# Scientific Panel on Plant Protection Products and their Residues

# Minutes of the 96th Plenary meeting

**Held on the 26-27 September 2018, Parma (Italy)**

**(Agreed on 10 November 2018)**

## Participants

- Panel Members

  Paulien Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja, Sabine Duquesne, Anne Louise Gimsing, Antonio Hernandez-Jerez, Maurice Millet, Olavi Pelkonen, Aaldrik Tiktak, Christopher Topping, Anneli Widenfalk.

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  Pesticides Unit: Federica Crivellente, Mark Egsmose, Anja Friel, Claudia Heppner, Dimitra Kardassi, Christopher Lythgo, Luc Mohimont, Laura Padovani, Jose Tarazona, Andrea Terron

  Scientific Evaluation of Regulated Products: Guilhem de Seze

## 1. Opening, apologies for absence and adoption of the draft agenda

The Chair of the Panel, Antonio Hernández-Jerez welcomed the participants. Apologies were received from Silvia Pieper, Ioanna Tzoulaki and Gerrit Wolterink.

## 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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Report on written procedures since 95th Plenary meeting

No written procedure took place since the 95th Plenary meeting.

## 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 mandate has been accepted by the EFSA Executive Director as an own initiative. The chair of the WG updated the panel on the terms of references, composition of the WG, the planning of meetings and timelines for delivery of the draft document for consultation and adoption by the panel. The structure of the document and the topics to be covered

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

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

in each chapter were presented. The panel was asked for feedback on the structure and proposed topics.

## 6. New Mandates

### 6.1. Request of an opinion on health-based reference values for metabolites of the active substance *terbuthylazine*

The secretariat presented the request of European Commission (EC) for an opinion or a statement on the setting of health-based reference values for metabolites of the active substance terbuthylazine. This concerns metabolites found in ground water and for which EFSA concluded in 2017 that information was not sufficient to establish such reference values.

EC invites the Panel to use, in addition to the documentation available to EFSA at the time of its earlier conclusions, other information and all scientifically valid methods available to fulfil the request.

As this request creates a potential source of divergence between 2 outputs of EFSA, the Panel agreed to use at least its guidance adopted in 2016 on the establishment of the residue definition for dietary risk assessment, as this guidance implies the setting of health-based reference values for pesticide metabolites in view of dietary risk assessment. The use of this guidance provides an *ex-ante* justification of eventual divergences as it will allow using the current scientific and technical knowledge.

The Panel agreed on the need to establish a working group and on the use of external expertise if needed to ensure the availability of all needed scientific competences. The nomination of the Chair of the WG and the identification of areas of scientific expertise to fulfil the mandate will proceed by written procedure.

## 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 17 September 2018, in particular regarding the draft guidance on the TTC approach, the

genotoxicity assessment of aneugenic substances, the 2018-2021 work programme and the Joint meeting with the International Liaison group on Methods for Risk Assessment of Chemicals in food (ILMERAC).

### 7.2. EFSA including its Working Groups /Task Forces

The Head of the Scientific Evaluation of Regulated Products Department informed the Panel about a reorganisation of the pesticide Risk Assessment in ESFA. The Panel is invited to provide its views and proposals on its involvement in methodological development, in the assessment of active substances and MRL applications.

## 8. Other scientific topics for information and/or discussion

### 8.1. Recommendations of the 2015-2018 PPR Panel on possible future activities supporting the risk assessment of plant protection products

The recommendations of the 2015-2018 Panel on possible future activities supporting the risk assessment of plant protection products were presented by the Secretariat. A number of initiatives have already been taken by EFSA to address some of these recommendations. In view of the fact that the current tasks of the Panel are limited, all ongoing and envisioned activities regarding methodological development will be considered during the next plenary meeting for possible involvement of the panel.

In addition, three specific topics with potential contribution of the Panel were discussed by breakout groups.

- Implementation of cumulative risk assessment: The Secretariat summarised the state of play of the ongoing activities. An active role of the Panel could be considered in the elaboration of cumulative assessment groups of pesticides. In particular, the Panel could be tasked to identify and characterise specific effects of relevance for cumulative risk assessment and participate to the associated uncertainty analyses (participation to expert knowledge elicitation sessions, assessment of the plausibility of the dose-addition model under different levels of information about modes/mechanisms of action of risk drivers). At a later stage, an update of the methodologies should be considered in the light of the experience acquired during their implementation for the effects on the nervous system and the

thyroid and taking account of the guidance of the Scientific Committee on harmonised methodologies for risk assessment of combined exposure to multiple chemicals.

- Environmental Risk Assessments: The Panel brainstormed on the way for moving forward in order to consider (agricultural) landscape characteristics and environmental variability in the risk assessment of pesticides, with two parallel groups covering the aquatic and terrestrial compartments. The approach suggested by a Panel member for characterising the landscape on the bases of three complementary attributes, landscape structure, landscape management, and landscape climate and environment was accepted. The next step is to implement these approaches into the problem definition and conceptual models for assessing the risk of pesticides to non-target organisms. The Panel was informed about horizontal EFSA activities and research projects recently initiated in this area, and considered that the Panel could lead the conceptual developments regarding the integration of landscape paradigms in the environmental guidance documents for pesticides, e.g. by producing as self-tasks two scientific opinions proposing landscape based problem definitions and conceptual models for assessing the risk of pesticides to non-target aquatic and terrestrial organisms respectively.
- Development of Adverse Outcome Pathways (AOPs) relevant for the identification of substances having endocrine disrupting (ED) properties: The secretariat presented a scoping document. The overall intention is to involve the Panel in the development of AOPs for ED focusing on the AO as identified in the regulatory dossiers submitted during the peer review process. The use of AOPs is intended to:

  a) Facilitate and support the coherence analysis and the biological plausible link between the adverse effects observed in the pivotal study and the underlying endocrine activity;

  b) Facilitate and support the postulation of an endocrine Mode of Action (MoA), in line with the scientific criteria and with the approach proposed by the EFSA/ECHA guidance (for both EATS and non-EATS MoAs);

  c) Facilitate and support the identification of data gaps and which further information could help to clarify the postulated MoAs;

  d) Provide evidence for comparative MoA analysis or concomitant Molecular Initiating Events (MIEs);

  e) Identify the critical test to be applied for non-EATS endocrine MoAs and provide transparent guidance on respective testing protocols;

f) Facilitate and support the uncertainty analysis.

## 9. Any other business

The following was brought to the attention of the Panel:

- Marina Marinovich's appointment as member of the PPR Panel as of 1st October 2018
- The draft report (17 September 2018) of a Special Committee of the European Parliament on the Union's authorisation procedure for pesticides
- The 2016 European Union report on pesticide residues in food endorsed on 21 June 2018
- The EFSA Workshop on 'In vitro comparative metabolism studies in regulatory pesticide risk assessment' taking place on 15 and 16 November 2018