

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 77th Plenary meeting

Held on 23 - 24 September, 2015, Parma (Italy)

(Agreed on 18 November 2015)

Participants

■ Panel Members:

Philippe Berny, Theodorus Brock (item 6.6), Sabine Duquesne, Sandro Grilli, Antonio F. Hernandez-Jerez, Susanne Hougaard Bennekou, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Kyriaki Machera, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Robert Smith, Michael Stemmer, Ingvar Sundh, Christopher Topping and Aaldrik Tiktak.

■ Hearing Experts¹:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Unit: Maria Arena, Arianna Chiusolo, Federica Crivellente, Mark Egsmose, Magda Florio, Paula Medina, Luc Mohimont, Federica Ruffo, Franz Streissl, Andrea Terron, and Jose Tarazona.

Assessment and Methodological Support Unit: Elisa Aiassa (item 7.2), Gilles Guillot and Olaf Mosbach-Schulz (items 6.2 and 7.1).

1. Welcome and apologies for absence

The Chair of the Panel, Colin Ockleford welcomed the participants.

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>.

Apologies were received from Paulien Adriaanse, Theodorus Brock, Ivana Teodorovic, Robert Smith (24 September) 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 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.

4. Agreement of the minutes of the 75th Plenary meeting held on 24-25 June and of the 76th Plenary meeting held on 8 - 9 July 2015, Parma (Italy).

The minutes of the 75th Plenary meeting, held on 24th and 25th June 2015, were agreed on 17th August 2015. The minutes of the 76th Plenary meeting, held on 8th and 9th July 2015, were under written agreement procedure.

5. Report on written procedures since 76th Plenary meeting

No written procedure took place since the 76th Plenary meeting.

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

6.1 Scientific Opinion addressing the state of the science on in-soil risk assessment ([EFSA-Q-2011-00978](#))

The Chair of the Working Group informed the Panel on the reorganisation of the Working Group and on the support needed from external experts. The Panel was also informed on issues discussed during the last meeting of the Working Group.

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

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

6.2 Scientific Guidance of the PPR Panel on the establishment of the residue definition to be used for dietary risk assessment ([EFSA-Q-2013-01001](#))

The Chair of the Working Group informed the Panel on the reorganisation of the Working Group and on the support needed from external experts. The Panel was also informed on issues discussed during the last meeting of the Working Group, which included a technical hearing of an expert representing the Committee for Medicinal Products for Veterinary Use of the European Medicine Agency.

The Panel asked EFSA to clarify the expected scope of the section on uncertainties of the guidance on the establishment of the residue definition for risk assessment and whether cooperation with the WG of the Scientific Committee on uncertainty in risk assessment is desired as part of this mandate.

6.3 Scientific Opinion of the PPR Panel investigating experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia ([EFSA-Q-2014-00480](#))

The Chair of the Working Group informed the Panel on the reorganisation of the Working Group and on the support needed from external experts. In addition, an external expert with specific expertise in childhood leukaemia was identified.

The Panel was also informed that a forthcoming meeting of the Working Group will include a technical hearing with Florianne Tschudi-Monnet, in her private capacity, for her particular expertise in neuroinflammation.

6.4 Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' (University of Ioannina Medical School, 2013) ([EFSA-Q-2014-00481](#))

The Chair of the Working Group informed the Panel that no change in the composition of the Working Group took place as a consequence of the renewal of the Panel. An external expert with practical experience in the integration of epidemiological data in the risk assessment of pesticides could not be found.

The Panel was informed that a call for tender for a human biomonitoring data collection from occupational exposure to pesticides had been launched by EFSA to support this mandate.

6.5 Scientific report on the assessment of the quality and scientific relevance of dermal absorption studies submitted to EFSA ([EFSA-QN-2015-00169](#))

A draft of the EFSA Scientific Report on the assessment of the quality and scientific relevance of dermal absorption studies submitted to EFSA was circulated to the Panel on 16th September. A member of the Panel agreed to review the document and provided comments on behalf of the Panel.

These comments were discussed during the Plenary meeting and EFSA explained how they will be addressed. A revised draft of the EFSA scientific report will be circulated to the Panel members for endorsement by written procedure during the weeks following the Plenary meeting.

6.6 Scientific Opinion of the PPR Panel on the state of effect modelling approaches for regulatory risk assessment of pesticides for aquatic organisms ([EFSA-Q-2012-00960](#))

The Panel discussed a proposal for an update of the terms of reference of this mandate, in the light of the current knowledge and recent developments in this area. A revised proposal will be prepared by the Secretariat for further discussion at the next Plenary meeting.

6.7 Scientific Opinion addressing the state of the science on risk assessment for amphibians and reptiles ([EFSA-QN-2011-00985](#))

The Chair of the Working Group informed the Panel on the consultation with the Unit regarding the establishment and the composition of the Working Group. The needed areas of expertise include amphibian and reptile biology/ecology/ecotoxicology, amphibian and reptile testing, regulatory risk assessment of plant protection products, population modelling (ideally for amphibians and reptiles), exposure assessment (including oral, dermal and inhalation exposure model development) and statistics. The Panel agreed with the need for external experts.

6.8 Scientific Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment on multiple stressors in honeybees at the landscape level

The Panel was informed on comments sent by the developer of the BEEHAVE model to EFSA after publication of the statement adopted during the 74th Plenary meeting, and agreed on explanatory corrections clarifying the content of the statement without changing the overall conclusions.

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

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

The Panel was informed about the status of discussions of the Scientific Committee regarding its work program 2015-2018 and possible new activities to be initiated, and about the input of the Panel Chair and Vice-Chairs in these discussions. Once consolidated, the Scientific Committee work program 2015-2018 will be taken into account for future activities of the PPR Panel to be proposed to EFSA as self-tasks.

The Assessment and Methodological Support Unit gave a presentation of the draft guidance of the Scientific Committee on uncertainty in EFSA scientific assessment. Thomas Kuhl was proposed as new member of the Working Group of the Scientific Committee to represent the PPR Panel. The Panel was invited by the Scientific Committee to propose one of its outputs for use during a trial phase of the draft guidance on uncertainty. However, no proposal could be made because the Panel delivered essentially opinions on generic assessment methodologies during the last years.

Due to the specificity of the risk assessment process applicable to plant protection products as defined by the sectorial regulations and the role of EFSA in this process, the Pesticides Unit will further consider how to make the best use of the trial phase of the Guidance on uncertainty in EFSA scientific assessment in the sector of plant protection products.

The Scientific Committee is setting up a Working Group on the risk assessment for infants and young children in the context of a request of the European Commission regarding the re-evaluation of food additives used in food destined to infants and young children. Colin Ockleford agreed to be member of this Working Group as representative of the PPR Panel.

7.2 EFSA including its Working Groups /Task Forces

The Assessment and Methodological Support Unit gave a presentation of the state of play regarding the PROMETHEUS project. A first deliverable has been published in June 2015 (EFSA Scientific Report 'Principles and process for dealing with data and evidence in scientific assessment').

The second deliverable, which is addressing an analysis of the methodological needs in EFSA as to strengthen the processes for data collection, appraisal and integration will be developed on the basis of the replies of the Scientific Panels and Units to a questionnaire developed by the Assessment and Methodological Support Unit. It was agreed that the Chair and Vice-Chairs will draft the answers on behalf of the Panel and provide feedback to the Panel at the forthcoming Plenary meeting. The answers from all Panels and Units will be discussed in a meeting of the PROMETHEUS Working Group and subsequently submitted to the Scientific Committee.

8. Other scientific topics for information and/or discussion

8.1 Exchange of views on future activities of the PPR Panel

The Panel endorsed the recommendations on possible future activities supporting the risk assessment of plant protection products, as reported in the annex to the minutes of the 75th Plenary meeting, noting that some of the recommendations might be covered by the Scientific Committee in its work program 2015-2018 and identifying 3 additional topics on which future activities might be initiated: Immunotoxicity assessment, risk assessment for residents and aged soil sorption studies (follow up to the statement adopted in June).

9. Any other business

The following was brought to the attention of the PPR Panel:

- a) From 7th to 9th September 2015, EFSA organised in Geneva a Stakeholder Meeting and a Scientific Workshop, co-sponsored by WHO and FAO, on Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food. The event report will be published before the end of 2015.
- b) 2 External Scientific reports were recently published:
 - Collection of pesticide application data in view of performing Environmental Risk Assessments for pesticide (FERA, UK)
 - Data collection on exposure assessment scenarios for operators exposed to pesticides (TNO, NL)
- c) 2 calls for tender were recently launched:
 - Data collection for the estimation of ecological data (specific focal species, time spent in the treated areas collecting food, composition of diet), residue level and residue decline of pesticides on food items to be used in risk assessment for birds and mammals

- Collection of Human biomonitoring data from occupational exposure to pesticides
- d) An open plenary meeting of the PPR Panel will take place on 22nd and 23rd June 2016 in Brussels.
- e) The Chair of the Panel has been invited to participate as observer representing the PPR Panel to a Pesticides Peer Review Teleconference taking place on 29th September on the classification of glyphosate following the IARC monograph.