

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 15th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 6 - 8 June 2016, Parma
(Agreed on 5 July 2016)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Susanne Hougaard Bennekou and Gerrit Wolterink

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Juan Manuel Parra Morte, Rositsa Serafimova and Andrea Terron

- **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 14th Working Group meeting held on 8 - 9 February 2016, Parma.

The minutes of the 14th Working Group meeting held on 8-9 February 2016 were agreed.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁵

The comments received during the public consultation procedure were discussed and agreement on replies/addressing was reached. The draft guidance has been amended reflecting the relevant comments. The WG agreed the draft to be present to the PPR Panel for discussion and possible adoption during the plenary meeting 22-23 June, 2016.

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/assets/ResidueDef.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

6. Any Other Business

Not Applicable

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 14th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 8 – 9 February 2016, Parma
(Agreed on 6 June 2016)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Susanne Hougaard Bennekou and Gerrit Wolterink

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Juan Manuel Parra Morte, Federica Ruffo, Rositsa Serafimova and Andrea Terron

- **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 13th Working Group meeting held on 12 – 13 January 2016, Parma.

The minutes of the 13th Working Group meeting held on 12-13 January 2016 were agreed.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁵

The draft guidance has been finalised. The WG agreed the draft to be present to the PPR Panel for discussion and possible endorsement before launching of a public consultation.

6. Any Other Business

Not Applicable

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

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

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

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

7. Next meeting(s)

6 pm – 7 (whole day) – 8 am June 2016, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 13th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 12 - 13 January 2016, Parma (Italy)
(Agreed on 8 February 2016)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Susanne Hougaard Bennekou and Gerrit Wolterink

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Federica Ruffo, Rositsa Serafimova

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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>.

Apologies were received from Susanne Hougaard Bennekou on 13 January.

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 30 November - 2 December 2015, Parma.

The minutes of the 12th Working Group meeting held on 30 November-2 December 2015 were agreed.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁵

The input data used for classification of metabolites as major/minor and exposure assessment were discussed. Module 3 (decision making scheme for residue definition) was also discussed and changes were done.

Case studies were discussed and changes reflect the changes in the guidance were done.

6. Any Other Business

Not Applicable

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/assets/ResidueDef.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

7. Next meeting(s)

8 pm – 9 (whole day) February 2016, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 12th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 30 November – 2 December 2015, Parma (Italy)
(Agreed on 12 January 2016)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Susanne Hougaard Bennekou and Gerrit Wolterink

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte, Federica Ruffo, Rositsa Serafimova

- **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 11th Working Group meeting held on 22-23 September 2015, Parma.

The minutes of the 11th Working Group meeting held on 22-23 September 2015 were agreed.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁵

Guidance

Module 3 (decision making scheme for residue definition) was discussed and changes were done.

Introduction and uncertainties part were discussed and action points for finalisation of the draft were noted.

Case studies were discussed and changes reflect the changes in the guidance were done.

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

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

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

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

6. Any Other Business

Not Applicable

7. Next meeting

12 (whole day) – 13 (morning) January 2016, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 11th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 22-23 September 2015, Parma
(Agreed on 30 November 2015)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Susanne Hougaard Bennekou, Bernadette Ossendorp

- **Hearing Experts¹:**

Bruno Urbain (EMA)

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte, Federica Ruffo

Food Ingredients and Packaging Unit: Rositsa Serafimova

- **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 Gerrit Wolterink.

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 23 June 2015, Parma.

The minutes of the 10th Working Group meeting held on 23 June 2015 were agreed.⁴

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁵

Case Studies

The second case study was discussed; changes in the text were done. It was agreed a quality check to be performed.

The WG discussed the third case study in the part of exclusion of genotoxicity.

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

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

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

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

Guidance

The text of the guidance was reviewed and discussed (Modules 2 and 3).

6. Any Other Business

Not Applicable

7. Next meeting(s)

30 (afternoon) November – 2 (morning) December 2015, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 10th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

**Held on 23 June 2015, Parma
(Agreed on 22 September 2015)**

Participants

- **Working Group Members:**

Thomas Kuhl (chair), Metka Filipič, Susanne Hougaard Bennekou, Bernadette Ossendorp

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte

Food Ingredients and Packaging Unit: Rositsa Serafimova

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alberto Mantovani.

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 9th Working Group meeting held on 26 May 2015, Parma.

The minutes of the 9th Working Group meeting held on 26 May 2015 were agreed.³

5. Scientific topic(s) for discussion

5.1. Preparation of guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)⁴

Case study

The working group widely discussed the second case study and amended parts of the text accordingly. Actions for finalisation of the case study were identified.

Guidance

Uncertainties – a general discussion on uncertainties, both in the specific case study as well in the text of the guidance, was done. It was agreed that reference to the Scientific Committee opinion on uncertainties and a more general introductory paragraph should be added to the case studies and to the text of the guidance.

Exposure section – the text was discussed and accordingly amended.

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

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01001>

Testing strategy – discussion on the testing strategy was done. The WG discussed the opportunity to include more options in the text in order to address DART endpoints.

A road map on adoption of the guidance was agreed.

6. Any Other Business

6.1. Not Applicable

7. Next meeting(s)

22 (afternoon) and 23 (morning) of September 2015, Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 9th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 26 May 2015, EFSA, Parma

(Agreed on 23/06/2015)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Bernadette Ossendorp, Susanne Hougaard Bennekou, Metka Filipic

- **Hearing Experts:**

- Andrew Worth (JRC)

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte, Chris Lythgo

FIP Unit: Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Bernadette Ossendorp

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 8th Working Group meeting held on 24 and 25-05 2015

The minutes were agreed on 26 05 2015 and published on the EFSA website on 24 07 2015.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)

Isomers – The working group discussed and reviewed the text proposed at the last meeting in the context of the EFSA proposal mandate for a guidance on isomers.

The working group discussed the case study. The hearing expert, Andrew Worth was questioned on the applicability of (Q)SAR and read across for the exclusion of genotoxicity. The working group appreciated his technical contribution which was considered valuable in the context of the applicability of (Q)SAR and read across as a tool in the risk assessment of pesticide active substances metabolites.

6. Any other business

None

7. Next Meeting

23-24 June 2015 in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 8th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 24 (afternoon) and 25 march 2015, EFSA, Parma

(Agreed on 26/05/2015)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Bernadette Ossendorp (by TC), Susanne Hougaard Bennekou, metka Filipic

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte,

FIP Unit: Rositsa Serafimova

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 7th Working Group meeting held on 21-22. 01. 2015

The minutes were agreed on 24 03 2015 and published on the EFSA website on 24 07 2015.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)

Module 4 - Exposure: the text of the guidance was reviewed and discussed

A proposal text for the evaluation of isomers was discussed

Module 3 – A proposal text and a decision making scheme for residue definition was discussed

The working group discussed the case study

6. Any other business

None

7. Next Meeting

26-27 May 2015 in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 7th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 20 (afternoon) and 21 January 2015, Istituto Superiore della Sanita' (Roma)

(Agreed on 24/03/2015)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Bernadette Ossendorp (by TC), Susanne Hougaard Bennekou

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron

FIP Unit: Serafimova Rositsa (by tc)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Metka Filipic

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 6th Working Group meeting held on 13-12 01 2015

The minutes were agreed on 20 01 2015 and published on the EFSA website on 18 02 2015.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)

Module 2 - General toxicology. The working group discussed and reviewed the decision scheme and supporting text.

Module 4 – Exposure. The working group discussed and reviewed the proposed text and the conditions for exposure analysis.

Module 3 – The working group discussed the decision scheme for residue definition.

The working group discussed the case studies that should be included in the guidance

6. Any other business

None

7. Next Meeting

24-25 March 2015 in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 6th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 03.12.2014 (morning) Parma, EFSA

(Agreed on 20/01/2015)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Bernadette Ossendorp (by TC), Susanne Hougaard Bennekou

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte,

FEED Unit: Serafimova Rositsa

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 5th Working Group meeting held on 07-08 10 2014

The minutes were agreed by written procedure on 3rd December 2014 and published on the EFSA website 19 01 2015.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)

The Working Group discussed and agreed on the assessment of minor metabolites. The Working Group agreed that the assessment of minor metabolites should take into consideration the toxicological profile of the parent and should be complemented by additional elements like uses, number and level of metabolites, number of commodities in which the metabolite is occurring or commonality with other active substances for which data exist. The Working Group also discussed the use of TTC approach for the cumulative toxicological assessment of metabolites

6. Any other business

The text of the guidance was discussed and tasks allocated.

7. Next Meeting

20-21 January 2015 in Rome.

PESTICIDES UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 5th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment.

Held on 07 – 08 October 2014, Parma

(Agreed on 03/12/2014)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Metka Filipič, Bernadette Ossendorp, Susanne Hougaard Bennekou

- **Hearing Experts:**

- none

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

- none

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte, Arianna Chiusolo; Rositsa Serafimova (Pesticides Unit support)

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment ([EFSA-Q-2013-01001](#))

The Working Group (WG) agreed to ask for the nomination of a hearing expert in the field of (Q)SAR in order to receive an update on the application of (Q)SAR for the genotoxicity assessment of chemicals.

The WG reviewed the proposal for the exclusion of genotoxicity that will be presented for feedback at the Standing WG on Genotoxicity of the Scientific Committee.

The WG discussed the boundary conditions for exposure analysis and agreed that the level of uncertainties in using an exposure based approach to identify the metabolites that should be toxicologically characterised might be very high.

The WG discussed the draft text of the guidance covering the toxicological assessment of metabolites.

5. Any other business

The text of the guidance was discussed and tasks allocated.

6. Next Meeting

3 December in Parma

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

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

PESTICIDES UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 4th meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 04 August 2014, Parma

(Agreed on 07/10/2014)

Participants

- **Working Group Experts:**

- Thomas Kuhl (chair), Alberto Mantovani, Metka Filipič

- **Hearing Experts:**

- none

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

- none

- **EFSA:**

Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte (Pesticides Unit support) ; Rositsa Serafimova (Food Ingredients and Packaging Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Bernadette Ossendorp and Susanne Hougaard Bennekou.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment ([EFSA-Q-2013-01001](#))

Genotoxicity strategy

Quality criteria to be considered when using QSAR and read-across as a possible tool in the genotoxicity assessment for pesticides metabolites were presented and discussed.

5. Any other business

The text of the guidance was discussed and tasks allocated.

6. Next Meeting

7 (afternoon) and 8 (morning) of October in Parma.

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

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

PESTICIDES UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 3rd meeting of the Working Group on preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 17 (afternoon) and 18 (morning only) June 2014, Berlin at BfR

(Agreed on 07/10/2014)

Participants

- **Working Group Experts:**
 - Thomas Kuhl (chair), Susanne Hougaard Bennekou, Alberto Mantovani, Bernadette Ossendorp, Metka Filipič (18th morning only by TC)
- **Hearing Experts:**
 - none
- **European Commission and/or Member States representatives:**
 - none
- **EFSA:**
 - Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Metka Filipič who participated to the working group (WG) on the 18th morning by teleconference.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding

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

Declarations of Interests², 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. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment ([EFSA-Q-2013-01001](#))

The following points were presented and discussed:

a) Genotoxicity and general toxicity:

- Report on the case studies following the so far proposed strategy
- Update on (Q)SAR, grouping and read across approach
- Genotoxicity strategy; proposal³
- Genotoxicity and isomers; proposal
- General Toxicity decision scheme: proposal

b) Isomers:

- Up-to-date experience, data requirements and general approach

5. Next Meeting

An *ad-hoc* meeting will be held in Parma on August 4th. The meeting will be dedicated to the in depth evaluation of the examples following the proposal for the possible application of (Q)SAR, grouping and read across.

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

³ <http://www.efsa.europa.eu/en/efsajournal/pub/2379.htm>

PESTICIDES UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 2nd meeting of the Working Group for the preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment.

Held on 25 (afternoon) and 26 (morning only) March 2014, Parma

(Agreed on 16 June 2014)

Participants

- **Working Group Experts:**
 - Thomas Kuhl (chair)
 - Susanne Hougaard Bennekou
 - Alberto Mantovani
 - Bernadette Ossendorp
 - Metka Filipc (26th morning only)
- **Hearing Experts:**
 - none
- **European Commission and/or Member States representatives:**
 - none
- **EFSA:**
 - Pesticides Unit: Anja Friel, Andrea Terron, Juan Parra Morte, Manuela Tiramani (25th afternoon only)

1. Welcome and apologies for absence

The Chair welcomed the participants. The second day the chair welcomed Metka Filipc as a new member of the working group.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Adoption of the minutes of the last Working Group meeting.

The minutes were agreed.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment (EFSA-Q-2013-01001)

Update and explanation of the strategy chart

The working group discussed the overall strategy approach to be applied in the guidance.

Genotoxicity strategy

The working group discussed options to define gates and triggers for the genotoxicity hazard assessment and decision tree. The different scenario proposed will be tested in different case studies before a final decision will be taken. Inclusion of (Q)SAR, grouping and read-across were considered as possible tools to apply in the genotoxicity hazard assessment.

Presentation and discussion of the relevant information extracted from guidance documents and opinions and discussion on steps forward

This was presented and discussed by the working group.

Next meeting will be held in Berlin on 17th (afternoon) and 18th (morning) of June.

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

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

PESTICIDES UNIT

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 1st meeting of the Working Group for the preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment

Held on 10 (afternoon) and 12 (morning only) February 2014, Parma

(Agreed on 25/03/2014)

Participants

1. Working Group Experts:

- Thomas Kuhl (chair)
- Susanne Hougaard Bennekou
- Alberto Mantovani
- Bernadette Ossendorp

2. Hearing Experts:

- none

3. European Commission and/or Member States representatives:

- none

4. EFSA:

Pesticides Unit: Anja Friel, Andrea Terron,
Manuela Tiramani (12 Feb only)

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Nomination of the rapporteur/s

The Working Group members nominated the rapporteurs.

5. Scientific topic(s) for discussion

Preparation of a guidance of the PPR Panel on the establishment of the residue definition for dietary risk assessment ([EFSA-Q-2013-01001](http://www.efsa.europa.eu/en/keydocs/docs/independencerule.pdf))

5.1 Develop common understanding of the content (scope), tasks required, and work plan for accomplishment of the mandate

The OECD guidance was recognized by the Working Group as a 'cornerstone' for the development of a guidance document on the residue definition for risk assessment.

The Working Group agreed that the 2012 Scientific Opinion on the relevance of metabolites will represent an important tool for the development of the guidance. However, the Working Group recognised and agreed that exposure to metabolites can only be calculated with many uncertainties, making the use of a TTC approach not workable as a sole criteria in a standard approach.

The guidance would represent a practical instrument for applicants, risk assessors and regulatory authorities to adopt the pesticide residue definition for risk assessment based on a combination of scientific tools. The guidance should also be used for identifying cases where further experimental data are needed.

5.2 Discuss and define the outline of the guidance and assignment of the task

The Working Group discussed the breakdown structure of the guidance document, and tasks were assigned to the members.

6. Next Meeting

Next meeting will be held in Parma on 25th (afternoon) and 26th (morning) of March 2014.

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

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