

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 78th Plenary meeting

Held on 2 - 3 December 2015, Parma (Italy)

(Agreed on 8 February 2016)

Participants

■ Panel Members:

Pauline Adriaanse, Theodorus Brock, 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 (only on 3 December 2015), Robert Smith, Michael Stemmer, Ivana Teodorovic, Aldrik Tiktak, 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, Anja Friel, Luc Mohimont, Federica Ruffo, Franz Streissl, Andrea Terron and Jose Tarazona.

Assessment and Methodological Support Unit: Elisa Aiassa (item 8.2)

Scientific Committee and Emerging Risk Unit: Lesley Koschel and Dimitrios Spyropoulos (item 9.1)

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 and apologies for absence

The Chair of the Panel, Colin Ockleford, welcomed the participants. Apologies were received from Philippe Berny, Silvia Pieper (2nd December), Ingvar Sundh and Christopher Topping.

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 76th Plenary meeting held on 8-9 July 2015, Parma (Italy) and of the 77th Plenary meeting held on 23-24 September, Parma (Italy)

The minutes of the 76th Plenary meeting, held on 8 and 9 July 2015, and the minutes of the 77th Plenary meeting, held on 23 and 24 September 2015, were agreed on 18 November 2015.

5. Report on written procedures since the 77th Plenary meeting

The Panel endorsed the EFSA scientific report on the assessment of new scientific studies on human *in vitro* dermal absorption on 16 October 2015 by written procedure.

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](#))

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

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

The Chair of the Working Group informed the Panel on issues discussed during the last 2 meetings of the Working Group.

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 issues discussed during the last meeting of the Working Group.

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 issues discussed during the last 2 meetings of the Working Group.

The Panel agreed that EFSA submits to the OECD one of the Adverse Outcome Pathways elaborated by the Working Group in relation with the Parkinson Disease ('Inhibition of complex I of the mitochondrial respiratory chain in dopaminergic neurons of the nigrostriatal pathway leading to motor deficit of Parkinson disease') and the respective information collected.

In the context of this mandate, a specific question prepared by the Secretariat was discussed by the Standing Working Group on genotoxicity of the Scientific Committee on 6 November 2015, and the feedback received was presented to the Panel. The Panel considered this feedback and agreed to refer to the Scientific Committee a potential issue identified regarding the capacity of current data requirements to capture a specific genotoxicity hazard possibly involved in the etiology of childhood leukaemia.

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 on the issues discussed during the last meeting of the Working Group. This meeting included a technical hearing of a representative of the US Environmental Protection Agency.

The Panel was informed that EFSA signed a procurement contract with Risk & Policy analysts (UK) for a literature review and data collection from human bio-monitoring studies on occupational exposure to pesticides.

6.5 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](#))

A revised proposal for the update of the terms of reference of the mandate was agreed by the Panel and will be proposed by the Chair of the Panel to EFSA.

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

The Chair of the Working Group informed the Panel on issues discussed during the first 2 meetings of the Working Group, which included technical hearings. The Secretariat informed the Panel that EFSA had proposed a service contract to the University of Koblenz-Landau on the biological relevance of the magnitude of effects (considering mortality, sub-lethal and reproductive effects) observed in studies with amphibians and reptiles in view of population level impacts on amphibians and reptiles.

7. New Mandates

7.1 EU Commission request for a Scientific Opinion on pesticides in foods for infants and young children

The secretariat presented a request of the EU Commission for a scientific opinion on pesticides in foods for infants and young children in the context of the implementation of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.

EFSA is currently considering the request in accordance with article 29 of the General Food Law, in particular in the light of current activities of the Scientific Committee on related issues. The Scientific Committee will be informed of the generic nature of some questions included in the request.

7.2 Scientific Opinion on integrated approach for testing and assessment of developmental neurotoxicity

The secretariat presented a work plan agreed by EFSA regarding developmental neurotoxicity. This plan includes a procurement on a literature review and appraisal of *in vitro* and alternative neurotoxicity testing methods and an EFSA stakeholder workshop during the 4th quarter of 2016 in collaboration with the OECD and with the support of the Joint Research Centre on the state of the art, future perspectives, best

strategy, most reliable endpoints and integrated approaches to the specific testing and assessment of developmental neurotoxicity.

This workshop will collect the state of scientific knowledge to support the preparation of a scientific opinion of the PPR Panel on an integrated approach for testing and assessment of developmental neurotoxicity.

A scientific conference is planned towards the end of 2018 to communicate the outcome of the scientific opinion.

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

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

The Panel was informed on the outcome of the last meeting of the Scientific Committee which took place on 11 and 12 November 2015, where 2 overarching Scientific Opinions on the environmental risk assessment were adopted, on the continuation of the discussions regarding the work program 2015-2018 of the Scientific Committee and on the progress of Working Groups of the Scientific Committee with representatives of the PPR Panel.

Sandro Grilli was nominated as member of the Standing Working Group on genotoxicity representing the PPR Panel and Theo Brock was proposed as new member of the Standing Working Group on guidance review representing the PPR Panel.

The Panel was informed on a call for tender launched by the Scientific Committee and Emerging Risks Unit on modelling human variability in toxicokinetic and toxicodynamic processes using Bayesian meta-analysis, physiologically-based modelling and in-vitro systems.

8.2 EFSA including its Working Groups /Task Forces

The Secretariat informed the Panel on the progress of the Must-B project of the Scientific Committee and Emerging Risks Unit. The Panel will be consulted in 2016 on the technical report on the specifications for outsourcing the development of a model to assess the combined and relative risks of multiple stressors on honeybee colonies.

The Assessment and Methodological Support Unit introduced the survey on the EFSA "methodological needs" for evidence use in scientific assessments, conducted in the context of the second deliverable of the PROMETHEUS project. Each member of the PPR Panel was invited to fill the on-line questionnaire.

9. Other scientific topics for information and/or discussion

9.1 Feedback to the Panel on the yearly customer feedback exercise with DG Santé

The Scientific Committee and Emerging Risk Unit presented the overall outcome of the 2015 Customer feedback exercise, and the specific comments on the outputs randomly selected in the area of plant protection products. Possible actions to be taken at unit level were also discussed.

9.2 Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters

The Secretariat informed the Panel on the outcome of the Pesticides Peer Review meeting No 133 on ecotoxicology (23rd, 24th and 25th September 2015) where several recommendations were agreed for clarifications of the guidance adopted by the Panel in 2013 on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. Additional provisions requiring clarification were identified by the Pesticides Unit on the basis of the progressive experience with the use of the guidance. The Panel agreed on the need for erratum and explanatory corrections of the guidance, referring also to its recommendations agreed during the 75th Plenary meeting. The Pesticides Unit will therefore coordinate the correction of the guidance with the support of members of the Panel and of the Pesticide Steering Network. Once available, a corrected guidance will be submitted to the agreement of the Panel at one of the forthcoming Plenary meetings.

10. Any other business

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

- a) A Technical Report of EFSA on the assessment of endocrine disrupting properties in EFSA Conclusions on pesticides peer review was published on 23 September 2015.
- b) The Scientific Report of EFSA on the assessment of new scientific studies on human *in vitro* dermal absorption was published on 12 November 2015.
- c) An External Scientific Report on the comparison of NOEC values to EC10/EC20 values, including confidence intervals, in aquatic and terrestrial ecotoxicological risk assessment was published on 3 December 2015.