Scientific Panel on Plant Protection Products and their Residues

Minutes of the 62nd plenary meeting

Held on 13/14 February 2013, Parma

(Agreed on 15 April 2013)

Participants

- **Panel Members:**

  Alf Aagaard, Theodorus Brock, Ettore Capri, Sabine Duquesne, Antonio F. Hernandez-Jerez, Karen Ildico Hirsch-Ernst, Susanne Hougaard Bennekou, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Matthias Liess, Alberto Mantovani, Colin Ockleford, Bernadette Ossendorp, Daniel Pickford, Paulo Sousa, Ingvar Sundh, Aaldrik Tiktak, and Ton van der Linden

- **EFSA:**
  - Pesticides Unit: Herman Fontier, Luc Mohimont, Alessandra Caffi, Maria Arena, Charlotte Bergkvist, Stephanie Bopp, Mark Egsmose, Hans Steinkellner, Franz Streissl, Giorgia Boschetto, Alessandra Pasquin, Maddalena Florio and Maria Sodani
  - Scientific Evaluation of Regulated Products Directorate: Per Bergman
  - Corporate Services Unit: Francesco Ciancio and Carolina di Bona
  - Finance Unit: Christina Karkanti
  - Editorial & Media Relations Unit: Simon Terry

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Michael Walsh (DG SANCO), Robert Smith and Metka Filipič.

Michael Klein and Aaldrik Tiktak did not participate in the discussion relating to agenda item 6.4.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[2], EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI as well as the Oral Declaration of Interest at the beginning of the meeting, please refer to Annex I.

4. Agreement of the minutes of the 61st Plenary meeting held on 28/29 November 2012, Parma

The minutes of the 61st Plenary meeting held on the 28th and 29th of November 2012 were agreed by written procedure on 14th of January 2013.

5. Report on written procedures since 61st Plenary meeting

The draft guidance document on tiered risk assessment for aquatic organisms in edge-of-field surface waters was endorsed by written procedure on the 10th of December 2012 in view of the public consultation.

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

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

The Chair of the Working Group presented the newly established Working Group comprising of four PPR Panel members and two external experts who have been invited for their specific expertise on (in vitro) developmental neurotoxicity. The Chair introduced the work carried out so far including a complete collection of relevant literature and regulatory documents (EU Draft Assessment Reports), and informed the Panel on the outcome of the first meeting of the Working Group.

The next Working Group meeting will take place after the Plenary meeting in April 2013.

6.2 Discussion on the Guidance on tiered risk assessment for aquatic organisms in edge-of-field surface waters (EFSA-Q-2009-00001)

The PPR Panel was informed about the public consultation on the draft guidance document on tiered risk assessment for aquatic organisms in edge-of-field surface water. The public consultation was open from 14th of December 2012 to 11th of February 2013. More than 500 comments were received, with the largest part of them being submitted from MS authorities. The Working Group will address the comments and take them into consideration when finalising the guidance document. A report on the public consultation will be prepared and published together with the guidance document.

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

6.3 Discussion on the Scientific Opinion on the effect assessment of pesticides for sediment organisms in edge-of-field surface water (EFSA-Q-2012-00959)

The PPR Panel is tasked, as part of the Mandate on the revision of the guidance on aquatic ecotoxicology, to develop a Scientific Opinion on the effect assessment of pesticides for sediment organisms in edge-of-field surface waters. The Panel agreed to establish a new Working Group that will prepare this output. Four Panel members indicated their interest in participating in the Working Group and the relevant expertise needed was identified, i.e., regulatory risk assessment for aquatic organisms, sediment organisms' standard effect and risk assessment, sediment higher tier studies, sediment exposure assessment, sediment organisms' ecology, and uncertainty in risk assessment.

6.4 Adoption of the Scientific Opinions on the 2009 report of the FOCUS Groundwater working group, lower tiers (EFSA-Q-2011-00753) and discussion on the Scientific Opinion on the 2009 report of the FOCUS Groundwater working group, higher tiers (EFSA-Q-2011-00754)

The Chair of the Working Group presented the first Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers. The Opinion was adopted by the Panel after proposed amendments.

The rapporteur presented an update on the progress of the second Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers. The Working Group will meet again in March 2013.

6.5 Discussion on the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile (EFSA-Q-2009-00860)

The Chair of the Working Group informed the Panel about the progress made on the draft opinion since the last Plenary meeting and gave a detailed introduction to the different chapters of the opinion. The opinion has been distributed to the Panel members beforehand prior to the Plenary meeting for a first review. A Working Group member presented the methodology for grouping pesticides posing a toxic threat to the nervous system. The Chair took note that the Panel recommended that the opinion should include a reflection upon the need for more mechanistic data on pesticide active substances.

Two Panel members agreed to review the draft opinion after the next meeting of the Working Group in March 2013.

6.6 Discussion on the Scientific Opinion on the relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticide residues (EFSA-Q-2011-01020)

The Chair of the Working Group reported that the first meeting of the Working Group was postponed until the tasks, entrusted to the Working Group in charge of preparing the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile, were completed.

6.7 Discussion on the Scientific Opinion addressing the state of science on risk assessment for non-target arthropods, the Scientific Opinion addressing the state of science on in-soil risk assessment, the Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products (EFSA-Q-2011-00975, EFSA-Q-2011-00978, EFSA-Q-2011-00989)

Robert Smith was appointed as Chair of the Working Group preparing the Scientific Opinions on state of science on in-soil risk assessment and non-target arthropod risk assessment. Ryszard Laskowski and Aaldrik Tiktak were appointed as co-chairs of this Working Group.

Theodorus Brock was appointed as Chair of the Working Group preparing the Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products.

6.8 Discussion on the Scientific Opinion addressing the state of the science on risk-assessment for non-target terrestrial plants (EFSA-Q-2011-00982)

An overview on the progress made by the Working Group on non-target terrestrial plant risk assessment was presented. The Working Group has nearly finalised the collection of background data and literature. A draft opinion should be available by the end of 2013. Three rapporteurs have been nominated for the Scientific Opinion.

The Panel identified an additional area of expertise (population modelling) for which external expertise is needed.

7. New Mandates

No new mandate has been adopted by the Mandate Review Committee since the 61st Plenary meeting.

8. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

8.1 Scientific Committee

The Chair informed the Panel about relevant agenda items that were discussed at the 59th Plenary meeting of the Scientific Committee, which took place on the 5th and 6th of February 2013. This included the EC mandate on endocrine disruptors, the draft mandate on environmental risk assessment, the work programme of the Working Groups of the Scientific Committee, and the draft Scientific Report of EFSA on chemical mixtures.

9. Other scientific topics for information and/or discussion

No further scientific topics were added to the agenda for information and/or discussion

10. Any Other Business

10.1 Centralisation of logistic activities supporting the PPR Panel

The EFSA Corporate Services Unit informed the Panel about the reorganisation and centralisation of the logistic tasks related to the organisation of meetings of Scientific Panels and their Working Groups.

10.2 EFSA guidance documents under development

The Pesticides Unit gave an overview of several EFSA guidance documents under development:

- Pesticide exposure assessment for workers, operators, bystanders and residents
- Evaluation of laboratory and field dissipation studies to obtain DegT50 values of active substances and transformation products in soil
- Prediction of environmental concentrations of active substances and their transformation products in soil
- Clustering and ranking of emissions of active substances and transformation products from protected crops
- Risk assessment of plant protection products on bees

10.3 Involvement of the members of the PPR Panel in the peer-review process

Further discussions took place on the possible modes of involvement of the members of the PPR Panel in the peer-review process of active substances of plant protection products.

10.4 Distribution of work between experts and EFSA staff

The Panel was informed about possible future changes in working practices and in the distribution of work between experts and EFSA staff in the area of regulated products.

Indeed, in its recommendations of December 2012, deriving from the second external evaluation, the EFSA's Management Board indicated in relation to the work of the Scientific Panels that "the nature of the work allocated to them should be adapted to the evolving needs in terms of increasing workload, complexity and multidisciplinary across several scientific areas".

10.5 Questionnaire to Panels and Units on the use of Scientific Committee guidance documents

A questionnaire has circulated to units and Panels on the use of guidance documents adopted by the Scientific Committee and on the needs for additional guidance document. The questionnaire needs to be returned to the Scientific Committee Unit by the end of March 2013.

10.6 Commission's feedback on EFSA scientific outputs

The Commission's feedback on EFSA scientific outputs, which has been delivered as impact indicator of the 2-year pilot study of EFSA on impact assessment methodologies, has circulated to members of the PPR Panel for information.

10.7 External evaluation of EFSA

The Panel has been informed on the second external evaluation report, which was commissioned by EFSA to the external auditors *Ernst and Young* in order to gain insight on stakeholder's perceptions of the Authority and the quality of its work, and on the recommendations of the Management Board for the period 2013-2017.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

In the ADoI or in the SDoI filled for the present meeting, Dr. Michael Klein and Dr. Aaldrik Tiktak declared the following interest: membership of the FOCUS Groundwater Working Group. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest regarding item 6.4 (Scientific Opinions on the 2009 report of the FOCUS Groundwater working group).

This resulted in the impossibility for the experts to be present when the item was discussed by the Panel.