

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 91st Plenary meeting

Held on 7-8 February 2018, Parma (Italy)

(Agreed on 8 March 2018)

Participants

■ Panel Members

Paulien Adriaanse, Philippe Berny, Theodorus Brock (7 February), Sandro Grilli, Antonio Hernandez-Jerez, Susanne Hougaard Bennekou, Michael Klein (7 February), Thomas Kuhl, Ryszard Laskowski, Kyriaki Machera, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Ingvar Sundh, Ivana Teodorovic (7 February), Aldrik Tiktak, Christopher Topping, Gerrit Wolterink.

■ Hearing Experts ¹:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Unit: Maria Arena, Arianna Chiusolo, Federica Crivellente, Mark Egsmose, Christopher Lythgo, Luc Mohimont and Jose Tarazona
Legal and Assurance Services Unit: Simone Gabbi

■ 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 Theodorus Brock (8 February), Sabine Duquesne, Michael Klein (8 February), Rob Smith, Michael Stemmer and Ivana Teodorovic (8 February).

The agenda was adopted without changes.

2. Declarations of Interest of 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 90th Plenary meeting held on 22-23 November 2017, Parma (Italy).

The minutes of the 90th plenary meeting held on 22-23 November 2017, were agreed on 2 February 2018 and published on the EFSA website.⁴

4. Report on the written procedures since the 90th Plenary meeting

No written procedure took place since the 90th 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, analyzed and used in regulatory assessments (Chemical Regulation Directorate, UK, 2016) ([EFSA-Q-2017-00620](#))

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

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

⁴ <https://www.efsa.europa.eu/sites/default/files/event/171122-0-m.pdf>

The Chair of the Working Group informed the Panel on the outcome of the meetings that took place since the last plenary meeting. Results were available from two out of the three case studies performed by the Working Group. This showed that the Guidance proposal was generally applicable for the intended use. The experience gained so far has helped to prepare recommendations for improvements to the guidance proposal.

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 meetings that took place since the last plenary. The Working Group decided to review the structure of the opinion for reason of readability and to dedicate one section to each of the 3 models in the focus of the mandate. The WG also decided to develop three different checklists for each model evaluation. The checklists were developed by adapting the Appendix B of the EFSA PPR Opinion on Good Modelling practice.

The panel asked the Working Group to include a section on its experience on the practicability of the Scientific Opinion on good modelling practice for the evaluation of the TK/TD models and, if appropriate, to propose recommendations for eventual improvements.

The Consultation of the Pesticide Steering Network will start in the forthcoming weeks. It was suggested to prepare a list of points of attention that the members of the PSN should consider in order to inform as much as possible the Working Group and the Panel on the practical usability of this Scientific Opinion in the regulatory assessment of active substances and plant protection products.

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

The Chair of the Working Group informed the Panel on the outcome of the meetings that took place since the last plenary. In particular, the Working Group was informed on the status of a Raw Primary Commodities (RPC) model, under development and aiming at converting food as consumed to raw agricultural commodities using refined and consolidated conversion factors. Exposure calculations based on this model were conducted for infants above 16 weeks of age and young children for the active substances selected for the case studies. The Working Group also considered the exposure of infants below 16 weeks of age on the basis of the infant formula (IF) consumption values recommended by the guidance of the Scientific Committee. The contribution to pesticides residues exposure from drinking water used to reconstitute IF was also discussed and considered negligible, based on EU Water Directive. It was also

agreed that metabolites in groundwater should not be considered because evaluated during the active substances approval/authorisation.

The Working Group also addressed elements related to the appropriateness of toxicological reference values for infants and young children and discussed the scope of a section on uncertainties affecting the different components of the assessment.

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

No meeting of the Scientific Committee took place since the last Plenary meeting of the PPR Panel.

6.2 EFSA including its Working Groups /Task Forces

The Legal & Assurance Services Unit presented the Decision of the Executive Director of EFSA on Competing Interest Management which became applicable as of 1st December 2017 for the experts having submitted an application pursuant to Article 28(5) of Regulation (EC) No 178/2002 for the term 2018-2021 and shall apply from 1st July 2018 for all other concerned individuals. The most relevant changes, in particular regarding activities with non-public institutions and the impact of the interests on the annual earnings, were highlighted.

A first version of draft roadmap for the use of landscape scale risk assessment in Europe was prepared by 2 members of the Panel and discussed. This document reviews the current system model capabilities and the extensions currently under development, and proposes an implementation strategy following short and long term timelines. The panel exchanged views on elements to develop or further consider, such as the integration of terrestrial, aquatic and residential risk mapping, the model validation, the development of regulatory scenarios and protection goals and the identification of representative focal species.

The feasibility and benefits of the approach should be discussed with Member States and Risk Managers. For this reason, the Panel decided to develop further the draft roadmap under dedicated meetings with in a small group sufficient to cover the terrestrial, aquatic and residential components of a landscape based risk assessment. Where appropriate, technical hearings will be considered to receive the views of risk managers, stakeholders and experts in the field.

The Secretariat informed the Panel on the annual plan related to the implementation of cumulative risk assessment of pesticide residues in

food. A presentation of the methodologies used for the preparation of the EFSA scientific reports on cumulative assessment groups will be presented during the next plenary meetings. The Secretariat invited Panel members to express interest to perform a scientific peer-review of these outputs.

The technical report 'Scientific risk assessment of pesticides in the European Union: EFSA contribution to on-going reflections by the EC' has been approved by EFSA on 23 January 2018 and published. This report aims at providing a contribution to the REFIT process solely based on the EFSA Risk Assessments experience. The Head of Pesticides Unit presented the main ideas of this technical report which explores in particular the assessment of all effects of active substances and plant protection products, including their co-formulants, at EU-level, and the development of tools integrating the agricultural and environmental diversity of the EU and its Member States.

The Panel started to review the recommendations on possible future activities supporting the risk assessment of plant protection products, agreed by the PPR Panel in its previous composition as an annex to the minutes of the 75th plenary meeting in June 2015. A number of suggestions were made to update the document and add new items, e.g. the risk assessment for residents and the uncertainties of standard assessment models. The Panel agreed to work on a new version of the document by written procedure.

A particular attention was dedicated to the article 'Don't attack science agencies for political gain' written by Bernhard Url, Executive Director of EFSA, and published in Nature journal. The 3 crucial questions raised in this document on the work of regulatory agencies were particularly appreciated by the Panel for their high relevance.

The Panel was informed about the implementation plan of the guidance of the Scientific Committee on uncertainty analysis in scientific assessment, in particular in the area of regulated products.

7. Any other business

The secretariat presented the guidelines for observers in view of the forthcoming open plenary meeting which will take place on 14 and 15 March.

The 93rd Plenary meeting of the PPR Panel will take place on 3 and 4 May 2018.

The Panel was informed about the report 'Industry writing its own rules' published by Generations Futures and the Pesticides Action Network.