

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 15th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 5-6 September 2017, Parma (Italy)

(Agreed on 20 Sept 2017)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez

Colin Ockleford

Paul Hamey

Marie-Odile Rambourg

Matteo Bottai via teleconference

Thorhallur Halldorsson has participated via teleconference (on September 5 only)

Ioanna Tzoulaki

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

- **EFSA:**

Pesticides Unit: Crivellente Federica

Executive Directorate: Hubert Deluyker has participated via teleconference on September 5 only

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 14th Working Group meeting held on 16-17 May 2017, Parma.

The minutes of the 14th Working Group meeting were agreed by written procedure on May 29th 2017.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of a Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report "Literature review on epidemiological studies linking

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

exposure to pesticides and health effects” - EFSA-Q-2014-00481 – revision of the drafted chapters⁵

The most relevant comments received during the Public Consultation phase were discussed. Changes in the draft Scientific Opinion were performed accordingly, and a proposal for the replies to be included in the Technical Report was agreed upon.

The draft agenda of the Scientific Conference (planned for November 21, 2017) was presented and discussed.

6. Next meeting

Not applicable

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 14th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 16-17 May 2017, Parma (Italy)

(Agreed on 29 May 2017)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez

Colin Ockleford

Paul Hamey

Marie-Odile Rambourg

Matteo Bottai has participated via teleconference (on May 17th only)

Thorhallur Halldorsson

Ioanna Tzoulaki

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

- **EFSA:**

Pesticides Unit: Court Marques Daniel, Crivellente Federica

Executive Directorate: Hubert Deluyker

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 13th Working Group meeting held on 21-22 March 2017, Parma.

The minutes of the 13th Working Group meeting were agreed by written procedure on April 3rd 2017.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of a Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report "Literature review on epidemiological studies linking

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

exposure to pesticides and health effects” - EFSA-Q-2014-00481 – revision of the drafted chapters⁵

Some chapters of the Scientific Opinion were reshuffled in order to improve the flow of the information and the reading. In addition, the comments received from the Scientific Committee were discussed and addressed in view to the re-endorsement by the PPR Panel by written procedure.

6. Next meeting

5-6 September 2017, Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 13th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 21-22 March 2017, Parma (Italy)

(Agreed on 3 April 2017)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez

Colin Ockleford

Paul Hamey

Marie-Odile Rambourg

Matteo Bottai

Thorhallur Halldorsson

Ioanna Tzoulaki has participated via teleconference

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

- **EFSA:**
Pesticides Unit: Federica Crivellente
Executive Directorate: Hubert Deluyker
- **Others:**
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 12th Working Group meeting held on 24-9 November 2016, Parma.

The minutes of the 12th Working Group meeting were agreed by written procedure on 1st February 2017⁴.

5. Scientific topic(s) for discussion

5.1. Preparation of a Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report "Literature review on epidemiological studies linking

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

exposure to pesticides and health effects” - EFSA-Q-2014-00481 – revision of the drafted chapters⁵

The entire Scientific Opinion was reviewed on the basis of the comments received from the reviewer designed by the PPR Panel and other Panel’s experts. The comments were addressed in view to the preliminary endorsement by the PPR Panel.

5.2. Scientific Conference

It was agreed that the Scientific Conference will probably take place in Parma, in November 2017. Invited speakers will be selected from different organisations and contacted soon.

6. Next meeting

16-17 May 2017, Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 12th meeting of the Working Group on Preparation of a Scientific Opinion of the PPR Panel on Epidemiological Studies in Pesticide Risk Assessment

Held on 24-25 January 2017, Parma (Italy)

(Agreed on 1 February 2017)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez

Colin Ockleford

Paul Hamey

Marie-Odile Rambourg

Matteo Bottai

Thorhallur Halldorsson

Ioanna Tzoulaki has participated via teleconference

- **Hearing Experts¹:**

David Miller (US-EPA) (for item 5)

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Federica Crivellente, Danièle Court-Marquez

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

- **Others:**

Executive Directorate Unit: Hubert Deluyker

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 11th Working Group meeting held on 8-9 November 2016, Parma.

The minutes of the 11th Working Group meeting were agreed by written procedure on 21 November 2016.⁴

5. Hearing Expert (s)

David Miller was invited to present his views for topic 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Selection bias/misclassification, power analysis and effect size magnification for selected (positive) epidemiological studies for Paraquat⁵

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

The Hearing Expert presented an overview of the selection bias/misclassification issue and an example of effect size magnification in the analysis of some selected epidemiological studies on Paraquat.

6.2. Preparation of a 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" - EFSA-Q-2014-00481 – revision of the drafted chapters

The different parts of the Scientific Opinion were reviewed with focus on the first part; some actions were agreed by the Experts and further tasks allocated.

7. Any Other Business

The Experts were informed that the Consultation with the Scientific Committee will take place in April (April 27, in the morning).

8. Next meeting

21-22 March 2017, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 11th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 8-9 November 2016, Parma (Italy)

(Agreed on 6 December 2016)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez

Colin Ockleford

Paul Hamey

Marie-Odile Rambourg

Matteo Bottai

Ioanna Tzoulaki

Thorhallur Halldorsson has participated via teleconference

- **Hearing Experts¹:**

Peter Floyd (Risk & policy Analysts Ltd), Ruth Bevan (IEH Consulting Ltd) and Kate Jones Expert name (UK Health & Safety Laboratory) (for item 5)

- **European Commission and/or Member States representatives:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

- **EFSA:**

Pesticides Unit: Federica Crivellente, Daniele Court-Marquez, Andrea Terron

- **Others:**

Executive Directorate Unit: Hubert Deluyker

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 10th Working Group meeting held on 20-21 September 2016, Parma.

The minutes of the 10th Working Group meeting were agreed by written procedure on 10 October 2016.⁴

5. Hearing Expert (s)

Mr. Peter Floyd, Ms. Ruth Bevan and Ms. Kate Jones invited to present their views for topic 6.1 of the present meeting.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

6. Scientific topic(s) for discussion

6.1. Human biomonitoring (HBM) data collection from occupational exposure to pesticides⁵

The Hearing Experts presented an overview of the available evidence for the potential role of HBM in occupational health and safety strategies.

6.2. Public Consultation of the Scientific Opinion on Parkinson's disease and childhood leukaemia

The most relevant comments received from the Public Consultation of the Scientific Opinion on Parkinson's disease and childhood leukaemia were shared and discussed.

6.3. Preparation of a 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"

The draft of the Scientific Opinion was reviewed and discussed and further tasks allocated for the Experts.

6.4. Presentation of a) a decision tree on how to weight epidemiological evidence and b) decision tree on how to integrate all available evidence

The decision trees were presented and discussed and further actions agreed.

7. Any Other Business

- 7.1.** The Experts identified the need of a Technical Hearing from David Miller (US-EPA) to discuss the selection bias/misclassification issue.

8. Next meeting

24-25 January 2017, Parma

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 10th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

**Held on 20-21 September 2016, Parma (Italy)
(Agreed on 10 October 2016)**

Participants

- **Working Group Members:**

Matteo Bottai, Antonio F. Hernández-Jerez, Paul Hamey, Colin Ockleford, Marie-Odile Rambourg, Ioanna Tzoulaki (by teleconference)

- **Hearing Experts¹:**

David Miller, US-EPA (by teleconference)

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Daniele Court Marques, Federica Crivellente, Andrea Terron

Executive Directorate: Hubert Deluyker

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 9th Working Group meeting held on 21 June 2016, DG Santé, Brussels (Belgium).

The minutes of the 9th Working Group meeting held on 21 June 2016 were agreed by written procedure by 15 July 2016.⁴

5. Scientific topics for discussion

5.1. Scope and regulatory impact of effect size magnification with low power studies

A presentation was given on this topic by the Hearing Expert and a discussion followed.

5.2. Case study on Paraquat

The case study on Paraquat was presented and discussed.

5.3. Scientific Conference in 2017

It was discussed the time and possible location of the Scientific Conference of end 2017.

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/sites/default/files/Epidemiologicalstudieswg.pdf>

5.4. Preparation of a 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” – EFSA-Q-2014-00481-revision of the draft chapters⁵

The different drafted chapters were reviewed, discussed and further tasks were allocated.

6. Any Other Business

- 6.1.** Considering that there is still work in progress, the WG Experts agreed to ask the Panel to extend the deadline of the WG’s activities of three additional months (June 2017 instead of March 2017).
- 6.2.** The Experts identified the need of a Technical Hearing from the following Contractors of the Human Biomonitoring data collection from occupational exposure to pesticides: Ruth Bevan (IEH Consulting Ltd), Peter Floyd (Risk & Policy Analysts Ltd), Kate Jones (UK Health & Safety Laboratory).

7. Next meeting

8-9 November, Parma (Italy)

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 9th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

**Held on 21 June 2016, Brussels (Belgium)
(Agreed on 15 July 2016)**

Participants

- **Working Group Members:**

Matteo Bottai, Antonio F. Hernández-Jerez, Paul Hamey, Colin Ockleford, Marie-Odile Rambourg, Ioanna Tzoulaki

- **Hearing Experts:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Arianna Chiusolo (by TC), Daniele Court Marques (by TC), Federica Crivellente

Executive Directorate: Hubert Deluyker

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 8th Working Group meeting held on 14-15 April 2016, Parma.

The minutes of the 8th Working Group meeting held on 14-15 April 2016 were agreed by written procedure on 26 April 2016.³

5. Scientific topics for discussion

5.1. Human biomonitoring

An update on some preliminary outcomes of the on-going outsourced project was presented and discussed.

5.2. Feedback from the presentation of the activities of the WG at the Scientific Committee

The outcome of the presentation at the Scientific Committee was presented and the actions proposed were discussed.

5.3. Examples of the CONTAM Panel on the use of epi data in Risk Assessment

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <https://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

A few examples on how the CONTAM Unit used the epidemiological evidence for the assessment of some contaminants were presented and discussed.

5.4. Preparation of a 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” – EFSA-Q-2014-00481-revision of the draft chapters⁴

The different drafted chapters were reviewed and discussed.

6. Any Other Business

6.1. Hearing Experts

The WG Experts agreed to invite David Miller at the next WG meeting as Hearing Expert to further discuss the scope and regulatory impact of effect size magnification with low power studies.

6.2. New Expert

The WG in consultation with the PPR Panel agreed to invite the Expert Thorhallur Halldorsson (University of Iceland) to be part of the WG.

7. Next meeting

20-21 September, Parma (Italy)

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 8th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 14-15 April 2016, Parma (Italy)

(Agreed on 26 April 2016)

Participants

- **Working Group Members:**

Antonio Hernandez-Jerez, Colin Ockleford, Paul Hamey, Marie-Odile Rambourg, Ioanna Tzoulaki, Matteo Bottai

- **Hearing Experts¹:**

Toby Athersuch (for item 6.1); David Miller (for item 6.3);

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Federica Crivellente, Daniele Court Marques

- **Others:**

Not Applicable

1. Welcome and apologies for absence

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 7th Working Group meeting held on 9-10 February 2016, Parma.

The minutes of the 7th Working Group meeting were agreed by written procedure on 25 February 2016.⁴

5. Hearing Expert (s)

Mr. Toby Athersuch and Mr. David Miller were invited to present their views for item 6.1 – Exposome and Metabolomics and item 6.3 – Effect size magnification, respectively, of the present meeting by teleconference.

6. Scientific topic(s) for discussion

6.1. Exposome and metabolomics

A presentation on Exposome and Metabolomics was given by providing the different definitions of exposome and metabolomics currently used and the analytical platforms in place for metabolic profiling (untargeted and targeted profiling). Some examples of exposome studies carried out with pesticides were presented and the correlation between exposome and systems toxicology was pointed out.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

6.2. Preparation of a 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” – EFSA-Q-2014-00481⁵

The overall structure and content of the draft Opinion were discussed, together with the possible inclusion of a few case studies. Some actions were allocated for the Experts.

6.3. Effect size magnification

A presentation on the association between the use of Diazinon with lung cancer, and Atrazine with thyroid and ovarian cancers was given. The effect size magnification was discussed together with some simulations: it was pointed out that such effect usually occurs when research findings of small studies are biased in favour of inflated effects. Effect size magnification is not regarding just epidemiological studies, but science in general and research findings in general. It was discussed how the effect size magnification can influence risk managers’ decisions and it was concluded that risk managers should be made aware of these limitations

7. Any Other Business

Not Applicable

8. Next meeting

21 June 2016, Brussels

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 7th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 9-10 February 2016, Parma (Italy)

(Agreed on 25 February 2016)

Participants

- **Working Group Members:**

Antonio Hernandez-Jerez, Colin Ockleford, Paul Hamey, Marie-Odile Rambourg

- **Hearing Experts:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

PRAS Unit: Federica Crivellente, Andrea Terron (Febr 10th only)

DATA Unit: Andrea Altieri (Febr 9th only)

Executive Directorate: Hubert Deluyker

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ioanna Tzoulaki and Matteo Bottai.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 6th Working Group meeting held on 3-4 December 2015, Parma.

The minutes of the 6th Working Group meeting were agreed by written procedure on 15 December 2015.³

5. Scientific topic(s) for discussion

5.1. Preparation of a 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"⁴

The overall structure and specific chapters of the Opinion were discussed. Some actions were allocated for the Experts.

6. Any Other Business

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

The WG agreed to invite two Hearing Experts at the next WG meeting: 1) Paolo Vineis from the Imperial College, London to present exposome/metabolomics; 2) David Miller from US EPA to present (by TC) effect size magnification with low power studies.

7. Next meeting

14-15 April, EFSA (Parma)

Scientific Panel on Plant Protection products/Pesticides Unit

Minutes of the 6th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 3-4 December 2015, Parma (Italy)

(Agreed on 15 December 2015)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez (chair), Colin Ockleford, Paul Hamey, Ioanna Tzoulaki, Marie-Odile Rambourg, Matteo Bottai

- **Hearing Experts¹:**

David Miller-US-EPA (for item 4.2)

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Danièle Court Marques, Andrea Terron (Dec 3rd only)

- **Others:**

Not Applicable

1. Welcome and apologies for absence

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

The Chair welcomed the participants.

Andrea Terron did not participate in agenda point 4.4, 4.5 and 4.6.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 5th Working Group meeting held on 24-25 September 2015, Parma.

The minutes of the 5th Working Group meeting held on 24-25 September 2015 were agreed by written procedure on 13 October 2015.⁴

5. Hearing Expert (s)

Dr. David Miller invited to present his views for item 6.2 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Update of the Glyphosate TC⁵

A report on Pesticides Peer Review Expert teleconference 117 held at the end of September and regarding the discussion of the herbicide glyphosate was delivered. It was also reported that the glyphosate case was discussed at the European Parliament at the beginning of December, where both EFSA and IARC presented their conclusions.

6.2. Tier II assessment of Diazinon

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-0048>

The Tier II assessment of diazinon (banned substance in Europe) was presented as still work in progress within US EPA. The different studies related to lung cancer, non-Hodgkin lymphoma (NHL), leukaemia, prostate cancer, birth outcomes and reproductive effects and other health outcomes investigated were presented. It was concluded that diazinon will probably undergo Tier III assessment.

Atrazine (banned in Europe) and studies related to hairy cell leukaemia were presented as well.

After the presentation, the discussion was focused on: a) statistical significance versus biological relevance (in some instances the statistical significance is given more consideration than biological relevance); b) small sample size; c) hypothesis testing (no new cases should be added in a second instance); d) how high an odds ratio (OR) should be in order to be incorporated in decision making; e) meta-analysis.

6.3. Literature appraisal and rules to select credible associations and diabetes meta-analysis

The identification of credible associations was presented and discussed. In particular, it was pointed out that heterogeneity can be a manifestation of bias, but also can emerge from genuine differences across studies. Finally, an update of diabetes meta-analysis was provided.

6.4. Preparation of a 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" – EFSA-Q-2014-00481

The structure of the draft opinion was discussed and plans to further progress were made.

7. Any Other Business

The WG agreed to invite a Hearing Expert from the Imperial College (UK) at the next WG meeting (by TC) to present exposome/metabolomics for assessing exposure.

8. Next meeting(s)

9-10 February 2016, EFSA, Parma

Scientific Panel on Plant Protection Products

Minutes of the 5th meeting of the Working Group on Epidemiological Studies in Pesticides Risk Assessment

Held on 24-25 September 2015, Parma (Italy)

(Agreed on 13 October 2015)

Participants

- **Working Group Members:**

Antonio Hernández-Jerez (chair)

Colin Ockleford

Paul Hamey

Ioanna Tzoulaki

Marie-Odile Rambourg

Matteo Bottai

- **Hearing Experts¹:**

Kent Thomas and David Miller (US-EPA) for item 5.2;

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Federica Crivellente, Daniele Court-Marques, Arianna Chiusolo, Marize Solano

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Andrea Altieri.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups 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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 4th Working Group meeting held on 6-7 July 2015, Parma.

The minutes of the of the 4th Working Group meeting held on 6-7 July 2015 were agreed on 4 August 2015⁴.

5. Scientific topic(s) for discussion

5.1. Tender Specifications of Open Call "Human Biomonitoring data collection from occupational exposure to pesticides"⁵

The three objectives of the Open Call launched at the end of August were presented, together with the methodology and the timelines. The WG discussed how the outcome of this outsourced project will be included in the opinion after public consultation.

5.2. Agricultural Health Study (AHS)

Kent Thomas from US-EPA presented a set of slides (by TC) summarizing general information from the Agricultural health Study

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/Epidemiologicalstudieswg.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00481>

(AHS), one of the largest prospective cohort studies in the world and the largest in US on cancer and other health outcomes. This study began in 1993 and it deals with pesticide applicators and their spouses from Iowa and North Carolina. The different phases of the project were presented together with the instruments used for exposure assessment (questionnaires, intensity algorithm). Regarding the health outcomes, cancer was assessed through “Cancer Registers” while other diseases were assessed through self-reports. The majority of cancer cases observed in the applicators until 2011 corresponded to prostate, lung, colon, bladder, rectum, non-Hodgkin lymphoma (NHL), melanoma, etc. For the spouses, the majority of cases of cancer was observed in the breast, lung, NHL, colon, bladder, skin (melanoma), etc. Regarding the non-cancer outcomes, respiratory, cardiovascular, neurologic, endocrine, reproductive, renal and immunologic effects were assessed. An example on a neurodegenerative disease (Parkinson’s disease-PD) was presented: overall, pesticide use was associated with an increased risk of PD and some potential interactions were found with certain genotypes and with dietary fat. Some additional add-on studies were presented. The strengths and limitations of the AHS were shown together with multiple comparisons and the need of replication of the studies.

5.3. Heterogeneity across results from different studies

Some thoughts on heterogeneity across results from different studies were presented. It was discussed how sensitivity analysis can be applied to epidemiological studies and how relevant factors should be taken into consideration when designing an epidemiological study.

5.4. Preparation of a 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” – EFSA-Q-2014-00481

The interpretation of the terms of reference of the opinion was discussed and it was agreed to clarify some points. Some additional tasks were allocated within the WG to further progress on the Scientific Opinion.

6. Any Other Business

The WG agreed to invite a Hearing Expert from US-EPA at the next WG meeting (by TC) to present Tier II assessment for Diazinon.

7. Next meeting(s)

3-4 December 2015, Parma, Italy.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 4th meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

Held on 6-7 July 2015 at EFSA, Parma

(Agreed on 4/8/2015)

Participants

- **Working Group Members:**

- Antonio Hernández-Jerez (chair)
- Colin Ockleford
- Paul Hamey
- Ioanna Tzoulaki
- Marie-Odile Rambourg
- Matteo Bottai

- **Hearing Experts:**

- Not Applicable

- **European Commission and/or Member States representatives:**

- Not Applicable

- **EFSA:**

- PRAS Unit: Federica Crivellente, Andrea Terron, Daniele Court Marques, Arianna Chiusolo, Marize Solano
- SCER Unit: Andrea Altieri

1. Welcome and apologies for absence

The Chair welcomed the participants.

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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests 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 3rd Working Group meeting held on 28-29 May, Parma

The minutes of the 3rd Working Group meeting held on 28-29 May in Parma were agreed on June 25th and published the EFSA website on 7 July 2015.

5. Scientific topic(s) for discussion

Preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment (EFSA-Q-2014-00481).

The WG discussed the chapters of the Scientific Opinion drafted so far and some additional tasks were allocated within the WG to further progress on this.

The Experts also discussed biostatistics issues, biomonitoring as a tool to assess human exposure to pesticides and omics techniques as promising tools for assessing both chemical exposures and also the mechanisms underlying the toxic effects.

The WG agreed to invite two Hearing Experts from US-EPA at the next WG meeting (by TC) to present the Agricultural Health Study (AHS).

6. Next Meeting

24-25 September 2015 in EFSA, Parma.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 3rd meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

**Held on 28-29 May 2015 at EFSA, Parma
(Agreed on 25/6/2015)**

Participants

- **Working Group Members:**

- Antonio Hernández-Jerez (chair)
- Colin Ockleford
- Paul Hamey
- Ioanna Tzoulaki
- Marie-Odile Rambourg
- Matteo Bottai (until May 29th at 9:40 am)

- **Hearing Experts:**

- Marie-Christine Lecomte, Sylvaine Cordier, Alexis Elbaz (INSERM, France)
- David Miller (US-EPA)

- **European Commission and/or Member States representatives:**

- Not Applicable

- **EFSA:**

- PRAS Unit: Federica Crivellente, Andrea Terron (May 29 only)
- EMRISK Unit: Andrea Altieri

1. Welcome and apologies for absence

The Chair welcomed the participants.

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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests 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 3rd Working Group meeting held on 28-29 May, Parma

The minutes of the 3rd Working Group meeting held on 28-29 May in Parma were agreed on June 25th and published the EFSA website on 7 July 2015.

5. Scientific topic(s) for discussion

Preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment (EFSA-Q-2014-00481).

The Hearing Experts from INSERM presented the INSERM Report entitled "Pesticides – effets sur la santé: Synthèse et recommandations". First, they introduced the role of INSERM as a public institution providing expertise on public health questions that can be asked by different French institutions. Then, they presented the literature review which was published in 2013: the objectives of this review were to assess the health risks related to exposure to pesticides. An exhaustive literature review was performed without any specific time limitation and the critical quality of the review was supported by experts in epidemiology and toxicology. Some specific outcomes related to occupational exposure to pesticides were selected and presented to the Working Group: neurodegenerative diseases (Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease); brain tumours, fertility, pregnancy and child development. A link between exposure to pesticides and the occurrence of the aforementioned adverse health outcomes was identified. The Inserm experts discussed issues related to exposure assessment, ranging from questionnaires and job-exposure matrices, to biomarkers, as well as issues related to critical windows of exposure. However, some limitations of the epidemiological studies evaluated precluded firm conclusions to be drawn on specific substances (poor quality of measurement of exposure, mixture of active substances and poor knowledge of complete exposure profiles). The INSERM Experts provided recommendations on how to improve the quality of epidemiological studies. These included how to: 1) improve the measurement of exposure (collect data on pesticides uses in agriculture by using pesticide reports, sales statistics, land use surveys, document exposure levels in various occupational tasks, record pesticide use at individual level during the whole working life, document levels and sources of exposure in the general population, record and analyse case reports of acute

poisoning, develop sensitive methods for pesticide measurement in biological samples (biomonitoring), gain access to the composition of commercial products); 2) strengthen research on health consequences (develop studies in countries outside US and on recently marketed pesticides; identify vulnerable subpopulations by taking into account individual susceptibility, document exposure during critical windows of vulnerability, promote joint toxicological and epidemiological evaluations, improve knowledge on the toxicity of pesticides mixtures).

During the discussion after the presentation, the INSERM Experts clarified and commented that: a) the literature review presented had no time restriction and that the starting date was not fixed in advance of the work and variable depending on the health outcomes analysed (e.g. for child development it was after 2000); b) the health outcomes were selected on the basis of a clinical diagnosis (no selection bias) and the expertise of the people performing the literature review and analysis; c) in their opinion, the hazard identification/characterisation should be considered an important piece of information when provided by epidemiological studies; d) with regard to the use of inclusion/exclusion criteria, the Experts clarified that no specific criteria for selection were defined a priori, but specific studies were excluded (e.g. case reports, retrospective mortality cohort studies with information on occupation only, and ecological studies); e) mechanisms of toxicity were taken into consideration; f) when different estimates came from the same study population, they were collected singularly in order to capture all the information available; g) no quantitative assessment of bias was performed; h) the analysis was focused on occupational exposure (except for child development); i) large cohort studies such as the Agricultural Health Study (AHS) should be carried out in Europe; j) consortium of cohort studies would also be useful and harmonization/standardization of methods across studies should be encouraged; the INSERM experts considered that heterogeneity may represent a difficulty, but could be considered helpful in order to help identify the origins of some differences; k) in some instances biomonitoring studies may provide useful information; l) small effects size might be seen as very relevant when they apply to the whole population; m) the main difference between the EFSA External Scientific Report (carried out by the Ioannina University) and the INSERM report are related to the fact that the latter study was focused on occupational exposure for both cancer outcomes and other chronic diseases; another important difference is that the Ioannina report was restricted to studies performed after 2006 and did not take into account many studies performed before that date.

The Hearing Expert from US-EPA presented of an update on the history of Chlorpyrifos risk assessment. This represented an example of the integration experimental toxicology, mechanistic data and possible MoAs/AOPs, epidemiologic and biomonitoring studies. Taken together, these studies indicated that chlorpyrifos likely plays a role in neurodevelopmental outcomes. However, the lack of establishment of MoA/AOP for neurodevelopmental effects and the potential exposure to multiple AChE-inhibiting pesticides precluded a definitive causal inference. For this reason, the statutory 10X FQPA Safety Factor was retained.

The WG discussed also a presentation on the subject of the Ontario College of Family Physicians Literature Review (OCFPLR). The results of the Pesticide Systematic Literature Review carried out between 1992 and 2003 and published in 2004 by the Ontario College of Family Physicians (Ontario, Canada) were assessed in a presentation and discussed by the Working Group.

Finally, the first draft of the Scientific opinion was discussed.

6. Next Meeting

6-7 July 2015 in EFSA, Parma.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 2nd meeting of the Working Group on preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment

**Held on 19.02.2015, Paris, Holiday Inn Porte de Clichy
(Agreed on 3/3/2015)**

Participants

- **Working Group Members:**
 - Antonio Hernández-Jerez (chair)
 - Paul Hamey
 - Ioanna Tzoulaki (by TC)
 - Marie-Odile Rambourg
 - Matteo Bottai
- **Hearing Experts:**
 - David Miller (US-EPA)
- **European Commission and/or Member States representatives:**
 - Not Applicable
- **EFSA:**
 - PRAS Unit: Federica Crivellente, Andrea Terron (May 29 only)
 - EMRISK Unit: Andrea Altieri

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Colin Ockleford.

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 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests 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 2nd Working Group meeting held on 19/02, Paris.

The minutes of the of the 2nd Working Group meeting held on 19 February 2015 were agreed on 3 March 2015 and published on the EFSA website on 5 May 2015.

5. Scientific topic(s) for discussion

Preparation of a Scientific Opinion of the PPR Panel on Epidemiological studies in Pesticide Risk Assessment (EFSA-Q-2014-00481).

The Working Group discussed the major drawbacks and limitations found in the literature review on epidemiological studies published in the EFSA External Scientific Report and the differences and similarities in the results shown in the INSERM report.

The experience of US-EPA in integrating epidemiological studies into the risk assessment process was also presented in a technical hearing of David Miller as representative of US-EPA. It was reported that the information on the toxic effects of pesticides is generally derived from studies with laboratory animals. However, US-EPA has recently started a more focused effort to integrate epidemiological studies in the risk assessment process. In particular, in 2010 the Office of Pesticide Programs (OPP) proposed a framework for incorporating human epidemiologic and incident data in health risk assessment by using a tiered process. In particular, epidemiological studies are included in a Tier I assessment only if the pesticide was part of the Agricultural Health Study (AHS) or if significant interest/concern is present. Tier I assessments are usually short documents that summarize facts; they generally emphasize pesticide poisoning incidents (but they don't include poison control center information). No conclusions or interpretation of the data are made in Tier I. In contrast to Tier I assessments, which are done early in the review process (docket/dossier opening), Tier II analysis is usually performed in preparation of the dossier and it is a more complete review of epi data if the Tier I review shows concern. Tier II assessments are composed of three parts: 1) medical case reports; 2) general pesticide incident; 3) epidemiological studies. In this stage, a standardised literature review is routinely performed and a narrative description of the

available data/studies is provided together with synthesis and conclusions. Conclusions can be that there is no issue of concern or that would warrant follow-up or there is an issue to follow-up. To date, no such follow-up activities have taken place, and internal discussions are ongoing with respect to what specific steps would be taken if a decision was made in a Tier II assessment that active follow-up was advisable. Discussion at present at EPA includes the possibility of conducting a "Tier III" Systematic Review and meta-analysis which would be performed together with evaluation of toxicity and adverse outcome pathway. Such a Tier III assessment would involve review of a specific chemical and a single health outcome (as suggested by the Tier II assessment), with a specific hypothesis for testing being made. However – given the limited time frame between the Tier II and the due date for the completed draft risk assessment - it is likely that any Tier III Systematic Review and meta-analysis would not be performed in time for the dossier and instead would be performed and released during the time period after the dossier/draft risk assessment was released.

The experience of US-EPA in integrating epi studies into the risk assessment process is at this time limited, and has been formally completed for the following substances: Acephate, Glyphosate, Malathion, Chlorpyrifos and – soon - Diazinon. The dossier on Malathion was presented with an emphasis on the conclusions and their language. The Columbia University study was mentioned in order to highlight the issue of raw data availability when analysing epidemiological studies retrospectively. The study was begun in the late 1990's and continues to the present, and a brief review of the results to date and ongoing cohort activities was presented.

In addition, the Working Group discussed the outcome of the break-out sessions of the Stakeholder Workshop. Finally, the structure of the Opinion and allocation of tasks were presented.

The Working Group identified the need to invite at least two external experts at the next WG meeting in order to present the INSERM Report.

6. Next Meeting

28-29 May 2015 in EFSA, Parma.

Scientific Panel on Plant Protection Products and their Residues
**Minutes of the 1st meeting of the Working Group on Epidemiological
Studies in Pesticide Risk Assessment**

Held by TC, 20 January 2015

(Agreed on 19 February 2015)

Participants

• **Working Group Members:**

- Antonio Hernández-Jerez
- Paul Hamey
- Ioanna Tzoulaki
- Marie-Odile Rambourg
- Matteo Bottai

• **EFSA:**

- PRAS Unit: Federica Crivellente, Maria Sodani
- EMRISK Unit: Andrea Altieri

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair, experts and EFSA staff introduced themselves.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 1st Working Group meeting held on 20 January 2015, Parma.

The minutes of the of the 1st Working Group meeting held on 20 January 2015 were agreed on 19 February and published on the EFSA website on 4 March 2015.

5. What EFSA is and what the Pesticides Unit does

A general presentation explaining the role of EFSA and the main activities carried out by the Pesticides Unit was provided to the WG Experts.

6. Scientific topic(s) for discussion

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](http://www.efsa.europa.eu/en/keydocs/docs/independencereport2014.pdf))

7. Mandate background and remit of the WG

Some background information was provided to the Experts in order to introduce the remit and the terms of references of the WG, which is part of a bigger project. Milestones and timelines were presented. The Rapporteur of the WG was nominated.

8. Stakeholder Workshop

The objectives and the agenda of the workshop with Stakeholders on the "Use of Epidemiological findings in Regulatory Pesticide Risk Assessment" to be held in Paris on February 18th, 2015, were presented: the importance of the break-out sessions was highlighted, since the outcome will provide the basis for discussion at the WG meeting in Paris.

9. WG meeting in Paris

It was agreed to have the focus on the following items: 1) EFSA External Scientific Report; 2) INSERM Report; 3) experience gained by US-EPA so far in the integration of epi studies in the risk assessment process; 4) conclusions from

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

the Stakeholder workshop; 5) how to structure the Opinion and allocate tasks in the WG. These items will be part of the draft agenda of the meeting which will be sent to Experts by end of January.

10. Any Other Business

None

11. Next meeting(s)

Next meetings will be the following:

- 19 February 2015, Paris
- 28-29 May 2015, Parma
- 7 July, Paris
- 24-25 September, Parma
- 3-4 December, Parma