y. PICO`, Mr A. SCHAEFFER, Mr P. SOUSA, Mr W. STEURBAUT, Ms A. STROMBERG, Mr T. VAN DER LINDEN.

Apologies

Ms M. TASHEVA, Ms C. VLEMINCKX

Commission

Ms J. HOUINS-ROULET (DG SANCO)

EFSA

PPR Panel secretariat: Mr H. FONTIER, 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. Apologies were received from Ms TASHEVA and Ms VLEMINCKX.

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

Mr SEBESTYEN gave an update on the state of the outsourced project on Identification of Common Assessment Groups of Pesticides. Based on the agreed actions proposed by the contractor as a part of the termination procedure, the final deadline of the report and the database is end October 2011.

The WG met in August and agreed on the performance of case studies in order to test the applicability of the grouping approaches. The next meeting of the WG (via teleconference) will be organized in October to discuss the results of the case studies and the updated parts of the draft opinion.

3. GUIDANCE ON DERMAL ABSORPTION

Mr STEINKELLNER informed the Panel about recent and on-going activities in regard to the mandate on the guidance on dermal absorption. The scientific opinion on the science behind the revision of the guidance document on dermal absorption and the report on the outcome of the public consultation were published on 12 July on the EFSA webpage. The draft guidance, together with a letter referring to the risk management elements contained therein, was sent to the Commission, together with the scientific opinion, for comments. Once a response from the Commission is received (expected by end of 2011), the draft guidance will be finalised.

4. OPINION ON THE GUIDANCE ON CLUSTERING AND RANKING OF EMISSIONS FROM PROTECTED CROPS

The Rapporteur gave an update on the development of the opinion. The WG will meet again on 23/24 September and consider the remarks received from the stakeholder consultation on the draft scientific opinion. More than 80 comments have been received from MSs, industry and consultants.

Mr CAPRI was proposed as chair of the WG and accepted the nomination.

5. GUIDANCE ON TERRESTRIAL ECOTOXICOLOGY

The Panel was informed about the updated mandate on terrestrial ecotoxicology. The updated mandate comprises development of EFSA guidance on risk assessment for non-target arthropods, in-soil organisms, non-target terrestrial plants, amphibians and reptiles as well as good modelling practice. The Panel agreed to establish new working groups for preparing each of the respective opinions. The chairpersons were presented and confirmed by the Panel. The expertise needed was discussed and agreed by the Panel as follows:

Working group on non-target arthropod risk assessment:
Chair: Tony Hardy
Expertise:

- Risk assessment of pesticides and non-target arthropods
- Risk assessment methodology
- Definition of protection goals and designing assessments to address the protection goals
- Expertise in biology of specific groups of non-target arthropods
- Expertise in statistical analysis and uncertainty analysis
- Exposure of non-target arthropods
- Expertise in field studies
- Expertise in laboratory studies

Working group on in-soil risk assessment:
Chair: Paulo Sousa, Co-chair: Andreas Schäffer
Expertise:

- Risk assessment of pesticides and in-soil non-target organisms
- Statistical analysis and uncertainty analysis

- Exposure of in-soil organisms
- Expertise in field studies
- Expertise in laboratory studies
- Expertise in soil micro-biology
- Expertise in biology of specific groups of in-soil organisms

Working group on non-target terrestrial plants risk assessment:
Chair: Robert Luttik
Expertise:

- Expertise in non-target terrestrial plant RA and regulatory requirements
- Expertise in plant screening tests and on efficacy tests
- Expertise in laboratory phytotoxicity studies
- Expertise in plant field studies
- Expertise in plant physiology and sensitive life stages
- Expertise in exposure routes relevant to plants
- Expertise in statistical analysis (SSD) and uncertainty analysis
- Expertise with crops and wild species

Working group on good modelling practice in effect modelling:
Chair: Robert Luttik
Expertise:

- Expertise in risk assessment of pesticides and the use of effect models
- Expertise in risk assessment of pesticides and the use of exposure models
- Expertise in statistical analysis and uncertainty analysis
- Expertise in developing effect models

The establishment of the working group on amphibian and reptile risk assessment was postponed until some of the other working groups have finished their tasks.

6. INFORMATION ON THE SCIENCE BEHIND THE DEVELOPMENT OF A RISK ASSESSMENT OF PPPS ON BEES (APIS MELLIFERA AND BOMBUS SPP.)

The panel was informed that Mr LUTTIK was appointed as Chair of the working group on bee risk assessment. A short presentation was given on a first analysis of the existing risk assessment schemes, on the outcome of the first meeting, ongoing activities and next steps (finalisation of overview tables on exposure routes and agreement on specific protection goals).

The applicability of the Druckrey-Küpfmüller equation in the context of sublethal effects of neonicotinoids on bees was briefly discussed. The toxicology panel members offered their help on this issue and the Chair of the Bee Working Group will liaise with them to investigate this issue further.

7. GUIDANCE ON AQUATIC ECOTOXICOLOGY

The Panel was updated on the progress of the WG on Aquatic Ecotoxicology. The Panel was informed that the Chair of the Panel had appointed Mr KLEIN as Chair of the WG for preparing the "Guidance Document on tiered risk assessment for aquatic organisms in edge-of-field surface waters" and the "Guidance Document on aquatic risk assessment procedures for individual and multiple plant protection products at the edge-of-field and catchment scale" and Mr BROCK was appointed as Chair of the WG for preparing the "Guidance Document on ERA modelling approaches for aquatic organisms" and the "Guidance Document on tiered risk assessment procedure for sediment organisms and exposure via the sediment compartment in edge-of-field surface waters" in a letter dated 23 August 2011. The WG had a meeting on 14 September and progressed well on several open issues, e.g. guidance for higher tier model ecosystem approaches, and chapters of the GD. There are still some delays since some potential WG members' Annual Declarations of Interest were only approved recently. The WG also identified the need to bring in additional expertise as documented in the minutes of the 1st meeting of the WG Aquatic Ecotoxicology on 30 June. The Head of the Pesticides Unit will consult the Expert Database and liaise with the Chair of the WG in view of the appointment of additional external experts. The Panel also proposed three Hearing Experts with particular relevant knowledge to attend WG meetings according to EFSA policy rules. This request will be forwarded to the competent director of EFSA.

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

The Panel endorsed a new draft version of the guidance in view of the second public consultation. The public consultation will be launched by EFSA and a period of 2 months will be given to stakeholders to submit comments. An extension of the deadline for final adoption of the guidance will be requested to the EFSA Executive Director.

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

The rapporteur informed the Panel about the progress made in the preparation of the draft opinion in particular on the elaboration of adjusted Threshold of Toxicological Concern values for acute exposure assessment, on the testing strategy when the TTC values are exceeded and on the uncertainties affecting the assessment of the toxicological relevance of metabolites and degradates of pesticide active substances.

The Panel was also informed about the request of EFSA to include the evaluation of changes of the isomer ratios of active substances in the scope of the mandate and to extend the deadline of the adoption of the opinion to 30 June 2012. This will allow the Panel to take due consideration of the opinion of the EFSA Scientific Committee on exploring options for providing preliminary advice about possible human health risks based on the concept of Thresholds of Toxicological Concern.

10. OPINION ON THE SCIENCE BEHIND THE GUIDANCE FOR SCENARIO SELECTION AND SCENARIO PARAMETERISATION FOR PREDICTING PEC IN SOIL

An update on ongoing work for the revision of the opinion on PECs in Soil was given by the rapporteur following the WG meeting on 22/23 September. The WG is considering the remarks received from the stakeholder consultation on the draft scientific opinion. More than 140 comments have been received from MSs, industry and an NGO.

11. OPINION ON DISSIMILAR MODES OF ACTION IN CUMULATIVE RISK ASSESSMENT OF PESTICIDE RESIDUES

Mr STEINKELLNER briefly informed the Panel about the progress of the procurement contract that was launched by EFSA in preparation of an opinion on the relevance of dissimilar modes of action for cumulative risk assessment of pesticides which should complement the already ongoing work on a scientific opinion on cumulative risk assessment of pesticides by similar modes of action. An interim report was produced and was accepted by EFSA in July. The final project report should be delivered to EFSA by latest 14 December 2011.

The mandate for drafting a scientific opinion on the relevance of dissimilar modes of action (response addition) and its appropriate application for cumulative risk assessment of pesticides in food was sent to the Chair of the Panel by EFSA's Executive Director on 14 September. Adoption of the new scientific opinion is expected by latest 24 months after delivery of the final report of the procurement contract resulting in an effective deadline of 14 December 2013.

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

Mr EGSMOSE 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 EU (2009).

The amended mandate has been received and was accepted by the EFSA Mandate Review Committee. Due to resource constraints, EFSA will not be able to start the work until the second quarter of 2012. An official reply from EFSA to the Commission regarding the expected delivery of the opinions is under preparation.

13. DIETARY EXPOSURE ASSESSMENT IN EFSA

On the request of the Scientific Committee, the draft Scientific report on the 'Overview of the procedures currently used at EFSA for the assessment of dietary exposure to different chemical substances' prepared by the Dietary and Chemical Monitoring Unit was presented to the Panel. Members have been invited to make comments before the end of October.

14. MISCELLANEOUS:

- ***Feed-back from the Scientific Committee and its Working Groups, including the last public consultations.***
  The Panel was informed of several public consultations launched on draft outputs of the Scientific Committee (draft guidance on default values, draft opinion on exploring options for providing preliminary advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC) and draft guidance on repeated dose 90-day oral toxicity study on whole food/feed in rodents). The draft guidance on default values was presented by Mr BOTTEX and feed-back was provided by the Panel.

- ***Presentation of the new Audio/Web conferencing tool.***
  Postponed.

- ***Election of a vice-chair for the PPR Panel.***
  The Panel unanimously elected Ms S. HOUGAARD BENNEKOU as Vice-Chair of the Panel.

- ***News from the EU Commission.***
  The PPR Panel was given feed-back from the Commission on the outputs of the PPR Panel and of the Pesticides Unit during the 6 first months of 2011.

- ***Guidance on operator, worker, bystander and resident exposure.***
  The Panel was informed about a request made to EFSA by the Commission to produce an EFSA guidance on operator, worker, bystander and resident exposure by the end of 2012.

The next Plenary meeting will take place on 23-24 November 2011 in Parma, starting at **14h00** on 23 November.