

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 93rd Plenary meeting

**Held on 3-4 May 2018, Parma (Italy)
(Agreed on 29 May 2018)**

Participants

■ Panel Members

Paulien Adriaanse, Philippe Berny, Theodorus Brock, Sabine Duquesne, Sandro Grilli, Antonio Hernandez-Jerez, Susanne Hougaard Bennekou, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Michael Stemmer, Ingvar Sundh, Ivana Teodorovic, Aaldrik Tiktak, Gerrit Wolterink.

■ Hearing Experts¹:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Unit: Maria Arena, Domenica Auteri, Stefania Barmaz, Arianna Chiusolo, Mark Egsmose, Luc Mohimont, Franz Streissl, Jose Tarazona and Andrea Terron.

Evidence Management Unit: Bruno Dujardin

■ Observers:

Not Applicable

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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

The Chair of the Panel, Colin Ockleford, welcomed the participants. Apologies were received from Kyriaki Machera, Robert Smith and Christopher Topping.

The agenda was adopted without changes.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

3. Agreement of the minutes of the 92nd Plenary meeting held on 14 March 2018, Parma (Italy).

The minutes of the 92nd Plenary meeting held on 14 March 2018, were agreed on 3 May 2018 and published on the EFSA website.⁴

4. Report on the written procedures since the 92nd Plenary meeting

No written procedure took place since the 92nd Plenary meeting.

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

5.1 Scientific Opinion on the Guidance proposal on how aged sorption studies for pesticides should be conducted,

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/sites/default/files/event/180314-m.pdf>

analyzed and used in regulatory assessments (Chemical Regulation Directorate, UK, 2016) ([EFSA-Q-2017-00620](#))

The Secretariat circulated a first draft of the Scientific Opinion to the Panel on 20 April 2018 and a scientific peer review was performed by one member of the Panel. The Chair of the Working Group presented an overview of the observations and conclusions achieved so far.

The working group is in the final stage for preparing the case studies for testing the guidance proposal, checking the procedure for assessing metabolites and the acceptability of deriving aged sorption parameters from field studies.

Based on the comments already received, the Working Group will finalize the draft scientific opinion in the upcoming weeks for possible adoption during the next plenary meeting.

5.2 Scientific Opinion on the state of Toxicokinetic/Toxicodynamic models for regulatory risk assessment of pesticides for aquatic organisms ([EFSA-Q-2012-00960](#))

The Chair of the Working Group informed the Panel on the outcome of the consultation of the Pesticide Steering Network and on the comments received by 6 April 2018 from individual members of the Panel on the draft scientific opinion.

Comments were made by 6 Member States and this meets the expectation in light of the technicality of the topic. The feedback was overall very positive with only few Member States expressing concern about the additional complexity in risk assessment.

The working group will meet at the end of May for finalizing the Scientific Opinion which will later be circulated in the first half of June for possible adoption during the next plenary meeting.

5.3 Scientific opinion on pesticides in foods for infants and young children ([EFSA-Q-2016-00702](#))

The Secretariat informed the Panel that the outcome of the discussion group, which dealt with pesticides residues in food for infants and children during the previous plenary meeting, had been considered by the Working Group to finalize a draft of the Scientific Opinion. This draft was submitted to the Scientific Committee and considered at its 88th plenary meeting. Comments of members of the Scientific Committee were collected by written procedure.

The same draft was also circulated to the Panel on 20 April 2018 by the Secretariat for comments and scientific peer review by a member of the Panel.

All collected comments were considered by the Working Group to prepare an amended version of the Scientific Opinion which was presented to the Panel by the Chair of the Working Group. An exchange of views took place and the Panel discussed in particular the establishment and use of the new health-based guidance value (HBGV), the proposed methodology for exposure assessment and the content of the recommendations. Minor final changes were agreed and the Panel adopted the opinion. It was agreed to finalize a reply to the comments of the Scientific Committee by written procedure.

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

6.1 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 11 and 12 April 2018. A guidance document on communication of uncertainty in scientific assessments has been endorsed for public consultation.

The guidance on harmonized risk assessment methodologies for human health, animal health and ecological risk assessment of combined exposure for multiple chemicals was also in an advanced stage of preparation and close to be published for public consultation.

7. Other scientific topics for information and/or discussion

7.1 Consultation of the PPR Panel on the Joint ECHA/EFSA guidance on ED hazard identification for pesticides and biocides ([EFSA-Q-2016-00825](#))

On 16 April 2018, according to the outline of Draft Guidance Document for the implementation of the hazard-based criteria to identify endocrine disruptors published on December 2016 and updated on January 2018, the Panel has been consulted on an updated version of the guidance document following the public consultation (version of the 16 April 2018 of the Drafting Group for consultation of the ECHA and EFSA scientific bodies). In particular the Panel, as the other scientific risk assessment bodies consulted at this stage, was invited to reply to 12 precise questions prepared by the EFSA/ECHA (supported by the JCR) drafting

team of the guidance. Replies were prepared individually by panel members and submitted, as requested, through an electronic platform until 27 April. They were later extracted by the secretariat and compiled into a single document reviewed by the Panel during the plenary meeting.

After discussion and agreement on a few changes, the document was collegially endorsed by the Panel, with the following additional recommendations:

- The Panel recommends the settlement of a centralised ECHA/EFSA structure that applicants and competent authorities can consult to receive scientific support in the implementation of the guidance.
- The Panel recommends an update of the guidance when the current scientific limitations restricting its scope of application will be addressed.
- The Panel highly recommends the development of AOPs for EATS and non-EATS modalities. This will help in linking observed adverse effect with endocrine activities through a weight of evidence approach and to define a testing strategy where molecular initiating events and/or intermediated key events need to be explored.

The document endorsed by the Panel will be published with the approved final guidance.

7.2 Draft mandate for a Panel output on the coverage of bats by the current pesticide risk assessment for birds and mammals

The Panel discussed a draft mandate on the pesticide risk assessment for bats. As a request to update the guidance on birds and mammals was received from the European Commission in 2016, it is important for EFSA to be aware whether or not the current risk assessment scheme applied for birds and mammals provides adequate protection for bats. This question is relevant in view of physiological and ecological features differentiating them from birds and mammals and given that all bats are protected species under the Agreement on the Conservation of Populations of European Bats.

The Panel discussed a number of scientific elements of relevance to address this question from the perspective of Regulation (EC) No 1107/2009, but highlighted that for a number of active substances an important contribution to the exposure of bats may result from the uses of these substances as biocides or veterinary drugs. Ignoring these sources of exposure would be problematic if an adequate mechanism of protection of bats is sought. Developing a risk assessment for exposure via biocides and veterinary drugs is however outside of the pesticide regulation and would need cooperation with ECHA and EMA.

The secretariat will prepare a revised mandate proposal on the basis of the exchange of views, and will list the information that would be made available to the panel in view of preparing a statement on the adequacy of the birds and mammals risk assessment scheme for protection of bats.

If it cannot be concluded that bats are covered, in a second step a more comprehensive output should be developed to elaborate the basis for a specific risk assessment for bats. Cooperation with ECHA and EMA should be considered at that stage.

7.3 EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

On 17 April 2018, the Secretariat circulated to the panel a draft EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system. This draft was elaborated by the EFSA Working Group, taking into account the outcome of the discussion group of the last plenary meeting on this topic. All members were invited to comment and two of them conducted a scientific peer review.

All submitted comments were considered by the Working Group and EFSA presented a revised version of the document, explaining how the comments were addressed. The most important changes were related to the residue definition for the risk assessment applicable to specific effects, the consequence of missing information on the uncertainties, the use of toxicokinetics and the content of recommendations.

After proposing a few changes to the text for the purpose of clarification, the Panel endorsed the draft document in view of the public consultation.

7.4 Roadmap on landscape scale risk assessment

The secretariat presented the outcome of the discussion group related to the roadmap on landscape scale environmental risk assessment which took place during the previous plenary meeting. A vision was elaborated on the purpose of the project and its associated inputs and outputs.

The intention is to make a systems-based landscape scale environmental risk assessment available to Member States. Standard models and approaches can be adapted to Member State requirements using Member State landscapes or generic landscapes. Landscape selection for single substance evaluation should take into account the key drivers in the landscape structure, agricultural management, climate and environmental

conditions. As an initial step there is a need to define agreed approaches to landscape selection.

7.5 Recommendations on possible future activities

The Panel was briefly informed about the contributions received by the Secretariat to the document providing recommendations on possible future activities supporting the continuous improvement of risk assessment methodologies.

8. Any other business

The following was brought to the attention of the Panel:

- An external scientific report 'Literature review and appraisal on alternative neurotoxicity testing methods' was published on 13 April 2018 (Leibniz Research Institute for Environmental Medicine, Università degli Studi di Milano and Flemish Institute for Technological Research);
- An external scientific report 'Proposal for a data model for probabilistic cumulative dietary exposure assessments of pesticides in line with the MCRA software' was published on 19 April 2018 (Dutch Institute of Public Health and Environment and Wageningen University & Research).