



PESTICIDE PEER REVIEW UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 99th Plenary meeting

Held on 03-04 April, 2019, Parma (Italy)

(Agreed on 23 April 2019)

Participants

Panel Members:

Paulien Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja, Sabine Duquesne, Anne Louise Gimsing, Antonio Hernandez-Jerez, Marina Marinovich, Maurice Millet, Olavi Pelkonen, Silvia Pieper, Aaldrik Tiktak, Christopher Topping, Anneli Widenfalk, Ioanna Tzoulaki and Gerrit Wolterink.

Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

EFSA:

Arena Maria, Chiusolo Arianna

3rd April: Crivellente Federica, Gatto Valeria, Kardassi Dimitra, Mohimont Luc, Parra Morte Juan, Serafimova Rositsa, Terron Andrea, Terry Simon

4th April: Auteri Domenica, Egsmose Mark, Leuschner Renata, Streissl Franz, Tiramani Manuela, Messinetti Silvia, Saari Katri

Observers:

Not Applicable





1. Welcome and apologies for absence

The Chair of the Panel, Antonio Hernández-Jerez, welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel Members

Declarations of Interest of Scientific Panel Members In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 98th Plenary meeting held on 6-7 February 2019, Parma (Italy)

The minutes of the 98th PPR Plenary were agreed via written procedure on 27 February.

5. Report on written procedures since 98th Plenary meeting

No written procedures were undertaken since the 98th PPR plenary.

6. Scientific outputs submitted for discussion and/or possible adoption

6.1 Request of an opinion on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances) (<u>EFSA-Q-2018-00830</u>)

The draft opinion based on the advice from the SCER Standing Working Group (SWG) on genotoxicity was presented for discussion. The panel was informed that two newly conducted genotoxicity studies are expected to be submitted by the applicants within 5th April and that these studies will be taken into consideration by the SCER SWG during the next meeting (teleconference 11 April). The draft opinion will be presented for possible adoption during the PPR Panel plenary in June.

¹http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

²http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6.2 Scientific Opinion of the PPR Panel for developing Integrated Approaches to Testing and assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment (<u>EFSA-Q-2019-00100</u>)

The status of the WG implementation was presented for information. Action plan for objectives and dates were also presented. Activities of the WG will be initiated in May and the scientific opinion is expected to be adopted by June 2020. The Panel was also updated on the progresses concerning the OECD Guidance on application and interpretation of in-vitro developmental neurotoxicity (DNT) assays under development as well as on the outcomes from the OECD Expert Group meeting held in March.

6.3 Development of Adverse Outcome Pathways relevant for the identification of substances having endocrine disruptors properties

The scientific background for undertaking the project was presented for discussion. The proposal is to develop a series of AOPs, selected based on the analysis of the most common EATS and non-EATS endocrine adverse effects as observed through the peer review process of pesticide risk assessment. Expression of interest from some Panel members was collected. Giving the horizontal nature of the project, the SCER Unit will be involved.

6.4 Scientific opinion on health-based reference values for metabolites of the active substance terbuthylazine (<u>EFSA-Q-2018-00950</u>)

Based on *ad hoc* request from the Commission received on 1st March, the draft opinion was updated by the WG in order to in order to extend the exposure calculations in the Scientific Opinion from the two worst case scenarios to include all European scenarios. The conclusions of the draft opinion as circulated for commenting by the Panel in February 2019 remain unchanged. The document was presented and minor changes were agreed. The opinion was adopted unanimously by the Panel.

6.5 Establishment of cumulative assessment groups of pesticides for their effects on the nervous system (<u>EFSA-Q-2017-00434</u>)

Main comments to the draft EFSA scientific report, received from the public consultation conducted in May-June 2018 and how they were addressed in the document, were presented. The revised report was submitted in advance to the Panel for comments and three members offered to perform a scientific peer review. The report including received comments was presented and changes to the document were discussed and agreed. The report was endorsed unanimously by the Panel. Publication is foreseen by June 2019.

6.6 Cumulative risk assessment for the effects of pesticides on the nervous system and the thyroid (<u>EFSA-Q-2018-00346</u> and <u>EFSA-Q-2018-00345</u>)

The Panel was informed about the status of development of the two EFSA scientific reports on the cumulative risk assessment of pesticides for their effects on the nervous system and on the thyroid.

The methodology used for cumulative exposure assessment used by the EFSA WG was presented, as well as the step-wise approach for uncertainty analysis. The draft reports will be circulated to the Panel by 4th June to be presented for possible endorsement during the Plenary in June.





The Panel was also informed that comments received from the public consultation on the draft EFSA scientific reports on the establishment of cumulative assessment groups of pesticides for their effects on the thyroid (February-March 2019) will be addressed by the WG and that the draft report will be circulated to the Panel, when finalised, for endorsement by written procedure.

The publication of the three reports is foreseen in June 2019.

6.7 Scientific Statement on the coverage of bats by the current pesticide risk assessment for birds and mammals (EFSA-Q-2018-00615)

The draft opinion was submitted in advance to the Panel for comments. Several aspects on exposure and toxicity of bats were discussed, as well as recommendations for future activities. The draft statement will be presented during the Plenary in June for possible adoption.

6.8 Panel experts support to peer review of chlorpyrifos and chlorpyrifos methyl

Two Panel members, Antonio Hernandez and Ioanna Tzoulaki, reported their experience in support to the peer review of two substances under re-evaluation (chlorpyriphos and chlorpyrifos methyl). Based on their area of knowledge and large expertise (developmental neurotoxicity and epidemiology) the two experts were requested by the PREV Unit to contribute to the specific assessments for the abovementioned substances during the peer review experts' meeting (1st April). Outcomes from the assessments were presented. It was highlighted by the Unit the high relevance of the Panel member expertise in contributing to the assessment of specific evidence during the peer review of active substances.

6.9 Framework for conducting environmental exposure and risk assessment for transition metals when used as active substances in PPPs

The background of the mandate was explained, as well as the aim of the activity and the collaboration with ECHA. Anne-Louise Gimsing was appointed as chair of the working group. Expression of interest from other Panel members were also collected. Their participation will be confirmed once the expertise for carrying out the activity is identified by the chair in consultation with EFSA.

6.10 Update from the Pesticide Residues Unit on the proposal for establishing a permanent PPR Panel WG on Pesticides Residues

The progress of procedural aspects of the activity was discussed and clarification was given regarding the remit of the Standing Working Group (SWG).

Three Panel members expressed interest in participating to the Working Group. Their participation will be further considered pending the clarification on the remit of the SWG.

6.11 PREV unit on-going activities in Environmental Risk Assessment

Due to time constraints, the item was not discussed.





6.12 Environmental Risk Assessment current approach and future perspective

A presentation was given focusing on the challenges in the area of environmental risk assessment (ERA) for non-target terrestrial organisms and on the need to address the identified issues regarding for example the integration of spatio-temporal aspects of ecological systems combined with long-term monitoring approaches. The need to initiate activities involving a wider community in the area of Environmental Risk Assessment was highlighted. It was clarified that the relevance of progressing in the field of ERA is well recognised in EFSA as demonstrated by the fact that the Environmental Risk Assessment is one of the 3 pillars of the EFSA strategy for the period 2020-2027.

7. On-going activities of the Scientific Committee

Due to time constraints, the item was not discussed.

8. Any other business

The Panel was informed that no meeting rooms are available in EFSA for the PPR Plenary in November. The possibility of having the meeting outside Parma was discussed and agreed.

The Panel was also asked to disseminate further the call for expressions of interest to establish a list of individuals (natural persons) with scientific expertise in toxicology to assist EFSA in carrying out the preparatory work in the areas of Novel Foods and Nutrient Sources.