

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 89th Plenary meeting

Held on 20-21 September 2017, Parma (Italy)
(Agreed on 17 November 2017)

Participants

■ Panel Members

Paulien Adriaanse, Philippe Berny, Theodorus Brock, Sabine Duquesne, Sandro Grilli, Antonio Hernandez-Jerez, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Kyriaki Machera, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Robert Smith, Michael Stemmer, Ingvar Sundh, Ivana Teodorovic, Aaldrik Tiktak, Christopher Topping.

■ 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 Nougadère, Franz Streissl, Jose Tarazona.

Scientific Committee and Emerging Risks Unit: Nikolaos Georgiadis

■ 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>.

- 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 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 88th Plenary meeting held on 5-6 July 2017, Parma (Italy)

The minutes of the 88th plenary meeting held on 5-6 July 2017, were agreed on 15 September and published on the EFSA website.

5. Report on the written procedures since the 88th Plenary meeting

No written procedure took place since the 88th plenary meeting.

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

6.1 Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific report 'Literature review

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

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

on epidemiological studies linking exposure to pesticides and health effects' (University of Ioannina Medical School, 2013) ([EFSA-Q-2014-00481](#))

A new draft of the Scientific Opinion was circulated to the Panel on 13 September 2017, containing changes proposed by the Working Group on the basis of the public consultation which resulted in the submission of 223 comments.

The Pesticide Steering Network did not identify the need to prepare a collegial input to be considered by the Panel.

The Chair of the Working Group presented the changes made to the opinion, and insisted on the care taken to clarify unambiguously for the reader that this opinion is strictly elaborated in the specific context of Regulation (EC) N° 1107/2009 concerning the placing on the market of plant protection products, in accordance with the terms of reference.

After agreeing on a few last changes, the Panel adopted the opinion.

A scientific conference on the use of epidemiological findings in regulatory pesticide risk assessment will take place in Parma on 21 November 2017.

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

The Vice-Chair of Working Group informed the Panel about the outcome of the last meeting of the Working Group. The Working Group discussed the methodology for pre- and post-marketing exposure assessment to be used in the case studies and selected 5 active substances. The structure of the opinion and a literature review on the physiology of developing systems in infants and young children (nervous, immune, reproductive and endocrine systems, ADME, gut) were also discussed.

A letter was sent to the Panel by Specialised Nutrition Europe (SNE - organisation representing the interests of the European specialised nutrition Industry) to express interest in this mandate and, in particular, to offer to provide information on chlorate and mercury. The secretariat liaised with the EU Commission to consider whether this request was falling under the Terms of Reference of the mandate and concluded that this was not the case. The Secretariat will send a reply to SNE with copy to the Panel.

6.3 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 about the main changes to the draft opinion proposed by the Working Group after the meeting and teleconferences which took place since the last plenary

meeting. The Working Group provided in particular clearer explanations for the choice of focal species and worked on appendices with suggested solutions for dermal exposure assessment, risk refinement options and risk mitigation options. Recommendations are also elaborated on what information and research is required for the development of a guidance document.

Furthermore, the Working Group considered the external scientific report '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' (Instituto de Investigación en Recursos Cinegéticos (IREC), Spain), published on 19 July 2017.

The Panel was finally informed that an additional expert will be included in the Working Group with expertise in ecotoxicology, testing and population biology of reptiles.

6.4 Scientific Opinion of the PPR Panel 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 about the progress made by the Working Group during its last meeting.

The Panel was informed that 3 hearing experts have been identified to provide their specific expertise on the General Unified Threshold Model of Survival (GUTS), the DEBTOX model, and on TK/TD modelling for aquatic plants.

6.5 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](#))

The mandate was accepted by EFSA on 3 August 2017 and a first meeting of the Working Group took place before the plenary meeting. The chair of the Working Group reminded the main conclusions that the Panel reached in 2015 in the form of a statement on an earlier version of the guidance proposal, introduced the updated draft guidance, as revised on the basis of the recommendations listed in the statement, and indicated the most important issues to be addressed by the opinion.

The Chair of the Working Group, in consultation with the Secretariat designated 2 rapporteurs.

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 Scientific Committee and Emerging Risks Unit presented the Guidance on the use of the weight of evidence approach in scientific assessments, which was adopted by the Scientific Committee on 12 July 2017 after a public consultation.

The Chair informed the Panel on the outcome of the last 2 meetings of the Scientific Committee which took place on 12 and 13 July (as an open plenary meeting) and on 13 and 14 September 2017. Beside the guidance on the use of the weight of evidence approach in scientific assessments, the Scientific Committee adopted a guidance on the assessment of the biological relevance of data in scientific assessments on 12 July 2017 and endorsed for public consultation a draft opinion on clarification of some aspects relative to genotoxicity assessment.

7.2. EFSA including its Working Groups /Task Forces

The Head of the Pesticides Unit informed the Panel about the request to EFSA from the European Commission SAM Unit (Scientific Advice Mechanism) to provide its High Level Group of Scientific Advisors with reflections on the scientific assessment of pesticides according to the experience generated through the current legislative frame and the EFSA peer-review process.

To meet this request a draft document summarising the EFSA experience and identified issues requiring consideration has been prepared by the Pesticides Unit. This draft was presented to the Panel for information. Panel members were invited to send their comments, which would be considered by EFSA during the finalisation of the document. A general explanation on how the comments have been addressed during the finalisation of the document will be provided to the PPR Panel during the next plenary meeting.

The Panel discussed possible follow-up actions to the External Scientific Report "Review of the published exposure data to pesticides for residents and bystanders, and for environmental risk assessment" (University of Hertfordshire, UK), which was presented by the Secretariat during the 87th plenary meeting.

The Panel noted the ongoing discussions between EFSA and the EU Commission on a possible mandate for the update of the EFSA guidance on pesticides exposure assessment of operators, workers, residents and

bystanders, based on the outcome of the External Scientific report and on other sources of information such as the BROWSE project.

8. Any other business

The following was brought to the attention of the Panel:

- An external scientific report 'Compilation of a database, specific for the pesticide active substance and their metabolites, comprising the main genotoxicity endpoints' (International Centre for Pesticides and Health Risk Prevention (ICPS), Italy) was published on 17 May 2017
- The EFSA scientific report 'Pilot study on uncertainty analysis in EFSA Reasoned Opinions on the modification of pesticide maximum residue levels' was published on 27 July 2017
- EFSA launch a call for proposals 'Entrusting new preparatory tasks falling within the mission of the EFSA Pesticides unit' on 8 August with deadline of 13 October.