



EFSA Working group of Pesticides Residues Unit

Minutes of the 18th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid and of the 10th meeting of the EFSA Working Group on the cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid (joint meeting)

Held on 27-29 January 2020, Parma

(Agreed on 07 February 2020)¹

Participants

■ Working Group Members:

Andrew David Hart, Susanne Hougaard-Bennekou, Bernadette Ossendrop, Antonion Hernandez-Jerez, Gerrit Wolterink, Peter Craig (29 January) and Carsten Kneuer (27 and 29 January)

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.



- EFSA:
The Pesticides Residues unit: Luc Mohimont (chair)
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Bruno Dujardin.

2. Adoption of agenda

The agenda was adopted with changes at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 EFSA Scientific reports on the cumulative risk assessment of pesticides residues regarding 2 acute effects of the nervous system and 2 chronic effects on the thyroid ([EFSA-Q-2018-00345](#) and [EFSA-Q-2018-00346](#))

The Working Group considered the responses to the comments submitted during the public consultation and discussed new versions of the 2 scientific reports, updated following these comments.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



5. Any Other Business

5.1. Not Applicable

6. Next meeting(s)

Not applicable



EFSA Working group of Pesticides Residues Unit

Minutes of the 17th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid and of the 8th meeting of the EFSA Working Group on the cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid (joint meeting)

Held on 29-31 July 2019, Parma

(Agreed on 13 August 2019)

Participants

- Working Group Members:
Andrew David Hart, Bernadette Ossendrop, Antonio Hernandez-Jerez
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Residues unit: Luc Mohimont (chair)
DATA Unit: Bruno Dujardin



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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

The meeting participants were invited to draw lessons from the cumulative risk assessments conducted for the nervous system and the thyroid and to make recommendations to optimize the different steps of the process (hazard identification and characterisation / exposure assessment / uncertainty analysis and risk characterisation). They were also asked to consider alternative leaner approaches based on exposure and/or toxicological screening and their advantages, requirements, limitations.

The outcome of the discussions and proposals were collected in a working document for EFSA consideration in the context of the planning of the forthcoming phases of implementation of cumulative risk assessment of pesticide residues.

5. Next meeting(s)

Not Applicable

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



EFSA Working group of Pesticides Residues Unit

Minutes of the 16th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid and of the 7th meeting of the EFSA Working Group on the cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid (joint meeting)

Held on 14-16 May 2019, Parma

(Agreed on 17 June 2019)

Participants

■ Working Group Members:

Andrew David Hart, Susanne Hougaard-Bennekou, Bernadette Ossendrop, Antonio Hernandez-Jerez, Gerrit Wolterink, Peter Craig and Carsten Kneuer

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticide Residues unit: Luc Mohimont (chair), Ragnor Pedersen

DATA Unit: Bruno Dujardin, Petra Gergelova



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Federica Crivellente, Antonio Hernández-Jerez, Paula Medina, Hermine Reich and Andrea Terron.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

EFSA Scientific reports on the cumulative risk assessment of pesticides residues regarding 2 acute effects of the nervous system and 2 chronic effects on the thyroid ([EFSA-Q-2018-00345](#) and [EFSA-Q-2018-00346](#))

The 2 working groups proceeded with the uncertainty analyses regarding the cumulative risk assessment of pesticide residues for 2 acute effects on the nervous system and 2 chronic effects on the thyroid. This was done in a three-step process using the Expert Knowledge Elicitation technique.

5. Any Other Business

5.1. Not Applicable

6. Next meeting(s)

Not Applicable

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



EFSA Working group of Pesticides Residues Unit

Minutes of the 15th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid

Held on 09-11 April 2019, Parma

(Agreed on 6 May 2019)

Participants

- Working Group Members:
Andrew David Hart, Susanne Hougaard-Bennekou and Gerrit Wolterink
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
The Pesticides Residues unit: Luc Mohimont (chair)
- Others:
Not Applicable



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Federica Crivellente and Andrea Terron.

2. Adoption of agenda

The agenda was adopted without changes at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 EFSA Scientific reports on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system and thyroid

The Working Group considered the comments received during the public consultation on the draft scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the thyroid. Replies and changes to the draft report were agreed.

Based on some of these comments, updated lines of evidence and further verification of the database, the Working Group repeated the Expert Knowledge Elicitation session regarding the capability of active substances included in the cumulative assessment group for hypothyroidism to produce this effect.

5. Any Other Business

5.1. Not Applicable

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



6. Next meeting(s)

The next meeting of the Working group will take place on 14 to 16 May 2019 in Parma



EFSA Working group of Pesticides Residues Unit

Minutes of the 14th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid (teleconference)

Held on 14 March 2019, Parma

(Agreed on 04 March 2019)¹

Participants

- Working Group Members:
Andrew David Hart, Antonio Hernandez, Susanne Hougaard-Bennekou, and
Gerrit Wolterink.
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
The Pesticides Residues unit: Luc Mohimont (chair)
- Others:

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.



Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Federica Crivellente and Andrea Terron.

2. Adoption of agenda

The agenda was adopted at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 EFSA Scientific reports on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system and thyroid

The Working group finalised the updated draft scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system in view of the endorsement process of the PPR panel.

5. Any Other Business

5.1. Not Applicable

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



6. Next meeting(s)

The next meeting will take place on 09-11/04/2019.

EFSA Working group of Pesticides Residues Unit

Minutes of the 13th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid (teleconference)

Held on 7 March 2019, Parma

(Agreed on 15 March 2019)¹

Participants

- Working Group Members:
Andrew David Hart, Antonio Hernandez, Susanne Hougaard-Bennekou, and Gerrit Wolterink.
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
The Pesticides Residues unit: Luc Mohimont (chair)
- Others:
Not Applicable

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Federica Crivellente and Andrea Terron.

2. Adoption of agenda

The agenda was adopted changes at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 **EFSA Scientific reports on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system and thyroid**

The Working Group agreed on a modified list of lines of evidence and respective weights regarding the actual capacity of active substances included in the cumulative assessment group on hypothyroidism to cause this effect.

The Working group also discussed an updated version of the draft scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system in view of its submission to the PPR panel for endorsement before final approval.

5. Any Other Business

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



5.1. Not Applicable

6. Next meeting(s)

The next teleconference will take place on 14 March 2019.

EFSA Working group of Pesticides Residues Unit

Minutes of the 12th meeting of the EFSA working group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid and of the 5th meeting of the EFSA Working Group on the cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid (joint meeting)

Held on 27-28 February 2019, Parma

(Agreed on 15 March 2019)¹

Participants

■ Working Group Members:

Andrew David Hart, Susanne Hougaard-Bennekou, Bernadette Ossendrop and Gerrit Wolterink.

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

The Pesticides Residues unit: Luc Mohimont (chair)

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.



The Evidence Management Unit: Bruno Dujardin, Ti Kian Seow

- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Federica Crivellente, Antonio Hernández-Jerez, Paula Medina, Hermine Reich and Andrea Terron.

2. Adoption of agenda

The agenda was adopted changes at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 State of play

The participants were informed about the ongoing procedure for the inclusion of 2 additional experts in the Working Group on the cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid.

Furthermore, the following was recently published by EFSA:

- The technical report on the raw primary commodity (RPC) model: strengthening EFSA's capacity to assess dietary exposure at different levels of the food chain, from raw primary commodities to foods as consumed;

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



- The draft EFSA Scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the thyroid.

4.2 EFSA Scientific reports on the cumulative risk assessment of pesticides residues regarding 2 acute effects of the nervous system and 2 chronic effects on the thyroid ([EFSA-Q-2018-00345](#) and [EFSA-Q-2018-00346](#))

The participants discussed the results of the cumulative exposure assessment to pesticides regarding their combined chronic effects on the thyroid using SAS[®] Software, the sensitivity analyses and the identified risks drivers.

The information collected so far to support the uncertainty analyses was discussed. Elicitation questions and a precise work plan to achieve the overall uncertainty analysis were defined.

5. Any Other Business

5.1. Not Applicable

6. Next meeting(s)

The next joint meeting of the 2 Working groups will take place on 14 to 16 May 2019, Parma

EFSA Working Group of the Pesticides Unit

Minutes of the 11th EFSA Working Group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid

Held on 17-18 January 2019

(Agreed 01 February 2019)

Participants

- **Working Group Members:**

Andrew David Hart, Susanne Hougaard-Bennekou, Antonio Hernández-Jerez and Gerrit Wolterink.

- **Hearing Experts:**

Not applicable

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

Not Applicable

- **EFSA:**

The Pesticides Unit: Federica Crivellente, Luc Mohimont (chair)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 EFSA Scientific report on the establishment of cumulative risk assessment of pesticides regarding their effects on the nervous system ()

The Working Group revised the toxicological characterisations of the active substances included in the cumulative assessment groups, following revised principles, which derived from the public consultation conducted in May 2018.

4.2 EFSA Scientific report on the establishment of cumulative risk assessment of pesticides regarding their effects on the thyroid ([EFSA-O-2017-00436](#))

The Working Group finalised the draft report in view of its endorsement by the PPR Panel and the public consultation.

5. Any Other Business (if applicable)

Not applicable

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

6. Next meeting

- 17 and 18 January 2019, 27 and 28 February 2019, 9 to 11 April 2019 and 14 to 16 May 2019, Parma
- Teleconference 7 and 14 March 2019

EFSA Working Group of the Pesticides Unit

Minutes of the 10th EFSA Working Group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid

Held on 13-14 December 2018

(Agreed 11 January 2019)

Participants

- **Working Group Members:**

Andrew David Hart, Susanne Hougaard-Bennekou, Antonio Hernández-Jerez and Gerrit Wolterink.

- **Hearing Experts:**

Not applicable

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

Not Applicable

- **EFSA:**

The Pesticides Unit: Federica Crivellente, Luc Mohimont (chair)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 State of play

EFSA gave feedback from the Third EuroMix workshop on international harmonisation on the risk assessment of combined exposures to chemicals and in particular regarding the discussion on the EFSA approach to establish cumulative assessment groups of pesticides.

4.2 EFSA Scientific report on the establishment of cumulative risk assessment of pesticides regarding their effects on the thyroid ([EFSA-Q-2017-00436](#))

Following some issues identified regarding the toxicological characterisation of pesticides included in the cumulative assessment groups for hypothyroidism and calcium imbalance, EFSA made a reassessment of a number of active substances and discussed the outcome with the Working Group. Remaining issues regarding the content of the Scientific Report were discussed.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4.3 Joint meetings with the EFSA WG on cumulative risk assessment

The WG agreed to lead the uncertainty analysis related to the hazard component of the cumulative risk assessments for the effects of pesticides on the nervous system and the thyroid and to meet jointly with the WG on cumulative risk assessment in view of the overall uncertainty analysis.

5. Any Other Business (if applicable)

Not applicable

6. Next meeting

- 17 and 18 January 2019, 27 and 28 February 2019, 9 to 11 April 2019 and 14 to 16 May 2019, Parma
- Teleconference 7 and 14 March 2019

EFSA Working Group of the Pesticides Unit

Minutes of the 9th EFSA Working Group on the establishment of cumulative assessment groups for effects on the nervous system and the thyroid

Held on 9/10 October 2018

(Agreed 21 November 2018)

Participants

- **Working Group Members:**

Andrew David Hart, Susanne Hougaard-Bennekou, Antonio Hernández-Jerez and Gerrit Wolterink.

- **Hearing Experts:**

Not applicable

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

Not Applicable

- **EFSA:**

The Pesticides Unit: Consuelo Civitella (first day), Daniele Court-Marques (first day), Federica Crivellente, Luc Mohimont (chair)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

Following a meeting of the EC WG on risk management questions related to cumulative risk assessment, new modelling assumptions to be used in tier 1 and 2 of Cumulative exposure assessment have been agreed. An official letter of the commission is expected at short term requesting recalculations with the MCRA following these assumptions. This will imply a postponement of the deadline of the entire project (tentatively estimation: end of June 2019).

The WG reviewed major changes to the document triggered by the public consultation, affecting all sections as described in the minutes of the 8th meeting of this Working Group. The process to allocate surrogate values to active substances with missing NOAELs was discussed and tested.

4.2 EFSA Scientific report on the establishment of cumulative risk assessment of pesticides regarding their effects on the thyroid ([EFSA-Q-2017-00436](#))

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

A revised version of the report, although still under construction, was briefly presented and discussed. It was prepared using as model the draft report on CAGs for the nervous system, as the main conceptual steps are the same in both cases.

5. Any Other Business (if applicable)

Not applicable

6. Next meeting

25 October, teleconference

13 and 14 December 2018, Parma

EFSA WG of the Pesticides Unit

Minutes of the 8th meeting of the Working Group on the establishment of cumulative assessment groups on the nervous system and the thyroid

Held on 20, 21 and 22 June 2018, Parma (Italy)

(Agreed on 31 August 2018)

Participants

- **External Experts:**

Andrew David Hart, Antonio Hernandez Jerez, Susanne Hougaard-Bennekou, Gerrit Wolterink

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Federica Crivellente, Luc Mohimont (Chair), Andrea Terron

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court-Marques.

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. Scientific topic for discussion

4.1. EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

The Working Group met in order to review the comments submitted on the draft scientific report during the public consultation. Very draft answers were elaborated for each comment.

It was agreed to inform the PPR Panel on the following main changes intended by the Working Group in view of preparing a final version of the scientific report by EFSA:

Section 1 (Introduction and TORs):

- Inclusion of additional information regarding important legal incentives and constraints

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Section 2 (Data and methodologies):

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

Section 3 (Assessment):

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

Section 4 (uncertainty analysis)

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

Section 5 (Recommendations)

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

The PPR Panel will be invited to consider endorsing these amendments. A new version of the Scientific Report implementing these changes will be prepared and circulated to the Working Group.

5. Next meetings

9 and 10 October 2018, Parma

25 October, teleconference

13 and 14 December 2018, Parma

EFSA WG of the Pesticides Unit

Minutes of the 7th meeting of the Working Group on the establishment of cumulative assessment groups on the nervous system and the thyroid

Held on 2 and 3 May 2018, Parma (Italy)

(Agreed on 31 August 2018)

Participants

- **External Experts:**

Andrew David Hart, Antonio Hernandez Jerez, Susanne Hougaard-Bennekou, Gerrit Wolterink

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Federica Crivellente, Luc Mohimont (Chair), Andrea Terron

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court-Marques.

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. Scientific topic(s) for discussion

4.1. EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

The comments made by the PPR Panel and the 2 scientific reviewers had been circulated to the members of the Working Group in advance of the meeting.

The meeting was fully dedicated to the preparation of a new version of the draft scientific report, making use of these comments and addressing a number of pending issues, including the internal consistency of the document.

The Working Group agreed to proceed with the formal consultation of the PPR Panel for endorsement in view of the public consultation.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5. Next meeting

20, 21 and 22 June 2018, Parma

EFSA WG of the Pesticides Unit

Minutes of the 6th meeting of the Working Group on the establishment of cumulative assessment groups on the nervous system and the thyroid

Held by teleconference on 11 April 2018

(Agreed on 31 August 2018)

Participants

- **External Experts:**

Andrew David Hart, Antonio Hernandez Jerez, Susanne Hougaard-Bennekou, Gerrit Wolterink

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Federica Crivellente, Luc Mohimont (Chair), Andrea Terron

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court-Marques.

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. Scientific topic for discussion

4.1. EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

The Working group discussed a version of the draft scientific report which was prepared on the basis of the outcome of the previous meetings of the Working Group. The input of a discussion group of the PPR Panel, organised during the plenary meeting of 15 March 2018, in particular regarding the second uncertainty question (see minutes of the 4th meeting), was also considered. The contribution of participants was collected during the meeting.

The Working Group agreed to circulate an updated draft following the discussion to the PPR Panel for comments and scientific review by 2 members.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5. Next meeting

2-3 May 2018, Parma

EFSA WG of the Pesticides Unit

Minutes of the 5th meeting of the Working Group on the establishment of cumulative assessment groups on the nervous system and the thyroid

Held on 5 and 6 March 2018, Parma (Italy)

(Agreed on 31 August 2018)

Participants

- **External Experts:**

Andrew David Hart, Antonio Hernandez Jerez, Susanne Hougaard-Bennekou, Gerrit Wolterink

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Federica Crivellente, Luc Mohimont (Chair), Olaf Mosbach-Schulz, Andrea Terron, Daniela Tomcikova

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court-Marques.

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. Scientific topic for discussion

4.1. EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

The Working Group discussed and agreed on 7 subgroups of active substances to be handled in the expert knowledge elicitation process.

Five experts participated to the expert knowledge elicitation process dealing with the first uncertainty question agreed during the 4th Working Group meeting. Each expert made first an own assessment and the individual assessments were subsequently discussed collegially. Collective agreements were reached for all 7 sub-groups.

With respect to the second uncertainty question agreed during the 4th Working Group meeting, the elements to consider were discussed and included the known or presumed modes of action, the number of known or presumed modes of action, adverse outcome pathways, toxicokinetics and chemical structures. This topic will be referred to the PPR Panel in order to gather the views of some of its members.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

It was agreed that EFSA would produce a draft of the scientific report and coordinate individual contributions in view of a consultation of the PPR panel followed by a public consultation.

5. Next meeting

11 April, teleconference

EFSA WG of the Pesticides Unit

Minutes of the 4th meeting of the Working Group on the establishment of cumulative assessment groups on the nervous system and the thyroid

Held on 20 and 21 February 2018, Parma (Italy)

(Agreed on 31 August 2018)

Participants

- **External Experts:**

Andrew David Hart, Antonio Hernandez Jerez, Gerrit Wolterink

- **Hearing Experts:**

Not Applicable

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

Not Applicable

- **EFSA:**

Eugen Christoph, Federica Crivellente, Luc Mohimont (Chair) and Olaf Mosbach-Schultz

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court-Marques, Susanne Hougaard-Bennekou and Andrea Terron.

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. Scientific topic for discussion

4.1. EFSA scientific report on the establishment of cumulative assessment groups of pesticides for their effects on the nervous system ([EFSA-Q-2017-00434](#))

The Working Group confirmed and further defined the specific effects of pesticides on the nervous system established by the PPR Panel in 2013 and of relevance for cumulative risk assessment. It agreed that one single cumulative assessment group (CAG) was appropriate for effects of both acute and chronic nature, in which active substances would be characterised in view of acute and chronic assessments. Indicators of these effects were discussed and consolidated.

The Working Group will dedicate a specific focus to the acetyl cholinesterase inhibition and the functional alteration of the motor division, because these 2 effects were selected by EFSA to perform cumulative risk assessments in a pilot phase of the implementation of

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

this new methodology. For these effects, it was agreed to perform an uncertainty analysis addressing 2 questions:

- How sure is it that these CAGs contain all the active substances causing the specific effect, and only those causing it?
- How sure is it that these active substances combine their individual toxicities according to the dose-addition model?

The first question will be addressed by the methodology of expert elicitation knowledge. To prepare for this exercise, the Working Group identified the relevant lines of evidence and weighted them. It was agreed that all active substances included in the CAG for neurochemical effects should also be included in the CAG for the effects on the motor division, as the biochemical mechanism of action was recognized to be a strong line of evidence in both cases.

It was agreed that lines of evidence would be collected for all active substances in the CAGs and, considering their number in the CAG for the effects on the motor division, that a proposal to allocate them in sub-groups of similar evidence and manageable size would be prepared in view of the forthcoming meeting.

5. Next meeting

5-6 March 2018, Parma

EFSA WG of the Pesticide Unit

Minutes of the 3rd meeting of the Working Group on the establishment of cumulative assessment groups (CAGs) for effects on the nervous system and the thyroid

Held on 22-24 January 2018, Parma (Italy)

(Agreed on 9 February 2018)

Participants

- **Working Group Members:**

Andy Hart

Susanne Hougaard-Bennekou

Antonio Hernandez Jerez

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **Observers:**

Not Applicable

- **EFSA:**

- Pesticides Unit: Federica Crivellente (chair), Luc Mohimont and Andrea Terron

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>.

- AMU Unit: Monica Aryeety, Eugene Christoph, Olaf Mosbach-Schultz

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court Marques.

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. Scientific topic(s) for discussion

4.1. Update of the weight of evidence of CAG2B

The weight of evidence on CAG2B (substances affecting the follicular cells and/or thyroid hormone (T3/T4) system) was updated with additional information and discussed amongst experts.

4.2. Weighting of evidence and grouping of substances⁴

The criteria and weightings were further discussed in order to evaluate if the effect secondary to liver effects should be treated as a separate question.

4.3. Protocol for expert knowledge elicitation

The protocol for elicitation by following the Sheffield approach using a modified version of the 'roulette' method was presented.

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

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

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

4.4. Expert knowledge elicitation for substances included in the CAGs for effects on the thyroid

The elicitation was carried out separately for each of the 7 sub-groups of pesticides identified in the weight of evidence assessment.

4.5. Next steps: including planning possible follow-up elicitation on the plausibility of dose addition for pesticides allocated in CAG2B

It was agreed that the effects which are considered a consequence of effects on the liver should be assessed separately.

5. Next meeting

20-21 February 2018, Parma

EFSA WG of the Pesticide Unit

Minutes of the 2nd meeting of the Working Group on the establishment of cumulative assessment groups (CAGs) for effects on the nervous system and the thyroid

Held on 11-12 October 2017, Parma (Italy)

(Agreed on 5 December 2017)

Participants

- **Working Group Members:**

Andy Hart

Susanne Hougaard-Bennekou

Antonio Hernandez Jerez

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **Observers:**

Andrea Richarz (JRC)

- **EFSA:**

- Pesticides Unit: Arianna Chiusolo, Federica Crivellente (chair), Kucheryavenko Olena, Mohimont Luc and Terron Andrea

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>.

- AMU Unit: Aryeety Monica, Christoph Eugene, Mosbach-Schultz Olaf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Daniele Court Marques.

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.

Andy Hart informed that he will be an assistant tutor for a training on Expert Knowledge Elicitation (training course on general methodology) in Sheffield, in January. This was not considered as leading to any conflict of interests considering that the aim of this WG is to produce a specific and sectorial scientific assessment (article 3.g of the Decision of the Executive Director on the declarations of interest).

4. Scientific topic(s) for discussion

4.1. Grouping of criteria for uncertainty analysis

The discussion was focused on CAG2B (substances affecting the follicular cells and/or thyroid hormone (T3/T4) system) and the need for grouping of substances on the basis of similar combinations of criteria scores, according to the lines of evidence defined for such CAG.

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

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

4.2. Weight of evidence of CAG2B⁴

The revised lines of evidence were presented and discussed. The experts were asked to provide a scoring system to a list of questions regarding the minimum evidence for hypothyroidism. The scores collected were then used to build 7 sub-groups of substances belonging to CAG2B and these sub-groups were then used of the Expert Knowledge Elicitation phase.

4.3. Review of all chapters of the draft EFSA report on CAGs for the thyroid (EFSA-Q-2017-00436)

The experts commented the different chapters in the draft report on CAGs for the thyroid and suggested some changes.

4.4. Protocol for expert knowledge elicitation

Elicitation was carried out by following the Sheffield approach using a modified version of the 'roulette' method. The elicitation was carried out separately for each of the sub-groups of pesticides identified in the weight of evidence assessment.

4.5. Expert Knowledge Elicitation for substances included in the CAGs for effects on the thyroid

The elicitation process was completed for 3 out of 7 sub-groups.

4.6. Next steps: including planning possible follow-up elicitation on the plausibility of dose addition for pesticides in CAG2B

The elicitation process should be finalised for the other sub-groups in order to address question 1 (how certain is it that the active substances included in the cumulative assessment group actually cause hypothyroidism?). The next step would be to address question 2 (which of the active substances included in the cumulative assessment group combine according to the dose-addition model?).

5. Next meeting

22-24 January 2018, Parma

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

EFSA Working Group of the Pesticides Unit

Minutes of the 1st meeting of the Working Group on the establishment of cumulative assessment groups (CAGs) for effects on the nervous system and the thyroid

Held on 6-7 July 2017, Starhotel, Parma (Italy)

(Agreed on 18 August 2017)

Participants

- **Working Group Members:**

Andy Hart

Susanne Hougaard-Bennekou

- **Hearing Experts¹:**

Not Applicable

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

Not Applicable

- **EFSA:**

Pesticides Unit: Arianna Chiusolo, Daniel Court Marques, Federica Crivellente (chair), Marcella De Maglie, Kucheryavenko Olena, Mohimont Luc and Terron Andrea

- **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. Scientific topic(s) for discussion

4.1. Background and summary of the content of the Draft Scientific Reports for effects on the thyroid (EFSA-Q-2017-00436) and nervous system (EFSA-Q-2017-00434)⁴

The content of the draft Scientific Report regarding the establishment of cumulative assessment groups (CAGs) for effects on the thyroid was presented. The weight of evidence approach to be used was discussed.

4.2. Introduction to uncertainty analysis and expert knowledge elicitation⁵

The basic principles of uncertainty analysis were introduced and agreement on problem formulation was reached.

4.3. Expert knowledge elicitation for substances included in the CAGs for effects on the thyroid

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

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

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

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

The expert knowledge elicitation protocol to be applied for CAGs for effects on the thyroid was discussed.

5. Next meeting

11-12 October 2017, Parma