Scientific Panel on Plant Protection Products and their Residues

Minutes of the 94th Plenary meeting

Held on 27-28 June 2018, Parma (Italy)

(Agreed on 09 August 2018)

Participants

- Panel Members

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

- Hearing Experts [1]:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  Pesticides Unit: Maria Arena, Lucie Ctverackova, Mark Egsmose, Luc Mohimont, Franz Streissl, Jose Tarazona and Joanke van Dijk.

- 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 Sandro Grilli, Kyriaki Machera and Robert Smith.

2. Adoption of the draft 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 Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], 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. Report on the written procedures since the 93rd Plenary meeting

The panel agreed by written procedure on the reply to the comments of the members of the Scientific Committee on the draft Scientific Opinion on pesticides in foods for infants and young children.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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

5.1 Scientific Opinion on the state of Toxicokinetic/Toxicodynamic models for regulatory risk assessment of pesticides for aquatic organisms (EFSA-Q-2012-00960)

The Secretariat circulated a revised draft of the Scientific Opinion to the Panel on 11 June 2018. The Chair of the Working Group and a rapporteur presented the document.

Minor changes were agreed after discussion and the Panel adopted the Scientific Opinion.

In this Opinion, three different types of TK/TD models are carefully reviewed following the principles of the Scientific Opinion of the Panel on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. Conclusions are drawn with respect to their possible use in prospective regulatory risk assessment for aquatic organisms.

5.2 EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system (EFSA-Q-2018-00345)

A public consultation took place on the draft document endorsed by the Panel during the last Plenary meeting. This public consultation closed on 13 June and about 50 comments were submitted by 7 organisations. The comments were reviewed by the EFSA Working Group and the following list of envisaged amendments was elaborated in view of the finalisation of the Scientific Report and its approval by EFSA:

Section 1 (Introduction and TORs):

- Inclusion of additional information regarding important legal incentives and constraints

Section 2 (Data and methodologies):

- Inclusion of precise definitions of 'supportive studies', 'unacceptable studies and 'secondary effects'
- Clarification about how 'adaptive effects' were considered
- Inclusion of additional information in the description of the EKE process

Section 3 (Assessment):

- Inclusion of additional rationale justifying the selection/non selection of nervous system effects as relevant for the establishment of CAGs

- Clarification of the handling of indicators which can be confused with local or secondary effects
- Allocation of surrogate values to active substances with missing NOAELs where possible
- Performance of an additional 1D Monte Carlo simulated distribution for the total number of ASs in the CAG for the functional alteration of the motor division, assuming positive dependence between subgroup assessments

Section 4 (uncertainty analysis)

- Inclusion of additional sources of uncertainties in section 4.5, to ensure the internal consistency of the document
- Deletion of the sentence 'Eventual situations of antagonism in case of co-exposure to ASs with opposite MoAs might also be considered'
- Qualification and clarification of the statement that Cumulative Risk Assessments conducted with the CAGs for the acetylcholinesterase inhibition and for the functional alteration of the motor division are worst cases

Section 5 (Recommendations)

- Inclusion of an additional recommendation to restrict the toxicological characterisation of CAGs to the identification of NOAELs for the specific effects, as risk characterisation methods not using an Index Compound and Relative Potency Factors are available and producing equivalent outcomes.

The Panel endorsed this list of intended amendments.

5.3 Draft mandate for a Panel output on the coverage of bats by the current pesticide risk assessment for birds and mammals

Based on the discussion which took place during the last Plenary meeting, a revised draft mandate was prepared by the Secretariat.

The envisaged output is a statement of the Panel on the adequacy of the birds and mammals risk assessment scheme for the protection of bats. The elaboration of this statement will use the results of a preparatory literature review on bats conducted by the Secretariat and presented to the Panel. The Panel agreed on the precise questions to be addressed on the basis of the collected scientific articles. Additional information could be used only if justified.

The Chair of the Panel will propose this mandate as an own initiative of EFSA by letter to its Executive Director. The proposed deadline for the adoption of the statement will be end of June 2019.

Subject to the acceptance of the mandate by the Executive Director, the Panel agreed on the need to establish a working group, and if needed, to involve external expertise. The needed areas of expertise were identified and include bat biology, behaviour and ecology, pesticide risk assessment for terrestrial vertebrates, pesticide residues in insects as well as exposure and effects in vertebrates (incl. bats) from oral and dermal exposure. Following consultation with the Secretariat, the Chair further nominated Chris Topping as Chair of this Working Group.

5.4 Scientific Opinion on the Guidance proposal on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments (Chemical Regulation Directorate, UK, 2016) (EFSA-Q-2017-00620)

The Secretariat circulated a revised draft of the Scientific Opinion to the Panel on 19 June 2018. The Working Group had a last meeting just before the Plenary in order to consider the submitted comments, address a few pending issues and prepare a revised version of the Scientific Opinion. The Chair of the Working Group presented the document.

Minor changes were agreed and the Panel adopted the Opinion which proposes to update the draft guidance on aged sorption on the basis of a number of recommendations. After this update, the Panel considers the guidance document for aged sorption suitable for use in groundwater leaching assessment. The Panel considers the guidance suitable for both active substances and their metabolites when metabolite-dosed studies are applied. The Panel did not receive examples for the use of the procedure for field studies. For this reason the Opinion recommends further development and testing of the guidance for field studies. It is recommended to provide a user-friendly software tool that supports the entire workflow including the combination of higher tier and lower tier degradation data. To improve the applicability for regulatory purposes, the Opinion contains recommendations for simplifying the guidance.

6 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

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

The Chair informed the Panel on the outcome of the meeting of the Scientific Committee which took place on 28 and 29 May 2018.

In particular, a draft guidance document on risk assessment of chemical mixtures and a draft statement on genotoxicity assessment of chemical mixtures were endorsed in view of public consultations. The Scientific Committee also commented the draft EFSA-ECHA guidance for the implementation of the hazard-based criteria to identify endocrine disruptors. A pilot phase is also proposed to test the draft guidance on risk assessment of nanotechnologies with the relevant EFSA Panels and Units.

7 Other scientific topics for information and/or discussion

7.1 Recommendations of the 2015-2018 PPR Panel on possible future activities supporting the risk assessment of plant protection products

The Panel finalized its recommendations on possible future activities supporting the risk assessment of plant protection products. The recommendations are compiled in the document in annex to these minutes.

8 Any other business

The following was brought to the attention of the Panel:

- The EFSA/ECHA guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 has been published on 7 June 2018.
- The Scientific Opinion 'EU authorisation processes of plant protection products from a scientific point of view' of the Group of Chief Scientific Advisors, established under the Scientific Advice Mechanism of the European Commission, has been published in June 2018. This Opinion was supported by the Evidence Review Report 'Improving authorisation processes for plant protection products in Europe - A scientific perspective on the assessment of potential risks to human health' produced under the auspices of the SAPEA (Science Advice for Policy by European Academies) Consortium following a grant agreement with the European Commission.

Before the closure of the meeting, Jose Tarazona, Head of the Pesticides Unit, and Luc Mohimont, on behalf of the Secretariat, thanked the Chair and the members of the Panel for their outstanding contributions during the last 3 years.