

Scientific Committee

Minutes of the 7th meeting of the Working Group on TTC

Held on 5-6 February 2019, Parma

(Agreed on 20 February 2019)

Participants

- **Working Group Members:**

Diane Benford,¹ Ursula Gundert-Remy, Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **EFSA:**

SCER Unit: George Kass

PRAS Unit: Rositsa Serafimova

NUTRI Unit: Annamaria Rossi

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

¹ By teleconference

3. Declarations of Interest of Working Groups members

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

4. Presentation of the comments received from the public consultation

An overview of the comments received as part of the public consultation was presented. Overall 23 organisations or private individuals contributed to the public consultation with a total of 102 comments submitted through the commenting tool and an additional three letters.

5. Discussion of the comments received from the public consultation

Each comment was discussed individually during the meeting and replies to the comments will be included in the technical report that will be published alongside the Guidance once adopted by the Scientific Committee. The draft guidance was revised to incorporate clarifications or changes as identified from the comments received.

6. Next steps and distribution of tasks

The Working Group will be provided with the final version of the draft Guidance together with the draft technical report. All WG members were asked to review both documents.

The finalised version of the draft Guidance will be presented for discussion and possible adoption by the Scientific Committee at the 93rd SC Plenary that will Take place in Brussels on 24 April 2019. The technical report will be presented for endorsement.

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

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

Scientific Committee

Minutes of the 6th meeting of the Working Group on TTC

Held on 24-25 October 2018, Parma

(Agreed on 25 October 2018)

Participants

- **Working Group Members:**

Diane Benford, Ursula Gundert-Remy,¹ Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **EFSA:**

SCER Unit: George Kass, Linda Reilly

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with minor changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest

¹ By teleconference, morning day 1

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

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

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

4. Feedback from the Scientific Committee

The Chair presented the feedback received from the Scientific Committee at the 90th SC Plenary during the presentation of the draft guidance for endorsement for public consultation.

5. Discussion and agreement on the text of the draft Guidance

The text of the draft guidance was discussed in light of the comments received from the Scientific Committee and editorial changes were made.

6. Feedback to the Scientific Committee

A report was prepared listing all the comments made by the Scientific Committee together with the changes made to the draft guidance document.

7. Next steps and distribution of tasks

The Scientific Committee will be provided with the above report together with the revised draft guidance with all changes highlighted in the text. All WG members were asked to review the final draft.

8. Next meetings

The following date was agreed:

7th meeting: February 5-6 [14.00 (day 1) - 14.00 (day 2)]

Scientific Committee

Minutes of the 5th meeting of the Working Group on TTC

Held on 29 August 2018, by teleconference

(Agreed on 29 August 2018)

Participants

- **Working Group Members:**

Diane Benford, Ursula Gundert-Remy, Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **Hearing Experts¹:**

Beat Brüsweiler

- **EFSA:**

SCER Unit: George Kass, Linda Reilly

NUTRI Unit: Annamaria Rossi

PRAS Unit: Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with no changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

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>.

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Discussion and agreement on the text of the draft Guidance

Each section of the draft Guidance was discussed and editorial changes were made. The text of the draft Guidance was agreed for presentation at the 90th SC Plenary for endorsement for public consultation.

5. Next meetings

The following date was agreed:

6th meeting: October 24-25 [09.00 (day 1) - 14.00 (day 2)]

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

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

Scientific Committee

Minutes of the 4th meeting of the Working Group on TTC

Held on 30-31 May 2018, Parma

(Agreed on 31 May 2018)

Participants

- **Working Group Members:**

Diane Benford, Ursula Gundert-Remy, Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **Hearing Experts¹:**

Beat Brüsweiler

- **EFSA:**

SCER Unit: George Kass, Linda Reilly

FIP Unit: Annamaria Rossi

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with no changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

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>.

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd Working Group meeting held on 27 April 2018

The minutes of the 3rd Working Group meeting held by TC on 27 April 2018 were agreed. The minutes will be published on the EFSA website.

5. Discussion and agreement on the structure and content of the Guidance

The first four chapters of the draft Guidance were discussed and revised.

6. Next steps

The text will be cleaned up and sent out to the members of the WG for additional comments.

7. Next meetings

The following date was agreed:

5th meeting: August 29-30 [14.00 (day 1) - 15.00 (day 2)]

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

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

Scientific Committee

Minutes of the 3rd meeting of the Working Group on TTC

**Held on 27 April 2018, by teleconference
(Agreed on 30 May 2018)**

Participants

- **Working Group Members:**

Diane Benford, Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **Hearing Experts¹:**

Beat Brüscheweiler

Sylvia Escher

- **EFSA:**

SCER Unit: George Kass

Executive Office: Juliane Kleiner

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ursula Gundert-Remy.

2. Adoption of agenda

The agenda was adopted with no changes.

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

4. Agreement of the minutes of the 2nd Working Group meeting held on 15-16 February 2018

The minutes of the 2nd Working Group meeting held in Parma on 15-16 February 2018 were agreed. The minutes will be published on the EFSA website.

5. Discussion and agreement on the structure and content of the Guidance

The first three chapters of the draft Guidance were discussed and editorial changes were made. The TTC decision tree was discussed and provisionally agreed. The overall approach to Chapter 4, that will contain the description of the guidance, was agreed.

6. Next steps

The tasks for the next meeting were discussed and agreed upon.

7. Next meetings

The following date was agreed:

4rd meeting: May 30-31 [09.00 (day 1) - 14.00 (day 2)]

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

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

Scientific Committee

Minutes of the 2nd meeting of the Working Group on TTC

Held on 15-16 February 2018, Parma

(Agreed on 27 April 2018)

Participants

- **Working Group Members:**

Diane Benford, Sylvia Escher, Ursula Gundert-Remy,¹ Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **Hearing Experts²:**

Beat Brüscheweiler

Szabina Stice and Tim Adams (US-FDA)

- **EFSA:**

SCER Unit: George Kass

FIP Unit: Anna Maria Rossi

Executive Office: Juliane Kleiner

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted with minor changes.

¹ By teleconference.

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 1st Working Group meeting held on 8-9 November 2017

The minutes of the 1st Working Group meeting held in Parma on 8 and 9 November 2017 were agreed. The minutes will be published on the EFSA website.

5. Discussion and agreement on the structure and content of the Guidance

The structure of the draft Guidance was further discussed and the Working Group members confirmed that the guidance should be a single document. Reference to the 2012 EFSA scientific opinion on the TTC⁵ should be made except where pertinent new developments were identified from the EFSA-WHO workshop on the TTC⁶ or from new publications. The general structure of the guidance was agreed.

6. Presentation of an updated Cramer et al Decision Tree

Szabina Stice and Tim Adams (US-FDA) were invited to present the US-FDA updated Cramer et al. Decision Tree that is currently under development. Their participation was limited to providing the scientific input for which they were invited, without the possibility to draft, discuss or vote on any of the outputs being developed by the WG. The hearing experts from US-FDA attended the WG meeting by teleconference on 15 February 2018 from 16:00 to 17:00 h.

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

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

⁵ EFSA Scientific Committee; Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012;10(7):2750 [103 pp.] doi:10.2903/j.efsa.2012.2750

⁶ EFSA and WHO, 2016. Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA supporting publication 2016: EN-1006. 50 pp

7. Next steps

The tasks for the next meeting were discussed and agreed upon.

8. Next meetings

The following date was agreed:

3rd meeting: April 27 (10.00-13.00 h) (by teleconference)

Scientific Committee

Minutes of the 1st meeting of the Working Group on TTC

Held on 7-8 November 2017, Parma (Italy)

(Agreed on 15 February 2018)

Participants

- **Working Group Members:**

Diane Benford, Ursula Gundert-Remy,¹ Josef Schlatter, Heather Wallace (Chair) and Maged Younes

- **EFSA:**

SCER Unit: Georges Kass, Daniela Maurici

FIP Unit: Anna Maria Rossi

PRAS Unit: Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sylvia Escher. A round-the-table presentation of the participants took place.

2. Adoption of agenda

The agenda was adopted with minor changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

¹ By video link.

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

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Presentation and general discussion of the mandate and terms of reference

The mandate and terms of references were presented to the Working Group members and were discussed. The draft Guidance, once endorsed by the Scientific Committee, will be published for public consultation.

5. Discussion and agreement on the structure and content of the Guidance

The structure of the draft Guidance was discussed in light of the terms of reference. The Working Group members agreed that a single document comprising guidance and an update of the 2012 EFSA scientific opinion on the TTC⁴ should be developed. The latter should take into consideration the outcome of the EFSA-WHO workshop on the TTC⁵ published in 2016 and new publications since 2012. A separate facts sheet on the TTC Guidance will also be drafted for the lay public.

6. Next steps

The tasks for the next meeting were discussed and agreed upon.

7. Next meetings

The following dates for the next meetings in 2018 (to be held in Parma) were identified:

2nd Meeting: 15 February (14:00 - 18:00 h) and 16 February (9:00 - 15:00 h)

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

⁴ EFSA Scientific Committee; Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012;10(7):2750 [103 pp.] doi:10.2903/j.efsa.2012.2750

⁵ EFSA and WHO, 2016. Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA supporting publication 2016: EN-1006. 50 pp