

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 71st Plenary meeting

**Held on 03-04 December 2014, Parma (Italy)
(Agreed on 02 February 2015)**

Participants

• **Panel Members:**

Theodorus Brock, Ettore Capri, Sabine Duquesne, Antonio F. Hernandez-Jerez, Karen Ildico Hirsch-Ernst, Susanne Hougaard Bennekou, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Alberto Mantovani, Colin Ockleford, Bernadette Ossendorp (by webconference for point 7.1), Robert Smith, Ingvar Sundh, Aaldrik Tiktak, Ton van der Linden.

• **EFSA:**

- Pesticides Unit: Federica Crivellente, Arianna Chiusolo, Mark Egsmose, Magda Florio, Anja Friel, Luc Mohimont, Marize Solano, Franz Streissl, Andrea Terron, Manuela Tiramani and Jose Tarazona.
- Assessment and Methodological Support Unit: Didier Verloo (point 5.7)
- Scientific Committee and Emerging Risks Unit: Agnès Rortais (point 6.1) and Reinhilde Schoonjans (point 7.1)

1. Welcome and apologies for absence

Apologies were received from Alf Aagaard, Metka Filipič, Matthias Liess, Bernadette Ossendorp and Paulo Sousa (Panel Members) and Michael Walsh (DG SANCO). In the absence of Bernadette Ossendorp, Theodorus Brock, Vice-Chair of the Panel, chaired the meeting and welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

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 70th Plenary meeting held on 07 – 08 October 2014, Parma (Italy)

The minutes of the 70th Plenary meeting, held on 7th and 8th October 2014, were agreed by written procedure on 16th of December 2014.

4.1 Report on the written procedures since 70th Plenary meeting

No written procedure took place since the 70th Plenary meeting.

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

5.1 Scientific Opinion on a proposal for a Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessment (FERA, 2012) ([EFSA-Q-2014-00217](#))

The Chair of the Working Group informed the Panel on the outcome of the technical hearing which took place on 4th and 5th November 2014.

5.2 Scientific opinion addressing the state of science on risk assessment for non target arthropods ([EFSA-Q-2011-00975](#)) and Scientific Opinion addressing the state of the science on in-soil risk assessment ([EFSA-Q-2011-00978](#))

A revised draft of the Scientific Opinion addressing the state of science on risk assessment for non-target arthropods was circulated to the Panel on 21st November and discussed during the Plenary meeting. An agreement was reached on the final changes to make, in particular in the section dealing with the suggested specific protection goals. The final draft will be circulated to the Panel for adoption by written procedure.

The Panel was informed by the Chair of the Working Group about the timelines and the next steps for the development of the Scientific Opinion addressing the state of the science on in-soil risk assessment.

5.3 Scientific opinion on the effect assessment of pesticides for sediment organisms in edge-of-field surface water ([EFSA-Q-2012-00959](#))

The Chair of the Working Group informed the Panel on the designation of 2 rapporteurs and on progress of the activities, in particular regarding the exposure assessment of sediment organisms.

5.4 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 outcome of meeting of the Standing Working Group of the Scientific Committee on genotoxicity which was consulted on the strategy proposed by the Working Group for the assessment of the genotoxicity of pesticide metabolites.

During its meeting of 11th and 12th November, the Pesticide Network was informed on the ongoing activities regarding this mandate, as agreed during the 70th Plenary meeting. The work carried out by the Working Group was much appreciated by the Network and the EFSA offer for providing specific training on the tools to be used was welcomed.

The Working Group identified a possible area of divergence between the content of the draft Scientific Guidance and the existing Guidance of the European Commission on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC³. Referring to the article 30 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the Panel invited EFSA to contact the European Commission, share information and engage cooperation in order to address the identified divergence.

The Secretariat informed the Panel that EFSA and the Azienda Ospedaliera L. Sacco, Polo Universitario/ICPS signed a grant agreement on the compilation of a database, specific for the pesticide active substances and their metabolites, comprising the main genotoxicity endpoints, which is intended to support the future implementation of the Scientific Guidance.

5.5 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 participated to the OECD workshop on Integrated Approach for Testing and Assessment (IATA) which took place in United States in November 2014 and updated the Panel on the initiatives of the OECD and US EPA to develop the use of Adverse Outcome Pathways in regulatory assessment processes. The Panel agreed to take full account of these activities in the context of the 2 opinions to be delivered with regard to epidemiological studies.

The Working Group is established and its first meeting is taking place on the 4th and 5th December.

5.6 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 Secretariat informed the Panel on draft agenda of a stakeholder conference, organized by EFSA and ANSES, on the 'Use of Epidemiological findings in Regulatory Pesticide Risk Assessment' which will take place in Paris in February 2015. The objective of this conference is to gather a series of speakers representing different points of views (civil society and institutional stakeholders, industry, academia) and to collect the views of the participants in the context of this mandate.

The Chair of the Working Group will represent the Panel in this event.

³ Sanco/221/2000 –rev.10- final (25 February 2003)

5.7 Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid (EFSA-Q-2012-00958)

The Chair of the Working Group informed the Panel that the Working Group carried out a detailed assessment of the comments submitted by the manufacturers of acetamiprid (Response to EFSA PPR Scientific Opinion on the acetamiprid developmental neurotoxicity study, prepared by Exponent for Nippon Soda, March 10, 2014 and presentation submitted by Exponent to EFSA on behalf of Nippon Soda, June 4, 2014) and imidacloprid (Imidacloprid developmental neurotoxicity study: Interpretation of findings of concern to the European Food Safety Authority (EFSA), Bayer CropScience LP, RTP, NC, USA, 2014-06-20, Study Report Number: US0426, Edition Number: M-488888-01-1) to the Scientific Opinion adopted by the PPR Panel on 21 November 2013.

The Working Group came to the conclusion that the information provided has not altered the content of the Scientific Opinion and did not recommend the organization of a technical hearing.

The Panel agreed to the conclusion of the Working Group. The Working Group outlined its arguments in 2 documents which are included in these minutes as annexes I and II.

6. New Mandates

6.1 Statement of the PPR Panel on the Beehave model

The Secretariat presented a new mandate allocated to the PPR Panel at the initiative of EFSA. The Panel is requested to prepare a Statement on the suitability of the BEEHAVE⁴ model for its potential use in a regulatory context and for the risk assessment on multiple stressors in honeybees at landscape level.

The panel agreed to the terms of references and agreed to establish a Working Group. Robert Smith was appointed as the chair of this working group.

The areas of scientific expertise needed for this mandate include population modeling (preferably regarding arthropods/bees), bee diseases, honeybee biology, beekeeping and pesticide effects and exposure assessment for bees. The need for external expertise was identified.

This mandate is part of a wider EFSA initiative on European Union efforts for the development of a holistic approach for the risk assessment of multiple stressors in bees which was presented to the Panel by the Scientific Committee and Emerging Risks Unit.

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

The Panel was informed on the outcome of the last meeting of the Scientific Committee which took place in November 2014, in particular regarding the preliminary discussions on

⁴ The BEEHAVE model and supporting information can be found under the following webpage: <http://beehave-model.net/>

a possible mandate on internal dose exposure and the feedback of the annual meeting of the Nanonetwork.

The Scientific Committee and Emerging Risks Unit informed the Panel on the state of play regarding the development of 3 Scientific Opinions of the Scientific Committee on deriving specific protection goals, on the environmental risk assessment of endangered species as potential non-target organisms and on addressing the temporal/spatial recovery of non-target organisms in environmental risk assessment. These draft opinions will be submitted for scrutiny by the PPR panel during March-April 2015.

7.2 EFSA including its Working Groups /Task Forces

No discussion took place on this point.

8. Other scientific topics for information and/or discussion

No additional scientific topic was discussed.

9. Any Other Business

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

- a) The EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products was approved on 17th October 2014.
- b) The updated version of the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile has been published on the EFSA website.