

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 86th Plenary meeting

**Held on 22-23 March 2017, Parma (Italy)
(Agreed on 12 May 2017)**

Participants

■ Panel Members

Philippe Berny, Theodorus Brock, Sabine Duquesne, Antonio Hernandez-Jerez, Susanne Hougaard Bennekou, Michael Klein, Ryszard Laskowski, Kyriaki Machera, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Robert Smith, Michael Stemmer, Ingvar Sundh, Ivana Teodorovic, Aaldrik Tiktak, Christopher Topping, Gerrit Wolterink.

■ Hearing Experts ¹:

Bernadette Ossendorp (point 6.5)

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Unit: Maria Arena, Arianna Chiusolo, Federica Crivellente, Mark Egsmose, Luc Mohimont, Ragnor Pedersen, Franz Streissl, Benedicte Vagenende

■ Observers:

Not Applicable

■ Others:

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>.

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 Paulien Adriaanse, Sandro Grilli and Thomas Kuhl.

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 85th Plenary meeting held on 25-26 January 2017, Parma (Italy).

The minutes of the 85th plenary meeting held on 25-26 January 2017, were agreed on 17 March 2017 and published on the EFSA website.⁴

5. Report on the written procedures since the 85th Plenary meeting

No written procedure took place since the 85th 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/170322>

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 informed the Panel on the progress related to the establishment of the Working Group. A first meeting will take place on 29 and 30 March 2017 and will be attended by representatives of the European Commission who will provide clarifications on the Terms of Reference.

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 Secretariat circulated a draft of the Opinion on 10 March 2017 to the Panel. A member of the Panel acted as reviewer of the document and comments were submitted by other Panel members. The Working Group subsequently updated the draft on the basis of these comments.

The resulting draft was presented by the Chair of the Working Group to the Panel. According to the comments received, no major concerns on the scientific content were raised. Mainly requests of clarification and/or reshuffling were addressed and the outcome of such revision was presented.

The Chair of the Working Group indicated that additional amendments were still proposed by the Working Group and the Panel agreed to consider a new draft including these amendments and to proceed with the endorsement of this revised draft by written procedure.

If endorsed, the draft opinion will be presented to the Scientific Committee before its publication for public consultation and consultation of the Pesticide Steering Network.

6.3 Scientific Opinion of the PPR Panel on the state of Toxicokinetic/Toxicodynamic (TK/TD) and Simple Food Chain effects modeling for regulatory risk assessment of pesticides for aquatic organisms ([EFSA-Q-2012-00960](#))

The Chair of the working group presented the outcomes of the Working Group meetings which took place before the plenary. The Working Group worked at the description of the existing toxicokinetic-toxicodynamic (TK/TD) models, including GUTS, DEBtox and plant models. The problem

formulation was also discussed, considering the type and level of effects, the specific protection goals and the tiered approach defined in the guidance of the Panel on the tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters.

The Chair of the working group highlighted difficulties in finding experts covering simple food chain modelling with potential impact on the deadline to prepare the Opinion and referred to the Panel the wish of members of the Working Group to organize a public consultation on a draft opinion before its adoption. This will be considered by the Secretariat and addressed at the next plenary meeting.

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

A new draft of the Opinion was circulated to the Panel on 9 March 2017, which included changes proposed by the Working Group in reply to the points raised by the Panel during the last plenary meeting.

The chair of the Working group presented the revised opinion. The introduction was expanded with additional examples including a better explanation regarding indications of impacts on amphibians from uses that pass the current risk assessment. Some of the scientific concepts such as the choice of the baseline for specific protection goals and the mixed TER approach were explained in more detail. Section 10 was streamlined and much text was moved to Appendices or Annexes. This should enhance the flow of reading and highlight more clearly the main conclusions in this section. Furthermore, the structures of the terrestrial and the aquatic parts were better aligned. New information on toxicity-endpoint comparisons (terrestrial life stages) was added. The dermal toxicity subsection was expanded and more detailed recommendations for dermal testing and TK/TD modelling were added.

Furthermore, the main conclusions were added at the end of each section. The summary was rewritten and structured with subheadings. A glossary and a list with abbreviations were added.

At the end of the discussion, the Panel endorsed the draft opinion in view of the public consultation.

6.5 Pilot study on the inclusion of an uncertainty analysis in Reasoned Opinions on the modification of pesticide maximum residue levels

The secretariat and Bernadette Ossendorp, participating to the discussion as hearing expert and representative of the PPR Panel in the WG of the Scientific Committee on uncertainties, presented the context and the outcome of the case study on the inclusion of an uncertainty analysis in an output of the Pesticides Unit, conducted as part of the trial phase of

the draft guidance of the Scientific Committee on uncertainty in EFSA scientific assessment.

In a first step, an External Scientific Report (Pilot study on the inclusion of an uncertainty analysis in a non-regulatory evaluation report on the modification of fictitious MRLs) was prepared by the Ctgb (Dutch Board for the Authorization of Plant Protection Products and Biocides) and approved by EFSA on the 16 January 2017. In a second step, a draft EFSA Reasoned Opinion (Pilot study on the inclusion of an uncertainty analysis in Reasoned Opinions on the modification of pesticide maximum residue levels) was prepared by the Pesticides unit on the fictitious MRLs and sent by the Secretariat to the Panel on 10 March. This draft was reviewed by a member of the Panel and further discussed during the plenary meeting.

The Panel endorsed the draft reasoned opinion, supporting the overall principle of identifying and analyzing the non-standard uncertainties, and formulating the following comments to be considered in the finalization of the reasoned opinion:

- An explanation of method selection, justification of the strategy and the choice of complexity should be provided.
- Subjective upper bound probability percentiles without justification introduce an un-validated measure for risk assessment and forces quantification of uncertainties.
- Probability statements should be avoided where uncertainty is not analysed quantitatively.
- The uncertainty assessment should quantify the overall uncertainty of the risk assessment, i.e. toxicology and exposure.

Other minor comments were made to improve the clarity and the consistency of the document.

The Panel supported the implementation of uncertainty analysis in the area of pesticides and recommended the preparation of a reference document identifying and assessing the generic uncertainties inherent to the standard procedures of the various types of risk assessment with respect to the precise assessment question and respective desired level of protection.

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 Chair informed the Panel on the outcome of the last meeting of the Scientific Committee which took place on 13 and 14 March 2017.

In particular the Panel was informed on the adoption of the Opinion on scientific motivations and criteria to consider updating EFSA scientific assessments, and on the endorsement for public consultation of the draft opinions on biological relevance, on the risk assessment of substances present in food intended for infants below 16 weeks of age and on the weight of evidence approach.

7.2. EFSA including its Working Groups /Task Forces /Networks

The panel was informed on the outcome of the discussions of the Pesticides Steering Network on the preliminary action plan for improving the EU peer-review on Pesticides active substances, which took place during the meeting of February 2017.

A discussion about the possible involvement of the Panel in the EU peer-review of active substance will be discussed during the next plenary meeting.

8. Any other business

The Panel examined a proposal for a new mandate to prepare a Scientific Opinion on the Guidance proposal of the Chemical Regulation Directorate (UK) on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments (CRD, 2016). This mandate proposal was supported by the Panel, with a few changes, and will be sent by the Chair of the Panel to EFSA as a proposal of self-task.