

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 97th Plenary meeting

**Held on 28-29 November 2018, Parma (Italy)
(Agreed on 11 January 2019)¹**

Participants

■ Panel Members²

Annette Aldrich, Philippe Berny (28 November), Tamara Coja, Sabine Duquesne, Anne Louise Gimsing, Antonio Hernández-Jerez, Marina Marinovich, Olavi Pelkonen, Silvia Pieper, Aaldrik Tiktak, Christopher Topping, Anneli Widenfalk and Gerrit Wolterink.

■ Hearing Experts³:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Unit: Mark Egsmose, Claudia Heppner, Alessio Ippolito, Frédérique Istace, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Luc Mohimont, José Tarazona, Franz Streissl, Andrea Terron, Benedicte Vagenende,

FEED Unit: Manuela Tiramani

¹ Minutes should be published within 15 working days of the final day of the relevant meeting. This provision does not apply to Pesticides Risk Assessment Peer Review meetings, which should follow the steps stated in Article 6 of the Decision of the Executive Director of the European Food Safety Authority concerning Pesticides Risk Assessment Peer Review (http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/eddecisionppr.pdf).

² Indicate first full name and then surname (John Smith) all throughout the document.

³ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair of the Panel, Antonio Hernández-Jerez, welcomed the participants. Apologies were received from Paulien Adriaanse, Philippe Berny (29 November), Maurice Millet and Ioanna Tzoulaki. Apologies were also received from Guilhem de Seze with respect to the item 8.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.⁶

4. Report on written procedures since (96th) Plenary meeting

Consultations between the Secretariat and the Chair of the Panel took place in order to nominate a Chair for the Working Group on health-based reference values for terbutylazine metabolites.

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

5.1 Statement on the coverage of bats by the current pesticide risk assessment for birds and mammals ([EFSA-Q-2018-00615](#))

The Chair of the Working Group informed the Panel on the progress. A comparison between bats, birds and mammals is ongoing for ten biological, physiological and ecological life-history traits. Oral and non-oral

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ Please refer to footnote 5

exposure routes of bats to pesticides are reviewed for their relative importance and comparison with birds and mammals.

The panel was informed that EUROBATS (agreement aiming at the protection of European bats under the umbrella of the United Nations Environmental Program) have passed a resolution in the meeting of parties in October 2018 that bats should be considered in the pesticide risk assessment.

5.2 Scientific opinion on health-based reference values for metabolites of the active substance terbuthylazine ([EFSA-Q-2018-00950](#))

The mandate has been accepted by the EFSA Executive Director following the modalities discussed during the previous meeting of the Panel.

Tamara Coja was nominated as Chair of the Working Group. The areas of expertise needed to fulfil the mandate include the assessment of general toxicity and genotoxicity, toxicokinetics and metabolism of pesticides, structure–activity relationship ((Q)SAR), read-across and other alternative in silico and non-testing methods and tools, threshold of toxicological concern (TTC), guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment and dietary exposure assessment to metabolites of pesticides in groundwater. The Working Group has been established and will meet for the first time in December 2018.

6. New Mandates

6.1 Request of an opinion on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances) ([EFSA-Q-2018-00830](#))

The secretariat presented a request of European Commission (EC) for an opinion of the PPR Panel on the genotoxic potential of triazine amine. The secretariat presented the background of this request and referred to the EFSA outputs having dealt with active substances producing this metabolite.

In consultation with the Chair of the Panel, it was agreed with the Secretariat to ask advice from Standing Working Group of the Scientific Committee on genotoxicity. Therefore, no ad-hoc Working Group of the Panel needs to be established. The need for additional expertise to support the Working Group on genotoxicity will be considered by its Chair in consultation of the respective Secretariat. Two members of the PPR panel expressed interest to contribute

7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

7.1 Scientific Committee and/or Scientific Panel(s) including their Working Groups

The Chair informed the Panel on the outcome of the meeting of the Scientific Committee which took place on 21 and 22 November 2018, in particular regarding the draft guidance on chemical mixtures, the draft guidance on communication of uncertainty in scientific assessments and the draft statement on genotoxicity assessment of chemical mixtures.

The 2018-2021 work programme of the scientific Committee and the EFSA crisis response and preparedness were also discussed.

8. Other scientific topics for information and/or discussion

8.1 Prioritised and envisioned activities related to methodological development in the area of plant protection products.

The secretariat provided the Panel with a list of activities related to methodological development in the area of plant protection products, either internally prioritised for 2019 or envisioned at longer term.

The Panel discussed these activities and expressed interest to support these activities by:

- a) Producing scientific outputs in following areas or issues:
 - identification of toxicological effects relevant for cumulative risk assessment and the respective characterisation principles
 - development of Adverse Outcome Pathways (AOPs) relevant for the identification of substances having endocrine disrupting properties
 - Integrated Approaches to Testing and Assessment (IATA) case studies related to developmental neurotoxicity of pesticides
 - landscape-based problem definitions and conceptual models for assessing the risk of pesticides to non-target aquatic and terrestrial organisms
 - risk assessment of aquatic organisms
- b) Following, supporting and endorsing other EFSA scientific outputs on:
 - Cumulative assessment groups
 - Cumulative risk assessments
 - study protocols and interpretative analysis of in vitro comparative interspecies metabolism

- non-dietary exposure of operators, workers, residents and bystanders to plant protection products
- acute Acceptable Operator Exposure Level (AAOEL)
- risk assessment of non-target terrestrial organisms, including birds and mammals

Two Panel Members made a presentation of a manuscript “Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009” to be published in 2019 and raised Panel’s awareness on scientific issues concerning groundwater monitoring and the use of models. Based on this, the Panel encourages EFSA to make risk managers aware of the document when published, e.g. during forthcoming meetings of the Pesticide Steering Network and of the Standing Committee on Plants, Animals, Food and Feed, section phytopharmaceuticals.

The Panel also recommends revising the pesticide drift assessment methodology and scenarios that represent realistic worst-case conditions when feasible and preferably following the publication of the report of the drift risk assessment workshop of SETAC which took place in October 2018.

8.2. Involvement of the PPR Panel in the assessment of active substances under Regulation (EC) No 1107/2009 and in the assessment of pesticide residues under Regulation (EC) No 396/2005.

Following the request of the Head of the Scientific Evaluation of Regulated Products Department, the Panel expressed a general interest and willingness to support the units in charge of the evaluation of pesticides under Regulations (EC) No 1107/2009 and 396/2005.

Any modality defined by EFSA policies to allow the Panel to provide its collegial input in the relevant processes should be considered. This includes the production of the Scientific Opinions and Scientific Statements, the endorsement of EFSA outputs as well as the elaboration of minuted replies to specific consultations. The best modality should be defined on a case per case basis, taking into account the nature of the scientific issue to address and the procedural constraints of the regulatory processes.

On the basis of proposals made by the Pesticides Unit, the Panel also supported the establishment of 2 standing working groups:

- A standing Working Group on ecotoxicological effect models to be consulted in the context of dossiers supporting the approval of active substances. This Working Group would conduct assessments

following the Scientific Opinion of the PPR Panel on Good Modelling Practices.

- A standing Working Group on pesticides residues risk assessment to be consulted on scientific questions as needed during the preparation of EFSA outputs in the context of Regulation (EC) No 396/2005 (such as MRL applications, MRL reviews, annual monitoring on pesticide residues) or under peer review activities related to Regulation (EC) No 1107/2009.

These proposals will be further discussed during the forthcoming plenary meeting of the Panel, on the basis of draft terms of reference defining the precise remit of these Working Groups and practical conditions under which they would operate, taking the regulatory timelines into account.

9. Any other business

The Secretariat updated the Panel on the state of play regarding the reorganisation of the pesticide Risk Assessment in EFSA.