

37th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

09 December 2025, 14:00 – 17.30 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group (WG) Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukula-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner
- European Commission: Fruzsina Nyemecz
- EFSA:
NIF Unit: Simone Crisopulli, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijevic, Ariane Titz
MESE UNIT: Alexis Nathanail
- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked to Jacqueline Wiesner. No new interests were declared.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Agreement of the minutes of the 36th Working Group meeting held on 03rd December 2025

The minutes of the 36th Working Group meeting were agreed by written procedure on 11 December 2025.

V. Scientific topics for discussion

a) Draft opinion on Berberine-containing plant preparations – EFSA-Q-2022-00803.

The integration of the evidence on berberine and protoberberine alkaloids and the formulation of data gaps were discussed with the WG and comments from the experts were addressed.

VI. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organised.

VII. Next meeting

The next meeting will be held on 11th December, via web-conference.

36th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

03 December 2025, 9:00 – 13.00 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group (WG) Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Virginia Kukula-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Simone Crisopulli, Agnès De Sesmaisons, Lucia Fabiani, Leonard Matijevic, Ariane Titz
- MESE UNIT: Alexis Nathanail

FEED UNIT: Paola Manini

- Others:
Observers from the European Medicines Agency: Jorge Rodrigues
- Mario Negri Institute: Emilio Benfenati

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 35th Working Group meeting held on 27th November 2025

The minutes of the 35th Working Group meeting were agreed by written procedure on 03 December 2025.

V. Scientific topics for discussion

VI. Draft opinion on Berberine-containing plant preparations – EFSA-Q-2022-00803.

The results of the Quantitative structure-activity relationship analysis for berberine and protoberberine alkaloids was discussed with the WG and comments from the experts were addressed.

VII. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organised.

VIII. Next meeting

The next meeting will be held on 9th December, via web-conference.

35th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

27 November 2025, 9:00 – 13.00 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group (WG) Members:
Alexandre Maciuk (WG chair), Jacqueline Castenmiller, Eugenia Dogliotti, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Océane Albert, Simone Crisopulli, Lucia Fabiani, Thibault Fiolet, Leng Heng, Vânia Mendes, Ariane Titz
- MESE UNIT: Rita Ferreira De Sousa

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Wirginia Kukula-Koch, Carlo Bicchi and Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 34th Working Group meeting held on 14th November 2025

The minutes of the 34th Working Group meeting were agreed by written procedure on 27 November 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Scientific topics for discussion

a) Draft opinion on hydroxycitric acid (HCA) and plant preparations containing HCA – EFSA-Q-2022-00805.

The updated draft text on the above-mentioned opinion, regarding sections on HCA salts, *Garcinia gummi-gutta* (L.) Roxb and *Hibiscus sabdariffa* L. was discussed with the WG and comments from the experts were addressed. The exposure assessment was presented and discussed with the WG.

VI. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organised.

VII. Next meeting

The next meeting will be held on 03rd December, via web conference.

34th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

14 November 2025, 9:00 – 13.00 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Jacqueline Castenmilller, Eugenia Dogliotti, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Simone Crisopulli, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leng Heng, Leonard Matijević, Vânia Mendes, Annamaria Rossi, Ariane Titz
FEED UNIT: Paola Manini

MESE UNIT: Alexis Nathanail, Alicia Paini

- Others:
Observers from the European Medicines Agency: Erika Svedlund
Mario Negri Institute: Emilio Benfenati

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Wirginia Kukula-Koch, Carlo Bicchi, Inge Mangelsdorf and Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Agreement of the minutes of the 33rd Working Group meeting held on 7th November 2025

The minutes of the 33rd Working Group meeting were agreed by written procedure on 14 November 2025.

V. Scientific topics for discussion

a) Draft opinion on hydroxycitric acid and plant preparations containing hydroxycitric acid – EFSA-Q-2022-00805.

The updated draft text on toxicological studies of HCA and plant-preparations and case reports of *G. gummi gutta* was discussed with the WG and comments from the experts were addressed.

b) Draft opinion on Berberine-containing plant preparations – EFSA-Q-2022-00803.

The updated draft text on case reports of *Chelidonium majus* was discussed with the WG and comments from the experts were addressed. The use of read-across for chemical safety assessment and its potential application in the context of this assessment was discussed.

VI. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organized.

VII. Next meeting

The next meeting will be held on 27th November, via web conference.

33rd Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

7 November 2025, 9:00 – 13.00 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Jacqueline Castenmiller, Eugenia Dogliotti, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner
- EFSA:
NIF Unit: Simone Crisopulli, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leng Heng, Vânia Mendes, Annamaria Rossi, Ariane Titz
- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Wirginia Kukula-Koch and Carlo Bicchi.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 32nd Working Group meeting held on 4th November 2025

The minutes of the 32nd Working Group meeting were agreed by written procedure on 7 November 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Scientific topics for discussion

a) Draft opinion on hydroxycitric acid and plant preparations containing hydroxycitric acid – EFSA-Q-2022-00805.

The updated draft text on the characterisation and conclusions of HCA and plant-preparations was discussed with the WG and comments from the experts were addressed.

VI. AOB

The WG received an update on the MOE discussion regarding the fennel opinion, held by the MOE WG on 5 November 2025.

VII. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organized.

VIII. Next meeting

The next meeting will be held on 14th November, via web conference.

32nd Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

4 November 2025, 14:00 - 17:30 hours (CET)

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Jacqueline Castenmiller, Eugenia Dogliotti, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner
- EFSA:
NIF Unit: Simone Crisopulli, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leng Heng, Vânia Mendes, Annamaria Rossi, Ariane Titz
- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Wirginia Kukula-Koch and Carlo Bicchi.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 31st Working Group meeting held on 22nd October 2025

The minutes of the 31st Working Group meeting were agreed by written procedure on 4 November 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Scientific topics for discussion

a) Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The data from animal studies on plant preparations were presented to the WG and discussed.

b) Draft opinion on preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl) – EFSA-Q-2022-00804.

The WG was updated on the comments received during the public consultation.

VI. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organized.

VII. Next meeting

The next meeting will be held on 7th November, via web conference.

31st Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

22 October 2025, 9:00 - 13:00 hours (CEST)

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Inge Mangelsdorf, Ulla Beckman Sundh
- EFSA:
NIF Unit: Océane Albert, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijević, Vânia Mendes, Ariane Titz
MESE UNIT: Alexis Nathanail
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner and Kirsten Pilegaard.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 30th Working Group meeting held on 15th October 2025

The minutes of the 30th Working Group meeting were agreed by written procedure on 22 October 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topics for discussion

a) Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The updated draft text on the toxicological studies and human case reports of the HCA opinion was discussed with the WG and comments from the experts were addressed.

b) Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The human case reports on *Chelidonium majus* were presented to the WG and discussed.

VI. Any other business

The WG members were requested to provide their availabilities for 2026.

VII. Preparatory meeting(s)

Since the last WG meeting, no preparatory meetings chaired by EFSA Staff were organized.

VIII. Next meeting

The next meeting will be held on 4th November, via web conference.

30th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)

15 October 2025, 9:00 - 13:00 hours (CEST)

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Victor Bunea, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijević, Vânia Mendes, Ariane Titz.
MESE UNIT: Alexis Nathanail
- Others:
Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 29th Working Group meeting held on 7th October 2025

The minutes of the 29th Working Group meeting were agreed by written procedure on 13 October 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topics for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The updated draft text on the toxicological studies of the HCA opinion was discussed with the WG and comments from the experts were addressed.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The draft text of the opinion on the data from animal and human studies on berberine, other protoberberine alkaloids and *Chelidonium majus* was presented to the WG and discussed.

VI. Preparatory meeting(s)

Since the 29th WG meeting, one preparatory meeting was organized on 13th October, as follows:

- **1.a** Working Group Members: Calor Bicchi, Wirginia Kukula-Koch and Alexandre Maciuk
- **1.b** Discussion points: assessment strategy for future evaluations of plant preparations under article 8(2) of Regulation 1925/2006

VII. Next meeting

The next meeting will be held on 22nd October, via web conference.



**SCIENTIFIC PANEL ON
NUTRITION, NOVEL FOODS AND FOOD ALLERGENS**
29th Working Group meeting on substances other than
vitamins and minerals (Art.8(2) of Regulation (EC) No
1925/2006)



7 October 2025
09:00-13:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmilller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Victor Bunea, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijević, Vânia Mendes, Ariane Titz.
FEEDCO UNIT : Paola Manini
MESE UNIT: Alexis Nathanail
- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked by the WG chair. No new interests were declared.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 28th Working Group meeting held on 2nd October 2025.

The minutes of the 28th Working Group meeting were agreed by written procedure on 14 October 2025.

V. Scientific topic(s) for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The updated draft text of the HCA opinion on the absorption, digestion, metabolism and extraction of HCA, on toxicological and mechanistic data on HCA salt, *Garcinia gummi-gutta* and *Hibiscus sabdariffa* was discussed with the WG and comments from the experts were addressed.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The draft text of the opinion on the data from animal and human studies on berberine and other protoberberine alkaloids was presented to the WG and discussed.

VI. Preparatory meeting(s)

Since the last 28th WG meeting, one preparatory meeting was organized on 3 October as follows:

- **1.a** Working Group Members: Alexandre Maciuk, Jacqueline Castenmiller, Eugenia Dogliotti, Inge Mangelsdorf
- **1.b** Discussion points: assessment strategy for future evaluations of plant preparations under article 8(2) of Regulation 1925/2006

VII. Next meeting

The next meeting will be held on 15 October, via web conference.



**SCIENTIFIC PANEL ON
NUTRITION, NOVEL FOODS AND FOOD ALLERGENS**
28th Working Group meeting on substances other than
vitamins and minerals (Art.8(2) of Regulation (EC) No
1925/2006)



2 October 2025
09:00-13:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wiriunia Kukuła-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Victor Bunea, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijević, Vânia Mendes, Annamaria Rossi, Ariane Titz.

MESE UNIT: Alexis Nathanail

- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked by the WG chair. No new interests were declared.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 27th Working Group meeting held on 25th September 2025.

The minutes of the 27th Working Group meeting were agreed by written procedure on the 3rd of October 2025.

V. Scientific topic(s) for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The updated draft text of the HCA opinion on the absorption, digestion, metabolism and extraction of HCA, on toxicological and mechanistic data on HCA salt, *Garcinia gummi-gutta* and *Hibiscus sabdariffa* was discussed with the WG and comments from the experts were addressed.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The use of read-across and QSAR predictions for chemical safety assessment in food and feed and its potential application in the context of this assessment was discussed.

VI. Preparatory meeting(s)

Since the last 27th WG meeting, no preparatory meetings chaired by EFSA Staff were held.

VII. Next meeting

The next meeting will be held on 7 October, via web conference.



SCIENTIFIC PANEL ON

NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

27th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)



25th September 2025
14:00-18:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wiriunia Kukuła-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman Sundh
- EFSA:
NIF Unit: Elisa Beneventi, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Heng Leng, Leonard Matijević, Vânia Mendes, Annamaria Rossi, Iciar Saenz, Ariane Titz, Emanuela Turla.
FEED UNIT: Paola Manini

KNOW UNIT: Bernard Bottex

MESE UNIT: Alexis Nathanail
- Others:
Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues
Mario Negri Institute: Emilio Benfenati

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



An oral DOI was asked by the WG chair. No new interests were declared.

IV. Agreement of the minutes of the 26th Working Group meeting held on 18th September 2025.

The minutes of the 26th Working Group meeting were agreed by written procedure on the 26th of September 2025.

V. Scientific topic(s) for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The updated draft text of the HCA opinion was discussed with the WG and comments from the experts were addressed.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

An overview on EFSA's Guidance on the use of read-across for chemical safety assessment in food and feed and its potential application in the context of this assessment was presented to the WG.

VI. Preparatory meeting(s)

Since the last 26th WG meeting, no preparatory meetings chaired by EFSA Staff were held.

VII. Next meeting

The next meeting will be held on 2nd October, via web conference



18th September 2025
09:00-13:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Eugenia Dogliotti, Wirginia Kukuła-Koch, Inge Mangelsdorf, Kirsten Pilegaard, Ulla Beckman-Sundh
- EFSA:
NIF Unit: Victor Bunea, Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Heng Leng, Vânia Mendes, Annamaria Rossi, Iciar Saenz, Ariane Titz.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Castenmiller and Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked by the WG chair. No new interests were declared.

IV. Agreement of the minutes of the 25th Working Group meeting held on 10th September 2025.

The minutes of the 25th Working Group meeting were agreed by written procedure on the 18th of September 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

An update on the discussion of evidence integration for HCA and HCA-containing plants was given to the WG. Comments from the WG experts were addressed. The section on genotoxicity was discussed and an overview on the toxicological data gathered on *Hibiscus sabdariffa* was presented.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

An update of the draft text on the genotoxicity assessment was presented to the WG and comments were addressed. The WG discussed also the updated text on the assessment of preparations of rhizome of *H. canadensis*.

VI. Preparatory meeting(s)

Since the last 25th WG meeting, no preparatory meeting chaired by EFSA Staff were held.

VII. Next meeting

The next meeting will be held on 25th September, via web conference.



10th September 2025
09:00-13:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh.
- EFSA:
NIF Unit: Victor Bunea, Agnes De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Heng Leng, Vânia Mendes, Iciar Saenz, Ariane Titz.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Inge Mangelsdorf and Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked by the WG chair. No new interests were declared.

IV. Agreement of the minutes of the 24th Working Group meeting held on 4th September 2025.

The minutes of the 24th Working Group meeting were agreed by written procedure on the 12th of September 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

An update on the discussion of evidence integration for HCA and HCA-containing plant. An update on the structure for the HCA opinion was presented to the WG. The draft text on the characterization of the exposure, the absorption, digestion, metabolism and extraction of HCA and HCA-containing plant preparations, and on the genotoxicity, assessments were discussed. Comments from the WG experts were addressed. An overview on the toxicological data gathered on Hibiscus Sabdariffa was presented to the WG.

The sections on characterization of the exposure, genotoxicity and the absorption, digestion, metabolism and extraction of HCA and HCA-containing plant preparations will be presented for endorsement to the NDA panel the 29th and 30th of September.

VI. Preparatory meeting(s)

Since the last 24th WG meeting, no preparatory meeting chaired by EFSA Staff were held.

VII. Next meeting

The next meeting will be held on 18th September, via web conference



SCIENTIFIC PANEL ON

NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

24th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)



4th September 2025
09:00-13:00

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh.
- EFSA:
NIF Unit: Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Heng Leng, Leonard Matijević, Vânia Mendes, Alexis Nathanail, Iciar Saenz, Ariane Titz.
MESE Unit: Alicia Paini
- Others:
Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

II. The Chair welcomed the participants. Apologies for absence were received from Inge Mangelsdorf and Jacqueline Wiesner. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked by the WG chair. No new interests were declared.

IV. Agreement of the minutes of the 23rd Working Group meeting held on 11th and 12th June 2025, in person

The minutes of the 23rd Working Group meeting were agreed by written procedure on the 26th of June 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803

An update on the structure for the berberine opinion was presented to the WG. The draft text on the absorption, digestion, metabolism and extraction of berberine and other protoberberine alkaloids, and on the genotoxicity assessments were discussed, and comments from the WG experts were addressed. An overview on the toxicological data gathered for preparations of *Hydrastis canadensis* and *Chelidonium majus* was provided to the WG.

VI. Preparatory meeting(s)

Since the last 23rd WG meeting, two preparatory meeting chaired by EFSA Staff were held as follows:

1 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 2nd July 2025

1.a Working Group Members: Jacqueline Castenmiller, Jacqueline Wiesner.

1.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the integration of evidence and the outcomes of the toxicity studies related to the above mandate.

2 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 23rd July 2025

1.a Working Group Member: Jacqueline Castenmiller, Jacqueline Wiesner.

1.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the integration of evidence and the outcomes of the toxicity studies related to the above mandate.

VII. Next meeting

The next meeting will be held on 10th September, via web conference



SCIENTIFIC PANEL ON

NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

23rd Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)



11th and 12th June 2025

First day 09:00-18:00

Second day 09:00-13:00

Location: EFSA Premises, Meeting Room 00/M06A (11/06) & 00/M03 (12/06) - Parma, and via Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner¹.
- Hearing Experts²:
Inge Mangelsdorf
- EFSA:
 - NIF Unit: Lucia Fabiani, Thibault Fiolet, Heng Leng, Leonard Matijević, Vânia Mendes, Annamaria Rossi¹, Iciar Saenz, Ariane Titz.
 - MESE Unit: Alicia Paini¹, Rita de Sousa Ferreira, Angelica di Fazio
 - FEED Unit: Paola Manini
- Others:
Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

An oral DOI was asked to Ulla Beckman Sundh. No new interests were declared.

¹ Only on 11th June

² As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 22nd Working Group meeting held on 12th May 2025, via web-conference

The minutes of the 22nd Working Group meeting were agreed by written procedure on the 26th of May 2025.

V. Scientific topic(s) for discussion

a. Draft opinion on Fennel – EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)

The feedback from the scientific committee meeting was presented to the WG.

The final draft opinion on the safety of fennel preparation was discussed. The WG was presented with an updated ADME section, and amendments were made to the discussion and conclusion. After further editorial changes the draft will be presented to the NDA panel.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

The feedback from the Scientific Committee cross-cutting Genotoxicity Working Group meeting on the genotoxicity section was presented to the WG and comments from the experts were addressed. The discussion, conclusions and recommendations on berberine genotoxicity were reviewed.

The approach to integration of the evidence from animal and human studies retrieved was discussed with the WG. The evidence from the animal toxicity studies was presented. The WG also discussed the sections on characterisation of the plant preparations. Preliminary results of the exposure assessment on berberine were presented.

c. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

An update on the discussion of evidence integration for HCA and HCA-containing plant preparations was given to the WG. The evidence from the animal toxicity studies, case reports and human trials was addressed. The available consumption data and the exposure assessment being carried out for HCA and HCA containing plant preparations was presented.

d. Draft opinion on Monacolins in red yeast rice - EFSA-Q-2023-00424 - Scientific Opinion on additional scientific data related to the safety of monacolins from red yeast rice submitted pursuant to Article 8(4)

The feedback from the ad-hoc meeting with food business representatives was discussed with the WG. Minor amendments and editorial changes will be made to the opinion before re-publication.



VI. Preparatory Meeting(s)

Since the last 22nd WG meeting, seven preparatory meeting chaired by EFSA Staff were held as follows:

1 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 16th May 2025

1.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard.

1.b Discussion points: integration of the evidence from toxicity studies related to the above mandates.

2 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, 21st May 2025

2.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard.

2.b Discussion points: results from general toxicology studies related to the above mandate.

3 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 21st May 2025

3.a Working Group Members: Jacqueline Wiesner.

3.b Discussion points: results from general toxicology studies related to the above mandate.

4 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 23rd May 2025

4.a Working Group Member: Jacqueline Castenmiller

4.b Discussion points: results from general toxicology studies related to the above mandate.

5 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 28th May 2025

5.a Working Group Members: Jacqueline Castenmiller, Jacqueline Wiesner.

5.b Discussion points: results from general toxicology studies related to the above mandate.

6 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, 28th May 2025

6.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard.

6.b Discussion points: results from general toxicology studies related to the above mandate.

7 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 4th June 2025

7.a Working Group Members: Jacqueline Castenmiller, Jacqueline Wiesner.

7.b Discussion points: integration of the evidence from toxicity studies related to the above mandate.



8 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, 4th June 2025

8.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard.

8.b Discussion points: integration of the evidence from toxicity studies related to the above mandate.

VII. Next meeting

The next meeting will be held on the 29th July, via web conference.



12th May 2025
14:00-17:30

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner.
- EFSA:
NIF Unit: Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Thibault Fiolet, Georges Kass, Heng Leng, Leonard Matijević, Vânia Mendes, Annamaria Rossi, Iciar Saenz, Ariane Titz.
MESE Unit: Alicia Paini.
- Others:
Observers from the European Medicines Agency: Erika Svedlund.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 21st Working Group meeting held on 9th April 2025, via web-conference

The minutes of the 21st Working Group meeting were agreed by written procedure on the 27th of April 2025.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Upcoming Article 8.2.

An update on the upcoming twelve mandates under Article 8.2. of Regulation (EC) 1925/, was presented to the WG, including the drafting of protocols for the scientific assessments, and the preparatory work being carried out based on the EFSA's current knowledge.

b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.

An overview on the data gathered on berberine and other protoberberine alkaloids was presented to the WG. The characterisation of the plant preparations in the European Commission (EC) mandate, the ADME data for berberine and the evidence from general toxicity and genotoxicity studies were discussed. Comments from the WG experts were addressed. The identification of data gaps and the different possible approaches to this risk assessment were discussed.

The evidence from the genotoxicity studies, the discussion and the conclusion on berberine genotoxicity will be presented to the Scientific Committee cross-cutting Genotoxicity Working Group.

c. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.

The draft opinion on the HCA and HCA-containing plant preparations was reviewed, and the comments from the WG experts were addressed. The ADME section, toxicity data and the characterisation section of the plants in the EC mandate were discussed.

VI. Preparatory Meeting(s)

Since the last 21st WG meeting, three preparatory meeting chaired by EFSA Staff was held as follows:

1 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 10th April 2025

1.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard

1.b Discussion points: results from general toxicology studies related to the above mandates

2 Preparatory meeting on berberine-containing plant preparations – EFSA-Q-2022-00803, 5th May 2025

1.a Working Group Member: Eugenia Dogliotti

1.b Discussion points: genotoxicity section



3 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 6th May 2025

1.a Working Group Members: Ulla Beckman Sundh, Kirsten Pilegaard.

1.b Discussion points: integration of the evidence from toxicity studies related to the above mandates.

VII. Next meeting

The next meeting will be held on 11th and 12th June, in Parma.



**SCIENTIFIC PANEL ON
NUTRITION, NOVEL FOODS AND FOOD ALLERGENS**
21st Working Group meeting on substances other than
vitamins and minerals (Art.8(2) of Regulation (EC) No
1925/2006)



9th April 2025
14:00-17:30

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner.
- Hearing Experts¹:
- European Commission: Fruzsina Nyemecz.

- EFSA:
NIF Unit: Victor Bunea, Agnes De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Leonard Matijević, Vânia Mendes, Costanza Michelini, Annamaria Rossi, Iciar Saenz, Ariane Titz.
MESE Unit: Rita de Sousa Ferreira.
FEEDCO Unit: Paola Manini.
- Others:
Observers from the European Medicines Agency: Erika Svedlund.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 20th Working Group meeting held on 26th March 2025, via web-conference

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



The minutes of the 20th Working Group meeting were agreed by written procedure on the 8th April 2025.

V. Scientific topic(s) for discussion

- a. Draft opinion on Fennel – EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

The final draft opinion on the safety of fennel preparation was discussed. The comments submitted by WG experts before the meeting were addressed. Amendments to the draft opinion were made regarding the terms of references, discussion, conclusions and recommendations sections. After further editorial changes, the draft will be submitted to the NDA Panel for possible adoption.

- b. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.**

An update on the feedback received from the WG on Berberine genotoxicity was presented to the WG. The genotoxicity section of Berberine and the results were discussed. The draft of the genotoxicity on Berberine will be presented at the next WG meeting for further discussion on the conclusions, consistency of the terminology used and on the weight of evidence.

- c. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.**

The genotoxicity section on the HCA opinion was discussed with the WG and the evidence on the genotoxicity studies was presented using tables. Comments from the WG experts on the discussion, conclusion and recommendations sections were addressed, and amendments to these sections were made.

VI. Preparatory Meeting(s)

Since the last 20th WG meeting, one preparatory meeting chaired by EFSA Staff was held as follows:

1 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 2nd April 2025

1.a Working Group Member: Jacqueline Wiesner.

1.b Discussion points: A preparatory meeting was held with the toxicology expert to discuss the endpoints of the appraisal of studies related to the above mandates.



VII. Next meeting

The next meeting will be held on 12th May, via web conference.



26th March 2025

14:00-17:30

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner.
- Hearing Experts¹:
- European Commission: Fruzsina Nyemecz.

- EFSA:
NIF Unit: Lucia Fabiani, Thibault Fiolet, Georges Kass, Heng Leng, Leonard Matijević, Vânia Mendes, Costanza Michelini, Iciar Saenz, Ariane Titz.
MESE Unit: Rita de Sousa Ferreira, Angelica Di Fazio.
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues, Erika Svedlund.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 19th Working Group meeting held on 3rd March 2025, via web-conference

The minutes of the 19th Working Group meeting were agreed by written procedure on the 14th of March 2025.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

- a. Draft opinion on Fennel – EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

The draft opinion on the safety of fennel preparation was discussed. The comments submitted by WG experts before the meeting were addressed and amendments to the draft opinion were made. The data from the exposure assessment was discussed. A revised draft opinion will be presented at the next WG meeting.

- b. Draft opinion on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805.**

The structure of the characterization section of the draft opinion was discussed with the WG members. The results of the risk of bias appraisal of multidose toxicological studies were discussed.

- c. Draft opinion on berberine-containing plant preparations – EFSA-Q-2022-00803.**

The structure of the characterization section of the draft opinion was discussed with the WG members. The results of the risk of bias appraisal of multidose toxicological studies were discussed.

VI. Preparatory Meeting(s)

Since the last 19th WG meeting, two preparatory meetings chaired by EFSA Staff were held as follows:

1 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 10th March 2025

1.a Working Group Members: Kirsten Pilegaard, Ulla Beckman Sundh

1.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the conclusions that could be drawn from the RoB assessment related to the above mandates.

2 Preparatory meeting on HCA and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 19th March 2025

2.a Working Group Members: Kirsten Pilegaard, Ulla Beckman Sundh

2.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the outcome of the appraisal of studies related to the above mandates.



VII. Next meeting

The next meeting will be held on 9th April, via web conference.



SCIENTIFIC PANEL ON

NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

19th Working Group meeting on substances other than vitamins and minerals (Art.8(2) of Regulation (EC) No 1925/2006)



3rd March 2025

14:00-17:30

Location: EFSA – Web conference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Jacqueline Castenmiller, Eugenia Dogliotti, Wirginia Kukuła-Koch, Kirsten Pilegaard, Ulla Beckman Sundh, Jacqueline Wiesner
- Hearing Experts¹:
- Not applicable European Commission and/or Member States representatives:
Not Applicable
- EFSA:
NIF Unit: Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Nena Karavasiloglou, Georges Kass, Heng Leng, Leonard Matijević, Vânia Mendes, Costanza Michelini, Iciar Saenz, Ariane Titz
MESE Unit: Rita de Sousa Ferreira, Angelica di Fazio, Alicia Paini
FEEDCO Unit: Paola Manini
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues, Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 18th Working Group meeting held on 27th and 28th January 2025, in Parma and via web-conference

The minutes of the 18th Working Group meeting were agreed by written procedure on the 10th February 2025.

V. Feedback from the 156th Panel plenary meeting

The working group was informed that Monacolins in red yeast rice – EFSA-Q-2023-00424 – opinion were adopted at the last NDA Panel plenary meeting.

VI. Scientific topic(s) for discussion

- a. Draft opinion on Fennel – EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

The draft opinion on the safety of fennel preparation was discussed. The comments submitted by WG experts before the meeting were addressed and amendments to the draft opinion were made, when relevant.

The revised exposure assessment as well as possible preliminary conclusions were discussed. The draft opinion will be presented at the next WG meeting for further discussion.

VII. Preparatory Meeting(s)

Since the last 18th WG meeting, four preparatory meetings chaired by EFSA Staff were held as follows:

1 Preparatory meeting on hydroxycitric acid (HCA) and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 6th February 2025

1.a Working Group Members: Kirsten Pilegaard, Ulla Beckman Sundh

1.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the outcome of the appraisal of some of the pertinent toxicological studies related to the above mandates.

2 Preparatory meeting on HCA and HCA-containing plant preparations – EFSA-Q-2022-00805, and berberine-containing plant preparations – EFSA-Q-2022-00803, 12th February 2025

2.a Working Group Members : Kirsten Pilegaard, Ulla Beckman Sundh

2.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the outcome of the appraisal of studies related to the above mandates.



3 Preparatory meeting on HCA and HCA-containing plant preparations – EFSA-Q-2022-00805, 11th February 2025

3.a Working Group Members: Carlo Bicchi, Wirginia Kukuła-Koch

3.b Discussion points: A preparatory meeting was held to discuss the outcome of the appraisal of the subquestion on the characterisation of the exposure for the pertinent toxicological studies on HCA.

4 Preparatory meeting on HCA and HCA-containing plant preparations – EFSA-Q-2022-00805, 20th February 2025

4.a Working Group Members: Kirsten Pilegaard, Ulla Beckman Sundh

4.b Discussion points: A preparatory meeting was held with the toxicology experts to discuss the outcome of the appraisal of toxicological studies on HCA.

VIII. Next meeting

The next meeting will be held on 26th March 2025, via web conference.

27th and 28th January 2025

First day 14:00-18:00

Second day 9:00-18:00

Location: EFSA - Parma (Meeting Room 00/M05)/Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh, Jacqueline Wiesner.
- Hearing Experts¹:
European Medicines Agency : Jorge Rodrigues
- European Commission and/or Member States representatives:
European Commission: Fruzsina Nyemecz
- EFSA:
NIF Unit: Ana Afonso², Agnès De Sesmaisons, Lucia Fabiani, Thibault Fiolet, Nena Karavasiloglou, Georges Kass³, Heng Leng, Leonard Matijević, Vânia Mendes, Costanza Michelini, Annamaria Rossi², Iciar Saenz, Ariane Titz, Silvia Valtueña Martínez³
MESE Unit : Alicia Paini³, Rita de Sousa Ferreira³, Angelica di Fazio³
FEED Unit : Paola Manini³
- Others:
Not applicable

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Only on 27th January

³ Only on 28th January

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 17th Working Group meeting held on 13th January 2025, via web-conference

The minutes of the 17th Working Group meeting were agreed by written procedure on the 23rd January 2025.

V. Scientific topic(s) for discussion

a. Draft opinion on Berberine-containing plant preparations – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine (Art. 8(2))

The updated section on berberine genotoxicity was presented and discussed by the WG.

An overview of the results from the risk of bias assessment of the multi-dose level studies on berberine and berberine-containing plant preparations was given to the WG. An update on the process of appraising single-dose level toxicological studies was discussed.

The draft opinion will be presented at the next WG meeting for further discussion.

b. Draft opinion on Hydroxycitric acid (HCA) – EFSA-Q-2022-00805 - Scientific opinion on the evaluation of the safety in use of HCA and plant preparations containing HCA (Art. 8(2))

The updated section on HCA genotoxicity was presented and discussed by the WG. Some issues related to the characterization of HCA-containing plant extracts in the relevant studies were highlighted.

The WG was reminded about the outcome of the systematic review and was presented with preliminary information on the characterization of the plants containing HCA, animal studies on *G. cambogia* and the risk of bias assessment of toxicological studies in animals

The draft opinion will be presented at the next WG meeting for further discussion.

c. Draft opinion on Monacolins in red yeast rice - EFSA-Q-2023-00424 - Scientific Opinion on additional scientific data related to the safety of monacolins from red yeast rice submitted pursuant to Article 8(4)

The final draft of the scientific opinion was discussed by the WG. The final draft of the opinion will be submitted to the NDA Panel for possible adoption during their plenary meeting on 29-30 January.

d. Draft opinion on Fennel – EFSA-Q-2022-00804) - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)

The WG was presented with the results of the physiologically based kinetic models which were used to model the differences in p-allylalkoxybenzene metabolism between rats and humans.

An update on the exposure assessment was presented and discussed.



e. Upcoming mandates on Art.8 (2) and Art. 8(4)

The WG was informed that EFSA will soon receive 12 new mandates under Article 8 of Regulation (EC) No 1925/2006. A preliminary work plan was discussed.

VI. Any Other Business

o **Update on the safety of green tea extracts containing (-)-epigallocatechin-3-gallate (EFSA-Q-2023-00420)**

Regarding the risk assessment related to Art. 8(4) procedure on the safety of green tea extracts containing (-)-epigallocatechin-3-gallate (EFSA-Q-2023-00420), the WG was informed that no data was submitted to EFSA during the period of Union scrutiny, which ended on 21 December 2024. Therefore, the mandate has been considered as closed.

VII. Preparatory Meeting/s

Since the last 17th WG meeting, 4 preparatory meetings chaired by EFSA Staff were held as follows:

1 Preparatory meeting on Hydroxycitric acid – EFSA-Q-2022-00805, 15th January 2025

1.a Ulla Beckman Sundh, Kirsten Pilegaard.

1.b A preparatory meeting was held with the toxicology experts to discuss the outcome of the appraisal of some of the pertinent toxicological studies on HCA.

2 Preparatory meeting on berberine-containing plant preparations -EFSA-Q-2022-00803, 16th January 2025

2.a Eugenia Dogliotti.

2.b A preparatory meeting was held with the expert to discuss the appraisal of studies on genotoxicity on berberine and berberine-containing plant preparations.

3. Preparatory meeting on Hydroxycitric acid – EFSA-Q-2022-00805 and berberine-containing plant preparations -EFSA-Q-2022-00803, 20th January 2025

3.a Carlo Bicchi, Wirginia Kukuła-Koch.

3.b A preparatory meeting was held to discuss the outcome of the appraisal of the subquestion on the characterisation of the exposure for some of the pertinent toxicological studies.

4 Preparatory meeting on berberine-containing plant preparations -EFSA-Q-2022-00803, 22nd January 2025

4.a Ulla Beckman Sundh, Kirsten Pilegaard.

4.b A preparatory meeting was held with the toxicology experts to discuss the appraisal of studies on berberine and berberine-containing plant preparations with endpoints other than genotoxicity.

VIII. Next meeting

The next meeting will be held on March 3rd 2025, via web conference.

Held on 13th January 2025 via web-meeting
10:00-12:00

Attendees:

○ Working Group Members:

Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh.

○ EFSA:

NIF Unit: Leonard Matijević, Nena Karavasiloglou, Thibault Fiolet, Heng Leng, Silvia Valtueña, Costanza Michelini, Vânia Mendes, Iciar Saenz

○ Others:

Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues.

European Commission Representative: Fruzsina Nyemecz.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

An oral DoI has been asked to all participants.

No new interests were declared.

IV. Scientific topic(s) for discussion

- **Safety of monacolins in red yeast rice (EFSA-Q-2023-00424) under Art. 8(4)**

The final draft of the mandate on monacolins was discussed with the working group, editorial changes were reviewed, and content revisions were addressed. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 29-31 January for further discussion and possible adoption.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Any Other Business

Since the last WG meeting preparatory meetings chaired by EFSA Staff were held on the following:

- **Hydroxycitric acid - EFSA-Q-2022-00805 - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

1. Date: 8/01/2025

WG Members: Carlo Bicchi, Wirginia Kukuła-Koch.

EFSA staff: Thibault Fiolet, Lucia Fabiani, Leonard Matijević, Nena Karavasiloglou, Iciar Saenz, Costanza Michelini.

A preparatory meeting was held with the experts to discuss the Risk of Bias assessment of papers on Hydroxycitric acid (HCA).

2. Date: 10/01/2025

WG Members: Ulla Beckman Sundh, Kirsten Pilegaard.

EFSA staff: Thibault Fiolet, Lucia Fabiani, Leonard Matijević, Nena Karavasiloglou, Iciar Saenz, Costanza Michelini, Ariane Titz.

A preparatory meeting was held with the toxicology experts to discuss the Risk of Bias assessment of papers on HCA.

VI. Next meeting

The next meeting will be held on the 27th of January 2025, in-person in Parma

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

16th Working Group meeting on substances other than
vitamins and minerals (Art. 8(2) of Regulation (EC) No
1925/2006)



Held on 11th December 2024 via web-meeting
14:00-17:30

Location: Webconference

Attendees:

- Working Group Members:

Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti.

- EFSA:

NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Iciar Saenz, Nena Karavasiloglou, Thibault Fiolet, Costanza Michelini, Heng Leng, Silvia Valtueña Martinez.

MESE Unit : Alicia Paini, Rita de Sousa Ferreira, Angelica di Fazio.

FEED Unit: Paola Manini.

- Others:

Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues.

European Commission Representative: Fruzsina Nyemecz.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

An oral DoI has been asked to Carlo Bicchi, Wirginia Kukula-Koch and Eugenia Dogliotti.

No new interests were declared.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Scientific topic(s) for discussion

- **Safety of monacolins in red yeast rice (EFSA-Q-2023-00424) under Art. 8(4)**

The WG discussed the draft scientific opinion, especially the data received from the interested parties during the scrutiny period. After amendments, the draft opinion will be presented at the next WG meeting for further discussion.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

The PBK modelling approach for the exposure assessment on estragole was discussed with the WG.

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine, Hydroxycitric acid - EFSA-Q-2022-00805 - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

The approach and the internal instructions for risk of bias assessment of toxicological studies in animals were discussed.

V. Any Other Business

Since the last WG meeting a preparatory meeting chaired by EFSA Staff was held on the following:

- **Berberine – EFSA-Q-2022-00803**

Date:06/12/2024

WG Member: Eugenia Dogliotti

EFSA staff: Annamaria Rossi, Leonard Matijević, Thibault Fiolet, Iciar Saenz

A preparatory meeting was held with the expert to discuss the appraisal of the papers on Berberine genotoxicity.

VI. Next meeting

The next meeting will be held on 13th January 2024, via webconference.

Held on 4th December 2024 via web-meeting
14:00-17:00

Attendees:

○ Working Group Members:

Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh.

○ EFSA:

NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Iciar Saenz, Nena Karavasiloglou, Thibault Fiolet, Costanza Michelini, Vânia Mendes, Georges Kass

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

An oral DoI has been asked to Carlo Bicchi, Wirginia Kukula-Koch and Eugenia Dogliotti.

No new interests were declared.

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine. Hydroxycitric acid - EFSA-Q-2022-00805) - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**
- **Hydroxycitric acid - EFSA-Q-2022-00805 - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

The approach for risk of bias assessment for animal toxicological studies was discussed. The planning for the appraisal of studies for the Berberine and the HCA Opinions was presented to the WG.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Any Other Business

Since the last WG meeting a preparatory meeting chaired by EFSA Staff was held on the following:

- **Hydroxycitric acid - EFSA-Q-2022-00805**

Date:02/12/2024

WG Member: Eugenia Dogliotti

EFSA staff: Annamaria Rossi, Leonard Matijević, Thibault Fiolet, Iciar Saenz

A preparatory meeting was held with the experts to discuss the appraisal of the papers on genotoxicity.

VI. Next meeting

The next meeting will be held on 11th December 2024, via web conference.

Held on 20th and 21st November 2024 via web-meeting
First day 9:00-13:00
Second day 9:00-13:00

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh.
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Iciar Saenz, Nena Karavasiloglou, Thibault Fiolet, Annamaria Rossi¹, Costanza Michelini, Vania Mendes, Heng Leng²
MESE Unit: Alicia Paini², Rita de Sousa Ferreira², Angelica di Fazio²
FEED Unit: Paola Manini¹
- Others:
Observers from the European Medicines Agency: Erika Svedlund²
European Commission representative: Fruzsina Nyemecz²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item VI. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

An oral DoI has been asked to Wirginia Kukula-Koch. No new interests were declared.

¹ Only on 20th November

² Only on 21st November

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**

An update on the genotoxicity section was presented and discussed by the WG. The evidence and appraisal table for genotoxicity data was reviewed, and the weight of evidence approach was explained. The WG discussed how to proceed with the genotoxicity assessment.

The risk of bias assessment approach for animal studies was discussed. The tool was refined, the algorithm was explained, and the evaluation criteria were presented.

The evaluation of *Hydrastis canadensis* L. was discussed, including the results of the developmental studies. An update on the evidence on *Chelidonium majus* was also described.

- **Safety of monacolins from red yeast rice (EFSA-Q-2023-00424) under Art. 8(4).**

The WG discussed the draft scientific opinion, especially the new data received from the interested parties during the scrutiny period. After amendments, the draft opinion will be presented at the next WG meeting for further discussion.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

An update on the available data was given. The exposure assessment for estragole was discussed, the results from the consumption data were presented graphically and the possibility of running modeling scenarios was contemplated for future WG meetings.

V. Any Other Business

VI. Preparatory meetings

Since the last WG meeting, preparatory meetings chaired by EFSA staff also were held on the following:

- **Berberine – EFSA-Q-2022-00803. Hydroxycitric acid - EFSA-Q-2022-00805**

Date: 15/11/2024.

WG Members: Eugenia Dogliotti

A preparatory meeting was held with the expert to discuss the appraisal of the papers on genotoxicity, for the Berberine and the HCA opinions.

- **Berberine – EFSA-Q-2022-00803. Hydroxycitric acid - EFSA-Q-2022-00805**

Date: 11/11/2024.

WG Members: Kirsten Pilegaard, Ulla Beckman Sundh and Eugenia Dogliotti

A preparatory meeting was held with the experts to discuss some examples of the approach on the risk of bias assessment for the Berberine and the HCA opinions.

VII. Next meeting

The next meeting will be held on December 4th of 2024, via web conference.

Held on 05 November 2024 via web-meeting 14:00-17.30 (CET)

Location: Webconference

Attendees:

○ Working Group Members:

Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh.

Hearing expert: Jacqueline Wiesner

○ EFSA:

NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Iciar Saenz, Nena Karavasiloglou, Thibault Fiolet, Leng Heng, Annamaria Rossi, Costanza Michelini, Vania Mendes, Georges Kass.

MESE Unit: Rita de Sousa Ferreira, Angelica di Fazio

○ Others:

Observers from the European Medicines Agency: Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

No new interests were declared.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**
- **Hydroxycitric acid - EFSA-Q-2022-00805) - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

An example of the suggested approach on the risk of bias assessment, as laid down in the protocol, was presented and discussed. The WG discussed how to refine and optimise the tool for the purpose of the present assessments.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

An update on the exposure assessment was presented, reviewed and discussed by the WG. Some refinements and additional analyses will be necessary and will be presented for discussion in upcoming meetings.

V. Any Other Business

VI. Next meeting

The next meeting will be held on November 20th and 21st of 2024, via web conference.

Held on 2 and 16 October 2024 via web-meeting

First day: 14:00-17.30

Second day: 09:00-13:00

Location: Webconference

Attendees:

○ Working Group Members:

Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh

Hearing expert: Jacqueline Wiesner¹

○ EFSA:

NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Iciar Saenz, Nena Karavasiloglou, Thibault Fiolet, Leng Heng, Annamaria Rossi, Costanza Michelini, Vania Mendes², Georges Kaas²

MESE Unit: Alicia Paini², Rita de Sousa Ferreira²

○ Others:

Observers from the European Medicines Agency: Erika Svedlund, Jorge Rodrigues²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

No new interests were declared.

¹ Only on 2nd October

² Only on 16th October

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**

A proposed approach on the risk of bias assessment and the structure of the Opinion was presented and discussed (both days).

Results of the genotoxicity studies were presented and discussed on the 1st day.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

During the 2nd day, updated results on the exposure assessment, focusing on herbal infusions, were presented and discussed with the WG. The proposed approach for the remaining work on exposure assessment was presented and discussed. Further analysis with refined results will be shared in upcoming meetings.

- **Hydroxycitric acid - EFSA-Q-2022-00805) - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

A proposed approach on the risk of bias assessment and the structure of the Opinion was presented and discussed (both days).

V. Any Other Business

VI. Next meeting

The next meeting will be held on November 5th 2024, via web conference.

Held on 5 and 11 September 2024 via web-meeting

First day: 09:00-13:00

Second day: 14:00-17.30

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard¹,
Jacqueline Castenmiller, Eugenia Dogliotti, Ulla Beckman Sundh, Jacqueline Wiesner²
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Victor Bunea, Nena Karavasiloglu,
Annamaria Rossi¹, Costanza Michelini

FEED Unit: Paola Manini²

MESE Unit: Rita Ferreira de Sousa², Guoda Bubnyte²
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues, Karin Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

An oral DoI has been asked to Wirginia Kukuła-Koch. No new interests were declared.

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**

¹ Only on 5th September

² Only on 11th September

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Results of the systematic review of studies were presented and discussed with the WG, including the results of genotoxicity and acute toxicity studies. Human case reports and adverse events reported in human intervention trials have also been presented and discussed within the WG.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

The methodology and results encompassing the first step of the exposure assessment, including data sources (consumption and estragole content of fennel fruit preparations) and methodology applied have been presented and discussed with the WG. Further analysis with refined results will subsequently be shared.

- **Hydroxycitric acid - EFSA-Q-2022-00805) - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

Results of the systematic review of studies were presented and discussed with the WG, including the results of ADME, genotoxicity, pancreatitis and neurotoxicity.

- **Safety of monacolins in red yeast rice (EFSA-Q-2023-00424) under Art. 8(4)**

The WG was presented with the previous risk assessment on monacolins from RYR conducted by the ANS Panel (2018), data received during the scrutiny period by the interested parties, as well as with the timelines to evaluate new data.

V. Any Other Business

VI. Next meeting

The next meeting will be held on 2nd October 2024, via web conference.

16 May 2024
09:00-12:00 hours

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller
- Hearing experts:
Josef Schlatter
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea, George Kass
- FEEDCO Unit: Paola Manini
- MESE Unit: Alicia Paini, Rita Sofia Ferreira De Sousa¹, Guoda Bubnyte¹
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence have been received by Jacqueline Wiesner.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**

¹ Only for Agenda item 7 on Fennel fruits.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



An updated draft section on ADME for berberine was presented and discussed by the WG. Updated results of the systematic review were presented, and the approach for the assessment of animal studies was also discussed.

- **Hydroxycitric acid - EFSA-Q-2022-00805) - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

The approach for the assessment of animal studies was discussed.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

A presentation was held on the exposure assessment with data on occurrence and consumption and discussed with the WG.

V. Any Other Business

The dates for the WG meetings from September to December 2024 were presented.

VI. Next meeting

The next meeting will be held on 12th June 2024, via web conference.

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18 March 2024
14:00-17:00 hours

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea, George Kass
- FEEDCO Unit: Paola Manini
- MESE Unit: Jean Lou Dorne, Alicia Paini

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence have been received by Jacqueline Wiesner and Joseph Schlatter.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Scientific topic(s) for discussion

- **Berberine – EFSA-Q-2022-00803 – Scientific opinion on the evaluation of the safety in use of plant preparations containing berberine**

A draft section on ADME was presented and discussed by the WG. Updated results of the systematic review on genotoxicity were also presented and discussed.

- **Fennel - EFSA-Q-2022-00804 - Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl)**

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



A presentation was held on the tiered approaches for the risk assessment of combined exposure to methyl-eugenol, estragole and safrole. Definition of the exposure of interest section of the draft opinion was presented and the comments were discussed.

- **Hydroxycitric acid - EFSA-Q-2022-00805 - safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid**

Updated results of the systematic review were presented and discussed

V. Any Other Business

Not applicable.

VI. Next meeting

The next meeting will be held on 12th April 2024, via web conference.

06 March 2024
09:00-11:50 hours

Location: Teleconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard, Jacqueline Castenmiller
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea, Leng Heng
- FEEDCO Unit: Paola Manini
- MESE Unit: Jean Lou Dorne, Alicia Paini

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Scientific topic(s) for discussion

- **Draft scientific Opinion on additional data on the safety of plant preparations containing hydroxyanthracene derivatives submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006 (EFSA-Q-2022-00790)**

The WG discussed the comments related to the draft scientific Opinion on additional data on the safety of plant preparations containing hydroxyanthracene derivatives.

V. Any Other Business

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Not applicable.

VI. Next meeting

The next meeting will be held on 18th March 2024, via web conference.

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13 February 2024
09:00-11:50 hours

Location: Teleconference

Attendees:

○ Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard,
Jacqueline Castenmiller

Hearing Experts:
Josef Schlatter

○ EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea,
George Kass, Leng Heng

FEEDCO Unit: Paola Manini

MESE Unit: Jean Lou Dorne, Alicia Paini, Rita Sofia Ferreira De Sousa

○ Others:
Observers from the European Medicines Agency: Jorge Rodrigues, Karin Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Scientific topic(s) for discussion

- **Scientific Opinion on the safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl) (EFSA-Q-2022-00804)**

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



A revised draft section on ADME (Absorption, Distribution, Metabolism, Excretion) of estragole was discussed by the working group.

In addition, a general discussion on the guidance documents/statements of the Scientific Committee related to the assessment of genotoxic carcinogens and chemical mixtures took place.

- **Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)**

The WG was presented with an overview about the studies which were retrieved and considered pertinent for the assessment of genotoxicity of berberine containing plant preparations.

V. Any Other Business

Not applicable.

VI. Next meeting

The next meeting will be held on 6th March 2024, via teleconference.

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26 January 2024
09:00-11:50 hours

Location: Teleconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard
- Hearing Experts:
Josef Schlatter
- European Commission representatives:
Fruzsina Nyemecz¹
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea, George Kass
FEEDCO Unit: Paola Manini
MESE Unit: Jean Lou Dorne, Alicia Paini
- Others:
Observers from the European Medicines Agency: Jorge Rodrigues, Karin Erika Svedlund

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Castenmiller.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Scientific topic(s) for discussion

¹ From 10.45 onwards

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



The sixth Working Group (WG) meeting was dedicated to the presentation of the data received through the call for data and the outcome of the systematic reviews which were conducted in relation to the following mandates:

- Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl) (EFSA-Q-2022-00804)
- Safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)
- Safety in use of plant preparations containing hydroxycitric acid and of isolated hydroxycitric acid (EFSA-Q-2022-00805)

The WG was also presented with an overview about the status of the evaluation of data submitted on botanical species containing hydroxyanthracene derivatives submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006 for safety evaluation of substances placed under Union scrutiny in Part C of Annex III (EFSA-Q-2022-00790). The evaluation is carried out by the cross-cutting WG on Genotoxicity of the EFSA Scientific Committee.

V. Any Other Business

VI. Next meeting

The next meeting will be held on 13th February 2024, via teleconference.

16 October 2023
14:00-17:00 hours

Location: Teleconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Jacqueline Castenmiller, Josef Rasinger, Wirginia Kukuła-Koch
- Hearing Experts:
Jacqueline Wiesner, Josef Schlatter, Kirsten Pilegaard
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea
- Others:
FEEDCO Unit: Paola Manini
MESE Unit: Jean Lou CM Dorne¹

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

IV. Scientific topic(s) for discussion

The fifth Working Group (WG) meeting was dedicated to the introduction of TKplate tool and the WG was informed about the ongoing work on hydroxyanthracene derivatives (HADs).

a. Presentation of TKPlate tool: An open access Platform for toxicokinetic and toxicodynamic modelling of chemicals

The TKPlate tool was presented and commented on by the members of the WG.

¹ Present only for the first agenda point.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



b. HYDROXYANTHRACENE DERIVATIVES (HADS): FILES FOR THE SAFETY OF SUBSTANCES LISTED IN ANNEX III, PART C OF REGULATION 1925/2006

New data related to botanical species containing Hydroxyanthracene derivatives (HADs) have been presented and commented by the WG, pursuant to Article 8(4) of Regulation (EC) No 1925/2006 for safety evaluation of substances placed under Union scrutiny in Part C of Annex III.

V. Any Other Business

The WG agreed on the meeting dates for the next year.

VI. Next meeting

The next meeting will be held on 26th January 2024, via web conference.



Annex

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

With regard to this meeting, Alexandre Maciuk declared the following interests: Member of scientific advisory entities (Association Française de Normalisation, European pharmacopoeia) and a research funding project on plant-derived vaccine adjuvants. In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.

With regard to this meeting, Wirginia Kukuła-Koch declared the following interests: a public funded research project and a patent related emodin glucoside. In accordance with EFSA's Policy on Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, 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.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

12 and 14 June 2023

14:00-17:00 hours (day 1) / 09:00-13:00 hours (day 2)

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Jacqueline Castenmiller, Josef Rasinger
- Hearing Experts¹:
Jacqueline Wiesner², Josef Schlatter²
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leng Heng³, Leonard Matijević, Pedro das Neves Ferreira, Roanne Saad, Thibault Fiolet
- Others:
KNOW Unit: Bernard Bottex
FEEDCO Unit: Paola Manini², Yvette Dirven²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

The fourth Working Group (WG) meeting was dedicated to discussing the comments received from the public consultation on the draft protocols, taking place between 12th May and 11th June (see following).

- a. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine ([EFSA-Q-2022-00803](#))**

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Participation only on the 2nd day of the meeting in relation to EFSA-Q-2022-00804

³ Participation only on the 1st day of the meeting in relation to EFSA-Q-2022-00803 and EFSA-Q-2022-00805

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid ([EFSA-Q-2022-00805](#))

The WG was presented with, and discussed the comments submitted by the interested parties during the public consultation, regarding both protocols. The appropriate changes were applied in the documents, and the answers to be included in the technical report were agreed by the WG members.

The meeting proceeded with a discussion on methodological aspects of the call for data which will address some of the risk assessment sub-questions.

c. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))

The second day of the WG was fully dedicated to review the comments from the public consultation on the protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel.

The approach to the call for data to be launched was also reviewed.

V. Any Other Business

None.

VI. Next meeting

The next meeting will be held on 11th September 2023, via web conference.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

3rd Working Group meeting on substances other than
vitamins and minerals (Art. 8(2) of Regulation (EC)
No 1925/2006)



13 and 21 April 2023

09:00-13:00 hours (day 1) / 09:00-13:00 hours (day 2)

Location: Webconference

Attendees:

- Working Group Members:
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukula-Koch, Josef Rasinger
- Hearing Experts¹:
Josef Schlatter²
- EFSA:
NIF Unit: Pedro das Neves Ferreira³, Lucia Fabiani, Thibault Fiolet, George Kass², Leonard Matijević³, Roanne Saad, Ariane Titz
- Others:
KNOW Unit: Bernard Bottex³
MESE Unit: José Ángel Ruiz Gómez²
FEEDCO Unit: Paola Manini², Yvette Dirven²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

The third Working Group (WG) meeting resumed the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following).

a. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Participation only on the 2nd day of the meeting in relation to EFSA-Q-2022-00804

³ Participation only on the 1st day of the meeting in relation to EFSA-Q-2022-00803 and EFSA-Q-2022-00805

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))

The WG resumed the discussion on the two draft protocols, taking into account the feedback received from the NDA Panel during its meeting on 30 March 2023. For the protocol related to the assessment of the safety of plant preparations containing berberine, the assessment of the exposure to berberine was rediscussed and some amendments were proposed. Specific discussions took place on the evidence needs for answering the risk assessment questions for both protocols. The draft protocols will be submitted to the NDA Panel for endorsement for public consultation during its meeting on 27 April 2023.

c. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))

The WG resumed the discussion on the draft protocol, taking into account the feedback received from the NDA Panel during its meeting on 30 March 2023. The discussion of the WG focused mainly on the exposure assessment to be carried out, followed by the ADME of estragole, the risk characterization and the evidence needs for answering the risk assessment questions. The draft protocol will be submitted to the NDA Panel for endorsement for public consultation during its meeting on 27 April 2023.

V. Any Other Business

None.

VI. Next meeting

The next meeting will be held on 12th of June 2023, via web conference.

6 and 7 March, 2023

14:00-17:00 hours (day 1) / 09:00-13:00 hours (day 2)

Location: Webconference

Attendees:

- Working Group Members:
Alexander Maciuk (WG Chair), Wirginia Kukula-Koch, Carlo Bicchi, Jacqueline Castenmiller
- Hearing Experts¹:
Jacqueline Wiesner², Josef Rasinger
- EFSA:
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Pedro das Neves Ferreira, Roanne Saad
- Others:
KNOW Unit: Bernard Bottex²
MESE Unit: José Ángel Ruiz Gómez²
ED Office: George Kass
FEEDCO Unit: Paola Manini², Yvette Dirven²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

The second Working Group (WG) meeting resumed the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following).

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Participation only on the 1st day of the meeting in relation to EFSA-Q-2022-00804 (fennel fruit preparations)

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



a. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))

The WG was updated with the feedback received in the 132nd NDA plenary meeting and presented with a new version of the draft protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel. The discussion of the WG focused on the exposure assessment to be carried out, and the evidence needs for answering the risk assessment questions.

b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))

c. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))

The WG was presented with, and discussed, the endpoints to be taken under consideration in both Scientific Opinions, based on scoping searches of potential adverse health effects. Following, the evidence needs and the research methodologies to be used for answering the assessment sub-questions were defined.

V. Any Other Business

None.

VI. Next meeting

The next meeting will be held on 26th of April 2023, via web conference.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

1st Working Group meeting on substances other than vitamins and minerals (Art. 8(2) of Regulation (EC) No 1925/2006)



13 and 17 February 2023

09:00-12:30 hours (day 1) / 13:30-16:30 hours (day 2)

Location: Webconference

Attendees:

- Working Group Members:
Alexander Maciuk (WG Chair), Wirginia Kukula-Koch, Carlo Bicchi, Jacqueline Castenmiller
- Hearing Experts¹:
Jacqueline Wiesner², Josef Rasinger
- European Commission and/or Member States representatives:
EC: Carolin Bendadani, Fruzsina Nyemecz²
- European Medicines Agency:
Wieland Peschel²
- EFSA:
NIF Unit: Leng Heng, Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Pedro das Neves Ferreira, Roanne Saad
- Others:
KNOW Unit: Bernard Bottex²
MESE Unit: José Ángel Ruiz Gómez²
ED Office: George Kass
FEEDCO Unit: Paola Manini², Yvette Dirven²

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Participation only on the 2nd day of the meeting in relation to EFSA-Q-2022-00804 (fennel fruit preparations)

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



The first Working Group (WG) was dedicated to the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following). WG members were informed about the background of the mandates. The Secretariat presented to WG members the EFSA framework for the use of protocols in scientific assessment.

- a. **Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))**
- b. **Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))**

The WG discussed the first drafts of the protocols, addressing the following elements: problem formulation, target population and definition of the exposure of interest. Discussions took also place on the relevant endpoints to be included in the opinion.

- c. **Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))**

The second day of the WG meeting was dedicated to reviewing the first draft of the protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel. The discussion of the WG focused on previous assessments of fennel fruit preparations and on how to conduct the exposure assessment.

V. Any Other Business

None.

VI. Next meeting

The next meeting will be held on 6th and 7th March 2023, via web conference.
