SCIENTIFIC COMMITTEE WORKING GROUP

20th Working Group meeting on Bromide

24 October 2024

9:30-13:30

MINUTES - Agreed on 17 December 2024

Location: Web conference

Attendees:

- Working Group Members:

Diane Benford (chair), Vasileios Bampidis, Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Marco Vinceti

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová
Pesticides Peer Review (PREV) Unit: Judit Janossy

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Martin Rose.

II. Adoption of agenda

The agenda was adopted. The second half day scheduled for this meeting was cancelled.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Agreement of the minutes of the 19th Working Group meeting held on 3 October 2024, via web conference

The minutes of the 18th Working Group meeting were agreed by written procedure on 17 October 2024.

V. Scientific topics for discussion

a. Technical report of Public Consultation

The Working group discussed the draft responses provided by area experts and EFSA staff to address the comments submitted through public consultation on the draft opinion. The WG agreed on the language and finalised the responses and related revisions in the document where needed.

b. Draft Opinion text

The Working Group discussed all text revisions introduced in response to the comments received in public consultation and agreed on the final language. The Working Group agreed

[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

that the draft opinion was ready to be submitted to the Scientific Committee plenary meeting scheduled on 20-21 November 2024 for adoption.

VI. Actions before next meeting

No further actions were planned.

VII. Next meeting

The next meeting will be held on 2-3 December 2024 via web conference, if needed.

SCIENTIFIC COMMITTEE WORKING GROUP

19th Working Group meeting on Bromide

3 October 2024

9:30-16:30

MINUTES - Agreed on 17 October 2024

Location: Web conference

Attendees:

- Working Group Members:
Diane Benford (chair), Vasileios Bampidis, Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Marco Vinceti

- European Commission representatives:
Siret Surva, Frans Verstraete

- EFSA:
Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová
Pesticides Peer Review (PREV) Unit: Judit Janossy

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Martin Rose; Vasileios Bampidis in the afternoon.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Agreement of the minutes of the 18th Working Group meeting held on 3 June 2024, via web conference

The minutes of the 18th Working Group meeting were agreed by written procedure on 17 June 2024.

V. Scientific topics for discussion

a. Outcome of Public Consultation

The Working group was presented with an overview of the comments submitted through public consultation on the draft opinion. Comments were assigned to WG experts and/or EFSA staff for consideration prior to the meeting, according to subject area. Draft responses provided in writing were made available to the Working Group for discussion. The WG

[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

reviewed all comments in detail and agreed on responses to be provided and whether revisions to the text of the Opinion were warranted.

b. Draft Opinion text

The Working Group discussed sections of the opinion where revisions were introduced based on the comments received and agreed on appropriate language. Specific tasks and actions for addressing remaining comments were agreed upon. The Working Group agreed to submit the draft opinion to the Scientific Committee plenary meeting scheduled on 20-21 November 2024 for possible adoption.

VI. Actions before next meeting

The draft technical report of the public consultation and working document of the draft scientific opinion will be shared with the WG for review and finalisation of responses to all comments. The future meetings were planned for finalisation of the opinion.

VII. Next meeting

The next meeting will be held on 24 and 25 October 2024 as two half-day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

18th Working Group meeting on Bromide

3 June 2024

9:00-16:00

MINUTES - Agreed on 17 June 2024

Location: Web conference

Attendees:

- Working Group Members:
Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- European Commission representatives:
Frans Verstraete

- EFSA:
Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová, Irene Cattaneo
Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Vasileios Bampidis.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Agreement of the minutes of the 17th Working Group meeting held on 30 April and 7 May 2024, via web-conference

The minutes of the 17th Working Group meeting were agreed by written procedure on 30 May 2024.

V. Scientific topics for discussion

a. Feedback from the Scientific Committee

The Working group was updated on the outcome of the discussion of the opinion at the 119th Scientific Committee plenary meeting held on 30 May. The Scientific Committee postponed endorsement of the draft scientific opinion for public consultation to the next plenary 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

in June. All the comments received from the Scientific Committee were made available to the Working Group and the major comments were outlined for discussion.

b. Draft Opinion text

The Working Group discussed all comments provided in the opinion and the proposed revisions introduced before the meeting. Specific tasks and actions for addressing remaining comments were agreed upon. The Working Group agreed to submit the draft opinion to the Scientific Committee plenary meeting scheduled on 25 June for endorsement for public consultation.

VI. Actions before next meeting

The timeline of the mandate was discussed and future meetings were planned to account for the timing of the public consultation.

VII. Next meeting

The next meeting will be held on 3 October 2024 as one full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

17th Working Group meeting on Bromide

30 April and 7 May 2024

9:00-16:00/9:00-16:00

MINUTES - Agreed on 30 May 2024

Location: Web conference

Attendees:

- Working Group Members:
Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller (Day 2), Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp (Day 1), Secundino Lopez Puente, Martin Rose (Day 1), Marco Vinceti (Day 2)

- European Commission representatives:
Frans Verstraete (Day 1)
Siret Surva

- Hearing expert[1]:
Robert Thomas Zoeller (for item V.b)

- EFSA:
Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová
Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti
Plant Health (PLANTS) Unit: Luna Greco, Judit Janossy

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received on Day 1 from Jacqueline Castenmiller and Marco Vinceti; and on Day 2 from Jürgen Gropp and Martin Rose.

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 Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], 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.
Regarding this meeting, Dr Gropp's Annual Declaration of Interest was under assessment for a new commitment as hearing expert to the FEEDAP Panel. In accordance with EFSA's Policy on Independence[Error! Bookmark not defined.] and the Decision of the Executive Director on Competing Interest Management[Error! Bookmark not defined.], and taking into account the specific matters discussed at the meeting in question, no additional Conflict of Interest for the expert concerned was present.

[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] 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 16th Working Group meeting held on 26-27 March 2024, via web-conference

The minutes of the 16th Working Group meeting were agreed by written procedure on 19 April 2024.

V. Scientific topics for discussion

a. Screening of bromide safety

The Working Group was presented with the finalised results of the screening of bromide safety based on the scenario using monitoring data of bromide in foods and comparison with the scenario of safety screening assuming presence of bromide at the level of current Maximum Residue Limits. The related sections of the opinion were also finalised for discussion with the working group. The updated estimation was based on new occurrence data of bromide in foods, which were received in fall 2023 through EFSA's annual chemical occurrence data collection programme and extracted in February 2024.

b. Draft Opinion text

The Working Group discussed and finalised all areas of the opinion and addressed remaining comments. The sections of Conclusions, Recommendations and the Summary of the opinion were reviewed and finalised. The Working Group agreed to submit the draft opinion to the Scientific Committee plenary meeting in May 29-30, 2024 for possible endorsement for public consultation.

c. Uncertainty analysis

The Working Group was updated on the outcome of the uncertainty analysis discussion, held on 16 April, on identified uncertainties in the scenarios of safety screening of bromide. Since these screening calculations do not constitute a refined exposure assessment, in accordance with the terms of reference, the uncertainties were related to data gaps related to the monitoring data for bromide and consumption data for relevant foods. Recommendations to fill these data gaps are included in the opinion so that a refined exposure assessment is possible in the future.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 3 June 2024 as one full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

16th Working Group meeting on Bromide

26-27 March 2024

9:00-16:00/9:00-16:00

MINUTES - Agreed on 19 April 2023

Location: Web conference

Attendees:

- Working Group Members:
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- European Commission and/or Member States representatives:
  Frans Verstraete

- EFSA:
  Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová, Olaf Mosbach-Schulz
  Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti
  Plant Health (PLANTS) Unit: Luna Greco

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Secundino Lopez-Puente for part of the second day.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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.

[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 15th Working Group meeting held on 16 February 2024, via web-conference

The minutes of the 15th Working Group meeting were agreed by written procedure on 1 March 2024.

V. Scientific topics for discussion

a. Dietary bromide screening

The Working Group was presented with an updated analysis of the screening of bromide intake based on a scenario using monitoring data of bromide in foods and comparison with the scenario of intake assuming presence of bromide up to the MRLs. The updated analysis was based on new occurrence data of bromide in foods, which were received through EFSA's monitoring program in the fall of 2023.

b. Draft Opinion text

The Working Group was informed that EFSA was able to obtain the redacted report of an unpublished 90-day study on sodium bromide from the submitter Member State, which was reviewed by ECHA in the context of the Harmonised Classification and Labelling (CLH) of bromide. The study was requested by EFSA for the purpose of obtaining more detailed data and information on thyroid hormone evaluation compared to the summary data available in the CHL report and related documents. These additional data were considered relevant and useful for completing the hazard assessment of bromide in this mandate.

The Working Group reviewed sections of the draft opinion and addressed comments with text revisions as needed. The sections referring to thyroid effects were discussed in light of access to the data in the unpublished 90-day study and the BMD modelling of the data. The risk characterisation was discussed in the context of the overall evidence.

c. Uncertainty analysis

The Working Group was updated on the outcome of the Expert Knowledge Elicitation (EKE) session, held on 1 March, for uncertainty analysis of the hazard assessment of bromide and the proposed reference value. The possible impact of the additional unpublished study on the overall uncertainty and reference value was discussed.

Uncertainties related to the monitoring data for bromide and consumption data for relevant foods were discussed in the presence of EFSA staff providing support with uncertainty assessment. EFSA staff proposed a few revisions to prepare the data for a follow up uncertainty analysis of bromide intake screening. An EKE session was agreed to follow before the next Working Group meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 30 April and 7 May 2024 as two full-day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

Expert Knowledge Elicitation of uncertainties in the assessment of bromide ion

1 March 2024
9:00-11:30
MINUTES - Agreed on 19 March 2024

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- Working Group Members:
Diane Benford (chair), Marie-Christine Chagnon, Keyvin Darney (EKE experts)
Marco Vinceti (EKE observer)

- EFSA:
Methodology and Scientific Support (MESE) Unit:
Maria Bastaki (WG coordinator), Olaf Mosbach-Schulz (EKE moderator), Yannick Spill (EKE observer)
Pesticides Peer Review (PREV) Unit: Andrea Terron (EKE expert)

I. Welcome and apologies for absence

The moderator of the session and WG coordinator welcomed the participants.

II. Adoption of agenda

The agenda of the meeting was agreed.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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. Protocol of Expert Knowledge Elicitation

The Protocol for an Expert Knowledge Elicitation on the uncertainties in the assessment of the risk of bromide in food was presented to the participants. Prior to the meeting, the participants were invited to individually consider the key limitations in the body of evidence contributing to the relative uncertainty of the reference value for the hazard assessment of bromide in humans.

[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. Expert Knowledge Elicitation phase

The moderator of the Expert Knowledge Elicitation presented the experts with the main conclusion of the draft opinion and invited the experts to discuss the key limitations resulting in uncertainty in the evidence providing a reference point for the hazard assessment of bromide. The elicitation of expert knowledge was administered according to the protocol and resulted in estimates of the likely range of the reference point based on expert judgment.

VI. Actions

The moderator of the Expert Knowledge Elicitation will draft the report of the session. The WG coordinator will provide the draft report to the experts for feedback and finalisation. The report will be added to the documentation of the scientific opinion on the assessment of the risks to human and animal health from the presence of bromide ion in food and feed.

SCIENTIFIC COMMITTEE WORKING GROUP

15th Working Group meeting on Bromide

16 February 2024
9:00-16:30

MINUTES - Agreed on 1 March 2024

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete

- **EFSA:**
  Methodology and Scientific Support (MESE) Unit: Maria Bastaki
  Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti
  Plant Health (PLANTS) Unit: Luna Greco

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jürgen Gropp.

II. Adoption of agenda

The agenda was adopted without changes, for the second of the two days initially planned for the 15th Working Group meeting. The meeting on 13 February was cancelled due to conflict with the participation of experts and staff in the 19th meeting of the Working Group on Endocrine Disrupters, held by the Pesticides Peer Review Unit.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

Regarding this meeting, Dr Benford's Annual Declaration of Interest was under assessment as part of the annual update with no new interest declared. In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, no additional Conflict of Interest for the expert concerned was present.

[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 14th Working Group meeting held on 23 and 24 January 2024, via web-conference

The minutes of the 14th Working Group meeting were agreed by written procedure on 8 February 2024.

V. Scientific topics for discussion

a. Feedback from meeting with Working Group on Endocrine Disrupters

The WG was updated on the discussion held during the 19th meeting of the Working Group on Endocrine Disrupters, specifically on the evidence available for effects of bromide on the thyroid.

b. Draft Opinion text

The Working Group reviewed the text of the draft opinion to address comments and revise as needed for accuracy and clarity. The sections referring to thyroid effects were discussed taking into account the input received from the Working Group on Endocrine Disrupters (V.a.). Clarifications were made in the sections on kinetics and on animal health.

The Working Group was informed that the updating of the dataset with new occurrence data of bromide in foods, which were received through EFSA's monitoring program in the fall of 2023, is underway. An update on the follow up analysis will be presented at the next WG meeting.

c. Uncertainty analysis

The Working Group reviewed the revised table of uncertainties identified in the opinion, in preparation for a scheduled Expert Knowledge Elicitation (EKE) session to conclude the uncertainty assessment. The WG agreed to review the identified uncertainties and revise accordingly based on this discussion. It was also agreed to schedule time for an EKE session with selected WG experts, observers, and EFSA staff before the next WG meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 26 and 27 March 2024 as two full-days meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

14th Working Group meeting on Bromide

23-24 January 2024
9:00-16:30
MINUTES - Agreed on 8 February 2024

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete

- **Hearing expert[1]:**
  Robert Thomas Zoeller (for item V.b)

- **EFSA:**
  Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová
  Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti
  Plant Health (PLANTS) Unit: Luna Greco
  Pesticides Review (PREV) Unit: Anna Lanzoni, Andrea Terron

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marco Vinceti in the morning of both days and Jacqueline Castenmiller in the morning of the first day.

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 Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], 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.

[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] 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 13th Working Group meeting held on 27 and 30 November 2023, via web-conference

The minutes of the 13th Working Group meeting were agreed by written procedure on 11 December 2023.

V. Scientific topics for discussion

a. Extension of the deadline

The WG was updated on the EFSA request to the European Commission for an extension of the original deadline of this mandate to the end of 2024. The extension was requested to allow sufficient time for the WG to consult with the EFSA standing WG on endocrine disruptors for input in the interpretation of the evidence on thyroid effects of bromide. The extension was also needed to allow sufficient time for EFSA to consult with the European Chemicals Agency (ECHA) for harmonisation of the assessments between the two agencies under the policy of One-Substance One-Assessment (OSOA). The WG was also updated on other current engagements between EFSA and ECHA.

b. Draft Opinion text

The WG reviewed the text of the draft opinion to address comments and revise as needed for accuracy and clarity. All sections of the opinion were reviewed except sections referring to thyroid effects for which a dedicated discussion followed (see V.c.). Clarifications were made in the sections on kinetics and on animal health.

In light of the extension of the deadline for this mandate, the WG discussed the prospect of updating the dataset obtained from EFSA's monitoring program with new occurrence data of bromide in foods that were received in the fall of 2023. A comparison of these data to the MRLs for bromide is made in the opinion according to the mandate terms of reference. Although not foreseen in the current mandate, the WG agreed in previous meetings that these data can also be used for a semi-refined estimated human exposure. The WG considers this refinement indicative of more realistic exposure estimates compared to the high level screening of the MRLs for bromide conducted according to the terms of reference of the mandate. The European Commission advised to take into consideration the new data so that the opinion represents the current state of bromide levels in foods in Europe. The WG agreed that EFSA staff will proceed with processing and analysis of the new data.

c. Discussion of thyroid effects

The hearing expert and EFSA staff from the WG on endocrine disruptors with expertise in thyroid histopathology joined the WG meeting for a focused discussion of the evidence of bromide effects on thyroid from experimental animal studies. Written reports on the points of discussion were presented to the WG ahead of the meeting and were used as reference for the discussion. The reports included the appraisal of the quality of the studies, as well as the interpretation of the changes, if any, in thyroid hormones, TSH and the histopathological assessment of the thyroid gland reported in the studies. Questions from the WG experts and additional clarifications were addressed during the discussion.

d. Uncertainty analysis

The WG held a dedicated discussion on the approach to assess uncertainties in the opinion. EFSA staff with expertise in uncertainty assessment was invited to the meeting to address questions and assist the WG with finalising the identification of the uncertainties and with

planning a follow up Expert Knowledge Elicitation (EKE) session to conclude the assessment. The WG agreed to review the identified uncertainties and revise accordingly based on this discussion. It was also agreed to schedule time for an EKE session with selected WG experts, observers, and EFSA staff before the next WG meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 13 and 16 February 2024 as two full-days meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

13th Working Group meeting on Bromide

27 and 30 November 2023
9:00-12:00, 13:00-16:00/14:00-18:00
MINUTES - Agreed on 11 December 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **Hearing expert[1]:**
  Robert Thomas Zoeller (for agenda item 7)

- **European Commission and/or Member States representatives:**
  Frans Verstraete

- **EFSA:**
  Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Petra Gergelová
  Feed and Contaminants (FEEDCO) Unit: Matteo Lorenzo Innocenti
  Plant Health (PLANTS) Unit: Judit Janossy

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 Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], 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.

Regarding this meeting, Dr Benford declared the following interest: participation as vice chair in the 97th JECFA meeting focused on assessing the safety of INS171 and three groups of flavourings. In accordance with EFSA's Policy on IndependenceError! Bookmark not defined. and the Decision of the Executive Director on Competing Interest ManagementError! Bookmark not defined., and taking into account the specific matters

[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] 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

discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

IV. Agreement of the minutes of the 12th Working Group meeting held on 23 October 2023, via web-conference

The minutes of the 12th Working Group meeting were agreed by written procedure on 10 November 2023.

V. Scientific topics for discussion

a. Feedback from SC Plenary

EFSA staff updated the WG on the outcome of the discussion of the Scientific Committee (SC) on the draft opinion on bromide, held during its 116th Plenary meeting which took place on 21 to 23 November 2023. EFSA provided the WG with comments and suggestions made by SC members to be addressed during the 13th WG meeting and before the next SC Plenary in February 2024.

b. Draft Opinion text

The WG focused the discussion on specific aspects of the evidence of bromide effects on thyroid from human and experimental animal studies, specifically, on aspects of study design and dose-response profile that impact the interpretation of the evidence. The hearing expert joined this discussion in the afternoon and provided the WG with his views on assessment of substances with effects on the thyroid system, in addition to written comments provided before the meeting. The hearing expert was also invited to answer specific questions prepared by the WG experts for further clarifications.

The approach selected for the benchmark dose modelling of key studies in experimental animals and the technical aspects of the model were discussed in detail. The selection of a benchmark response (BMR) representing adverse changes in the thyroid was revisited. Comments and revisions in the text were reviewed and addressed.

The WG discussed options proposed for refining the estimated human exposure based on available occurrence data for bromide in foods. Such refinement would be indicative of more realistic exposure estimates compared to the high level screening of the MRLs for bromide conducted according to the terms of reference of the mandate. A refined exposure assessment is not foreseen in the current mandate.

The WG experts in animal health held a focused meeting to resolve questions related to the evidence of bromide effects in food producing and non-food producing animals, specifically related to the limited information on thyroid effects in these species. The discussion focused on the nature and strength of the evidence, and the limitations of the literature in target species. The prospect of using data generated in experimental animals for the hazard characterisation of bromide in the context of animal health was discussed. Refinements and revisions to the draft opinion were agreed to be made before the next meeting.

c. Uncertainty analysis

The WG revisited the uncertainties identified and clarified their prioritisation with the purpose of proceeding to the overall uncertainty assessment in the next step.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 23 and 24 January 2024 as two full-days meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

12th Working Group meeting on Bromide

23 October 2023
09:00-16:00
MINUTES - Agreed on 10 November 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Diane Benford (chair), Vasileios Bampidis, Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission representatives:**
  Frans Verstraete (DG-SANTE); Siret Surva (DG-SANTE)

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Secundino Lopez Puente in the morning and from Martin Rose in the afternoon.

II. Adoption of agenda

The agenda was adopted with changes to accommodate the presence of experts.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 11th Working Group meeting held on 2 and 9 October 2023, via web-conference

The minutes of the 11th Working Group meeting were agreed by written procedure on 20 October 2023.

V. Scientific topics for discussion

a. Draft Opinion text

The WG discussed the available evidence on the effects of bromide on thyroid from human and experimental animal studies in the context of hazard characterisation. Aspects of the benchmark dose modelling of data on thyroid effects from a key study in experimental animals were further discussed, including the selection of benchmark response and the presentation of the analysis in the opinion. The available evidence related to bromide effects on animal health was discussed in detail with due consideration of the limitations of the body of literature. Draft text on the hazard characterisation of bromide for food producing and non-food producing animals was presented and discussed.

The results of screening of the safety of the current MRLs for bromide using the tool PRIMo[3], as requested in the terms of reference, were presented and discussed. As it is recognised that this approach aims to only screen the safety of the MRLs, EFSA staff proposed some refinement of the exposure assessment based on occurrence data submitted to EFSA. The representatives of the European Commission for this mandate agreed to the proposed refinement with no further amendment to the terms of reference or their interpretation. Exposure assessment for food-producing and non-food producing animals is currently not feasible due to insufficient occurrence data.

Refinements and revisions to the draft opinion were agreed upon.

b. Uncertainty analysis

The WG continued discussion of the uncertainties identified in the area of human health and uncertainties related to assessment of exposure in humans and animals with the aim of clarifying sources of uncertainty and their prioritisation. Identification and prioritisation of uncertainties in the area of animal health remain to be completed based on the discussion of the evidence that took place during this meeting. The WG experts in animal health agreed to hold a follow up meeting to further discuss and finalise these uncertainties.

VI. Any other business

The WG evaluated the status of the draft opinion and agreed that, despite the efficient pace of the work conducted so far, the opinion is not yet ready to be presented to the Scientific Committee for endorsement for public consultation at the November 2023 plenary meeting. The WG aims to obtain endorsement for public consultation at the February 2024 plenary meeting of the Scientific Committee. This timing requires an extension of the initial deadline.

[3] Pesticide Residue Intake Model

VII. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the extended timeline of the mandate.

VIII. Next meeting

The next meeting will be held on 27 November 2023 as a full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

11th Working Group meeting on Bromide

2 and 9 October 2023
09:00-13:00 / 09:00-13:00
MINUTES - Agreed on 20 October 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete; Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Secundino Lopez Puente for parts of day 1 and 2.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

With regard to this meeting, Dr Chagnon and Dr Lopez Puente had their Declarations of Interest under assessment as part of the annual review without additional involvements or interests. In accordance with EFSA's Policy on IndependenceError! Bookmark not defined. and the Decision of the Executive Director on Competing Interest ManagementError! Bookmark not defined., and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

[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 10th Working Group meeting held on 29 August 2023, via web-conference

The minutes of the 10th Working Group meeting were agreed by written procedure on 11 September 2023.

V. Scientific topics for discussion

a. Updates from SC Plenary

EFSA staff updated the WG on the outcome of the discussion of the draft opinion on bromide held at the 115th Scientific Committee (SC) Plenary, which took place on 20 and 21 September 2023. EFSA provided the WG with comments and suggestions made by SC members to be addressed during the present meeting and before the next SC Plenary in November.

b. Draft Opinion text

The WG discussed the available evidence on the effects of bromide on thyroid from human and experimental animal studies. The results of benchmark dose modelling performed on a key study in experimental animals were presented. The selection of an appropriate benchmark response (BMR) representing adverse changes in the thyroid was discussed in the context of EFSA and other relevant guidance on interpretation of thyroid effects. The section on hazard characterisation was drafted and discussed in detail. The WG experts in animal health presented an overview of evidence to be considered in the hazard characterisation of bromide in food producing and non-food producing animals will be drafted for discussion at the next WG meeting. Refinements and revisions to the draft opinion were agreed to be made before the next meeting.

c. Uncertainty analysis

An EFSA staff member involved in the WG on uncertainty analysis was invited to this meeting to assist the WG with the analysis. The WG members were invited to prioritise uncertainties based on their magnitude and impact. The WG agreed to continue with uncertainty identification and prioritisation and prepare to assess overall uncertainties at the next WG meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 23 October 2023 as a full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

10th Working Group meeting on Bromide

29 August 2023
09:00-16:30
MINUTES - Agreed on 11 September 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Judit Janossy, Silvia Tangianu

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 9th Working Group meeting held on 10 July 2023, via web-conference

The minutes of the 9th Working Group meeting were agreed by written procedure on 19 July 2023.

V. Scientific topics for discussion

a. Overview of the task assigned

EFSA staff briefly updated the WG on the outcome of the tasks assigned during the previous meeting.

b. Draft Opinion text

Refinements and revisions were made to the draft opinion during the meeting. Written comments provided by WG members were addressed. The WG experts in animal health updated the WG on their review of the related literature, discussed the relevant studies identified and presented the updated version of a summary table. The WG experts in human health updated the WG on their review of the related literature and discussed the relevant studies identified, addressing the received comments. The WG experts in toxicology presented an overview of the evidence related to the mode of action of bromide.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 2 and 9 October 2023 as two half-day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

9th Working Group meeting on Bromide

10 July 2023
09:00-16:30
MINUTES - Agreed on 19 July 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete, Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Silvia Tangianu

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 8th Working Group meeting held on 9 and 12 June 2023, via web-conference

The minutes of the 8th Working Group meeting were agreed by written procedure on 28 June 2023.

V. Scientific topics for discussion

a. Updates from the SC Plenary

EFSA staff updated the WG on the outcome of the discussion of the draft opinion on bromide held at the 114th Scientific Committee (SC) Plenary that took place on 28 and 29 June 2023 in Parma. EFSA provided the WG with a list of questions raised and suggestions made by SC members. These were either addressed during the present meeting or will be addressed during the next draft revision.

b. Draft Opinion text

Refinements and revisions were made to the draft opinion during the meeting. Written comments provided by WG members were addressed. The WG expert in ADME updated the WG on the retrieved literature related to bromide transfer to food of animal origin and will continue drafting related text in the opinion. The WG experts in human health updated the WG on their review of the related literature and discussed the relevant studies identified.

c. Uncertainty

The WG members discussed the structure of the uncertainty table and were invited to continue highlighting uncertainties identified during the review of the studies, before the next WG meeting. A revised template for animal health studies will be provided for this purpose.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 29 August 2023 as a full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

8th Working Group meeting on Bromide

9 & 12 June 2023
09:00-13:00 / 09:00-13:00
MINUTES - Agreed on 28 June 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete, Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Marco Vinceti for the 1st day and for the second half of the 2nd day;
Martin Rose for the second half of the 2nd day.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 7th Working Group meeting held on 8 and 11 May 2023, via web-conference

The minutes of the 7th Working Group meeting were agreed by written procedure on 29 May 2023.

V. Scientific topics for discussion

a. Updates on assignments

EFSA staff briefly updated the WG on the actions taken since the last meeting. An additional literature search for Occurrence in food has been conducted, and the results have been shared with the WG.

b. Draft Opinion text

Refinements and revisions were made to the draft opinion during the meeting. The WG experts in animal health presented an overview of the identified literature. The experts will proceed with drafting related text using relevant information found. The WG expert in ADME updated the WG on the retrieved literature related to bromide kinetics and transfer to food of animal origin and will continue drafting related text in the opinion.

c. Draft Opinion text - Human health

The WG experts in human health updated the WG on their review of the related literature and discussed the relevant studies identified, together with the new added sections.

d. Draft Opinion text - Occurrence

EFSA staff presented the WG with an advanced version of the draft text regarding bromide occurrence data in foods, including a complete table of food products in which the occurrence levels exceed the existing MRLs for bromide ion. Refinements and revisions were made to the draft text during the meeting. An additional literature search was conducted to find bromide levels for those foods for which the Occurrence data are limited, and the results were shared with the WG.

e. Uncertainty

The WG members were invited to highlight uncertainties identified during the review of the studies, before the next WG meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 10 July 2023 as a full-day meeting, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

7th Working Group meeting on Bromide

8 & 11 May 2023
09:00-13:00 / 09:00-13:00
MINUTES - Agreed on 29 May 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete; Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Vasileios Bampidis, Bruce Cottrill, Secundino Lopez Puente and Siret Surva (EC representative) for the 2nd day;
Marco Vinceti for the second half of the 2nd day.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 6th Working Group meeting held on 3 and 4 April 2023, via web-conference

The minutes of the 6th Working Group meeting were agreed by written procedure on 24 April 2023.

V. Scientific topics for discussion

a. Updates since last meeting

EFSA staff updated the WG on the actions taken since the last meeting. The title and abstract screening has been completed by EFSA staff and by the experts for the additional literature searches that were conducted, one to retrieve relevant toxicity studies for animal health, including studies on thyroid effects, and one to better understand the mode of action for thyroid toxicity. The list of selected relevant studies has been shared with the experts. EFSA staff has also contacted ECHA to request studies included in the assessment reports of two brominated biocides that may also be relevant to the EFSA assessment.

b. Draft Opinion - Occurrence and MRLs

EFSA staff presented the WG with a more advanced version of the draft text regarding bromide occurrence data in foods, including a preliminary table of food products in which the occurrence levels exceed the existing MRLs for bromide ion. Refinements and revisions were made to the draft text during the meeting.

c. Draft Opinion – Animal health

The WG experts in animal health presented an overview of the literature retrieved from the additional search conducted to identify relevant toxicity studies for animal health, including studies on thyroid effects. The experts will proceed with assessing the evidence in this literature and drafting related text.

d. Draft Opinion text

The WG reviewed the text of the draft opinion and discussed its structure. WG experts and EFSA staff were invited to provide additional input in their respective areas of expertise. Refinements and revisions were made to the draft opinion during the meeting. The WG experts in human health updated the WG on their review of the related literature and discussed the relevant studies identified. The WG expert in ADME updated the WG on the retrieved literature related to bromide kinetics and will continue drafting related text in the opinion.

e. Uncertainty

The WG members were invited to provide comments and to highlight uncertainties identified during the review of the studies, before the next WG meeting.

VI. Actions before next meeting

The tasks for the next meeting were discussed and agreed upon in the context of the timeline of the mandate.

VII. Next meeting

The next meeting will be held on 9 and 12 June 2023 as two half-day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

6th Working Group meeting on Bromide

3 & 4 April 2023
09:00-13:00 / 09:00-13:00
MINUTES - Agreed on 24 April 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Siret Surva, EC representative.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 5th Working Group meeting held on 6 and 13 March 2023, via web-conference

The minutes of the 5th Working Group meeting were agreed by written procedure on 28 March 2023.

V. Scientific topics for discussion

a. Updates since last meeting

EFSA staff updated the WG on the actions taken since the last meeting. An additional literature search was conducted to retrieve relevant toxicity studies for animal health, including studies on thyroid effects, and the title and abstract screening is nearly completed. Information about the use of bromide in human and animal medications was identified and shared with the WG.

b. Draft Opinion text

The WG reviewed the text of the draft opinion and discussed its structure. WG experts and EFSA staff were invited to provide additional input in their respective areas of expertise. Refinements and revisions were made to the draft opinion during the meeting. The WG experts in animal health and animal exposure were presented with an overview of the literature retrieved from a search conducted using targeted search terms for occurrence of bromide in marine sources. The experts will proceed with screening this literature. The WG experts in human health updated the WG on their review of the related literature and discussed the relevant studies identified. The WG experts on toxicology presented an overview of the evidence from *in vivo* studies in a summary table. The WG expert on ADME updated the WG on the retrieved literature related to bromide kinetics and will continue drafting related text in the opinion.

c. Draft Opinion - Uncertainty

The WG members were presented with a proposal on how to approach the uncertainty analysis in this opinion. The WG discussed the possibility of inviting an expert from the EFSA WG on uncertainty analysis for assistance with implementation of the EFSA Guidance on Uncertainty Analysis in this context.

d. Draft Opinion - Occurrence and MRLs

EFSA staff presented the WG with draft text regarding bromide occurrence data in foods. The geographical origin of the available data and some examples of commodity foods were provided. The WG discussed how to account for exposure to bromide through drinking water. Lack of data for some food categories was also discussed. Refinements and revisions were made to the draft text during the meeting.

VI. Actions before next meeting

The timeframe of activities planned in the future WG meetings was discussed in the context of the timeline of the mandate. The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The next meeting will be held on 8 and 11 May 2023 as two half-day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

5th Working Group meeting on Bromide

6 & 13 March 2023
09:00-13:00 / 09:00-13:00
MINUTES - Agreed on 28 March 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete, Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Secundino Lopez Puente did not participate in agenda point 8.
Marco Vinceti did not participate in agenda point 10 to 13.

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[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 4th Working Group meeting held on 27 January 2023, via web-conference

The minutes of the 4th Working Group meeting were agreed by written procedure on 15 February 2023.

V. Scientific topics for discussion

a. Uncertainty

The WG members were presented with principles of uncertainty analysis and examples from other EFSA opinions. A proposal on how to approach the uncertainty issues in this opinion was discussed.

b. Opinion template and structure

The WG reviewed the draft opinion outline and discussed its structure. WG experts and EFSA staff were invited to provide additional input in the template in their respective areas of expertise. Refinements and revisions were made to the draft version of the outline during the meeting.

c. Data extraction: template for input decision on format of results

The WG was presented with a proposal for a data extraction template, and possible alternatives were discussed.

d. Informal RoB: set of questions for quality issues

The WG discussed the possibility of performing an informal Risk of Bias assessment, since a systematic literature review is not foreseen in this mandate. The proposal was to informally document study quality using a set of key questions, and track the reasons of inclusion/exclusion decisions.

e. Human health studies update

The human health experts updated the WG on the literature retrieved for human health. According to the experts, some useful information was found. The list of experimental animal studies was further considered during the meeting. Additionally, a "snowballing" approach of literature citations was suggested to complement the results of the literature search, including citations in the last JMPR assessment.

f. ADME update

The ADME expert updated the WG on the literature retrieved related to bromide kinetics. The expert will start drafting related text to be included in the opinion.

g. Animal health effects update – additional literature search

EFSA staff updated the WG on the ad hoc search conducted to retrieve more relevant toxicity studies, including studies on thyroid effects, the endocrine endpoint of possible interest. According to the experts, very few of the studies retrieved seemed relevant. It was decided that the first step of title and abstract screening will be conducted internally.

h. Bromide occurrence in algae, fish – additional literature search

The animal health and exposure experts updated the WG on the overview of the literature retrieved from a search conducted using targeted search terms for occurrence of bromide

in marine sources. According to the experts, some useful information was found but further targeted search is needed to look for additional information.

i. **Comparison occurrence data - MRLs**

EFSA staff presented the WG with draft text regarding bromide occurrence data in foods. The geographical origin of the available data and some examples of commodity foods were provided. The WG discussed how to account for exposure to bromide through drinking water. Lack of data for some food categories was also discussed. Refinements and revisions were made to the draft text during the meeting.

VI. Actions before next meeting

The timeframe of activities of the WG meetings was discussed in the context of the timeline of the mandate. The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The next meeting will be held on 3 and 4 April 2023 as two half day meetings, via web conference.

SCIENTIFIC COMMITTEE WORKING GROUP

4th Working Group meeting on Bromide

27 January 2023
09:30-12:30 / 13:30-16:30
MINUTES - Agreed on 15 February 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Jacqueline Castenmiller, Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose, Marco Vinceti

- **European Commission and/or Member States representatives:**
  Frans Verstraete, Siret Surva

- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Agreement of the minutes of the 3rd Working Group meeting held on 28 November 2022, via web-conference

The minutes of the 3rd Working Group meeting were agreed by written procedure on 12 December 2022.

[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. Update on Public Consultation of the Protocol

The WG was updated on the ongoing Public Consultation of the Protocol. At the time of the meeting, no comments were received.

b. Animal Health literature review / Discussion (six subject areas)

The WG experts in areas of Animal Health presented brief summaries of the literature in each of the subareas, including health effects of bromide on farmed and companion animal health, animal exposure, bromide kinetics and tissue distribution in animals. According to the experts, some useful information was found, but further search of the literature is needed to look for additional information if possible before drafting the opinion.

c. ADME / Human Health

The WG expert updated the other WG members on the literature on kinetics of bromide in humans and experimental animals. Useful information can be extracted from the papers, but it is suggested to run a targeted search to retrieve more information if possible and have a clearer idea.

d. Current MRL overview

EFSA presented to the WG with background information and history of the existing MRLs for bromide, how they were established and their use in acute risk assessments. The WG discussed their application in this project and what additional information is needed to better understand the source of bromide when detected in foods where no MRLs are established and/or levels exceed existing MRLs.

e. Update on Bromide monitoring data

The WG was updated on the occurrence data analysis, the geographical origin of the available data, and some examples of commodity foods were provided.

f. Update on literature screening contract for human health

The WG was updated on the ongoing screening process of the literature related to human health. The screening at title and abstract level is completed, and the full text screening is about to begin.

VI. Actions before next meeting

The timeframe of activities of the WG meetings were discussed in the context of the timeline of the mandate. The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The next meeting will be held on 6 and 13 March 2023 as two half day meetings, via web conference.

SCIENTIFIC COMMITTEE

MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON BROMIDE

Held on 28 November 2022 via Teleconference

(Agreed on 12 December 2022)

Participants

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Secundino Lopez Puente, Martin Rose
- **European Commission and/or Member States representatives:**
  Frans Verstraete
- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

1. Welcome, apologies for absence, and introductions

The Chair welcomed the participants and the new WG member Secundino Lopez Puente. A brief tour de table followed.

2. Adoption of agenda

The agenda was adopted with no changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 2nd Working Group meeting held on 27 October 2022, by TELE-conference

The minutes of the 2nd Working Group (WG) meeting held on 27 October 2022 were agreed by written procedure on 10 November 2022.

5. Feedback from Scientific Committee on the draft Protocol

The WG proceeded with detailed review of the protocol, incorporating the feedback received from the Scientific Committee (SC) during the 111th SC Plenary, held on 16 and 17 November 2022. The SC formally endorsed the protocol for public consultation conditionally upon addressing the changes discussed. The WG revised the draft Protocol, taking into account written comments previously provided by WG members and agreed during the meeting. Based on the feedback received from the SC on the draft protocol, systematic literature review was not discussed further. The final draft will be published for public consultation in the following weeks.

6. Literature search on human health

The WG members were updated on the literature search approach that was constructed to retrieve literature relevant to human health outcomes associated with oral exposure to bromide, according to eligibility criteria stated in the protocol. The search terms were reviewed and agreed upon.

7. Inclusion/Exclusion criteria and categories for Level I screening

The WG members were updated on the ready to begin Level I literature screening contract. The WG discussed proposed adjustments to the inclusion and exclusion criteria and use of labelling categories during screening.

8. Overview of literature on animal health

The WG was updated on the outcome of the literature search and screening that was conducted in relation to effects of bromide on farmed and companion animal health and associated areas, including animal exposure, bromide kinetics and tissue distribution in animals. The lists of relevant titles will be made available to WG members in the next days for selection of titles for

[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

further review. Literature identification through "snowballing" was suggested to complement the results of the literature search.

9. Occurrence data in food

The WG was updated on the availability of occurrence data for human exposure in EFSA's databases, and possible avenues to obtain additional relevant data were discussed. In addition, considerations for comparison of occurrence data with the maximum residue limits for bromide were discussed.

10. Literature search on ADME in humans

The WG was updated on the approach, search terms and results from the preliminary literature search on ADME for humans. The search terms were revised and agreed upon, and the Level I screening process will start in the next weeks.

11. Actions before next meeting

The timeframe of activities and scheduling of WG meetings were discussed in the context of the timeline of the mandate. The tasks for the next meeting were discussed and agreed upon.

12. Next meetings

The next WG meeting is scheduled on 27 January 2023.

SCIENTIFIC COMMITTEE

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON BROMIDE

Held on 27 October 2022 via Teleconference

(Agreed on 10 November 2022)

Participants

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Marie-Christine Chagnon, Bruce Cottrill, Keyvin Darney, Jürgen Gropp, Martin Rose
- **European Commission and/or Member States representatives:**
  Siret Surva, Frans Verstraete, Eva Zuskova
- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy, Silvia Tangianu

1. Welcome, apologies for absence, and introductions

The Chair welcomed the participants and the new WG members Marie Christine Chagnon and Jürgen Gropp. A tour de table followed with introductions of all participants.

2. Adoption of agenda

The agenda was adopted with no changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 1st Working Group meeting held on 15 September 2022, by TELE-conference

The minutes of the 1st Working Group (WG) meeting held on 15 September 2022 were agreed by written procedure on 5 October 2022.

5. Planning of WG activities and milestones

The WG discussed and agreed on the timeline of WG activities and milestones to achieve the final adoption of the Opinion by the Scientific Committee by March 2024, and meet the deadline requested in the European Commission Mandate.

6. Human health literature search criteria

The WG members were updated on the literature search terms that were compiled to retrieve literature related to human health according to the protocol. The WG reviewed the search strategy closely, due to the high numbers of results obtained from the pilot screening and identified a few terms to be removed to minimise "noise" in the results. The search terms will be refined with the assistance of the EFSA Library staff, according to the proposals made during the meeting.

7. Specifications for contract for literature screening

The WG members were updated on the activity undertaken by EFSA to outsource the literature screening process. The WG discussed the possibility to perform a systematic literature review for the most pertinent endpoint(s) according to provisions detailed in the protocol, within the constraints of the mandate deadline.

8. Update on the outcomes of literature review on animal health

The WG was updated on the methodology, search terms and results of the literature review that was conducted for effects of bromide on farm and companion animal health. The approach and decisions taken to refine the search terms for this screening were presented and discussed to help refine the literature search for human health accordingly.

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[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

9. Protocol development

The WG proceeded with detailed review of the draft Protocol, according to the Draft framework for Protocol development for EFSA's scientific assessments[3], with the intention of presenting a final draft to the Scientific Committee at its next Plenary in November. Refinements and revisions were made to the draft protocol during the meeting, with related revisions to be completed before presenting to the Scientific Committee. The WG will finalise the protocol at the next WG meeting incorporating any feedback received from the Scientific Committee. WG experts and EFSA staff were invited to provide additional input in the protocol in their respective areas of expertise. Written comments on the protocol provided by WG members were discussed and agreed during the meeting.

10. Next steps and distribution of tasks

The timeframe of activities and scheduling of WG meetings were discussed in the context of the timeline of the mandate. The tasks for the next meeting were discussed and agreed upon.

11. Next meetings

The next WG meeting is scheduled on 28 November 2022.

[3] https://www.efsa.europa.eu/en/supporting/pub/en-1843

METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 1ST MEETING OF THE WORKING GROUP ON BROMIDE

Held on 15 September 2022 via Teleconference

(Agreed on 5 October 2022)

Participants

- **Working Group Members:**
  Vasileios Bampidis, Diane Benford (chair), Bruce Cottrill, Keyvin Darney, Martin Rose
- **European Commission and/or Member States representatives:**
  Almut Bitterhof, Siret Surva, Frans Verstraete
- **EFSA:**
  Maria Bastaki, Petra Gergelová, Matteo Lorenzo Innocenti, Judit Janossy

1. Welcome, apologies for absence, and introductions

The Chair welcomed the participants. A tour de table followed with introductions of all participants.

2. Adoption of agenda

The agenda was adopted with no changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, 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

4. Presentation of the Mandate

The mandate received from the EC was presented to the WG. In brief, the mandate tasks EFSA to draft a scientific opinion on the risks for human health related to the presence of bromide ion in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed, in particular in algae and seaweed and derived products. The scope and context of the mandate was elaborated by the representatives of the EC that were present in the meeting. The terms of reference were reviewed and clarified.

5. Interpretation of the Terms of Reference

A discussion on the interpretation of the Terms of Reference took place, within the scope of the mandate as defined by the EC representatives. The scope of the assessment will include bromide ion and bromine element. Bromate is relevant to the mandate under conditions of bromide oxidation that are relevant to exposure in animals and humans. Algae and seaweed are the sources of interest for bromide in feed. Animal exposure assessment will be based on available data. A refined human exposure assessment will be conducted, if necessary, as a follow up to the preliminary risk assessment. The levels of bromide obtained from monitoring data will be compared to the current MRLs of bromide in foods. Exposure to bromide from veterinary or medical products is out of scope for both animals and humans. The hazard characterisation of bromide will be based on the weight of evidence from the scientific literature taking into account existing reviews by authoritative bodies. Both farm and companion animals are within the scope of the mandate.

6. Protocol development

The WG discussed the development of a protocol outlining the data needed and the approaches and methods to be adopted. Standard procedures of exposure assessment and hazard assessment will be followed and will be described in the protocol in sufficient level of detail to ensure transparency and flexibility to adopt modifications as needed. Any modifications will be documented in protocol amendments.

7. Any other business

Not applicable.

8. Next steps and distribution of tasks

The timeframe of activities and scheduling of WG meetings were discussed in the context of the timeline of the mandate. The WG agreed that additional experts should be invited to join the WG in light of the anticipated workload. The tasks for the next meeting were discussed and agreed upon.

9. Next meetings

The next WG meeting is on 27 October 2022.