

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 85th Plenary meeting

Held on 25-26 January 2017, Parma (Italy)
(Agreed on 17 March 2017)

Participants

■ Panel Members

Paulien Adriaanse, Philippe Berny, Theodorus Brock, Sabine Duquesne, Sandro Grilli, Antonio Hernandez-Jerez, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Michael Stemmer, Ingvar Sundh, Ivana Teodorovic, Aaldrik 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, Danièle Court Marques, Federica Crivellente, Marcella De Maglie, Mark Egsmose, Frédérique Istace, Luc Mohimont, Alexandre Nougadere, Juan Manuel Parra Morte, Hermine Reich, Franz Streissl, Jose Tarazona and Andrea Terron

Scientific Committee and Emerging Risks Unit: Bernard Bottex

Evidence Management Unit: Davide Arcella, Bruno Dujardin

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>.

- Observers:
Not Applicable
- Others:
Not Applicable

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 Susanne Hougaard Bennekou, Kyriaki Machera and Robert Smith.

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 84th Plenary meeting held on 14-15 December 2016, Parma (Italy).

The minutes of the 84th plenary meeting held on 14-15 December 2016, were agreed on 19 January 2017 and published on the EFSA website.⁴

5. Report on the written procedures since the 84th Plenary meeting

No written procedure took place since the 84th plenary meeting.

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/en/events/event/161214>

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

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

The Secretariat and the Chair of the Working Group informed the panel on the outcome of consultations with the Pesticides Unit on the areas of expertise needed to cover the mandate. This includes general toxicology, developmental neurotoxicity, toxicokinetics, immunotoxicity, reproductive toxicity and endocrine disruption, infants and young children physiology and nutrition, mixture toxicity, (cumulative) dietary exposure assessment, food consumption surveys, baby food technology, crop production for baby foods, pesticide residues, analytical chemistry and epidemiology. Members of the Working Group of the Scientific Committee on the Risk Assessment for infants and young children with expertise in these areas have been consulted for their interest to be involved in this activity.

Considering the scope of the mandate, the Evidence Management Unit will cooperate with the Pesticides Unit in the scientific support to the Working Group.

In order to ensure the coherence between the scope of the opinion and the expectations of Risk Managers, the Panel stressed the importance of the participation of representatives of the EU commission as observers to the forthcoming meetings of the Working Group.

6.2 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 on the outcome of the last meeting of the Working Group.

In particular, during the technical hearing with the representative of US Environmental Protection Agency, selection bias/misclassification, power analysis and effect size magnification for selected (positive) epidemiological studies for Paraquat were presented. It was pointed out that usually epidemiological literature on pesticides tends to describe various biases (selection, information, etc.) in a qualitative way, but rarely deals with these in a quantitative sense through sensitivity analysis or quantitative uncertainty analysis. The 2010 FIFRA SAP suggested that biases should be addressed in a more quantitative way through (quantitative) sensitivity analyses. Power analysis and effect size

magnification for selected (positive) epidemiological studies for Paraquat and Parkinson's disease were presented. The simulation on the studies selected indicated that the risk of effect size magnification is minimal.

In regards to the preparation of the Scientific Opinion, a reshuffle of the structure of the opinion was discussed and agreed upon. In addition, further actions were agreed amongst the experts to further progress.

The Panel was also informed on the consultation process of the Scientific Committee before the launch of the public consultation.

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

The Panel was informed that the second meeting of the Working Group was foreseen to take place after the plenary meeting.

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

A draft of the scientific opinion was circulated by the Secretariat to the Panel on 17 January 2017. Several members submitted comments in advance of the meeting.

The panel discussed the draft scientific opinion. The main points of discussion and recommendations of the panel were the following:

- Inclusion of evidence from field observations that approved uses (those which pass the current risk assessment schemes) still pose a high risk to amphibians;
- Inclusion of further explanation on choice of the baseline for developing specific protection goal options i.e. what are the environmental conditions which lead to the greatest impact on populations exposed to pesticides;
- Better explanation of the "normal operating range of taxa" in the specific protection goal options;
- Better explanation of the calculation of mixed TER values.

Furthermore the panel made editorial recommendations to improve readability.

The Panel could not address all the issues raised and decided to postpone the endorsement of the opinion until the next plenary meeting.

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

No meeting of the Scientific Committee took place since the last meeting of the Panel in December. The Panel was informed about the progress of the Working Group of the Scientific Committee on the Risk Assessment for infants and young children.

The Scientific Committee and Emerging Risks Unit presented the new Guidance of the Scientific Committee on the use of the Benchmark Dose approach in risk assessment, adopted by the Scientific Committee in November 2016. The Panel welcomed this output and was informed about the EFSA workshop taking place in Brussels on 1st and 2nd March 2017 on this guidance.

7.2. EFSA including its Working Groups /Task Forces

The Head of Pesticides Unit presented a preliminary action plan for improving the EU peer-review on pesticides active substances and in particular the envisaged role of the Panel in this activity. This plan will be discussed by the Pesticides Steering Network in February. The new operational structure of the Pesticides Unit was also presented.

The Pesticides Unit informed the Panel on the progress regarding the EFSA scientific reports on cumulative assessment groups of pesticides and indicated that it will consult the Panel on the scientific approach developed internally for the practical implementation of the methodology adopted by the Panel in 2013 in its opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile.

8. Any other business

The Panel was informed about the agreed outline of draft EFSA/ECHA guidance for the implementation of the hazard-based criteria to identify endocrine disruptors and the call to EFSA stakeholder organisations for nominating stakeholder experts to the *ad hoc* ECHA/EFSA endocrine disruption guidance consultation group.