

Scientific Committee

Minutes of the 34th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 15-16 February 2018, Parma (Italy) (Agreed on 28 February 2018)

Participants

• Working Group Members:

Tony Hardy (day 1 pm & day 2), Andy Hart, Laura Maxim, Michael Siegrist

• EFSA:

SCER: Caroline Merten (day 1 pm & day 2)

RISKCOM: Cristina da Cruz, Majlinda Lahaniatis, Anthony Smith

AMU: Olaf Mosbach Schulz

1. Welcome and apologies for absence

Standing in for the WG chair, Tony Smith opened the meeting. No additional declarations of interests were made. Apologies were noted for Natalie Von Goetz.

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 Interest^{2,} 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

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

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



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

4. Scientific topic(s) for discussion

Sub-WG on communication

The group reflected on the comments made by the Scientific Committee Panel Members during the 87th SC Plenary, and prioritized action points and assigned responsibilities. The rest of the meeting was dedicated to testing the overall process to navigate the guidance. The group revised the overall process while discussing EFSA examples of different expressions of uncertainty, in particular 'no expression of uncertainty', 'inconclusive assessment', 'approximate probability', 'probability distribution' and 'two-dimensional probability distributions'.

5. Next meetings

Sub-WG uncertainty communication:

- TC 2 March 2018 (09.30–12.30 CET), preparatory for 35th meeting (part I)
- TC 16 March 2018 (09.30–12.30 CET), preparatory for 35th meeting (part II)
- 11–12 July, 35th meeting, Parma



Scientific Committee

Minutes of the 33rd meeting of the Working Group on Uncertainty in Risk Assessment

Held on 17-18 January 2018, Parma (Italy) (Agreed on 5 February 2018)

Participants

• Working Group Members:

Tony Hardy, Andy Hart, Laura Maxim, Michael Siegrist, Natalie Von Goetz

• EFSA:

SCER: Caroline Merten

RISKCOM: Anthony Smith, Cristina da Cruz, Majlinda Lahaniatis, Giulia Nicolini

AMU: Olaf Mosbach Schulz

1. Welcome and apologies for absence

The chair opened the meeting. No additional declarations of interests were made. No apologies were received.

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 Interest^{2,} 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

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

4. Scientific topic(s) for discussion

Sub-WG on communication

The WG was presented with the outcomes which may result from the uncertainty analyses performed in accordance with the EFSA Guidance on Uncertainty Analysis in Scientific assessments. These outcomes and their definitions will form the basis for structuring recommendations on communication messages, tools and additional considerations. The rest of the meeting was dedicated to finalising the "Evidence sources" chapter, in particular the review of scientific literature.

5. Next meetings

Sub-WG uncertainty communication:

- TC 30 January 2018 (09.30–12.30 CET), preparatory for 34th meeting
- 15-16 February 2018, 34th meeting, Parma
- TC 2 March 2018 (09.30–12.30 CET), preparatory for 35th meeting (part I)
- TC 16 March 2018 (09.30–12.30 CET), preparatory for 35th meeting (part II)
- 11–12 July, 35th meeting, Parma



Scientific Committee

Minutes of the 32nd meeting of the Working Group on Uncertainty in Risk Assessment

Held on 28-29 November 2017, Parma (Italy) (Agreed on 7 December 2017)

Participants

• Working Group Members:

Andy Hart, Laura Maxim, Michael Siegrist, Natalie Von Goetz

• EFSA:

SCER: Caroline Merten RISKCOM: Anthony Smith, Cristina da Cruz, Giulia Nicolini AMU: Olaf Mosbach Schulz, Monica Aryeetey

1. Welcome and apologies for absence

The chair opened the meeting. No additional declarations of interests were made. No apologies were received.

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 Interest^{2,} 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.

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



4. Scientific topic(s) for discussion

Sub-WG on communication

The first draft of the literature review was presented and discussed. After that, the meeting was mainly dedicated to analysing and discussing different types of uncertainty assessment outcomes based on EFSA real examples, for which the sub-WG drew recommendations and constructed messages.

5. Next meetings

Sub-WG uncertainty communication:

- 17-18 January 2018, 33rd meeting, Parma
- TC 30 January 2018, (9.30–12.30), preparatory for 34th meeting
- 15-16 February 2018, 34th meeting, Parma
- TC 16 March 2018, (9.30–12.30), preparatory for 35th meeting



Scientific Committee

Minutes of the 31st meeting of the Working Group on Uncertainty in Risk Assessment

Held on 18-20 October 2017, Parma (Italy) (Agreed on 10 November 2017)

Participants

• Working Group Members:

Tony Hardy (chair), Diane Benford (TC), Peter Craig, Andy Hart, Laura Maxim, Alicja Mortensen, Bernadette Ossendorp, Josef Schlatter, Michael Siegrist, Natalie Von Goetz (TC, Day 3), Michael John Jeger.

• EFSA:

SCER: Caroline Merten, Georgiadis Nikolaos RISKCOM: Anthony Smith, Cristina Da Cruz AMU: Laura Martino, Olaf Mosbach Schulz

1. Welcome and apologies for absence

The Chair opened the meeting. No additional declarations of interests were made. Apologies were received from Kostas Koutsoumanis.

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 Interest^{2,} EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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² 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 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. Review of the final draft of new concise guidance document: Guidance on Uncertainty in EFSA Scientific Assessment

The WG discussed the revised new concise prepared document and provided comments for finalising it.

4.2. Review of final draft of supporting document: Principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment

The WG discussed the prepared supporting document and provided comments for finalising it.

4.3. Sub-WG on communication

A summary of the scientific literature based on the list of references selected during the previous meeting was presented and discussed.

The Sub-WG on communication started to prepare the drafting the Guidance document on communication of uncertainty in scientific assessments (companion GD). The members devised strategies and started drawing recommendations on how to communicate uncertainty based on EFSA outputs with different types of uncertainty assessment outcomes.

5. Next meetings (Sub-WG uncertainty communication):

- 28-29 November 2017, 32nd 17-18 January 2018, 33rd meeting (9 am 6 pm day 1 and 09.00 3. 30 day 2)
- January 2018: Teleconference to prepare presentation to SC on 14-15 Feb (date to be confirmed)
- 15-16 Feb: 5th SWG meeting
- March: SWG meeting (Teleconference) (date to be confirmed).



Scientific Committee

Minutes of the 30th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 19-20 September 2017, Parma (Italy) (Agreed on 6 October 2017)

Participants

• Working Group Members:

Tony Hardy (chair), Diane Benford (TC), Peter Craig, Andy Hart, Kostas Koutsoumanis (Day 1), Laura Maxim, Alicja Mortensen, Bernadette Ossendorp, Josef Schlatter, Michael Siegrist, Natalie Von Goetz (TC), Michael John Jeger (TC).

• EFSA:

SCER: Caroline Merten, Georgiadis Nikolaos

RISKCOM: Smith Anthony

AMU: Martino Laura (Day 1), Mosbach Olaf (Day 2)

1. Welcome and apologies for absence

The chair opened the meeting. No additional declarations of interests were made. No apologies were received.

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 Interest^{2,} EFSA screened the Annual Declaration of

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



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. Review of the new concise guidance document

The WG discussed the revised new concise document and provided comments for improving the readability and utility of the document.

4.2. Review of first interim report of BfR-EFSA FPA on comparison between BfR Guidance and EFSA Guidance

The WG reviewed and discussed the first interim report of Bfr-EFSA FPA on comparison between BfR GD and EFSA GD.

4.3. Review of Workshop report on uncertainty

The WG reviewed and discussed the report on uncertainty. This report describes the structure, contents and outcome of the internal workshop organised by EFSA on the trial of the EFSA guidance document on uncertainty.

4.4. Sub-WG on communication

The Sub-WG on communication drafted the proposed table of contents for the Guidance document on communication of uncertainty in scientific assessment (companion GD). The members discussed and devised strategies for linking the communication GD to the main GD and inclusion/exclusion criteria for academic papers and grey literature. A first selection of papers for the literature review was made.

The Sub-WG on communication members presented and discussed the progress made over the previous 1.5 days. The core WG gave input and approved the table of contents and strategy for the literature review. The core WG provided examples of uncertainty assessment outcomes resulting from the main GD, to be used as examples in the communication GD.

5. Next meetings

Core WG:

- TC 4 October (am 9 12); preparatory meeting for 31st meeting
- 31st meeting ,18 19 October 2017, Parma



Sub-WG uncertainty communication:

- 19-20 October 2017, Parma
- 28-29 November 2017, 32nd meeting, Parma
 17-18 January 2018, 33rd meeting, Parma



Scientific Committee

Minutes of the 29th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 10-11-12 July 2017, Parma (Italy) (Agreed on 28 July 2017)

Participants

• Working Group Members:

Tony Hardy (chair, day 1 & 2), Diane Benford (day 1 and 2), Andy Hart, Kostas Koutsoumanis (Day 1 and 2(AM)), Laura Maxim (Days 2(PM) & 3), Alicja Mortensen (day 1 and 2), Josef Schlatter (day 1 & 2), Michael Siegrist (Days 2 (PM) & 3), Natalie Von Goetz, Michael John Jeger (Day 2, PM).

• EFSA:

SCER: Caroline Merten, Nikolaos Georgiadis (day 1 &2)

RISKCOM: Anthony Smith (day 2 pm & 3),

AMU: Laura Martino (via TC day 1 am)

1. Welcome and apologies for absence

The chair opened the meeting. No additional declarations of interests were made. Apologies were received from Peter Craig and Bernadette Ossendorp.

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

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



Declarations of Interest^{2,} 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. Main points of feedback from workshop participants

The WG discussed the main points of feedback received by the participants during the workshop. A dedicated workshop report will be published in October 2017.

4.2. A detailed proposal for the structure of the new short guidance document

The WG discussed a first draft outline of the short "cookbook" agreed at the workshop. This will become the new short guidance document containing flow charts and will provide cross links to the textbook (revised former guidance document). The table of content with list of sections, main points of each section (as bullets), and draft flow charts were discussed.

4.3. A proposed list of revisions needed in the text book, listing for each section

The WG members discussed the proposed list of revisions needed in the current guidance document which will become the textbook following up on the feedback at the internal workshop. A table was discussed with the needed revisions per headers and sections and the members commented and improved the structure.

4.4. Introduction of new communication experts and time for declaration of interests

The two new experts were introduced to the WG. Following a tour de table the two new experts were offered the floor to ask questions. A lengthy discussion was held on the status of the uncertainty in scientific assessment GD, EFSA's research on communicating uncertainty and the different approaches to the latter as espoused in the literature.

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



There was a discussion on the interlinkage and necessary overlap between the chapter on reporting in the scientific assessment GD and the future communications GD. It was agreed that the communications approach once developed in the new GD should feedback into the reporting section of the scientific assessment GD.

4.5. Discussion & finalization of the ToRs of the guidance on communicating uncertainty

Draft ToRs based on the scientific assessment GD were discussed and elaborated. Three high-level objectives were agreed upon. Specific tasks were then discussed and agreed under each. The tasks were then elaborated upon and a timeline was discussed and agreed. The timeline will be integrated into the project planning.

5. Next meeting

Core WG:

- TC 7 September, preparatory meeting for the 30th meeting
- 30th meeting: 19 20 September 2017, Parma
- TC 4 October (am 9 12); preparatory meeting for the 31st meeting
- 31st meeting ,18 19 October 2017, Parma

Sub-WG uncertainty communication:

- 19-20 September 2017, Parma
- 19-20 October 2017, Parma
- 28-29 November 2017, 32nd meeting, Parma
- 17-18 January 2018, 33rd meeting, Parma



Scientific Committee

Minutes of the 28th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 13-14 June 2017, Parma (Italy) (Agreed on 3 July 2017)

Participants

• Working Group Members:

Tony Hardy (chair), Natalie Von Goetz, Andy Hart, Kostas Koutsoumanis, Michael John Jeger, Alicja Mortensen (day 1), Bernadette Ossendorp (via TC on day 2), Peter Craig (via TC on day 2)

• EFSA:

SCER: Caroline Merten, Georgiadis Nikolaos (day2)

RISKCOM: Francesca Matteucci (day 1), Smith Anthony (day 1),

AMU: Martino Laura

1. Welcome and apologies for absence

The chair opened the meeting and welcomed the new WG member Kostas Koutsoumanis who was nominated by the BIOHAZ panel Apologies were received from Josef Schlatter, Diane Benford and Olaf Mosbach

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 Interest^{2,} EFSA screened the Annual Declaration of

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



Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 27th Working Group meeting held on 29 – 30 March 2017, Parma.

The minutes of the 27th Working Group meeting held on 29-30 March 2017 were agreed.³

5. Scientific topic(s) for discussion

5.1 Results on the survey on communicating uncertainties

The WG discussed the results of the online survey on communicating uncertainties. Following up on the recommendations from the outsourced project on communicating on uncertainties an online survey questionnaire had been developed by a sub group of the WG uncertainty. The aim of the on line survey was to:

- o Improve study design, simplified format
- Ensure compatibility (with previous research)
- Increase and broaden sample size
- Tentative indications > firmer conclusions?

The WG provided further suggestions for revisions of the presentation of the results. The WG was updated on the next steps which include the discussion of the findings with the Member States and the EFSA experts, the inclusion of two social scientists to join WG uncertainty to further develop communications approach as well as the draft of a new guidance on communicating uncertainty, for science communicators to be developed by a sub WG uncertainty

Preparation of the background materials for internal workshop 22-23 June

The overall objective of the workshop is to inform the WG Uncertainty on how to further tailor the draft guidance to make it more fit for purpose for the panels/units needs by discussing the conclusions from

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



the survey on impact analysis and by providing suggestions for revisions for the guidance document.

The WG discussed the case studies and developed a summary table to compare the case studies for each step of the uncertainty analysis framework. Pending gaps were highlighted. The summary table will be part of the background material for the workshop participants to provide a quick overview on all the case studies.

The results from the impact analysis were presented to the WG. The WG members then developed the break out questions for the first 2 breakout sessions at the workshop for the risk assessors and risk managers separately.

Next meeting

• 10 - 11 July 2017, 29th meeting, Parma



Scientific Committee

Minutes of the 27th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 29-30 March 2017, Parma (Italy) (Agreed on 13 June 2017)

Participants

• Working Group Members:

Laurence Castle (for CEF case study, via TC) Peter Craig, Tony Hardy (chair), Andy Hart, Alicja Mortensen (day 1 AM), Bernadette Ossendorp (via TC on day 2), Josef Schlatter, Natalie Von Goetz, Detlef Wölfle (for CEF case study, via TC).

• EFSA:

SCER: Germini Andrea, Georgiadis Nikolaos FEED: Lopez Gloria (day 1), Manini Paola (day 2) FIP: Castoldi Anna (day 1), Croera Cristina (day 1) RISKCOM: Cristina Da Cruz (day 1), Smith Anthony (day 1), AMU: Mosbach Olaf, Martino Laura PRAS: Pedersen Ragnor (day 1) BIOCONTAM: Guerra Beatriz (day 2)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jeger Michael and Diane Benford.

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 Interest^{2,} EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 26th Working Group meeting held on 1 – 3 February 2017, Parma.

The minutes of the 26th Working Group meeting held on 1-3 February 2017 were agreed.³

5. Scientific topic(s) for discussion

5.1 Update on the survey on communicating uncertainties

The WG discussed the results of the online survey on communicating uncertainties. The survey was be launched for two weeks and disseminated across the Member States.

5.2 Preparation for internal workshop 22-23 June

The WG discussed the purpose, participants and process for the uncertainty internal EFSA workshop on 22 -23 June in Parma. The overall objective of the workshop is to inform the WG Uncertainty on how to further tailor the draft guidance to make it more fit for purpose for the panels/units needs by discussing the conclusions from the survey on impact analysis and by providing suggestions for revisions for the guidance document.

5.3 Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, GMO CONTAM ANS, NDA, CEF, FEEDAP and PLH Panels and of the PRAS unit. Support was provided to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

Next meeting

• 13 - 14 June 2017, 28th meeting, Parma

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

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

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



Scientific Committee

Minutes of the 26th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 01 – 03 February 2017, Parma (Italy) (Agreed on 29 March 2017)

Participants

• Working Group Members:

Craig Peter (via TC), Hardy Tony (chair), Hart Andrew, Mortensen Alicja, Von Goetz Natalie, Jeger Michael (day 1 &2), Ossendorp Bernadette;

• EFSA:

SCER Unit: Germini Andrea, Merten Caroline AMU Unit: Martino Laura (day 2&3), Mosbach-Schulz Olaf (day 2) RISKCOM Unit: Smith Anthony (day 2) BIOCONTAM unit: Guerra Beatriz (day 3)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Schlatter Josef and Benford Diane.

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 Interest^{2,} EFSA screened the Annual Declaration of

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



Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 25 th Working Group meeting held on 21-22 November 2016, Parma.

The minutes of the 25th Working Group meeting held on 10-11 November 2016 were agreed by written procedure by end of November 2016.³

5. Scientific topic(s) for discussion

5.1 Update on the survey on communicating uncertainties

The WG discussed the plan to run an online survey on communicating uncertainties. The survey will be launched by end of February for two weeks and disseminated across the Member States.

Support from the WG is expected to analyse and interpret the results from the survey.

5.2 Brainstorming on internal workshop 22-23 June

The WG discussed the purpose, participants and process for the uncertainty internal EFSA workshop on 22 -23 June in Parma. The overall objective of the workshop is to inform the WG Uncertainty on how to further tailor the draft guidance to make it more fit for purpose for the panels/units needs by discussing the conclusions from the survey on impact analysis and by providing suggestions for revisions for the guidance document.

5.3 Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, BIOHAZ, ANS, CONTAM, GMO and PLH Panels and of the PRAS unit. Support was provided to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

Next meeting

• 29-30 March 2017, 27th meeting, Parma

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



Scientific Committee

Minutes of the 25th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 10 – 11 November 2016, Parma (Italy) (Agreed on 30 November 2016)

Participants

• Working Group Members:

Peter Craig (via TC), Tony Hardy (chair), Andrew Hart (not on AM on day 1), Alicja Mortensen (not on AM on day 1), Josef Schlatter, Natalie Von Goetz, Bernadette Ossendorp (on day1)

EFSA: SCER Unit: Germini Andrea, Merten Caroline AMU Unit: Martino Laura (day1), Mosbach-Schulz Olaf (day1) RISKCOM Unit: Smith Anthony (day 2)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest^{2,} 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

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



related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 24th Working Group meeting held on 21-22 September 2016, Parma.

The minutes of the 24th Working Group meeting held on 21-22 September 2016 were agreed.³

5. Scientific topic(s) for discussion

5.1. Follow up plans on risk communication

The WG discussed the feedback provided by the advisory forum working group on risk communication (AFWG) on the communication project related to uncertainty.

The study provides useful pointers for improving future study design as more research is needed before developing a new communications approach. An online survey is proposed as the best way forward to follow up on the research project with the aim of increasing and broadening the sample size. Support will be needed from the uncertainty WG to revise the materials for the online survey.

5.2. Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, BIOHAZ, CEF, CONTAM, GMO and ANS Panels and of the PRAS unit. Support was provided in starting to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

Next meeting

• 1 - 2 February 2017, 26th meeting, Parma

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



Scientific Committee

Minutes of the 24th meeting of the Working Group on Uncertainty in Risk Assessment

Held on 21 – 22 September 2016, Parma (Italy) (Agreed on 10 November 2016)

Participants

• Working Group Members:

Benford Diane, Hardy Tony (chair), Hart Andrew, Jeger Michael, Mortensen Alicja, Schlatter Josef. Craig Peter and Von Goetz Natalie have participated via teleconference.

• EFSA:

SCER Unit: Germini Andrea, Merten Caroline AMU Unit: Martino Laura, Mosbach-Schulz Olaf RISKCOM Unit: Smith Anthony (day 2)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest^{2,} EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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² 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 have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 22d Working Group meeting held on 21 – 22 June 2016, Parma.

The minutes of the 23rd Working Group meeting held on 21-22 September 2016 were agreed.³

5. Scientific topic(s) for discussion

5.1. Impact analysis of the Guidance Document on uncertainty

The WG discussed the latest draft of the questionnaire developed to assess the impact of the application of the Guidance during the trial phase. The questionnaire will be administered to experts and staff involved in the development of the case studies at the end of the trial period.

5.2. Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, BIOHAZ, CEF, CONTAM, NDA and PLH Panels. Support was provided in starting to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

5.3. Risk communication project on uncertainty

The WG discussed the draft report of the project on "Clear Communications and Uncertainty" outsourced by the RISKCOM Unit. The WG noted the elements of relevance for the WG activities and provided comments that will be taken into consideration for the finalization of the report.

5.4. Activities of the WG on Weight of evidence

The WG was informed on the status of the activities of the Weight of evidence WG. The discussion focussed on the framework developed for weighing evidence and the integration of uncertainty and variability analysis into the framework. The comments provided will inform the activities of the Weight of evidence WG.

Next meeting

• 10 – 11 November 2016, Parma.

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



Scientific Committee

Minutes of the 23rd meeting of the Working Group on Uncertainty in Risk Assessment

Held on 21 – 22 June 2016, Parma (Italy) (Agreed on 21 September 2016)

Participants

• Working Group Members:

Benford Diane, Hardy Tony (chair), Hart Andrew, Mortensen Alicjia (day 2), Schlatter Josef, Ossendorp Bernadette. Craig Peter, Jeger Michael and Von Goetz Natalie have participated via teleconference.

• EFSA:

SCER Unit: Germini Andrea, Merten Caroline. AMU Unit: Mosbach-Schulz Olaf (day 1) and Laura Martino

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Martino Laura (AMU).

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 Interest^{2,} EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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

² 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 have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 22d Working Group meeting held on 17 – 18 May 2016, Parma.

The minutes of the 22nd Working Group meeting held on 17-18 May 2016 were agreed. $^{\rm 3}$

5. Scientific topic(s) for discussion

5.1. Feedback on various presentations on uncertainty.

The WG was updated on a meeting on uncertainty and possible impact on risk management and communication held on 19 May with DG SANTE. The WG received feedback on a presentation on the EFSA guidance document on uncertainty given at the EFSA Stakeholder Platform on 1 June.

5.2. Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, BIOHAZ, PLH and PPR Panels. Support was provided in starting to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

5.3. Evaluation of the impact of the draft Guidance Document at the end of the trial phase

The WG discussed a first proposal on how to evaluate the impact of the implementation of the methodology proposed by the draft GD. The different assessment areas on which the draft GD may impact were mapped. The different target groups to be questioned were mapped out and the different elements to be tested were discussed. The aim is to agree on a final proposal at the next WG meeting.

5.4. Plan for 4th training session on uncertainty

The WG was informed that a 4th session on uncertainty training will be held on 5-6-7 October. Based on the content and experience of the three previous sessions the structure of this 4th session may be changed slightly. Further the WG agreed to offer the participation to the risk managers from DG SANTE.

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



Next meeting(s)

- 21 22 September 2016, Parma;
- 10 11 November 2016.



Scientific Committee

Minutes of the 22nd meeting of the Working Group on Uncertainty in Risk Assessment

Held on 17 – 18 May 2016, Parma (Italy) (Agreed on 21 June 2016)

Participants

• Working Group Members:

Benford Diane, Hardy Tony (chair), Hart Andrew, Jeger Michael, Mortensen Alicjia, Schlatter Josef, Von Goetz Natalie.

Craig Peter has participated via teleconference.

• EFSA:

SCER Unit: Germini Andrea, Merten Caroline. AMU Unit: Mosbach-Schulz Olaf. RISKCOM Unit: Smith Anthony. AFSCO Unit: Tabachnikoff Shira.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Martino Laura (AMU).

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 Interest^{2,} EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 21st Working Group meeting held on 24-25 February 2016, Parma.

The minutes of the 21st Working Group meeting held on 24-25 February 2016 were agreed.³

5. Scientific topic(s) for discussion

5.1. Feedback on case studies and related activities

The WG discussed the ongoing testing activities of the AHAW, BIOHAZ and PLH Panels. Support was provided in starting to develop an Uncertainty Analysis framework for the different WGs. Ad hoc support to the specific WGs activities will continue during the testing phase.

5.2. Evaluation of the impact of the draft Guidance Document at the end of the trial phase

The WG initiated a discussion on how to evaluate the impact of the implementation of the methodology proposed by the draft GD. The different areas on which the draft GD may impact were mapped. The discussion will continue during the next WG meeting.

5.3. Feedback on the training sessions

The WG was updated on the status of the training activities in support of the implementation of the draft GD. Approximately 60 EFSA Panel members and staff attended the first 2 training sessions. 30 more will attend the next session. Content of the sessions was revised after each session based on the feedback received from the participants.

5.4. Workplan of the WG activities

The WG discussed the plan for the activities during and after the testing phase. The WG also developed a plan for consulting the internal and external stakeholders on the draft GD at the end of the testing phase. Meanwhile the WG will continue discussions with EU

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

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

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



institutions on how to best integrate the approach proposed in risk assessment practice.

6. Next meeting(s)

- 21 22 June 2016, Parma;
- 21 22 September 2016, Parma;
- 10 11 November 2016.



Scientific Committee and Emerging Risks Unit (SCER UNIT)

Scientific Committee Minutes of the 21st meeting of the Working Group on Uncertainty in Risk Assessment Held on 24 – 25 February 2016, Parma (Italy) (Agreed on 17 May 2015)

Participants

WG Experts:

Benford Diane, Craig Peter (24/2 am and 25/2am via TC), Hardy Tony (chair), Hart Andrew, Jeger Michael, Luttik Robert (24/2am via TC), Mortensen Alicjia, Magne Nielsen Kaare, Renshaw Derek, Schlatter Josef, Von Goetz Natalie (24/2pm and 25/2 via TC), Wölfle Detlef.

EFSA:

Germini Andrea (SCER), Merten Caroline (SCER), Martino Laura (AMU), Smith Tony (RISKCOMM) (24/2).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from: Di Domenico Alessandro, Ossendorp Bernadette, Alexander Jan, Havelaar Arie, Nøerrung Birgit, Martin Ambroise, Thulke Hans-Hermann, Mosbach-Schulz Olaf.

2. Adoption of the 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.

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

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



4. Scientific topic(s) for discussion

The WG discussed the final draft of the Public Consultation report which summarizes how the comments received during the public consultation phase were addressed in the guidance document on uncertainty.

5. Next meeting(s)

- 17 18 May 2016, Brussels, 22nd meeting;
- 21 22 June 2016, Parma, 23rd meeting;
- 21 22 September 2016, Parma, 24th meeting;
- 10 11 November 2016, 25th meeting.



Scientific Committee and Emerging Risks Unit (SCER UNIT)

Scientific Committee Preparatory meeting for the 21st meeting of the Working Group on Uncertainty in Risk Assessment <u>Teleconference</u> 1 February 2016, 13:30 – 18:30 (Agreed on 24 February 2016)

Participants

WG Experts:

Jan Alexander, Diane Benford, Peter Craig, Tony Hardy (chair), Andrew Hart, Michael Jeger, Robert Luttik, Alicja Mortensen, Kaare Magne Nielsen, Derek Renshaw, Detlef Wölfle.

EFSA:

Andrea Germini (SCER), Caroline Merten (SCER), Laura Martino (AMU).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from: Alessandro Di Domenico, Arie Havelaar, Ambroise Martin, Birgit Nørrung, Bernadette Ossendorp, Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz.

2. Adoption of the 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.

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

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



4. Scientific topic(s) for discussion

The WG finalised the revised draft of the guidance document addressing the comments received from the public consultation.

5. Next meeting(s)

• 24 – 25 February 2016 : WG physical meeting in Parma



Scientific Committee and Emerging Risks Unit (SCER UNIT)

Scientific Committee Preparatory meeting for the 21st meeting of the Working Group on Uncertainty in Risk Assessment <u>Teleconference</u> 21 January 2016, 9:30 – 15:30 (Agreed on 24 February 2016)

Participants

WG Experts:

Diane Benford (chair), Peter Craig, Alessandro Di Domenico, Andrew Hart, Robert Luttik, Alicja Mortensen, Kaare Magne Nielsen, Derek Renshaw, Hans-Hermann Thulke, Detlef Wölfle.

EFSA:

Andrea Germini (SCER), Laura Martino (AMU).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from: Jan Alexander, Tony Hardy, Arie Havelaar, Michael Jeger, Bernadette Ossendorp, Birgit Nørrung, Josef Schlatter, Natalie Von Goetz.

2. Adoption of the 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.

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

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



4. Scientific topic(s) for discussion

The WG discussed the revised guidance document addressing the comments received from the public consultation.

5. Next meeting(s)

- 1 February 2016 : preparatory teleconference
- 24 25 February 2016 : WG physical meeting in Parma



Scientific Committee Minutes of the 20th meeting of the Working Group on Uncertainty in Risk Assessment Held on 05 – 07 January 2016, Parma (Italy) (Agreed on 24 February 2016)

Participants

WG Experts:

Diane Benford, Peter Craig (day 1 and 2), Tony Hardy (chair), Kaare Magne Nielsen, Andrew Hart, Michael Jeger (day 2 and 3), Robert Luttik, Alicja Mortensen, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz Detlef, Wölfle (day 2 and 3).

EFSA:

Andrea Germini (SCER), Caroline Merten (SCER), Laura Martino (AMU) (day 2 and 3), Anthony Smith (COMMS) (day 3).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from: Jan Alexander, Alessandro Di Domenico, Arie Havelaar Bernadette Ossendorp and Birgit Nørrung.

2. Adoption of the 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.

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

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



4. Scientific topic(s) for discussion

The WG discussed the revised guidance document addressing the comments received from the public consultation.

5. Next meeting(s)

- 22 January 2016 : preparatory teleconference
- 1 February 2016 : preparatory teleconference
- 24 25 February 2016 : WG physical meeting in Parma



Scientific Committee Minutes of the 19th meeting of the Working Group on Uncertainty in Risk Assessment Held on 08 – 10 December 2015, Parma (Italy) (Agreed on 05 January 2016)

Participants

WG Experts:

Benford Diane (day 3 pm), Craig Peter (day 2 and 3), Hardy Tony (chair), Havelaar Arie, Kaare Magne Nielsen (day 1 via TC), Hart Andrew, Jeger Michael (day 1), Luttik Robert, Ossendorp Bernadette, Renshaw Derek (day 1 and 2), Wölfle Detlef (day 1-3 via TC), Schlatter Josef (day 1 and 2), Von Goetz Natalie.

EFSA:

Germini Andrea (SCER), Merten Caroline (SCER) (day 1 and 2), Martino Laura (AMU) (day 2 and 3), Smith Anthony (RISKCOM) (day 1).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from: Di Domenico Alessandro, Alexander Jan, Nørrung Birgit, Martin Ambroise, Mosbach Olaf, Thulke Hans-Hermann, Mortensen Alicja.

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

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

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



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

The WG discussed the report prepared to address the comments received from the public consultation and the proposals for revisions of the guidance document.

5. Next meeting(s)

5 – 7 January 2016 (Parma)



Scientific Committee Minutes of the 18th meeting of the Working Group on Uncertainty in Risk Assessment Held on 21 – 23 October 2015, Parma (Italy) (Agreed on 8 December 2015)

Participants

WG Experts:

Benford Diane, Craig Peter, Di Domenico Alessandro, Hardy Tony (chair), Hart Andrew, Jeger Michael, Luttik Robert (day 2 & 3), Renshaw Derek, Wölfle Detlef, Mortensen Alicja, Thulke Hans-Hermann,

EFSA:

Germini Andrea (SCER), Merten Caroline (SCER), Martino Laura (AMU),

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alexander Jan , Noerrung Birgit, Schlatter Josef, Von Goetz Natalie, Magne Nielsen Kaare , Martin Ambroise , Smith Tony, Mosbach Olaf, Havelaar Arie, Ossendorp Bernadette.

2. Adoption of agenda

Two additional agenda items were added.

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.

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

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



4. Scientific topic(s) for discussion

The WG discussed the first draft of annex D of the main guidance document on an illustration of the overall characterisation of the uncertainty. Further, the WG discussed a first batch of themes to address the comments from the public consultation.

5. Next meeting(s)

- 8-10 December 2015 (Parma)
- 5 7 January 2016 (Parma)



Scientific Committee Minutes of the 17th meeting of the Working Group on Uncertainty in Risk Assessment Held on 23 – 24 September 2015, Parma (Italy) (Agreed on 23 October 2015)

Participants

• Working Group Members:

Jan Alexander (day 1), Peter Craig, Alessandro Di Domenico, Andrew Hart, Arie Havelaar, Alicja Mortensen (day 1), Kaare Magne Nielsen, Bernadette Ossendorp (day 1 from pm onwards), Josef Schlatter (chair), Natalie Von Goetz.

• EFSA:

Andrea Germini (SCER), Caroline Merten (SCER), Laura Martino (AMU), Tony Smith (day2) (Comm).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Benford Diane, Hardy Tony, Jeger Michael, Luttik Robert, Noerrung Birgit, Renshaw Derek, Ambroise Martin, Thulke Hans-Hermann, Wölfle Detlef, Mosbach Olaf.

2. Adoption of agenda

The agenda was changed. The item on the annex D was postponed to the next meeting.

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.

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

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



4. Scientific topic(s) for discussion

The WG discussed the comments received from the public consultation phase on the uncertainty guidance document. The WG developed a process how to categorize the comments and how to address the comments. The next step will be to revise the guidance document and to draft the report on the public consultation.

5. Next meeting(s)

21 – 23 October, Parma



Scientific Committee Minutes of the 16th meeting of the Working Group on Uncertainty in Risk Assessment Held on 16 – 17 July 2015, Parma (Italy) (Agreed on on 1 September 2015)

Participants

• Working Group Members:

Diane Benford, Peter Craig, Alessandro Di Domenico, Tony Hardy (by tele conference, day 1), Andrew Hart, Arie Havelaar (by teleconference, afternoon day 1), Michael Jeger, Robert Luttik, Alicja Mortensen, Birgit Nørrung (chair), Natalie Von Goetz, (by teleconference), Detlef Wölfle (by teleconference).

• EFSA:

Andrea Germini (SCER), Caroline Merten (SCER), Laura Martino (AMU by Teleconference day 1), Olaf Mosbach (day 2)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Josef Schlatter, Derek Renshaw, Hans-Hermann Thulke, Ambroise Martin, Jan Alexander, Kaare Magne Nielsen, Bernadette Ossendorp.

2. Adoption of agenda

The agenda was adopted without any further change.

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.

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

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



4. Scientific topic(s) for discussion

The WG developed the annex D of the guidance document in which the melamine case study is used to illustrate the characterisation of the overall uncertainty by combining two methods, the expert knowledge elicitation and interval analysis. In particular, expert knowledge was elicited for five different parameters used in the analysis, and additional uncertainties affecting the assessment were identified and discussed.

5. Next meeting(s)

23 – 24 September, Parma



Scientific Committee Minutes of the 15th meeting of the Working Group on Uncertainty in Risk Assessment Held on 27 – 28 May 2015, Parma (Italy) (Agreed on 12 June 2015)

Participants

• Working Group Members:

Diane Benford, Peter Craig, Alessandro Di Domenico, Andrew Hart, Robert Luttik (chair day 1), Birgit Nørrung (chair day 2), Bernadette Ossendorp (day 2 afternoon), Natalie Von Goetz, Tony Hardy (by tele conference), Alicja Mortensen (by tele conference).

• EFSA:

SAS Unit: Laura Martino,

SCER Unit: Andrea Germini, Caroline Merten

Communication: Tony Smith

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies: Josef Schlatter, Derek Renshaw, Hans-Hermann Thulke, Ambroise Martin, Jan Alexander, Arie Havelaar, Michael Jeger, Kaare Magne Nielsen and Detlef Wölfle.

2. Adoption of agenda

The agenda was adopted without any further change.

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.

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

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



4. Agreement of the minutes of the 14th Working Group meeting held on 31 March – 01 April 2015, Copenhagen.

The minutes of the 14th Working Group meeting held on 31 March - 1 April 2015, and the minutes of the preparatory teleconferences held on 28 April and 8 May 2015 were agreed.

5. Scientific topic(s) for discussion

Working Group members reviewed in the plenary session the annex on the melamine case study and the draft guidance document in order to prepare a compiled draft for the Scientific Committee plenary meeting on 8 - 10 June 2015.

6. Next meeting(s)

The next meeting will take place on 16-17 July 2015 in Parma, Italy.



Scientific Committee

Preparatory meeting for 15th meeting of the

Working Group on Uncertainty in Risk Assessment

<u>Teleconference</u> 08/05/ 2015, 14.00 – 18.00

(Agreed on 27 May 2015)

Participants

Working Group Members:

Ambroise Martin, Jan Alexander, Peter Craig, Tony Hardy, Diane Benford, Birgit Nørrung(chair), Andrew Hart, Alessandro Di Domenico, Natalie Von Götz and Robert Luttik

EFSA:

- AMU Unit: Olaf Mosbach,
- SCER Unit: Andrea Germini, Caroline Merten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from, Michael Jeger, Arie Havelaar, Bernadette Ossendorp, Derek Renshaw, Hans-Hermann Thulke, Josef Schlatter, Detlef Wölfle, Kaare Magne Nielsen, Josef Schlatter, and Alicjia Mortensen

2. 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.

3. Scientific topic(s) for discussion

The Working Group members reviewed the following drafts of the annexes to be finalised before being sent to the SC: the melamine case study, the annex on the structure of the assessment models, additional review comments on the quantitative methods, in particular, the one on assessment factor.

4. Next meeting(s)

The next meeting will be a physical meeting on 27 – 28 May 2015 in Parma, Italy.

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

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



Scientific Committee Preparatory meeting for the 15th meeting of the Working Group on Uncertainty in Risk Assessment <u>Teleconference</u> 28/04/15 2015, 09.00 – 13.00 (Agreed on 27 May 2015)

Participants

Working Group Members:

Peter Craig, Tony Hardy (chair), Andrew Hart, Michael Jeger and Detlef Wölfle

EFSA:

- AMU Unit: Olaf Mosbach, Laura Martino
- SCER Unit: Andrea Germini, Caroline Merten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jan Alexander, Arie Havelaar, Ambroise Martin, Bernadette Ossendorp, Derek Renshaw, Hans-Hermann Thulke, Diane Benford, , Josef Schlatter, Robert Luttik, Kaare Magne Nielsen, Birgit Nørrung, Josef Schlatter, Natalie Von Götz and Alicjia Mortensen.

2. 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.

3. Scientific topic(s) for discussion

The Working Group members reviewed the advanced drafts of the quantitative and qualitative methods to be included in the annex to illustrate the different methods to deal with uncertainty. In particular, the following qualitative methods were reviewed: descriptive expression of uncertainty, ordinal scale and matrices for confidence and uncertainty. Regarding the quantitative methods the ones on formal and informal expert knowledge elicitation (EKE) and on assessment factors were discussed.

4. Next meeting(s)

The next meeting will be a TC on 8 May 2015 14.00 – 18.00

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

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



Scientific Committee Minutes of the 14th meeting of the Working Group on Uncertainty in Risk Assessment Held on 31 March - 01 April 2015, Parma (Italy) (Agreed on 27 May 2015)

Participants

• Working Group Members:

Ambroise Martin, Jan Alexander (via TC on day 1), Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Kaare Magne, Nielsen Birgit Nørrung (Chair), Diane Benford, Detlef Wölfle, and Natalie Von Götz.

• EFSA:

- AMU Unit: Olaf Mosbach
- SCER Unit: Andrea Germini, Caroline Merten
- Communication: Laura Smilie

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alicjia Mortensen, Bernadette Ossendorp, Derek Renshaw, Hans-Hermann Thulke, Laura Martino and Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without any further change.

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.

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

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



4. Agreement of the minutes of the 13th Working Group meeting held on 26-28 February 2015, Brussels.

The minutes of the 13th Working Group meeting held on 26-28 February 2015 were agreed.

5. Scientific topic(s) for discussion

5.1 Working Group members reviewed in the plenary session the draft guidance document in order to prepare for the presentation and discussion with the Scientific Committee on 22 – 23 April.

6. Next meeting(s)

Two teleconference meetings will be held : 28 April and 8 May. The next physical meeting will take place on 27- 28 May 2015 in Parma, Italy.



Scientific Committee Minutes of the 13th meeting of the Working Group on Uncertainty in Risk Assessment Held on 25 - 27 February 2015, Parma (Italy) (Agreed on 31 March 2015)

Participants

• Working Group Members:

Jan Alexander, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Kaare Magne Nielsen Birgit Nørrung (Chair), Josef Schlatter, Natalie Von Götz and Alicjia Mortensen

• Hearing Experts¹:

- Lieve Busschots, Suzan Fiack, Piret Priisalu

• European Commission representatives:

 Panagiotis Daskaleros, Wim Debeuckelaere, Gudrun Gallhoff, Marina Marini, Maria Mirazchiyska, Frans Verstraete (DG SANCO)

• EFSA:

- AMU Unit: Olaf Mosbach
- SCER Unit: Andrea Germini, Caroline Merten
- Communication: Laura Smilie

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ambroise Martin, Bernadette Ossendorp, Derek Renshaw, Hans-Hermann Thulke, Laura Martino, Diane Benford, Detlef Wölfle and Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without any further change.

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 Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 12th Working Group meeting held on 29-30 January 2015, Parma.

The minutes of the 12th Working Group meeting held on 29-30 January 2015 were agreed.

5. Scientific topic(s) for discussion

- 5.1 Working Group members met Risk Managers (RM) and Risk Communicators (RC) to present and discuss the approach proposed in the draft guidance document. In summary, the guidance was welcomed very positively by the attendees, foreseen as a further step towards higher transparency and considered beneficial by RM and RC.
- 5.2 Main document: the working group reviewed the different chapters of the main document.
- 5.3 Appendices: the working group finalized some of the methods that will be included as appendix of the guidance document.

6. Next meeting(s)

The next meeting will take place on 31st March - 1st April 2015 in Copenhagen, Denmark.

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

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



Scientific Committee Minutes of the 12th meeting of the Working Group on Uncertainty in Risk Assessment Held on 29 - 30 January 2015, Parma (Italy) (Agreed on 26 February 2015)

Participants

• Working Group Members:

Jan Alexander, Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar (by via phone), Michael Jeger, Kaare Magne Nielsen (by phone), Birgit Nørrung (Chair), Natalie Von Götz, and Detlef Wölfle.

- EFSA:
 - AMU Unit: Laura Martino
 - SCER Unit: Andrea Germini, Caroline Merten
 - Communication: Laura Smilie

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alessandro Di Domenico, Bernadette Ossendorp, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke and Olaf Mosbach.

2. Adoption of agenda

The agenda was adopted without any further change.

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.

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

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



4. Agreement of the minutes of the 11th Working Group meeting held on 15-16 January 2015, Parma.

The minutes of the 11th Working Group meeting held on 15-16 January 2015 were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for addressing uncertainties

The working group developed further some of the methods that will be included in the appendix of the guidance document. In particular the following methods were further developed by adding an illustrative example: NUSAP, ordinal scale, uncertainty matrix, uncertainty table, sensitivity analysis, 1D and 2D MC.

5.2 Main document

The remaining time was used to review the different chapters of the main document.

6. Next meeting(s)

The next meeting will take place on 26-27 February 2015 in Brussels, Belgium.



Scientific Committee Minutes of the 11th meeting of the Working Group on Uncertainty in Risk Assessment Held on 15-16 January 2015, Brussels (Belgium) (Agreed on 29 January 2015)

Participants

• Working Group Members:

Ambroise Martin, Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Michael Jeger (first day) Robert Luttik, Kaare Magne Nielsen, Birgit Nørrung (Chair; second day), Natalie Von Götz, Jan Alexander, Detlef Wölfle

- EFSA:
 - SAS Unit: Laura Martino
 - SCER Unit: Andrea Germini, Caroline Merten
 - Communication: Laura Smillie

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alessandro Di Domenico, Bernadette Ossendorp, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke, Arie Havelaar and Jean- Charles Leblanc.

2. Adoption of agenda

The agenda was adopted without any further change.

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.

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

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



4. Agreement of the minutes of the 10th Working Group meeting held on 2-3 December 2014, Parma.

The minutes of the 10th Working Group meeting held 2-3 December 2014 were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for addressing uncertainties

The working group continued discussing some of the methods that will be included in the appendix of the guidance document. In particular the following methods were discussed: Ordinal scales; NUSAP; fuzzy logic; interval and probabilistic bounds analysis. In addition, the detailed outline of the main guidance document was discussed and in particular three chapters were discussed in more details: Identification and description of uncertainties using typologies; quantitative approaches; and communication on uncertainty. Further discussion on the examples to illustrate the methods will take place during the next meeting.

6. Next meeting(s)

The next meeting will take place on 29-30 January in Parma.



Scientific Committee Minutes of the 10th meeting of the Working Group on Uncertainty in Risk Assessment Held on 2-3 December 2014, Parma (Italy) (Agreed on 15 January 2015)

Participants

• Working Group Members:

Peter Craig, Tony Hardy, Andrew Hart, Robert Luttik, Kaare Magne Nielsen (first day), Birgit Nørrung (Chair), Derek Renshaw, Natalie Von Götz, Jan Alexander (via TC on day 1 and pm of day 2), Arie Havelaar (first day).

• EFSA:

- SAS Unit: Laura Martino, Olaf Mosbach-Schulz
- SCER Unit: Andrea Germini, Caroline Merten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ambroise Martin, Diane Benford, Jean-Charles Leblanc, Alessandro Di Domenico, Bernadette Ossendorp, Josef Schlatter, Hans-Hermann Thulke Michael Jeger and Detlef Wölfle.

2. Adoption of agenda

The agenda was adopted after acknowledging that the agenda item on communication on uncertainty has to be postponed to the next meeting due to apologies received from Laura Smillie.

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.

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

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



4. Agreement of the minutes of the 9th Working Group meeting held on 12-13 November 2014, Parma.

The minutes of the 9th Working Group meeting held 12-13 November 2014 were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for addressing uncertainties

The working group continued discussing some of the methods that will be included in the appendix of the guidance document. In particular the following methods were discussed: Ordinal scales, NUSAP, Categorical question, Monte Carlo and assessment factors. In addition two chapters of the main guidance document were discussed: Identification and description of uncertainties using typologies and key steps of uncertainty analysis. Further discussion on the methods will take place during the next meeting.

6. Next meeting(s)

The next meeting will take place on 15-16 January in Brussels



Scientific Committee Minutes of the 9th meeting of the Working Group on Uncertainty in Risk Assessment Held on 12-13 November 2014, Parma (Italy) (Agreed on 2 December 2015)

Participants

- Working Group Members:
 - Ambroise Martin, Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Michael Jeger, Jean-Charles Leblanc, Robert Luttik, Birgit Nørrung (Chair), Natalie Von Götz.
 - Kaare Magne Nielsen and Arie Havelaar participated via teleconference.
- EFSA:
 - SAS Unit: Laura Martino, Olaf Mosbach-Schulz
 - SCER Unit: Andrea Germini, Caroline Merten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jan Alexander, Alessandro Di Domenico, Bernadette Ossendorp, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke and Detlef Wölfle.

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.

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

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



4. Agreement of the minutes of the 8th Working Group meeting held on 28-29 Octopber 2014, Parma.

The minutes of the of the 8^{th} Working Group meeting held on 28-29 October 2014 were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for addressing uncertainties

The working group continued discussing some of the methods that will be included in the appendix of the guidance document. In particular the following methods were discussed: NUSAP, typologies, ordinal approaches, uncertainty matrices, expert knowledge elicitation, fuzzy logic, confidence intervals and sensitivity analysis Further discussion on the methods will take place during the next meeting.

6. Next meeting(s)

The next meeting will take place on 2-3 December in Parma



Scientific Committee Minutes of the 8th meeting of the Working Group on Uncertainty in Risk Assessment Held on 28-29 October 2014, Parma (Italy) (Agreed on 12 November 2014)

Participants

- Working Group Members:
 - Jan Alexander, Peter Craig, Tony Hardy, Andrew Hart, Jean-Charles Leblanc (2nd day), Robert Luttik, Birgit Nørrung (Chair), Bernadette Ossendorp, Natalie Von Götz.
 - Diane Benford, Michael Jeger, Kaare Magne Nielsen and Detlef Wölfle participated via teleconference.
- EFSA:
 - SAS Unit: Laura Martino, Olaf Mosbach-Schulz
 - SCER Unit: Jean-Lou Dorne, Andrea Germini, Caroline Merten

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ambroise Martin, Alessandro Di Domenico, Arie Havelaar, Josef Schlatter, Hans-Hermann Thulke, and Derek Renshaw.

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.

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

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



4. Agreement of the minutes of the 7th Working Group meeting held on 17-18 September 2014, Parma.

The minutes of the 7th Working Group meeting held on 17-18 September 2014 were agreed.

5. Scientific topic(s) for discussion

5.1 Revision of the workplan of the WG on Uncertainty in Risk Assessment³

The working group revised the structure of the Guidance Document, organised the work for the preparation of the different section of the document and planned the activities for the next meetings.

5.2 Methods for addressing uncertainties

The working group continued discussing some of the methods that will be included in the appendix of the guidance document. Further discussion on the methods will take place during the next meeting.

6. Next meeting(s)

The next meeting will take place on 12-13 November in Parma

³<u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00738</u>



SCER UNIT

Scientific Committee Minutes of the 7th meeting of the Working Group on Uncertainty in Risk Assessment Held on 17-18 September 2014, Parma (Agreed on 28 October 2014)

Participants

- Working Group Experts:
 - Jan Alexander, Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Ambroise Martin (1st day), Kaare Magne Nielsen, Birgit Nørrung (Chair), Bernadette Ossendorp (1st day), Josef Schlatter, Hans-Hermann Thulke (2nd day), Natalie Von Götz, Detlef Wölfle.
- EFSA:
 - COMMS: Laura Smillie
 - SAS Unit: Laura Martino, Olaf Mosbach-Schulz
 - SCER Unit: Jean-Lou Dorne, Andrea Germini

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alessandro Di Domenico, Jean-Charles Leblanc, and Derek Renshaw.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified

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

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



during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

4. Agreement of the minutes of the 6th Working Group meeting held on 2-3 July 2014, Parma

The minutes of the previous meeting were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for assessing uncertainty

The WG continued discussing the methods proposed for addressing uncertainty in risk assessment. The work focussed on qualitative and quantitative methods to characterise uncertainty. Criteria for the evaluation of each method were discussed during the meeting and will be further discussed at the next meeting.

5.2 Structure and contents of the guidance document

The WG discussed the structure of the guidance document and agreed on the contents for the different chapters. It was decided that all the methods will be presented in details as appendices of the main document.

5.3 Workplan of the Working Group

The WG discussed the organization of the future activities and revised its workplan accordingly. Interaction with the risk managers and risk communication issues were discussed and it was decided that a dedicated meeting on this issues should take place in January 2015.

6. Next meetings

The next meeting will take place on 28-29 October 2014 in Parma.



SCER UNIT

Scientific Committee Minutes of the 6th meeting of the Working Group on Uncertainty in Risk Assessment Held on 2-3 July 2014, Parma (Agreed on 17 09 2014)

Participants

- Working Group Experts:
 - Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Kaare Magne Nielsen, Birgit Nørrung (Chair), Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz.
- EFSA:
 - SCER Unit: Germini Andrea.
 - SAS Unit: Lara Congiu, Laura Martino

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jan Alexander, Alessandro Di Domenico, Mike Jeger, Jean-Charles Leblanc, Ambroise Martin and Derek Renshaw.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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



4. Agreement of the minutes of the 5th Working Group meeting held on 2-3 July 2014, Parma

The minutes of the previous meeting were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for assessing uncertainty

The WG continued discussing the methods proposed for addressing uncertainty in risk assessment. The work focussed on the following categories of methods : i) descriptive, ii) ordinal, iii) probabilistic and iv) deterministic.

5.2 Literature search

The WG assessed the outcomes of the new literature searches performed to complement the collection of methods to assess uncertainty in risk assessment. The assessment will continue in preparation for the next meeting.

5.3 Workplan of the Working Group

The WG discussed the organization of the future activities and revised its workplan accordingly. The WG also discussed the strategy for addressing in the guidance document the interaction with the risk managers and risk communication issues; this will be further discussed in the next meeting.

6. Next meetings

The next meeting will take place on 17-18 September 2014 in Parma.



SCER UNIT

Scientific Committee Minutes of the 5th meeting of the Working Group on Uncertainty in Risk Assessment Held on 10-11 June 2014, Brussels (Agreed on 02 07 2014)

Participants

• Working Group Experts:

- Jan Alexander, Diane Benford, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Ambroise Martin, Kaare Magne Nielsen, Birgit Nørrung (Chair), Josef Schlatter, Natalie Von Goetz.
- EFSA:
 - SCER Unit: Germini Andrea.
 - SAS Unit: Lara Congiu

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alessandro Di Domenico, Jean-Charles Leblanc, Derek Renshaw and Hans-Hermann Thulke.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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



4. Agreement of the minutes of the 4th Working Group meeting held on 27-28 May 2014, Brussels

The minutes of the previous meeting were agreed.

5. Scientific topic(s) for discussion

5.1 Methods for assessing uncertainty

The WG discussed the methods proposed for addressing uncertainty categorizing them into two broad categories: descriptive ad ordinal methods, and probabilistic and deterministic methods. This part of the workplan will continue during the next WG meetings.

5.2 Literature search

A literature search was initiated to identify relevant approaches to uncertainty analysis that may have not been considered yet. Search criteria were refined during the meeting. The outcome of the new literature search will be shared with WG experts in preparation fro the next meeting.

5.3 Meeting with risk managers

Risk managers working in different areas of interest for EFSA were interviewed to better understand their current perception on how EFSA deals with uncertainty in its scientific opinions. The inputs provided by these risk managers will be used by the WG to further structure its draft guidance document.

6. Next meetings

The next meeting will take place on 2 -3 July 2014 in Parma.



SCER UNIT

Scientific Committee Minutes of the 4th meeting of the Working Group on Uncertainty in Risk Assessment Held on 27-28 May 2014, Brussels (Agreed on 10 06 2014)

Participants

- Working Group Experts:
 - Jan Alexander, Peter Craig, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Jean-Charles Leblanc, Robert Luttik, Ambroise Martin, Kaare Magne Nielsen, Birgit Nørrung (Chair), Derek Renshaw, Josef Schlatter, Natalie Von Goetz.
- EFSA:
 - SCER Unit: Bottex Bernard, Germini Andrea.
 - SAS Unit: Martino Laura, Mosbach-Schulz Olaf

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Diane Benford, Alessandro Di Domenico, and Hans-Hermann Thulke.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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

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



4. Agreement of the minutes of the 3rd Working Group meeting held on 1-2 April 2014, Parma

The minutes of the previous meeting were agreed.

5. Scientific topic(s) for discussion

5.1 Working plan and criteria for evaluation of approaches

The WG discussed the working plan for the activities of the sub-WGs dealing with descriptive, ordinal, deterministic and probabilistic methods to address uncertainty. Working definitions were discussed and agreed. The WG further refined the criteria for the evaluation of the approaches proposed.

5.2 Overview of methods for assessing uncertainty

The sub-WG discussed the methods proposed for their area of competence. Each expert provided an overview of how its Panel's approaches could be categorized according to the definition agreed by the WG. It was decided to perform a literature search to identify if any relevant approach to uncertainty analysis has not been identified yet during the consultation with the EFSA Panels.

5.3 Meeting with risk managers

Risk managers working in different areas of interest for EFSA were interviewed to better understand their current perception on how EFSA deals with uncertainty in its scientific opinions. The inputs provided by these risk managers will be used by the WG to further structure its draft guidance document.

6. Next meetings

The next meeting will take place on 10-11 June 2014 in Brussels.



SCER UNIT

Scientific Committee Minutes of the 3rd meeting of the Working Group on Uncertainty in Risk Assessment Held on 01-02 April 2014, Parma (Agreed on 27 05 2014)

Participants

- Working Group Experts:
 - Jan Alexander, Diane Benford, Peter Craig, Alessandro Di Domenico, Tony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Jean-Charles Leblanc, Robert Luttik, Ambroise Martin, Birgit Nørrung (Chair), Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz.
 - Kaare Nielsen has participated via teleconference
- EFSA:
 - SCER Unit: Bottex Bernard, Dorne Jean-Lou and Germini Andrea.
 - SAS Unit: Martino Laura

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified

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

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



during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

4. Agreement of the minutes of the 2nd Working Group meeting held on 19-20 February 2014, Parma

The minutes of the previous meeting were agreed.

5. Scientific topic(s) for discussion

5.1 Draft text of the Guidance Document

The WG discussed the draft text of the Guidance Document. In particular the WG members addressed the definition of uncertainty, the reasons for addressing uncertainty, and what information is required. The WG also started to address the challenges for routinely implementing uncertainty analysis in EFSA's work tackling also the principles of good practice for this implementation.

5.2 Organization of the activities of the WG

The WG decided to organize its activities into four sub-WGs based on a categorization of the different methods proposed to address uncertainty. In particular the WG will address qualitative, semiquantitative, deterministic and probabilistic methods.

6. Next meetings

The next meetings will take place on 27-28 May and 10-11 June 2014 in Brussels.



SCIENTIFIC COMMITTEE and EMERGING RISKS UNIT

Scientific Committee

Minutes of the 2nd meeting of the Working Group on Uncertainty in Risk Assessment Held on 19-20 February 2014, Parma

(Agreed on 02 April 2014)

Participants

• Working Group Experts:

Alexander Jan, Benford Diane, Crag Peter, , Hardy Tony, Hart Andrew David, Havelaar Arie, Jeger Michael John, Luttik Robert, Martin Ambroise, Nøerrung Birgit (Chair), Schlatter Josef Rudolf, Slob Wout, Thulke Hans-Hermann, Von Goetz Natalie.

• EFSA:

- BIOCONTAM Unit: Romero Barrios Pablo
- FEED Unit: Manini Paola
- PRAS Unit: Mohimont Luc
- SAS Unit: Martino Laura and Mosbach-Schulz Olaf
- SCER Unit: Bottex Bernard, Dorne Jean-Lou and Germini Andrea.

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without change.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding

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European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • <u>www.efsa.europa.eu</u>

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



Declarations of Interests ², EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

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

4. EFSA Panels approaches to address uncertainty

Following the written feedback received from all the EFSA Panels, selected experts from the working group presented their Panel approach to address uncertainty during risk assessment. The presentations were followed by an open floor discussion.

5. Strategies available to characterise uncertainty in risk assessment

The working group was presented with a selection of approaches currently available to address uncertainty in the risk assessment process. These included: EFSA and WHO-IPCS guidance documents, national food safety agencies approaches, and an overview of other available approaches.

6. Draft guidance document

The working group discussed the first draft of the introductory sections of the guidance document and made proposals for the structure and contents of the whole document.

7. Next meeting

The next meeting will take place on 1-2 April 2014 in Parma.

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



Annex I

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

Dr. Hart Andrew David declared the following interests that will also be inserted in a new version of his Annual DOI and submitted for EFSA's approval:

- 06/2012 - 12/2012: European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)

Advisory role for a research project on modelling of species sensitivity distributions for ecological risk assessment, including ICE (interspecies correlations) and other methods. The expert organisation, Fera, was a subcontractor of Durham University (the project leaders).

- 01/2010 - now: European Commission (EC) FP7

Coordinator of BROWSE and contributor to ACROPOLIS projects, on developing new methods and models for assessing exposure of consumers, operators, workers, residents and bystanders to pesticides, including dealing with uncertainty (both projects) and cumulative exposures to mixtures of pesticides (ACROPOLIS). The expert organisation's contributions were partly supported by co-funding from UK government.

- 06/2012 - now: European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)

Member of organising committee for ECETOC workshop on 'Estimating toxicity thresholds for aquatic ecological communities from sensitivity distributions', held in Amsterdam on 11-13 February 2014, including chairing one session at the workshop and acting as rapporteur for another. This activity was unfunded except for travel and subsistence at the workshop which was provided by ECETOC.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned. Should in the future the working group decide to consider the outcome of these research projects for its work, the involvement of the expert will be reconsidered by means of an SDOI to ensure that he does not review his own work.



SCIENTIFIC COMMITTEE and EMERGING RISKS UNIT

Scientific Committee

Minutes of the 1st meeting of the Working Group on Uncertainty in Risk Assessment Held on 12 November 2013, Parma

(Agreed on 20 December 2013)

Participants

• Working Group Experts:

Jan Alexander, Diane Benford, Natalie von Götz, Tony Hardy, Andy Hart, Arie Havelaar, Mike Jeger, Robert Luttik, Birgit Nørrung (Chair), Josef Schlatter, Wout Slob.

- EFSA:
 - SCER Unit: Bernard Bottex, Jean-Lou Dorne and Andrea Germini
 - SAS Unit: Laura Martino and Olaf Mosbach-Schulz

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Hans-Hermann Thulke and Ambroise Martin.

2. Adoption of agenda

The agenda was adopted without change.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified

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

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



during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

5. Scientific topics for discussion

5.1 Presentation of the mandate (EFSA-Q-2013-00738)

The chair presented the mandate outlining the objectives of the activities of the WG. The WG agreed that the guidance document that will be developed should cover uncertainty in all aspects of the risk assessment carried out by EFSA and should be fit-for-purpose so as to be implemented in all working areas of EFSA.

5.2 Organization of the activities of the WG

The WG members discussed the outline of the activities. It was agreed that the WG will tackle overarching concepts during its first meetings and later address specific aspects of uncertainty related to the work of the individual EFSA Panels. The activities of the WG will start with a discussion on the methodologies currently available to address uncertainty in the different aspects of risk assessment and on the current approaches taken by EFSA to address uncertainty in its opinions. It was agreed that during the second phase of the work, when the WG will address the peculiarities of the different EFSA Panels, the WG should be further populated with one representative from each panel. The WG also agreed on a strategy to develop case studies to complement the guidance document that will be prepared in order to enhance its implementation within EFSA.

5.3 Timelines for the activities of the WG

The WG will develop its guidance document during 2014. It is expected that the draft guidance document will be submitted for public consultation during the first quarter of 2015 and endorsed by the EFSA Scientific Committee by July 2015. Case studies will be developed during the second half of 2015 to test the implementation of the guidance into the different areas of EFSA's work. The guidance document, revised according to the feedback received during the development of the cases studies, is expected to be finalized by mid 2016.

6. Any Other Business

6.1 Rapporteur

Andy Hart was appointed as rapporteur for the WG activities

7. Next meeting(s)

The next meeting will take place on 19-20 February 2014 in Parma.