Scientific Panel on Plant Protection Products and their Residues

Minutes of the 81st Open Plenary meeting

Held on 22-23 June 2016, Brussels (Belgium)
(Agreed on 25 July 2016)

Participants

- Panel Members

  Paulien Adriaanse, Philippe Berny, Theodorus Brock, Sabine Duquesne, Antonio F. Hernandez-Jerez, Susanne Hougaard Bennekou (22 June PM and 23 June), Michael Klein, Thomas Kuhl, Colin Ockleford, Olavi Pelkonen, Silvia Pieper, Michael Stemmer, Ingvar Sundh, Ivana Teodorovic, Aaldrik Tiktak, Christopher Topping, Gerrit Wolterink

- Hearing Experts [1]:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  Pesticides Unit: Maria Arena, Federica Crivellente, Mark Egsmose, Anja Friel, Luc Mohimont, Jose Tarazona, Andrea Terron

  Communications Unit: Flavio Fergnani, Steve Pagani

- Observers: (In application of the guidelines for Observers[2])

  Irena Bogoeva-Velichkova (Bulgarian Food Safety Agency), Hanne Cokelaere (Politico, 23 June), Peter Day (ECPA), Stephanie Fritz (Sumitomo Chemical AGRO SAS), Dirk Hoegaerts (Agilent Technologies, 22 June), Patrick Kabouw (BASF), Oliver Koerner (ADAMA Deutschland GmbH, 22 June), Pauline Landel (Pollinis, 23 June), Carole Langrand-Lerche (Bayer CropScience), Jeane Nicolas

[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.

[2] http://www.efsa.europa.eu/en/stakeholders/observers.html

(Environmental Protection Authority of New Zealand), Thomas Preuss (Bayer CropScience), Christian Strupp (ADAMA Agriculture), Felipe Villarroel Figueroa (Chilean Mission to the EU, 22 June).

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair of the Panel, Colin Ockleford, welcomed the participants.

Apologies were received from the Panel members Susanne Hougaard Bennekou (22 June AM), Sandro Grilli, Ryszard Laskowski, Kyriaki Machera and Robert Smith.

2. Brief introduction of Panel Members and Observers

The Panel members, the observers and the EFSA staff introduced themselves, indicating their affiliation and areas of interest.

3. Adoption of agenda

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], 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.

5. Presentation of the EFSA Guidelines for Observers

The secretariat presented the EFSA guidelines for observers and provided information on the code of conduct during and after the Plenary meeting.

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

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

6. Agreement of the minutes of the 80th Plenary meeting held on 13-14 April 2016, Parma (Italy)

The minutes of the 80th Plenary meeting held on 13-14 April 2016 were agreed under written agreement procedure.

7. Report on the written procedures since the 80th Plenary meeting

The draft Scientific Opinion addressing the state of the science on in-soil risk assessment was endorsed by written procedure on 22 April 2016 in view of the public consultation.

8. Scientific outputs submitted for discussion and possible adoption

8.1 Scientific Opinion addressing the state of the science on in-soil risk assessment (EFSA-Q-2011-00978)

The secretariat informed the Panel about the main outcomes of the public consultation on the draft opinion which took place from 3 May to 10 June 2016.

The panel replied to written questions 11.1, 11.2 and 11.3 sent by Patrick Kabouw (see point 11).

8.2 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 about the outcome of the public consultation and of the consultation of the Pesticide Steering Network and presented a new version of the draft guidance, including changes based on the comments received.

The Panel agreed to adopt the guidance with the exception of the case studies in appendixes B to D. These cases studies will be finalized within 10 working days and sent to the Panel for adoption by written procedure.

The panel replied to written questions 11.6 and 11.7 sent by Carole Langrand-Lerche (see point 11).

In response to oral questions by Carole Langrand-Lerche and Christian Strupp, the Panel indicated that:

- The potency considerations leading to specific provisions applicable to the metabolites of certain active substances

assessment may differ from those related to the identification of active substances with reference values 'significantly lower than those of the majority of the approved active substances' in the context of the identification of candidates for substitution, as the purpose of these exercises are different.

- Enhanced 28-day or 90-day rat studies have the same value for the characterization of the toxicological profile of metabolites in the context of this guidance.

8.3 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 progress in the last 2 months.

A first draft Scientific Opinion was circulated to the Panel by the Secretariat on 31 May 2016 and was peer reviewed by a member of the Panel. A revised version was circulated on 13 June 2016, discussed during the plenary and endorsed in view of the public consultation.

The secretariat informed the Panel on the status of the OECD review of the Adverse Outcome Pathway submitted with regard to the Parkinson Disease.

In response to an oral question/comment of Christian Strupp on the capacity of standard toxicity studies conducted up to the MTD to capture endpoints indicative of neurotoxicity involving the nigrostriatal pathway, the Panel specified that the design of the in-vivo studies should be tailored to enable the molecular initiating events to trigger the KEs for sufficient time. The pattern leading to cell death could depend on the combination of concentration, time of exposure and species sensitivity. These factors have to be taken into consideration for the interpretation of the study's result and extrapolation of potential low-dose chronic effect as this AOP refers to long-time exposure.

8.4 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 outcome of the last 2 meetings and proposed the nomination of an additional member representing the Scientific Committee in the Working Group, considering the potential multisectoral interest of the topic. The Panel supported this proposal.

In response to an oral question of Peter Day, EFSA indicated that future recommendations regarding epidemiological studies could reach researchers through the publication of the opinion, the Scientific Conference on the use of epidemiological studies in the framework of Regulation (EC) No 1107/2009 which will take place in 2017 and the possible preparation of a guidance by the Scientific Committee.

8.5 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)

The request to change the scope and the title of the opinion to 'Scientific Opinion of the PPR Panel on the state of Toxicokinetic/Toxicodynamic (TK/TD) and Simple Food Chain effects modelling for regulatory risk assessment of pesticides for aquatic organisms' was sent by the Chair of the Panel to EFSA.

The Panel established a Working Group and Colin Ockleford nominated Chris Topping and Theo Brock as Chair and vice-Chair of the Working Group, respectively. The areas of expertise needed for the preparation of the opinion include regulatory environmental risk assessment of plant protection products, ecotoxicology and ecology of aquatic organisms, higher tier effect studies with aquatic organisms, mechanistic effects models in general and TK/TD (for fish, invertebrates and primary producers) and simple food chain modelling in particular, good modelling practice in regulatory context, linking exposure and effects.The Panel agreed on the need for external expertise.

The panel replied to written questions 11.4 and 11.5 sent by Thomas Preuss (see point 11).

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

A member of the Working Group informed the Panel on the progress of the Working Group.

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

9.1. 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 20 and 21 April 2016, in particular the adoption of a Guidance to develop specific protection

goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services.

Additional information was provided on the progress of Working Groups of the Scientific Committee by members representing the Panel in meetings of these Working Groups.

The Panel was also informed on the publication of the Scientific Opinion on priority topics for the development of risk assessment guidance by EFSA's Scientific Committee in 2016–2018, which includes items of high relevance for the panel such as individual susceptibility and uncertainty factors, interpretation of epidemiological studies and chemical mixtures.

The Scientific Committee agreed to be consulted on the draft Scientific Opinion 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), before the launch of the public consultation.

10. Other scientific topics for information and/or discussion

10.1. Landscape-based environmental risk assessment

The Head of the Pesticides Unit presented a new project of EFSA under development and dedicated to the development of spatially explicit risk assessment approaches and environmental risk mapping. This project is based on proposals of the Panel for improving the environmental risk assessment, such as setting specific protection goals using ecosystem services and the need for landscape assessment. The project is intended to be conducted in cooperation with Members States and European institutions, in particular the Joint Research Center of the European Commission. The Panel would act as a scientific advisory body and would be invited to endorse specific outputs.

The Panel was invited to consider this future orientation in environmental risk assessment in its on-going mandates in this area.

In response to oral questions of Patrick Kabouw and Thomas Preuss, EFSA clarified that the aim of the project is to produce environmental risk assessments that could better support the Risk Managers decision making, in particular the approval of active substances at EU level and the authorisation of plant protection products by the Member State. Due to the complexity of the project, the implementation will be done stepwise. Once fully implemented the risk outcomes could serve other more general assessments if considered appropriate by Risk Managers or even support the selection of the most sustainable products by farmers, but the basic aim is the implementation of risk assessments under Regulation 1107/2009.

11. Questions from and answers to Observers (in application of the EFSA Guidelines for Observers)

11.1. ECPA has published several scientific publications that were made available to EFSA. However in recent outputs these publications are not referred to. What is the motivation for this?

The draft Scientific Opinion on the state of the science on the risk assessment of plant protection products for in-soil organisms cites those publications that were considered relevant to what is proposed, e.g. Ernst et al., 2015. Other publications or projects might be considered at a later stage for inclusion in the guidance document.

11.2. Frequently the panel identifies open point in Environmental Risk Assessment's (e.g. new test species). Some of these open points can currently not yet be addressed by scientifically sound methods. How can the panel help here?

All EFSA panels work on the premise that the best science should provide the basis of our recommendations. It is inevitable that there is a lag between new scientific developments and their practical incorporation into risk-assessment schemes.

In recent years, a stepwise approach has been adopted for the development of guidance documents for environmental risk assessment. A scientific opinion usually precedes development of a guidance document. Two important aims of a scientific opinion are (i) to analyse the state of the science on a specific topic, and (ii) to give recommendations based on the most recent developments, in order to develop scientifically robust risk-assessment schemes.

The next steps linked to recommendations of new test species are outside the remit of the panel. Any new developments (eg additional test species) have to be implemented in regulations setting out data requirements for active substances and Plant Protection Products before they can be introduced in risk-assessment schemes. Other international bodies are responsible for standardization of test protocols.

11.3. In EFSA's 2020 strategy the following is mentioned "Spatially explicit ecotoxicology and environmental fate and behaviour for pesticides". Can the panel mention the actions for achieving this goal?

The agenda item 10.1 covers this point. This is a large EFSA project currently under discussion as part of the EFSA strategy; the Panel would act as scientific advisory body.

11.4. What is the timeline (start and end) for the working group on the state of effect modelling approaches for aquatic organisms and will it deal with TKTD, Population and community models?

The Panel discussed in the Plenary meeting of December 2015 how and when to initiate panel activities for mechanistic effects models in the aquatic environment. The Panel agreed in a first step to prepare an opinion on toxicokinetic/toxicodynamic models and simple food-chain models as they present the most immediate interest in the context of the regulatory risk assessment of pesticides. In a mid to longer term plan, Panel activities are envisaged for other mechanistic models eg population, more advanced food web and ecosystem effects models.

When the preparation of a "Scientific Opinion of the PPR Panel on the state of Toxicokinetic/Toxicodynamic (TK/TD) and Simple Food Chain effects modelling for regulatory risk assessment of pesticides for aquatic organisms" has been approved by EFSA and the formalities for establishing the working group are completed, the work will start - probably in the second part of 2016. This scientific Opinion is expected to be adopted by the PPR Panel before 1 July 2018.

11.5. How and when is it planned to combine the 4 aquatic scientific opinions (edge of field, Sediment, modelling, landscape) into one guidance document?

Guidance for risk assessment can either be developed by the Panel or by EFSA. Often Scientific Opinions are prepared to provide the scientific background for developing the guidance. The "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013; 11(7):3290) is published. To address a complex environmental compartment the Panel prepared in a separate document the "Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water" (EFSA Journal 2015; 13(7):4176).

Concerning mechanistic effects models (eg population- food web- and ecosystem models) these will be possibly considered and dealt with in separate activities. See also answer to question 11.4 above.

EFSA and the Panel are also considering how landscape- and mapping of risk approaches could be developed and used to provide better and more informative risk assessments to risk managers. These approaches are being considered as relevant for the aquatic as well as the terrestrial compartment.

It will be further considered which of the above mentioned scientific activities are to be integrated into an updated aquatic guidance and which are better dealt with in separate scientific outputs.

In relation to the risk assessment of aquatic organism, the Panel refers also to a number of recommendations elaborated in the plenary meeting of June 2015 and included in the minutes, which include:

- The preparation of a number of scientific opinions on specific elements of the risk assessment of aquatic organisms;
- The development of landscape based environmental scenarios and risk assessment for all non-target organisms;
- The development of the surface water scenarios taking information on water bodies in EU into account.

More background information can be found in the annex to the PPR Plenary minutes (June 2015) in link below:

https://www.efsa.europa.eu/en/events/event/150624a

11.6. Uncertainties remain in the interpretation of many steps of the guidance. Clarification between notifier, RMS and EFSA is needed, besides the info session planned in September. Can the finalisation of the guidance be delayed?

Interpretation is usually possible for any guidance or even legislation.

It has not been intended to make the guidance document inadequately restrictive. To ensure sufficient clarity and comprehensibility amongst other aspects, the Pesticides Steering Network - consisting of Member State organisations and representatives of the Commission - was consulted on the draft guidance document. The resulting comments and recommendations were sent to the PPR Panel for consideration in the final version of the guidance document. In addition it has been agreed with the Pesticides Steering Network that training will be organised by EFSA for Member State experts in order to facilitate the application of the guidance document. Where necessary, according to Article 7(5) of Reg. (EC) 1107/2009 'when assessing the application the rapporteur Member State may at any time consult the Authority' to request advice and align views regarding peer review assessments.

The information session on 26/27 September will offer the possibility to present initial experiences of applicants with the new guidance document and to engage in a dialogue.

According to the mandate of the PPR Panel the guidance is scheduled for adoption during the June Plenary. Therefore, postponing adoption

is not possible unless cogent reasons (of conceptual or scientific nature) would be identified by the Panel during the plenary meeting. After adoption the guidance document will have to be submitted to the Standing Committee for Plants, Animals, Food and Feed (PAFF) for Note Taking.

11.7. The proposed strategy highly devalues the applicability of the TTC concept (application criteria not met for any of the case substances). In which cases the TTC approach will be accepted?

The PPR Panel does not share the view that the proposed strategy devalues to a significant extent the applicability of the TTC concept; it rather discloses the difficulties and limits of the TTC concept for application in the assessment of complex mixtures of similar/related compounds and of complex dietary exposure scenarios. The TTC concept can in general be applied, where reliable and robust exposure estimates - including all likely sources of exposure - can be performed and an informed regulatory decision can be drawn on that basis. The criteria described in the guidance document that should be used for exposure calculations are in line with the EFSA position on cumulative risk assessment, and in line with the EFSA PPR Panel and Scientific Committee opinions on dose addition and on the use of the TTC for co-exposure to multiple compounds. It is therefore considered scientifically appropriate to apply dose addition for exposure of co-occurring substances.

12. Any other business

The Communication of the European Commission and its draft regulation setting out scientific criteria for the assessment of endocrine disrupting properties of pesticides in the context of Regulation (EC) No 1107/2009 were brought to the attention of the Panel.