

Thessaloniki, 27-30 June 2017

Scientific Committee Minutes of the 15th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 27-30 June 2017, Thessaloniki (Greece)
(Agreed on 10 July 2017)**

Participants

• **WG Experts:**

Maged Younes (Chair), Tony Hardy, Emilio Benfenati, Peter Craig, Claude Lambre, Geoff Frampton, Andrew Hart, Christer Hogstrand, Robert Luttik, Matthias Greiner¹, David Makowski.

• **EFSA:**

- SCER Unit: Nikolaos Georgiadis
- AMU Unit: Laura Ciccolallo²

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Helene Wahlstroem, Alfonso Siani, Qasim, Chaudhry, Jim Slattery (observer EMA), Georges Fotakis (Observer ECHA), Christian Gortazar Schmidt, Emanuela Testai and Jan Alexander.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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

¹ Participated for the 3rd and 4th day

² Participated for the 1st, 2nd and 3rd day

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

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Scientific topic(s) for discussion

4.1. Review and full consideration of comments received during the public consultation

It was highlighted that the overall feedback from the comments that were received during the public consultation, which lasted from 6 March to 1 May 2017, was positive. The members discussed and addressed the comments and an amended final version of the guidance document was prepared in order to be sent to the EFSA SC for adoption in the July plenary.

4.2. Agreement on the text of annex I and finalization of the guidance text for public consultation

The members will work on the last agreed amendments and send their input via email to the secretariat before the document is sent to the SC.

5. AOB

None

6. Next meeting(s)

n/a

Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting.

With regard to this meeting, Robert Luttkik declared the following interest:

As part of a contract with the Nederlandse Voedsel en Waren Autoriteit, he plans to write a report on tank mixes and sequential use of pesticides in Netherlands in relation also with the potential risks for the surface water. This will be followed by methods and proposals for assessing mixtures.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Parma, 22-23 February 2017

Scientific Committee Minutes of the 14th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 22-23 February 2017, Parma (Italy)
(Agreed on 27 April 2017)**

Participants

- **WG Experts:**

Maged Younes (Chair), Tony Hardy, Emilio Benfenati, Peter Craig¹, Helene Wahlstroem², Alfonso Siani³, Claude Lambre⁴, Geoff Frampton, Andrew Hart, Christer Hogstrand, Robert Luttk, Qasim Chaudhry⁵, Matthias Greiner, David Makowski.

- **EFSA:**

- SCER Unit: Nikolaos Georgiadis, Jean-Lou Dorne

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jim Slattery (observer EMA), Georges Fotakis (Observer ECHA), Christian Gortazar Schmidt, Emanuela Testai and Jan Alexander.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

¹ Participated via teleconference

² Participated via teleconference

³ Participated via teleconference for the 1st day

⁴ Participated via teleconference

⁵ Participated via teleconference for the 1st day

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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 2017, Parma

The minutes of the 13th Working Group meeting held on 12-13 January 2017 were agreed.

5. Scientific topic(s) for discussion

5.1 Comments received at the SC meeting – General discussion and action points

The chair of the WG updated the members on the feedback received from the SC members during the February plenary where the document was endorsed for public consultation. He highlighted the fact that the SC welcomed the draft output and asked only for minor improvements before the publication of the document for public consultation. The chairman also informed the members about the fact that the SC would like to include all the annexes in the final output for public consultation.

The members of the working group discussed the received inputs and comments and considered those in developing the document.

The chairman assigned related tasks to several members and set deadlines for the receipt of their inputs.

5.2 Agreement on the text of annex I and finalization of the guidance text for public consultation

The WG discussed the last changes on the Annex I of the guidance.

The Annex, as well as the rest of the document, was developed following the comments received from the SC.

5.3 Next steps and timeframe

Specific tasks were assigned to individual members of the WG, focusing on the finalisation of the document before the opening of the public consultation.

6. AOB

None

7. Next meeting(s)

The next working group meeting will take place in Thessaloniki from 27 June (starting at 13:00) until 30 June (ending at 13.00h).

Parma, 12-13 January 2017

Scientific Committee Minutes of the 13th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 12-13 January 2017, Parma (Italy)
(Agreed on 25 January 2017)**

Participants

• **WG Experts:**

Maged Younes (Chair), Emilio Benfenati, Helene Wahlstroem¹, Alfonso Siani², Geoff Frampton, Andrew Hart, Christer Hogstrand, Robert Luttik, Emilio Benfenati, Qasim Chaudhry, Matthias Greiner³.

• **EFSA:**

- SCER Unit: Nikolaos Georgiadis, Jean-Lou Dorne
- NUTRI Unit⁴: Silvia Valtuena Martinez
- PRAS Unit⁵: Andrea Terron, Federica Crivellente, Marcella De Maglie
- BIOCONTAM Unit⁶: Michaela Hempen

1. Welcome and apologies for absence

The Chair welcomed the participants.

The chairman announced that Kristina Thayer is no longer able to participate in the WG as a hearing expert. Kristina has left her position with NIEHS to take over the leadership of the IRIS programme at US EPA. The chairman expressed, on behalf of the whole WG, his gratitude and appreciation for Kristina's valuable contributions to the development of the guidance.

Apologies were received from Tony Hardy, Peter Craig, Jim Slattery (observer EMA), Georges Fotakis (Observer ECHA), Christian Gortazar Schmidt, Emanuela Testai, Jan Alexander, Claude Lambre and David Makowski.

2. Adoption of agenda

The agenda was adopted.

¹ Participated via teleconference

² Participated via teleconference

³ Participated for the 2nd day

⁴ The NUTRI Unit member participated only for the agenda point 5

⁵ The PRAS Unit members participated only for the agenda point 5

⁶ The BIOCONTAM Unit member participated via teleconference only for the agenda point

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 were 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 Parma 29 November – 1 December 2016, Parma

The participants reviewed the draft minutes of the 12th working group meeting held on 29 November – 1 December 2016 in Parma and they were adopted.

The minutes will be published on the EFSA website.

5. Scientific topic(s) for discussion

5.1. Development of Annex I

The WG was presented with the progress on the development of Annex I which will focus on the application of WoE in chemical risk assessment. Two decision trees, one for the human health risk assessment and one for the ecotoxicological risk assessment, were prepared. Also a new shorter version of the introductory part of the annex was presented.

The members of the working group discussed the received inputs and considered those in developing the annex. Overall, the introductory text needed substantial shortening, and the individual examples needed further work. The chairman assigned related tasks to several members and set deadlines for the receipt of their contributions.

5.2. Final discussion on the overall text

The WG discussed some last minor editorial changes on the main text of the guidance. The chairman reminded the WG that the main text had already been updated in light of the comments received during the November SC plenary, and that it was agreed not to amend the text substantially at this point of time.

5.3. Next steps on Annex III

The WG was presented with the progress made on the development of Annex III, which will focus on the case studies to be developed by individual EFSA panels.

As agreed during the previous WG meeting, the Heads of responsible Units in EFSA assigned focal points for each Panel. Each Panel will or already has selected an opinion which has been adopted and which will be used by the focal point in developing a report on their weight of evidence approach applied therein in order to respond to the question identified in their problem formulation.

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

The focal points of the NDA Panel presented their case study and the experts provided their comments. Also, the focal point of the PPR Panel presented two cases proposed for WoE reporting, and asked the experts for their feedback.

The WG agreed to keep in touch with all the focal points and provide the necessary support.

5.4. Next steps and timeframe

Specific tasks were assigned to individual members of the WG, focusing on the finalisation of the annexes.

6. AOB

None

7. Next meeting(s)

The next working group meeting will take place in Parma on 22 February (starting at 09:00) and 23 February (ending at 15.30h).

Parma,
29 November-01 December 2016

Scientific Committee Minutes of the 12th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 29 November-01 December 2016, Parma (Italy)
(Agreed on 12 January 2017)**

Participants

- **Working Group Members:**
Maged Younes (Chair), Emilio Benfenati, Peter Craig¹, Qasim Chaudhry², Geoff Frampton, Andrew Hart, Claude Lambre, Christer Hogstrand, David Makowski, Robert Luttik, Emilio Benfenati.
- **Hearing Experts:**
Kristina Thayer³.
- **European Commission and/or Member States representatives:**
Not applicable
- **EFSA:**
SCER Unit: Nikolaos Georgiadis, Jean-Lou Dorne⁴

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Tony Hardy, Matthias Greiner, Helene Wahlstroem, Jim Slattery (observer EMA), Georges Fotakis (Observer ECHA), Christian Gortazar Schmidt, Alfonso Siani, Emanuela Testai and Jan Alexander.

2. Adoption of the draft agenda

The agenda was adopted.

¹ Participated via teleconference

² Participated via teleconference

³ Participated via teleconference

⁴ Participated via teleconference

3. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Review of the comments received during the November Scientific Committee plenary and update of the guidance

The chairman of the WG represented the WG in the open Scientific Committee plenary in Brussels (November 2016). There, the chairman presented the current version of the guidance document and answered the questions of the SC experts as well as the observers.

The chairman updated the WG members on the feedback received by the SC and highlighted that although it was the first time that the guidance document was sent to the SC, the comments were positive and only minor observations were made. The overall feedback of the SC was that the document reads well, the Terms of Reference had been adequately addressed and that only minor improvements were needed before the document goes for public consultation.

The members of the working group discussed the received comments and considered those in updating the main text of the guidance.

5. Next steps on Annex I

A first draft of Annex I, based on the template in section 5 for summarising weight of evidence assessments, was presented. Three substances were used (emerging contaminant, regulated substance, Cd) to illustrate different types of assessment (emergency, standardised, case-specific) and varying degrees of data availability.

6. Next steps on Annex III

Individual EFSA Panels will select an opinion they have adopted to be used in developing a report on their weight of evidence approach applied to respond to the question identified in their problem formulation.

7. Next steps - Assignment of tasks

Specific tasks were assigned to individual members of the WG, focusing on the finalisation of the annexes.

8. Dates of next meeting(s)

The next working group meeting will take place in Parma on 12 January (starting at 09:00) and 13 January (finishing at 13.00h).

Parma, 25-27 October 2016

Scientific Committee Minutes of the 11th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 25-27 October 2016, Parma (Italy)
(Agreed on 30 November 2016)**

Participants

- **Working Group Members:**

Maged Younes (Chair), Jan Alexander, Emilio Benfenati, Peter Craig, Qasim Chaudhry, Geoff Frampton, Andrew Hart, Claude Lambre¹, Christer Hogstrand², David Makowski, Helene Wahlstroem, Tony Hardy, Robert Luttk, Matthias Greiner.

- **Hearing Experts³:**

None.

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

Not applicable

- **EFSA:**

- SCER Unit: Nikolaos Georgiadis, Jean-Lou Dorne
- BIOCONTAM Unit: Michaela Hempten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies received from, Kristina Thayer, Jim Slattery (observer EMA), Georges Fotakis (Observer ECHA), Christian Gortazar Schmidt, Alfonso Siani, Emanuela Testai and Jan Alexander.

2. Adoption of the draft agenda

The agenda was adopted without changes.

¹ Participation via teleconference

² Participation via teleconference

³ 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>.

3. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Finalisation of the draft guidance document before the November Scientific Committee plenary (without the annexes)

The members of the working group discussed the content of the guidance based on the draft provided and considered the proposals received from members. At this point, the members mainly developed the main text. This part, without the annexes, was agreed to be provided to the SC in order to be discussed during the coming open SC plenary in Brussels (November 2016).

5. Discussion on provided contributions and further drafting tasks

The members of the working group discussed the content of the guidance based on the draft provided, and considered the proposals received from members.

6. Assignment of tasks and deadlines for contributions

The text provided on the approach to weighing the evidence for chemicals considering the data availability will be revised to better reflect its purpose and placed in an annex (Annex I) together with examples for data-rich and data-poor chemicals, as well as for a regulated product.

The previous section with the EFSA approaches on WoE, will be replaced by individual case studies prepared by Panel secretariats with the support of members of the WG on the basis of an existing assessment, and placed in an annex (Annex III).

7. Any Other Business

None

8. Dates of next meeting(s)

The next working group meeting will take place in Parma on 29 November (starting at 14.00h), 30 November and 1 December (finishing at 13.00h).

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Parma, 12-14 September 2016

Scientific Committee Minutes of the 10th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 12-14 September 2016, Parma (Italy)
(Agreed on 25 October 2016)**

Participants

- **Working Group Members:**

Maged Younes (Chair), Jan Alexander, Emilio Benfenati, Peter Craig, Qasim Chaudhry, Geoff Frampton, Andrew Hart, Christer Hogstrand, David Makowski, Alfonso Siani¹, Helene Wahlstroem, Tony Hardy, Robert Luttk, Matthias Greiner, Georges Fotakis (Observer ECHA).

- **Hearing Experts²:**

Kristina Thayer.

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

Not applicable

- **EFSA:**

- SCER Unit: Nikolaos Georgiadis
- PRAS Unit: Andrea Terron
- BIOCONTAM Unit: Marco Binaglia
- FEED Unit: Jaime Aguilera
- NUTRI Unit: Silvia Valtuena Martinez

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies received from, Jim Slattery (observer EMA), Christian Gortazar Schmidt, Claude Lambre and Jan Alexander.

2. Adoption of the draft agenda

The agenda was adopted without changes.

¹ Participation via teleconference

² 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>.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Discussion on provided contributions and further drafting tasks

The members of the drafting working group discussed the content of the guidance based on the draft provided, and considered the proposals received from members.

5. Assignment of tasks and deadlines for contributions

The members screened all the sections of the document and decided to further develop the guidance until the next meeting which will take place in October.

To achieve this, the members were assigned with specific tasks and a reshuffling of the table of content was decided.

6. Any Other Business

None

7. Dates of next meeting(s)

The next working group meeting will take place in Parma on 25 October (starting at 14.00h), 26 October and 27 October (finishing at 13.00h).

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

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Parma, 4-6 July 2016

Scientific Committee Minutes of the of the 9th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 4-6 July 2016, Parma (Italy)
(Agreed on 12 September 2016)**

Participants

- **Drafting Working Group Members:**

Maged Younes (Chair), Jan Alexander, Emilio Benfenati, Peter Craig, Qasim Chaudhry, Geoff Frampton, Andrew Hart, Christer Hogstrand, David Makowski, Alfonso Siani, Helene Wahlstroem, Emilio Benfenati, Tony Hardy, Robert Luttik, Christer Hogstrand.

- **Hearing Experts¹:**

None.

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

Not Applicable

- **EFSA:**

- BIOHAZ Unit: Michaela Hempen
- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Opening, apologies for absence, declarations of interests

The Chair welcomed the participants.

Apologies received from Georges Fotakis (Observer ECHA), Jim Slattery (observer EMA), Christian Gortazar Schmidt, Claude Lambre, Matthias Greiner and Kristina Thayer (Hearing Expert).

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>

2. Adoption of the draft agenda

The agenda was adopted.

3. Declarations of Interest of Working Group 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 Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Discussion on provided contributions and further drafting tasks

The members of the drafting working group discussed the content of the guidance based on the draft provided, and considered the proposals received from members.

5. Assignment of tasks and deadlines for contributions

Tasks were distributed among members of the drafting group to start developing the guidance based on the agreed general framework.

6. Any Other Business

None

7. Dates of next meeting(s)

The next working group meeting will take place in Parma on 12 September (starting at 14.00h), 13 September and 14 September (finishing at 16.00h).

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

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

Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Robert Luttk declared the following interest: He has been invited to present a lecture on uncertainty at two workshops organised on behalf of the Umweltbundesamt (UBA, Federal Environment Agency) of Germany: one on QSARs and one on Read Across. It was noted that the UBA is a government agency.

With regard to this meeting, Andrew Hart and Peter Craig declared the following interest:

They recently gave a course on uncertainty in risk assessment at JRC and one of the case studies used by JRC in the course was an example of Weight of Evidence.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the experts concerned.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Parma, 8-10 June 2016

Scientific Committee

Minutes of the 8th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments (drafting sub-group)

**Held on 8-10 June 2016, Parma (Italy)
(Agreed on 4 July 2016)**

Participants

- **Drafting Working Group Members:**

Maged Younes (Chair), Qasim Chaudhry¹, Geoff Frampton, Andrew Hart, Christer Hogstrand, David Makowski.

- **Hearing Experts²:**

None.

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

Not Applicable

- **EFSA:**

- AMU Unit: Laura Martino

- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Opening, apologies for absence, declarations of interests

No apologies were received.

2. Adoption of the draft agenda

The agenda was adopted.

¹ Participated via teleconference only for the 2nd and 3rd day

² 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>

3. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Discussion on provided contributions and further drafting tasks

The members of the drafting working group discussed the content of the guidance based on the draft provided and agreed on the general framework considering the proposals received from members.

5. Assignment of tasks and deadlines for contributions

Tasks were distributed among members of the drafting group to start developing the guidance based on the agreed general framework, with the aim of providing a first draft of the guidance to the full WG planned for July. The drafting WG agreed on the actions to be taken before the next meeting in Parma.

6. Any Other Business

None

7. Dates of next meeting(s)

4-7 July 2016

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

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Parma, 21-22 April 2016

Scientific Committee

Minutes of the 7th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments (drafting sub-group)

**Held on 21-22 April 2016, Parma (Italy)
(Agreed on 8 June 2016)**

Participants

- **Drafting Working Group Members:**

Maged Younes (Chair), Qasim Chaudhry, Geoff Frampton, Andrew Hart, Christer Hogstrand, David Makowski.

- **Hearing Experts¹:**

None.

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

Not Applicable

- **EFSA:**

- AMU Unit: Laura Martino

- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Opening, apologies for absence, declarations of interests

No apologies were received.

2. Adoption of the draft agenda

The agenda was adopted.

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>

3. Declarations of Interest of Working Group 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 Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Discussion on provided contributions and further drafting tasks

The members of the drafting working group discussed the structure of the table of contents, based on the draft provided, and considering the proposals received from the members. It was decided to put the main focus at this stage on the development of concepts and definitions, to adding details to the evidence flow and the general framework, and to reviewing qualitative and quantitative methods of evidence weighing and integration. The next steps in developing the guidance will be discussed during the June meeting.

5. Assignment of tasks and deadlines for contributions

Tasks were distributed among members of the drafting group to start developing the guidance based on the agreed structure, concentrating on the issues agreed as initial steps, with the aim of providing a first draft of the guidance to the full WG planned for July. The drafting WG agreed on the actions to be taken before the next meeting in Parma planned for June.

6. Any Other Business

None

7. Next meeting(s)

8-10 June 2016

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

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

Parma, 1 April 2016

Scientific Committee

Minutes of the 6th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments (drafting sub-group)

**Held on 1 April 2016 by teleconference
(Agreed on 21 April 2016)**

Participants

- **Drafting Working Group Members:**

Maged Younes (Chair), Qasim Chaudhry, Geoff Frampton, Andrew Hart, Christer Hogstrand, David Makowski, Georges Fotakis (Observer ECHA).

- **Hearing Experts¹:**

None.

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

Not Applicable

- **EFSA:**

- AMU Unit: Laura Martino

- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Opening, apologies for absence, declarations of interests

No apologies were received.

2. Adoption of the draft agenda

The agenda was adopted.

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>

3. Declarations of Interest of Working Group 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 Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Update on ECHA's WoE approach

The ECHA observer presented how ECHA, on the basis of their Guidance and relevant international work, considers the WoE approach and the members were updated on an approach which is followed by an agency with similarities in the risk assessment process.

5. Discussion and agreement on the table of contents

The members of the drafting working group discussed the structure of the table of contents.

It was agreed that the skeleton would follow the guidance on Uncertainty which is currently undergoing a trial phase in order to ensure the consistency between EFSA's relevant documents and enhance the readability of the document. A table of contents was proposed and further amended by the members.

6. Assignment of drafting needs and deadlines

The drafting WG agreed on actions to be taken before the next meeting in Parma which is planned for 21 April, focusing mainly on adding text on the agreed sections.

7. Initial discussion on case studies and agreement on those to be included

The drafting WG considered as quite early to start any discussion on the case studies. It was agreed that the WG be provided with a list including the case study examples of the Guidance on Biological Relevance to assess whether these could apply in the WoE guidance.

8. Assignment of tasks and deadlines for contributions

See point 5 above.

9. 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>

10. Next meeting(s)

21-22 April 2016 (EFSA, Parma)

8-10 June 2016 (EFSA, Parma)

Parma, 18-19 February 2016

Scientific Committee

Minutes of the 5th Meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 18-19 February 2016, Parma (Italy)
(Agreed on 20 May 2016 by written procedure)**

Participants

- **Working Group Members:**

Maged Younes (Chair), Tony Hardy, Emilio Benfenati, Qasim Chaudhry, Peter Craig¹, Geoff Frampton, Andrew Hart, Christer Hogstrand², Claude Lambre, Robert Luttik, David Makowski, Helene Wahlstroem.

- **Hearing Experts³:**

Kristina Thayer

- **EFSA:**

- AFSCO unit: Djien Liem
- AMU Unit: Laura Martino
- BIOCONTAM: Marco Binaglia
- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Opening, Apologies for absence, Declarations of Interests

The Chair welcomed the participants.

Apologies were received by Jan Alexander, Georges Fotakis (Observer ECHA), Jim Slattery (observer EMA), Christian Gortazar Schmidt, Alfonso Siani and Matthias Greiner.

¹ Participation via teleconference

² Participation via teleconference

³ 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>.

2. Adoption of the draft agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 were 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 meeting held on 20-21 October 2015

The minutes were agreed.⁶

5. Where we are:

• Progress made and agreed framework

The members of the WG were updated on the progress made since October 2015 when the last WG meeting took place.

Presentations were given to the WG: one providing a basis for problem formulation in the context of regulated products and contaminants, the other showing a tiered approach based on mapping the type of evidence and data availability in human risk assessment of chemicals. Last but not least, different examples of WoE methods used globally were illustrated.

• Update on WG on Biological Relevance

The WG was updated on the progress of the WG on Biological Relevance and the timelines. A short presentation was also given on the current status of the draft guidance.

• Update on WG on Uncertainty

The WG was updated on the progress of the WG on Uncertainty and its timelines.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁶ <http://www.efsa.europa.eu/sites/default/files/assets/useofweight.pdf>

6. Presentations of individual contributions

The members briefly presented their contributions according to the actions agreed during the last WG meeting.

7. ANSES report on Weight of Evidence

The WG was informed about the ANSES report on the weight of evidence and the approach followed.

8. Human Risk Assessment of chemicals: from qualitative to quantitative methods

A presentation was made to the WG on qualitative and quantitative approaches for integration of evidence, illustrated by the example of the EFSA opinion on BPA. The presentation also highlighted the impact such approaches can have in the guidance.

9. Next steps and timeframe

It was decided to form a sub-WG consisting of five experts tasked with contextualising the guidance and providing a first draft to the WG at the July meeting.

The aforementioned drafting WG will meet initially in April via teleconference in order to organise its work and start drafting the guidance.

10. Any other business

Not applicable

11. Next meeting(s)

1st April 2016 (by telecon)

Scientific Committee

Minutes of the 4th meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 20-21 October 2015, Parma (Italy)
(Agreed on 18 February 2016)**

Participants

- **Working Group Members:**

Tony Hardy (Acting Chair), Emilio Benfenati, Qasim Chaudhry, Peter Craig, Geoff Frampton, Matthias Greiner, Andrew Hart, Christer Hogstrand, Gijs Kleter, Claude Lambre, Robert Luttik¹, David Makowski and Alfonso Siani².

- **Hearing Experts³:**

None.

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

Not Applicable

- **EFSA:**

- AFSCO Unit: (Djien Liem)
- ALPHA Unit: Sybren Vos
- AMU Unit: Elisa Aiassa, Laura Martino
- BIOCONTAM Unit: Marco Binaglia and Michaela Hempen
- FEEDAP Unit: Jaime Aguilera
- FIP Unit: Anna Castoldi, Camilla Smeraldi
- GMO Unit: Antonio Fernandez-Dumont
- NDA Unit: Silvia Valtuena-Martinez

¹ Present on the 2nd day

² Participation via teleconference

³ 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>

- PRAS Unit: Andrea Terron
- SCER Unit: Jean Lou Dorne, Nikolaos Georgiadis

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies received by Jan Alexander, Georges Fotakis (Observer ECHA), Jim Slattery (observer EMA), Kristina Thayer (Hearing Expert), Maged Younes (chair).

2. Adoption of agenda

The agenda was modified. The Chairman proposed to start with a discussion on the Milan conference on WoE and uncertainty.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Summary and outcome of Milan conference

It was highlighted that the main purpose of the Milan conference was innovation in the area of food safety.

The members of the working group discussed the structured approach for weight of evidence and the relationship between weight of evidence and uncertainty as well as the WoE approach in the context of ecological risk assessment.

5. Tasks from previous meetings: Tour de table Presentations of individual contributions

The WG discussed the different definitions of weight of evidence reviewed by the ANSES group.

Afterwards, the members presented their contributions and further discussions took place on the evidence flow. The below pattern was discussed.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Evidence flow

1. Problem formulation; definition of the hierarchy of sub-questions
2. Selection of studies/data extraction
3. Appraisal of evidence
4. 1st level of integration: integrate studies of the same or similar design in order to produce a "line of evidence"
5. 2nd and higher level of integration: integrate different lines of evidence to answer the sub-question
6. Integration of the sub-questions to conclude clearly and transparency on the question (i.e. extent of uncertainty of conclusions, recommendations to decrease uncertainty, any novel communication issues?)

6. Distribution of Tasks

As discussed in the September meeting, the review of definitions and methods in each field under EFSA's remit are needed together with a structured evidence flow and general framework. In parallel, experts can also work on examples and case studies (including problem formulation).

In order to finalise the summary of relevant WoE approaches (including definitions) in each field of expertise: international, European and national scientific advisory bodies (WHO, FAO, FDA, US-EPA, ECHA, EFSA etc), each expert should review what has been produced and finalise as much as possible his/her part.

In addition, each member of the group and relative to the field of expertise, will bring some concrete examples to the group.

Tasks were agreed amongst members of the Group.

7. Next meeting(s)

The next meeting working group meeting will take place in Parma on 18 February 2016 (starting at 14:00h) and 19 February 2016 (finishing at 16.30h).

Scientific Committee

Minutes of the 3rd meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 2-3 September 2015, Parma (Italy)
(Agreed on 20 October 2015)**

Participants

- **Working Group Members:**

Emilio Benfenati, Qasim Chaudhry, Peter Craig, Geoff Frampton, Matthias Greiner, Anthony Hardy, Claude Lambré, Robert Luttik, Andrew Hart, Gijs Kleter, Maged Younes (Chair) participated for all agenda points.

- **Hearing Experts¹:**

None.

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

Not Applicable

- **EFSA:**

- AFSCO Unit: (Djien Liem)
- AMU Unit: (Elisa Aiassa)
- BIOCONTAM: (Michaela Hempen)
- FEEDAP unit: (Jaime Aguilera)
- FIP Unit: (Camilla Smeraldi)
- GMO Unit: (Antonio Fernandez-Dumont)
- PRAS unit: (Andrea Terron)
- SCER Unit: (Jean Lou Dorne)

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 Andrew Hart, Kristina Thayer, George Fotakis (ECHA), Jim Slattery (EMA) and Alfonso Siani.

2. Adoption of agenda

The agenda was modified and adopted. Item 6 was switched with item 5.

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 Declarations of Interest and the Specific Declarations 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Summary and outcome of workshop held in Brussels (29-30 June) on "Increasing Robustness, Transparency and Openness of Scientific Assessments"

The members discussed the workshop questions related to weight of evidence (definitions and examples of frameworks) and implications for the WG.

They further discussed the existing WoE definitions and proposed to further clarify this definition in the context of a scientific assessment taking account that the WoE is the balance of evidence for the question being addressed of reliability, relevance and consistency of the available evidence expressed in terms of relative likelihood of alternative conclusions.

The WG members also shared their experience/views on the development of methods for WoE using qualitative and quantitative approaches and their positive experience with using the WoE approach in terms of transparency and unbiased assessment of evidence to answer the questions.

There was also an update on the current existing WoE framework used internationally.

The group re-discussed the need to further define the evidence flow and terms related to WoE approaches for scientific assessments. The current state of the evidence flow and the terms to be defined is as follows and the discussions included the need to define a case study for environmental risk assessment of chemicals (ERA).

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

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

Evidence Flow and Definitions

Evidence flow

1. Problem formulation; definition of the hierarchy of sub-questions
2. Selection of studies/data extraction
3. Appraisal of evidence
4. 1st level of integration: integrate studies of the same or similar design in order to produce a "line of evidence"
5. 2nd and higher level of integration: integrate different lines of evidence to answer the sub-question
6. Integration of the sub-questions to conclude clearly and transparently on the question (i.e. extent of uncertainty of conclusions, recommendations to decrease uncertainty, any novel communication issues?)

Key concepts for which definitions are needed

1. Weight of evidence (definition under development!)
2. Question (e.g. step of RA such as exposure or hazard identification, hazard characterisation)
3. Sub-question (e.g. within exposure: occurrence)
4. Evidence synthesis
5. Data
6. Evidence
7. Piece of evidence
8. Line of evidence
9. Individual study
10. Relevance
11. Reliability
12. Internal validity
13. External validity
14. Precision
15. Biological plausibility
16. Evidence integration
17. Data scatter
18. Weights

5. Open discussion: case studies and Work Plan

Members of the group discussed in silico methods with specific regards to QSAR and chemicals. It was agreed that potential case studies will also emerge from the relative fields under EFSA's remit as methods and approaches for weighing evidence have been reviewed.

Overall, it has been agreed that each member of the working group will work on their contribution in the document, and will refine and summarise relevant WoE approaches (including definitions) in their field of expertise from international, European and national scientific advisory bodies (WHO, FAO, FDA, US-EPA, ECHA etc ...). In addition, each member of the group will bring initial thoughts to develop case studies in their fields of expertise.

6. Next meeting(s)

The next meeting is planned for 20- 21 October 2015.

Scientific Committee

Minutes of the 2nd meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 11-12 June 2015, Parma (Italy)
(Agreed on 2 September 2015)**

Participants

- **Working Group Members:**

Emilio Benfenati, Qasim Chaudhry, Peter Craig, Geoff Frampton, Matthias Greiner, Anthony Hardy, Claude Lambre, Robert Luttik, Andrew Hart, Gijs Kleter, Maged Younes (Chair) participated for all agenda points on 11-12 June 2015.

Christer Hogstrand and Alfonso Siani participated to all agenda point on 11 June 2015.

Qasim Chaudhry, David Makowski and Jim Slattery participated via teleconference for agenda points 1-6 on 11-12 June 2015.

- **Hearing Experts¹:**

Kristina Thayer (National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP)) did not participate.

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

Not Applicable

- **EFSA:**

- AFSCO Unit: Djien Liem

- AMU Unit: Elisa Aiassa

- BIOCONTAM: Michaela Hempen

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>

- FEEDAP unit: Jaime Aguilera
- FIP Unit: Camilla Smeraldi
- GMO Unit: Antonio Fernandez-Dumont
- PRAS unit: Andrea Terron
- SCER Unit: Jean Lou Dorne

- **Others:**

Georges Fotakis (ECHA), Jim Slattery (EMA)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jan Alexander, Kristina Thayer, Geoff Frampton, David Makowski and George Fotakis (ECHA).

Christer Hogstrand and Alfonso Siani did not participate on 12 June 2015.

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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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

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

4. Scientific topic(s) for discussion

4.1. The use of the weight of evidence approach in scientific assessments⁴

The chair and the secretariat proposed a tour de table to the working group members to summarise frameworks available for the use of weight of evidence in different scientific areas (chemical risk assessment, microbiological risk assessment etc). The group then discussed initial ideas for development of case studies/methods for the use of Weight of evidence in scientific assessments. Finally, the working group discussed the questions for the Brussels Workshop "Increasing robustness, transparency and openness of scientific assessments", to be held on the 29-30th June, in relation to the definitions of the weight of evidence and qualitative and quantitative methodologies.

5. Any Other Business

Not Applicable

6. Next meeting(s)

The next meeting is planned for 2-3 September 2015.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00007>

Scientific Committee

Minutes of the 1st meeting of the Working Group on the use of the weight of evidence approach in scientific assessments

**Held on 19-20 March 2015, Parma (Italy)
(Agreed on 20 April 2015)**

Participants

- **Working Group Members:**

- Emilio Benfenati, Qasim Chaudhry (Chair), Peter Craig, Matthias Greiner, Claude Lambre, Robert Luttik, Alfonso Siani, Maged Younes participated for all agenda points on 19 and 20 March 2015.
- Andrew Hart participated for agenda points 1-7 on 19 March 2015.
- Anthony Hardy participated for agenda points 1-6 on 20 March 2015.
- Geoff Frampton, Christer Hogstrand, Gijs Kleter participated via teleconference for agenda points 1-6 on 20 March 2015.

- **Hearing Experts¹:**

- Kristina Thayer (National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP)) participated for all agenda points on 19-20 March 2015.

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

- Not Applicable

- **EFSA:**

- AFSCO Unit: Djien Liem
- AMU Unit: Elisa Aiassa
- BIOCONTAM: Marco Binaglia, Michaela Hempen
- FEEDAP unit: Jaime Aguilera

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>.

- FIP Unit: Camilla Smeraldi
- GMO Unit: Antonio Fernandez-Dumont
- PRAS unit: Andrea Terron
- Quality Management Unit: Roy Kirby
- SCER Unit: Jean Lou Dorne
- **Others:**
 - Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jan Alexander, David Makowski and George Fotakis (ECHA).

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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Hearing Expert(s)

Dr Kristina Thayer (National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP) was invited to present her views for item 6 on 19 March 2015 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>

5. Scientific topic(s) for discussion

5.1 The use of the weight of evidence approach in scientific assessments⁴

6. Any Other Business

Not Applicable

7. Next meeting(s)

The next meeting is planned for 11-12 June 2015.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00007>