

Scientific Committee

Minutes of the 9th meeting of the Working Group on Substances in Food for Infants

Held on 06 & 07 April 2017, Parma

(Agreed by written procedure on 08 June 2017)

Participants

Working Group Members

Jean-Louis Bresson, Birgit Dusemund, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter. Dominique Turck¹ and Ine Waalkens-Berendsen

EFSA

SCER Unit: George Kass

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Diane Benford, Ursula Gundert-Remy, Mathilde Kersting and Angelika Tritscher and Ruud Woutersen

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 Declarations of Interest,³ 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 Participated day 1 only.

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

³ 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. Agreement of minutes of the 8th Working Group meeting held on 11 - 13 January 2017.

The minutes of the 8^{th} Working Group meeting held in Parma on 11 - 13 January 2017 were agreed. The minutes will be published on the EFSA website.

5. Presentation of the outcome from the public consultation

A presentation of the comments received during the public consultation was made to inform the Working Groups members on the number, types and origin of the comments received.

6. Discussion of the comments received and revision of the draft Guidance

The Working Group members discussed the comments received as part of the public consultation and appropriate replies were drafted in support of the technical report that will be published alongside the Guidance once adopted by the Scientific Committee. In addition, a set of comments that had been received separately from the CONTAM Panel was presented and discussed by the Working Group members. Where appropriate, the draft Guidance was revised to take the comments received into consideration. The Working Group members thanked the providers of comments for their input and interest in the Guidance. The revised draft Guidance will be presented for adoption to the Scientific Committee at its 83rd Plenary Meeting to be held in Parma on 26-27 April 2017.



Scientific Committee

Minutes of the 8th meeting of the Working Group on Substances in Food for Infants

Held on 11-13 January 2017, Parma

(Agreed on 7 April 2017)

Participants

• Working Group Members

Jean-Louis Bresson, Birgit Dusemund (via telecon), Ursula Gundert-Remy (via telecon), Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Dominique Turck (via telecon), Ine Waalkens-Berendsen and Ruud Woutersen.

Observers

Andreia Alvarez-Porto (EC)

EFSA

SCER Unit: George Kass

1. Welcome and apologies for absence

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

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 Processes¹ and the Decision of the Executive Director on

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



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.

4. Agreement of minutes of the 7th Working Group meeting held on 8 and 9 December 2016

The minutes of the 7th Working Group meeting held in Parma on 8 and 9 December 2016 were agreed. The minutes will be published on the EFSA website.

5. Finalisation of the draft guidance

The Working Group members went through the various sections of the draft guidance documents to address any outstanding issues from past meetings. The approach for the Conclusion and Recommendation sections was agreed and appropriate text was drafted. The Working Group members finalised the draft guidance for presentation (for endorsement for public consultation) to the Scientific Committee at its 82nd Plenary Meeting to be held in Parma on 13-14 February 2017.

6. Next meetings

The following date for the next meeting in 2017 was identified. The meeting place will be Parma.

9th Meeting: April 6 (14:00-18:00) to 7 (9:00-15:00)

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 $^{^2\ \}mathsf{http://www.efsa.europa.eu/en/keydocs/docs/independencerules 2014.pdf}$



Scientific Committee

Minutes of the 7th meeting of the Working Group on Substances in Food for Infants

Held on 8 & 9 December 2016, Parma

(Agreed on 11 January 2017)

Participants

Working Group Members

Diane Benford,¹ Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Dominique Turck, Ine Waalkens-Berendsen² and Ruud Woutersen²

EFSA

SCER Unit: Jean-Lou Dorne, Georges Kass

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 Processes³ and the Decision of the Executive Director on Declarations of Interest,⁴ 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.

¹ Via conference call

² Present on day 1 and via conference call on day 2

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

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



4. Agreement of minutes of the 6th Working Group meeting held on 20 & 21 October 2016

The minutes of the 6th Working Group meeting held in Parma on 20 & 21 October 2016 were agreed. The minutes will be published on the EFSA website.

5. Feedback from the 81st Scientific Committee Plenary Meeting

The feedback received following the presentation of the draft guidance by the Chair of the Working Group was presented to the Working Group. The recommendations made by members of the Scientific Committee concerning content and presentation were discussed and the draft guidance was amended accordingly. Specifically, the section on testing strategy was revised and information on the comparative postnatal development phases in laboratory animals and humans was added in the form of a table.

6. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents dealing with methodological aspects and organ system development and agreed on revisions or updates to be inserted for the next working group meeting. In particular, the Conclusions section was discussed.

7. Next steps

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

8. Next meetings

The following date for the next meeting in 2017 was identified. The meeting place will be Parma.

8th Meeting: January 11 (14:00-18:00) to 13 (9:00-13:00)



Scientific Committee

Minutes of the 6th meeting of the Working Group on Substances in Food for Infants

Held on 20 & 21 October 2016, Parma

(Agreed on 8 December 2016)

Participants

Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Dominique Turck, Ine Waalkens-Berendsen¹ and Ruud Woutersen

Observers

Andreia Alvarez-Porto (EC)

• EFSA

SCER Unit: Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Angelika Tritscher.

2. Adoption of agenda

The agenda was adopted without changes.



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.

4. Agreement of minutes of the 5th Working Group meeting held on 15 & 16 September 2016

The minutes of the 5th Working Group meeting held in Parma on 15 & 16 September 2016 were agreed. The minutes will be published on the EFSA website.

5. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents dealing with methodological aspects and organ system development and agreed on revisions or updates to be inserted for the next working group meeting. In particular, the sections on the development of the gastrointestinal tract, ADME and brain barriers were revised and strategies for the risk assessment were discussed.

6. Next steps

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

7. Next meetings

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

7th Meeting: December 8 (14:00-18:00) to 9 (9:00-15:00)

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

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



Scientific Committee

Minutes of the 5th meeting of the Working Group on Substances in Food for Infants

Held on 16 & 17 September 2016, Parma

(Agreed on 20 October 2016)

Participants

• Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund,¹ Ursula Gundert-Remy,² Mathilde Kersting,¹ Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Dominique Turck, Ine Waalkens-Berendsen³ and Ruud Woutersen

Observers

Andreia Alvarez-Porto (EC)¹ Francesco Carlucci (EC)¹

EFSA

SCER Unit: Georges Kass, Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

DATA Unit: Davide Arcella

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Angelika Tritscher.

2. Adoption of agenda

The agenda was adopted with no changes.

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¹ Via conference call

² Participated day 2 only

³ Via conference call, day 2 only



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of minutes of the 4th Working Group meeting held on 8 & 9 July 2016

The minutes of the 4th Working Group meeting held in Parma on 8 & 9 July 2016 were agreed. The minutes will be published on the EFSA website.

5. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents dealing with methodological aspects and organ system development and agreed on revisions or updates to be inserted for the next working group meeting.

6. Hearing Experts

Cristine Bradley, Jossie Garthof, A. Wallace Hayes, Jari Korhonen and Aurélie Perrichet (representing SNE-ISDI) were invited to present their views on the topic of the mandate at the present meeting. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA had invited the above named persons to submit an ADoI. Their participation was limited to providing testimony, without the possibility to take on any role undertaken by members of the WG, in accordance with the applicable legal framework.²

The hearing experts attended the WG meeting on 17 September 2016 from approximately 10:15 to 11:45.

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

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



7. Next steps

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

8. Next meetings

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

6th Meeting: October 20 (14:00-18:00) to 21 (9:00-15:00)



Scientific Committee

Minutes of the 4th meeting of the Working Group on Substances in Food for Infants

Held on 7 & 8 July 2016, Parma

(Agreed on 15 September 2016)

Participants

• Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Dominique Turck and Ine Waalkens-Berendsen

EFSA

SCER Unit: Georges Kass, Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

DATA Unit: Davide Arcella, Sofia Ioannidou, Evangelia Mavromichali

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Angelika Tritscher and Ruud Woutersen. Apologies were also received from Andreia Alvarez-Porto (EC).

2. Adoption of agenda

The agenda was adopted with no changes.

¹ Via conference call, day 2 only

² Via conference call



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest^{4,} 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 minutes of the 3rd Working Group meeting held on 19 & 20 May 2016

The minutes of the 3^{rd} Working Group meeting held in Parma on 19 & 20 May 2016 were agreed. The minutes will be published on the EFSA website.

5. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents dealing with methodological aspects and organ system development and agreed on revisions or updates to be inserted for the next working group meeting.

6. Next steps

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

7. Next meetings

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

5th Meeting: September 15 (14:00-18:00) to 16 (8:00-15:00)

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

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



Scientific Committee

Minutes of the 3rd meeting of the Working Group on Substances in Food for Infants

Held on 19 & 20 May 2016, Parma

(Agreed on 07 July 2016)

Participants

• Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), André Penninks, Josef Schlatter, Ine Waalkens-Berendsen and Ruud Woutersen

Observer

Andreia Alvarez-Porto (EC)1

EFSA

SCER Unit: Georges Kass, Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

DATA Unit: Davide Arcella, Sofia Ioannidou

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Colin Ockleford, Angelika Tritscher and Dominique Turck.

2. Adoption of agenda

The agenda was adopted with no changes.

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¹ Via conference call.

² Participated on day 1 afternoon and day 2 only



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 minutes of the 2nd Working Group meeting held on 18 and 19 April 2016

The minutes of the 2nd Working Group meeting held in Parma on 18 and 19 April 2016 were agreed. The minutes will be published on the EFSA website.

5. Update on the draft mandate and terms of reference

The Working Groups members were informed by the EC observer that the mandate and the terms of reference for a scientific and technical guidance for the risk assessment of chemical substances present in food intended for infants will be sent to EFSA over the coming month.

6. Discussion on the scope of the guidance

The WG members agreed that the guidance should be aimed at identifying the toxicological requirements for assessing substances in the food for infants during the first weeks of age when health based guidance values such as ADI and TDI do not apply, without specifying a defined cut-off point (e.g. 12 weeks or 16 weeks).

7. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents and agreed on revisions or updates to be inserted for the next working group meeting.

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

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



8. Next steps

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

9. Next meetings

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

4th Meeting: July 7 (14:00-18:00h) to 8 (8:00-15:00h)



Scientific Committee

Minutes of the 2nd meeting of the Working Group on Substances in Food for Infants

Held on 28 & 29 April 2016, Parma

(Agreed on 19 May 2016)

Participants

Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter and Ine Waalkens-Berendsen

Observers

Andreia Alvarez-Porto (EC)

EFSA

SCER Unit: George Kass, Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Angelika Tritscher, Dominique Turck and Ruud Woutersen.

2. Adoption of agenda

The agenda was adopted without changes.



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of minutes of the 1st Working Group meeting held on 11 and 12 February 2016

The minutes of the of the 1st Working Group meeting held on 11 and 12 February 2016 were agreed.³

5. Update on the draft mandate and terms of reference on the terms of reference

The Working Groups members were informed that the European Commission was in the process of finalising a mandate and the terms of reference for a scientific and technical guidance for the risk assessment of chemical substances present in food intended for infants. It was agreed that the specified age period covered should be supported by nutritional and physiological arguments and will be defined in the section of the guidance document entitled 'Interpretation of the terms of reference'.

6. General discussion on the draft guidance

The Working Groups members went through the various sections of the draft guidance documents and agreed on revisions or updates to be inserted for the next working group meeting.

7. Next steps

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

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

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

http://www.efsa.europa.eu/sites/default/files/WGFoodInfants.pdf



8. Next meeting

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

3rd Meeting: May 19 (09:00-18:00) to 20 (9:00-13:00)



EFSA/SC/2102

Scientific Committee

Minutes of the 1st meeting of the Working Group on Substances in Food for Infants

Held on 11 & 12 February 2016, Parma

(Agreed on 28 April 2016)

Participants

Working Group Members

Diane Benford, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy, Mathilde Kersting, Claude Lambré, Alicja Mortensen (Chair), Colin Ockleford, André Penninks, Josef Schlatter, Angelika Tritscher, Dominique Turck, Ine Waalkens-Berendsen and Ruud Woutersen

Observers

Andreia Alvarez-Porto (EC)

EFSA

SCER Unit: Georges Kass, Jean-Lou Dorne

PRAS Unit: Daniele Court Marques

1. Welcome and apologies for absence

The Chair welcomed the participants. This was followed by a round-thetable presentation of all the participants

2. Adoption of agenda

The agenda was adopted without changes.

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¹ Via webconference.



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 on the terms of reference

The terms of reference as proposed by EFSA were endorsed by the Working Group members subject to editorial changes.⁴ It was agreed that the next step was to formalise the draft mandate as a self-tasking mandate proposed to EFSA by the Scientific Committee.

5. General discussion with presentations related to the terms of reference

Several presentations by members of the WG on elements of the terms of reference were made.

6. Next steps

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

7. Next meeting

The following date for the next meeting in 2016 was identified. The meeting place will be Parma.

2nd Meeting: April 28 (14:00-18:00) to 29 (8:00-15:00)

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

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

⁴ EFSA was informed following the WG meeting that EC will be providing a mandate for the risk assessment of substances present in food intended for infants.