

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 15th meeting of the Working Group on Procedure under Article 8

Held on 12 June 2018, as web-conference

(Agreed on 15 June 2018)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Birgit Dusemund, Pierre Galtier, Patrizia Restani and Ursula Gundert-Remy.

- **EFSA:**

FIP Unit: Fabiola Pizzo, Camilla Smeraldi.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Alicja Mortensen.

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 Processes and the Decision of the Executive Director on Declarations of Interest, 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 By written procedure

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of monacolin in red yeast rice ([EFSA-Q-2017-00138](#))

The Working Group finalised the draft opinion for the forthcoming ANS Plenary meeting in June, for possible adoption.

5. Any Other Business

None.

6. Next meeting(s)

-

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 14th meeting of the Working Group on Procedure under Article 8

Held on 2 May 2018 (as web-conference)

(Agreed on 15 May 2018)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Birgit Dusemund, Cristina Fortes, Pierre Galtier, Ursula Gundert-Remy, Alicja Mortensen, Patrizia Restani, Ivan Stankovic.

- **EFSA:**

FIP Unit: Fabiola Pizzo, Camilla Smeraldi.

- **European Commission**

Fruzsina Nyemecz

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Raul Andrade and Agneta, Oskarsson.

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 Processes and the Decision of the Executive Director on

¹ By written procedure

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

4. Scientific topic for discussion

4.1. Scientific opinion on the safety of monacolin in red yeast rice ([EFSA-Q-2017-00138](#))

Further to the previous discussion at the last meeting in April 2018, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at the forthcoming Plenary meeting in May.

5. Any Other Business

None.

6. Next meeting(s)

M15: 12 June 2018 (PM, as web-conference)

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 13th meeting of the Working Group on Procedure under Article 8

Held on 4 April 2018 (as web-conference)

(Agreed on 17 April 2018)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul Andrade, Birgit Dusemund, Cristina Fortes, Pierre Galtier, Ursula Gundert-Remy Agneta, Oskarsson, Patrizia Restani, Ivan Stankovic.

- **EFSA:**

FIP Unit: Fabiola Pizzo, Camilla Smeraldi.

NUTRI Unit: Andrea Germini.

- **European Commission**

Fruzsina Nyemecz, Athanasios Raikos

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Alicja Mortensen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

¹ By written procedure

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

4. Scientific topic for discussion

4.1. Scientific opinion on the safety of monacolin in red yeast rice ([EFSA-Q-2017-00138](#))

Further to the previous discussion at the last meeting in February 2018, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at the forthcoming Working Group meeting.

5. Any Other Business

None.

6. Next meeting(s)

M14: 2nd May 2018 (PM, as web-conference).

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 12th meeting of the Working Group on Procedure under Article 8

Held on 14-16 February 2018 in Parma

(Agreed on 27 February 2018)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul Andrade, Birgit Dusemund, Cristina Fortes, Pasquale Mosesso, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Pierre Galtier, Alicja Mortensen and Ursula Gundert-Remy attended via web-conference.

- **EFSA:**

FIP Unit: Fabiola Pizzo, Camilla Smeraldi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Ursula Gundert-Remy (for the first day of the meeting) and from Birgit Dusemund and Pasquale Mosesso (for the last day of the meeting).

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 Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest

¹ By written procedure

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. Scientific opinion on the safety green tea catechins ([EFSA-Q-2016-00627](#))

The Working Group finalised the draft opinion for the forthcoming ANS Plenary meeting in March, for possible adoption.

4.2. Scientific opinion on the safety of monacolin in red yeast rice ([EFSA-Q-2017-00138](#))

The Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at the forthcoming ANS Plenary meeting in March.

5. Any Other Business

None.

6. Next meeting(s)

Dates for the next meetings will be agreed between the Members of the Working Group in writing.

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 11th meeting of the Working Group on Procedure under Article 8

Held by WEB-conference, 19 January 2018

(Agreed on 24 January 2018)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul Andrade, Birgit Dusemund, Cristina Fortes, Pierre Galtier, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

- **EFSA:**

FIP Unit: Fabiola Pizzo, Camilla Smeraldi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies for absence 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 Processes and the Decision of the Executive Director on Declarations of Interest, 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

¹ By written procedure

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

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety green tea catechins ([EFSA-Q-2016-00627](#))

Further to the previous discussion at the last meeting in November 2017, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at the forthcoming meeting of the ANS Panel, in January.

4.2. Scientific opinion on the safety of monacolin in red yeast rice ([EFSA-Q-2017-00138](#))

The Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at a forthcoming Working Group meeting.

5. Any Other Business

None.

6. Next meeting(s)

M12: 13-15 February 2018 (as physical meeting in Parma).

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 10th meeting of the Working Group on Procedure under Article 8

Held by WEB-conference, 14 November 2017

(Agreed on 28 November 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Pierre Galtier, Pasquale Mosesso, Patrizia Restani, Ivan Stankovic.

Agneta Oskarsson and Cristina Fortes partly participated in agenda point 4.1.

- **EFSA:**

FIP Unit: Adamantia Papaioannou, Fabiola Pizzo, Camilla Smeraldi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies for absence 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 Processes and the Decision of the Executive Director on Declarations of Interest, 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

¹ By written procedure

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. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

The Working Group finalised the draft opinion for transmission to the forthcoming ANS Plenary meeting in November, for possible adoption.

4.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

This topic was not discussed due to lack of time and it will be scheduled on the agenda of a forthcoming meeting.

5. Any Other Business

None.

6. Next meeting(s)

Dates for the next meetings will be agreed between the Members of the Working Group in writing.

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 9th meeting of the Working Group on Procedure under Article 8

Held by WEB-conference, 11 October 2017

(Agreed on 23 October 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Cristina Fortes, Pierre Galtier, Alicja Mortensen, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 4.2.

Pasquale Mosesso participated in agenda point 4.1.

- **EFSA:**

FIP Unit: Adamantia Papaioannou, Fabiola Pizzo.

Nutri Unit: Andrea Germini

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Raul Andrade.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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

¹ By written procedure

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

Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

Following the discussion at the plenary meeting in September 2017, the Working Group produced a draft opinion based on the comments received from the panel members. The draft opinion will be scheduled for discussion at the forthcoming meeting of the ANS Panel in October, for possible adoption.

4.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

Following the discussion at the plenary meeting in September 2017, the Working Group produced a draft opinion based on the comments received from the panel members. The draft opinion will be scheduled for discussion at a forthcoming meeting.

5. Any Other Business

None.

6. Next meeting(s)

Dates for the next meetings will be agreed between the Members of the Working Group in writing.

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

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 8th meeting of the Working Group on Procedure under Article 8

Held on 12-13 September 2017, in Parma

(Agreed on 28 September 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul Andrade, Cristina Fortes, Pierre Galtier, Alicja Mortensen, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated via teleconference in agenda points 4.2 and 4.3.

Pasquale Mosesso participated in agenda points 4.1 and 4.3.

- **EFSA:**

FIP Unit: Adamantia Papaioannou, Fabiola Pizzo, Camilla Smeraldi.

- **Observer:**

Hellen A. Oketch on behalf of the USPharmacopeia, participated in agenda point 4.2 - Scientific opinion on the safety of green tea catechins.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Pasquale Mosesso (for the first day of the meeting).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

¹ By written procedure

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

Further to the previous discussion at the last meeting in June 2017, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at a forthcoming meeting of the ANS Panel.

4.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

Further to the previous discussion at the last meeting in June 2017, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled at a forthcoming meeting of the ANS Panel, for possible adoption.

4.3. Scientific opinion on the safety of monacolins in red yeast rice ([EFSA-Q-2017-00138](#))

Further to the previous discussion at the last meeting in June 2017, the Working Group produced a draft opinion based on the available data. The draft opinion will be scheduled for discussion at a forthcoming meeting.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 11 October 2017, as web conference.

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

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

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Minutes of the 7th meeting of the Working Group on Procedure under Article 8

Held by WEB-conference, 26 June 2017

(Agreed on 21 July 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul J. Andrade, Cristina Fortes, Pierre Galtier, Alicja Mortensen, Pasquale Mosesso, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 4.2 and 4.3.

- **EFSA:**

FIP Unit: Adamantia Papaioannou, Fabiola Pizzo, Camilla Smeraldi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Agneta Oskarsson.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

¹ By written procedure

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

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

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

Following the discussion at the plenary meeting in June 2017, the Chair updated the Working Group on the initial feedback received from the Panel on the approach to be followed.

In addition, the Working Group was informed about the outcome of the call for data launched to gather information from relevant interested parties. Compilation of the information will require some time and therefore a request for extension of the deadline until the end of November 2017 has been sent to the European Commission.

Individual tasks and deadlines were assigned to the Working Group members. The draft opinion will be scheduled for discussion at a forthcoming meeting.

4.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

Further to the previous discussion at the last meeting in June 2017, the Working Group produced a draft opinion based on the available data.

In addition, the Working Group was informed about the outcome of the call for data launched to gather information from relevant interested parties.

Individual tasks and deadlines were assigned to the Working Group members. The draft opinion will be scheduled for discussion at a forthcoming meeting.

4.3. Scientific opinion on the safety of monacolins in red yeast rice ([EFSA-Q-2017-00138](#))

Further to the previous discussion at the last meeting in June 2017, the Working Group produced a draft opinion based on the available data. The Working Group agreed to seek the view of the ANS Panel on the interpretation of the terms of reference and the approach to be taken in the evaluation. Individual tasks and deadlines were assigned to the WG members. The draft opinion will be scheduled for discussion at a forthcoming meeting.

5. Any Other Business

None.

6. Next meeting(s)

The next meetings are scheduled as follows:

- 12-13 September 2017, as physical meeting in Parma.

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 6th meeting of the Working Group on Procedure under Article 8

Held on 13-15 June 2017 in Milan

(Agreed on 27 June 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul J. Andrade, Cristina Fortes, Pierre Galtier, Pasquale Mosesso, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 5.2 and 5.3.

- **EFSA:**

FIP Unit: Alessandra Giarola, Fabiola Pizzo, Camilla Smeraldi.

- **Hearing expert:**

Jacqueline Wiesner (for agenda point 5.1)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Alicja Mortensen and from Cristina Fortes (only for 14 June, PM).

Birgit Dusemund and Cristina Fortes participated via teleconference.

Birgit Dusemund did not participate in agenda point 5.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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

¹ By written procedure

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

Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Hearing Expert(s)

Dr. Jacqueline Wiesner, on behalf of the Herbal Medicinal Products Committee (HMPC) of the European Medicines Agency (EMA), was invited to present her views for agenda item 5.1 – Scientific opinion on the safety of hydroxyanthracene derivatives of the present meeting.

5. Scientific topic(s) for discussion

5.1. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

Further to the previous discussion at the last meeting in April 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

The draft opinion will be scheduled for discussion at the next ANS Plenary meeting in June.

5.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

Further to the previous discussion at the last meeting in April 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

5.3. Scientific opinion on the safety of monacolins in red yeast rice ([EFSA-Q-2017-00138](#))

The new mandate received was considered by the WG members and the draft opinion will be scheduled for discussion at a forthcoming meeting.

6. Any Other Business

6.1. None.

7. Next meeting(s)

The next meeting are scheduled as follows:

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

- 26 June 2017, as web-conference
- 12-13 September 2017, as physical meeting in Parma.

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 5th meeting of the Working Group on Procedure under Article 8

Held on 19-20 April 2017 in Milan

(Agreed on 15 May 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Cristina Fortes, Pierre Galtier, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 4.2.

- **EFSA:**

FIP Unit: Camilla Smeraldi, Fabiola Pizzo, Adamantia Papaioannou

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Raul Andrade.

Birgit Dusemund and Alicja Mortensen participated via teleconference.

Birgit Dusemund did not participate in agenda point 4.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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

¹ By written procedure

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

Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives ([EFSA-Q-2016-00562](#))

Further to the previous discussion at the last meeting in March 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

In addition, the Working Group was informed about the launch of a call for data to gather information from relevant interested parties. The call is published on the EFSA website.⁴

4.2. Scientific opinion on the safety of green tea catechins ([EFSA-Q-2016-00627](#))

Further to the previous discussion at the last meeting in March 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

In addition, the Working Group was informed about the launch of a call for data to gather information from relevant interested parties. The call is published on the EFSA website.⁵

4.3. Scientific opinion on the safety of monacolins in red yeast rice ([EFSA-Q-2017-00138](#))

A Rapporteur was appointed for the drafting of the scientific opinion. The draft opinion will be scheduled for discussion at a forthcoming meeting.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 13-15 June 2017, as a physical meeting, in Parma, Italy.

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

⁴ <http://www.efsa.europa.eu/en/data/call/170410-0>

⁵ <http://www.efsa.europa.eu/en/data/call/170410>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 4th meeting of the Working Group on Procedure under Article 8

Held on 6-7 March 2017 in Parma as teleconference

(Agreed on 23 March 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (Chair), Raul Andrade, Cristina Fortes, Pierre Galtier, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 4.2.

- **EFSA:**

FIP Unit: Camilla Smeraldi, Fabiola Pizzo, Adamantia Papaioannou

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Agneta Oskarsson and Alicja Mortensen, for the second day of the meeting (7th March).

Birgit Dusemund did not participate in agenda point 4.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

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

¹ By written procedure

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

Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives (EFSA-Q-2016-00562)⁴

Further to the previous discussion at the last meeting in February 2017, the Working Group produced a draft opinion based on the data available. An update on the exposure assessment was presented by the DATA Unit. Individual tasks and deadlines were assigned to the WG members.

4.2. Scientific opinion on the safety of green tea catechins (EFSA-Q-2016-00627)⁵

Further to the previous discussion at the last meeting in February 2017, the Working Group produced a draft opinion based on the data available. An update on the exposure assessment was presented by the DATA Unit. Individual tasks and deadlines were assigned to the WG members.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 19-20 April 2017, as a physical meeting, in Milan, Italy.

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00562>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00627>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 3rd meeting of the Working Group on Procedure under Article 8

Held on 6-7 February 2017 in Parma

(Agreed on 20 February 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (chair), Raul Andrade, Cristina Fortes, Pierre Galtier, Alicja Mortensen, Pasquale Mosesso, Patrizia Restani, Ivan Stankovic.

Birgit Dusemund participated in agenda point 4.2.

- **EFSA:**

FIP Unit: Camilla Smeraldi, Fabiola Pizzo, Adamantia Papaioannou

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received from Agneta Oskarsson.

Birgit Dusemund did not participate in agenda point 4.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of

¹ By written procedure

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

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

Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives (EFSA-Q-2016-00562)⁴

Further to the previous discussion at the last meeting in January 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

4.2. Scientific opinion on the safety of green tea catechins (EFSA-Q-2016-00627)⁵

Further to the previous discussion at the last meeting in January 2017, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 6-7 March 2017 as web-conference.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00562>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00627>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 2nd meeting of the Working Group on Procedure under Article 8

Held on 16-17 January 2017 in Parma

(Agreed on 31 January 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (chair), Raul Andrade, Cristina Fortes, Pierre Galtier, Pasquale Mosesso, Agneta Oskarsson, Ivan Stankovic, Patrizia Restani.

Birgit Dusemund participated in agenda point 4.2.

- **EFSA:**

FIP Unit: Camilla Smeraldi, Fabiola Pizzo, Adamantia Papaionnaou

1. Welcome and apologies for absence

The Chair welcomed the participants.

Since the first meeting in December, two new experts joined the Working Group. All the participants introduced themselves and presented their scientific background. EFSA secretariat introduced the remit of this newly established Standing Working Group (WG) of the ANS Panel.

Birgit Dusemund did not participate in agenda point 4.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

¹ By written procedure

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives (EFSA-Q-2016-00562)⁴

Further to the initial discussion at the previous meeting in December 2016, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

4.2. Scientific opinion on the safety of green tea catechins (EFSA-Q-2016-00627)⁵

Further to the initial discussion at the previous meeting in December 2016, the Working Group produced a draft opinion based on the data available. Individual tasks and deadlines were assigned to the WG members.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 6-7 February 2017 in Parma.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00562>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00627>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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

Minutes of the 1st meeting of the Working Group on Procedure under Article 8

Held on 13th December 2016 (Web-conference)

(Agreed on 04 January 2017)¹

Participants

- **Working Group Members:**

Matthew Wright (chair), Cristina Fortes, Pierre Galtier, Pasquale Mosesso, Agneta Oskarsson, Ivan Stankovic.

Birgit Dusemund has participated in agenda point 4.2.

- **European Commission:**

Yvette Azzopardi (DG SANCO) partially attended the meeting.

- **EFSA:**

FIP Unit: Camilla Smeraldi, Fabiola Pizzo, Adamantia Papaionnaou

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alicja Mortensen.

All the participants introduced themselves and presented their scientific background. EFSA secretariat introduced the remit of this newly established Standing Working Group (WG) of the ANS Panel.

Birgit Dusemund did not participate in agenda point 4.1 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

¹ By written procedure

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Scientific topic(s) for discussion

4.1. Scientific opinion on the safety of hydroxyanthracene derivatives⁴

The WG discussed the approach to be taken regarding the new mandate received and on the availability of the data. A Rapporteur was appointed for the drafting of the scientific opinion. The draft opinion will be scheduled for discussion at a forthcoming meeting. Individual tasks and deadlines were assigned to the WG members.

4.2. Scientific opinion on the safety of green tea catechins⁵

The WG discussed the approach to be taken regarding the new mandate received and the on availability of the data. A Rapporteur was appointed for the drafting of the scientific opinion. The draft opinion will be scheduled for discussion at a forthcoming meeting. Individual tasks and deadlines were assigned to the WG members.

5. Any Other Business

None.

6. Next meeting(s)

The next meeting will be held on 16-17 January 2017 in Parma.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00562>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00627>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In her SDoI Dr. Dusemund Birgit declared the following interest: 'I finalised on 27.06.2014 a report on behalf of BfR, on the safety evaluation of "whole Aloe arborescens leaves" as food supplements. This included an evaluation of hydroxyanthracene derivatives as the main components of this botanical. This report was sent to the Federal Ministry of Food and Agriculture (BMEL) and is not published until now but may be published in near future'.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of item 4.1 'Scientific opinion on the safety of hydroxyanthracene derivatives' by the concerned scientific group.

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

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