



**SCIENTIFIC COMMITTEE**  
25<sup>th</sup> Working Group meeting on Fluoride



30 and 31 July 2024  
11:00-18:00/14:00-18.00  
MINUTES - Agreed on 26 August 2024

**Location:** Webconference

**Attendees:**

- Working Group Members:

Jacqueline Castenmiller  
Keyvin Darney  
Mary Gilbert  
Thorhallur Halldorsson (Chair)  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman<sup>2</sup>

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz, Claudia Roncancio-Pena

Pesticides Peer Review Unit: Anna Lanzoni<sup>3</sup>, Andrea Terron<sup>3</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received from WG expert Heather Wallace on 31 July 2024.

## **II. Adoption of agenda**

The agenda was adopted with some changes in the time schedule.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> Participated in part of agenda points Va and Vb

<sup>3</sup> Participated in part of agenda point Va

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 24<sup>th</sup> Working Group meeting held on 10-11 July 2024, via web-conference**

The [minutes of the 24th Working Group Meeting](#) were agreed by written procedure on 1 August 2024.

#### **V. Scientific topics for discussion**

##### **a. Draft opinion sections on Fluoride Toxicity in human and animal studies**

The WG members continued the discussion and text revisions of the draft opinion sections on Fluoride Toxicity in human and animal studies reporting on (Developmental) Neurotoxicity ((D)NT), effects on thyroid and on bone health. The WG discussed feedback received through exchanges with the EFSA Nutrition and Food Innovation Unit (NIF) on the evidence from human studies. Specific discussion on the assessment of (D)NT histopathology data from animal studies was held.

##### **b. Human and Animal evidence integration and Weight of Evidence Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints. Discussion on the approach for the derivation of reference points and of Health Based Guidance Value (HBGV) for fluoride was also continued. Further discussions will be held at the next meetings toward the finalization of the assessment.

#### **VI. Any Other Business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

#### **VII. Next meetings**

Next meetings are scheduled for:

- 27 and 28 August 2024
- 6 and 7 November 2024
- 19 and 22 November 2024



# SCIENTIFIC COMMITTEE

## 24<sup>th</sup> Working Group meeting on Fluoride

10 and 11 July 2024  
11:00-18:00/14:00-18.00  
MINUTES - Agreed on 1 August 2024



**Location:** Tele conference

**Attendees:**

- Working Group Members:

Jacqueline Castenmiller  
Keyvin Darney  
Mary Gilbert  
Thorhallur Halldorsson (Chair)  
Martin Paparella  
Marco Vinceti

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Laura Cicolallo, Olaf Mosbach-Schulz

### I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received by WG members Evangelia Ntzani and Heather Wallace.

### II. Adoption of agenda

The agenda was adopted with some changes in the timeschedule.

### III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 23<sup>rd</sup> Working Group meeting held on 4-14 June 2024, via web-conference

The [minutes of the 23rd Working Group Meeting](#) were agreed by written procedure on 5 July 2024.

### V. Scientific topics for discussion

#### a. Draft opinion sections on Fluoride Toxicity in human and animal studies

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



**SCIENTIFIC COMMITTEE**  
25<sup>th</sup> Working Group meeting on Fluoride



30 and 31 July 2024  
11:00-18:00/14:00-18.00  
MINUTES - Agreed on 26 August 2024

**Location:** Webconference

**Attendees:**

- Working Group Members:

Jacqueline Castenmiller  
Keyvin Darney  
Mary Gilbert  
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Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman<sup>2</sup>

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz, Claudia Roncancio-Pena

Pesticides Peer Review Unit: Anna Lanzoni<sup>3</sup>, Andrea Terron<sup>3</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received from WG expert Heather Wallace on 31 July 2024.

## **II. Adoption of agenda**

The agenda was adopted with some changes in the time schedule.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>2</sup> Participated in part of agenda points Va and Vb

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 24<sup>th</sup> Working Group meeting held on 10-11 July 2024, via web-conference**

The [minutes of the 24th Working Group Meeting](#) were agreed by written procedure on 1 August 2024.

#### **V. Scientific topics for discussion**

##### **a. Draft opinion sections on Fluoride Toxicity in human and animal studies**

The WG members continued the discussion and text revisions of the draft opinion sections on Fluoride Toxicity in human and animal studies reporting on (Developmental) Neurotoxicity ((D)NT), effects on thyroid and on bone health. The WG discussed feedback received through exchanges with the EFSA Nutrition and Food Innovation Unit (NIF) on the evidence from human studies. Specific discussion on the assessment of (D)NT histopathology data from animal studies was held.

##### **b. Human and Animal evidence integration and Weight of Evidence Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints. Discussion on the approach for the derivation of reference points and of Health Based Guidance Value (HBGV) for fluoride was also continued. Further discussions will be held at the next meetings toward the finalization of the assessment.

#### **VI. Any Other Business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

#### **VII. Next meetings**

Next meetings are scheduled for:

- 27 and 28 August 2024
- 6 and 7 November 2024
- 19 and 22 November 2024



The WG members continued the discussion and text revisions of the draft opinion sections on Fluoride Toxicity in human and animal studies reporting on (Developmental) Neurotoxicity ((D)NT), effects on thyroid and on bone health.

#### **b. Discussion on the NTP meta-analysis on (D)NT**

The WG was presented with an overview of the meta-analysis performed by the National Toxicology Program (NTP) in the context of the systematic review of the scientific research on fluoride exposure and neurodevelopmental and cognitive health effects in humans. A discussion on whether and how to take note in the draft opinion of other existing systematic reviews and meta-analysis in the peer-reviewed literature was held.

#### **c. Human and Animal evidence integration and Weight of Evidence Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at the next meetings toward the finalization of the assessment.

### **VI. Any Other Business**

#### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

### **VII. Next meetings**

Next meetings are scheduled for:

- 30 and 31 July 2024
- 27 and 28 August 2024
- 6 and 7 November 2024
- 19 and 22 November 2024



# SCIENTIFIC COMMITTEE

## 23<sup>rd</sup> Working Group meeting on Fluoride

4 and 14 June 2024  
09:30-17:00/09.00-16.30  
MINUTES - Agreed on 5 July 2024



**Location:** Webconference

**Attendees:**

- Working Group Members:

Jacqueline Castenmiller  
Keyvin Darney  
Mary Gilbert  
Thorhallur Halldorsson (Chair)  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing Expert:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz

## I. Welcome and apologies for absence

The Chair welcomed the participants and the new working group member Mary Gilbert. No apologies for absence were received. The hearing expert Svante Twetman participated only to part of the meeting held on 14 June 2024.

## II. Adoption of agenda

The agenda was adopted with some changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 ad hoc Working Group meeting held on 24 May 2024, via web-conference

The [minutes of the ad hoc Working Group Meeting](#) were agreed by written procedure on 13 June 2024.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## V. Scientific topics for discussion

### a. Feedback from 119th Scientific Committee (SC) Plenary

The WG members were informed about the outcome of the discussion held at the 119<sup>th</sup> Scientific Committee Plenary on 29 May 2024, where the opinion sections on hazard assessment were presented to the SC for discussion. The SC was presented with an overview of the status of the opinion, a summary of the overall evidence collected and an outline of the work in progress. The SC acknowledged the complexity of this risk assessment and the quality work done so far by the WG but requested that a more developed text be presented before providing further specific comments to the draft opinion, including synthesis and integration of all the lines of evidence from human and animal studies following a Weight of Evidence Approach for establishing an Health Based Guidance Values (HBGV). The revised and complete document will be tabled at the September inaugural plenary of the new SC for possible endorsement for public consultation.

### b. Review of available evidence on Fluoride Toxicity: Human studies

The WG members continued the discussion on the opinion section on bone health and thyroid effects.

### c. Review of available evidence on Fluoride Toxicity: Animal studies

The WG members discussed that the total fluoride exposure in animal studies must be accounted for, including the possible contribution of background concentrations of fluoride naturally occurring in the feed and drinking water administered to experimental animals. Despite the poor availability of data in this regard, available information will be considered in the estimation of total exposure of animals to fluoride.

### d. Human and Animal evidence integration and Weight of Evidence Approach

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at the next meetings toward the finalization of the assessment.

## VI. Any Other Business

#### o Extension of the mandate deadline

Due to the volume of the body of literature identified through the targeted and updated systematic literature searches performed in 2024 and following the discussion held at the 119th Scientific Committee Plenary, EFSA will request an extension of the current deadline of the mandate of 30 September 2024 from the European Commission DG SANTE.

#### o Planning of next steps

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The WG agreed to schedule additional WG meetings on 6, 7, 19 and 22 November 2024.

## VII. Next meetings

Next meetings are scheduled for:

- 10 and 11 July 2024
  - 30 and 31 July 2024
  - 27 and 28 August 2024
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MEETING MINUTES – 4 and 14 June 2024  
23<sup>rd</sup> Working Group meeting on Fluoride



- 6 and 7 November 2024
- 19 and 22 November 2024



**SCIENTIFIC COMMITTEE**  
Ad hoc Working Group meeting on Fluoride

24 May 2024  
09:00-13:00  
MINUTES - Agreed on 13 June 2024



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by WG member 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 22<sup>nd</sup> Working Group meeting held on 12, 23 and 24 April 2024, via web-conference**

The [minutes of the 22nd Working Group Meeting](#) were agreed by written procedure on 21 May 2024.

## **V. Scientific topics for discussion**

### **a. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the opinion section on bone health.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## **b. Human and Animal evidence integration and Risk Characterisation Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at next meetings toward the finalization of the assessment.

## **VI. Any Other Business**

### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The draft opinion sections on hazard assessment will be presented at the 119<sup>th</sup> Scientific Committee Plenary on 29 May 2024 for discussion.

The WG agreed to reschedule the 24<sup>th</sup> WG meeting, from 4 and 5 June 2024 to 4 and 14 June 2024.

## **VII. Next meetings**

Next meetings are scheduled for:

- 4 and 14 June 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024



# SCIENTIFIC COMMITTEE

## 22<sup>nd</sup> Working Group meeting on Fluoride



12, 23 and 24 April 2024  
09:30-17:30/09:30-17:30/09:30-18:30  
MINUTES - Agreed on 21 May 2024

**Location:** Webconference

**Attendees:**

○ Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Karlien Cheyns  
Keyvin Darney  
Jean-Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

○ Hearing experts<sup>1</sup>:

Mary Gilbert  
Svante Twetman  
Thomas Zoeller

○ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Pesticides Peer Review (PREV) Unit: Luna Greco, Anna Lanzoni, Andrea Terron

## I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from WG member Karlien Cheyns on 12 and 24 April 2024, WG member Jean-Charles Leblanc on 12 April 2024 and WG member Marco Vinceti on 23 and 24 April 2024. On 23 April 2024, WG experts Heather Wallace and Martin Paparella only participated in agenda item Vc. The hearing experts Mary Gilbert and Thomas Zoeller participated on 12, 23 and 24 April during agenda item Vb. The hearing expert Svante Twetman participated on 23 and 24 April 2024.

## II. Adoption of agenda

The agenda was adopted with some changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by

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**SCIENTIFIC COMMITTEE**  
Ad hoc Working Group meeting on Fluoride

24 May 2024  
09:00-13:00  
MINUTES - Agreed on 13 June 2024



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by WG member 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 22<sup>nd</sup> Working Group meeting held on 12, 23 and 24 April 2024, via web-conference**

The [minutes of the 22nd Working Group Meeting](#) were agreed by written procedure on 21 May 2024.

## **V. Scientific topics for discussion**

### **a. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the opinion section on bone health.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

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## **b. Human and Animal evidence integration and Risk Characterisation Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at next meetings toward the finalization of the assessment.

## **VI. Any Other Business**

### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The draft opinion sections on hazard assessment will be presented at the 119<sup>th</sup> Scientific Committee Plenary on 29 May 2024 for discussion.

The WG agreed to reschedule the 24<sup>th</sup> WG meeting, from 4 and 5 June 2024 to 4 and 14 June 2024.

## **VII. Next meetings**

Next meetings are scheduled for:

- 4 and 14 June 2024
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**SCIENTIFIC COMMITTEE**  
Ad hoc Working Group meeting on Fluoride



24 May 2024

09:00-13:00

MINUTES - Agreed on 13 June 2024

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**Attendees:**

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## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by WG member Jacqueline Castenmiller.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

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## **VI. Any Other Business**

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Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Olaf Mosbach-Schulz

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by WG member Jacqueline Castenmiller.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

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### **a. Review of available evidence on Fluoride Toxicity: Human studies**

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## **b. Human and Animal evidence integration and Risk Characterisation Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at next meetings toward the finalization of the assessment.

## **VI. Any Other Business**

### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The draft opinion sections on hazard assessment will be presented at the 119<sup>th</sup> Scientific Committee Plenary on 29 May 2024 for discussion.

The WG agreed to reschedule the 24<sup>th</sup> WG meeting, from 4 and 5 June 2024 to 4 and 14 June 2024.

## **VII. Next meetings**

Next meetings are scheduled for:

- 4 and 14 June 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024



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 Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex.

#### **IV. Agreement of the minutes of the 21<sup>st</sup> Working Group meeting held on 19 and 25 March 2024, via web-conference.**

The [minutes of the 21st Working Group Meeting](#) were agreed by written procedure on 12 April 2024.

#### **V. Scientific topics for discussion**

##### **a. Feedback from 118<sup>th</sup> Scientific Committee (SC) Plenary**

The WG members were informed about the outcome of the discussion held at the 118<sup>th</sup> Scientific Committee Plenary on 10 and 11 April 2024, where the opinion sections on exposure assessment were endorsed for public consultation by the SC. The sections of the draft opinion on analytical methods, kinetics and hazard assessment, will be presented at the next SC Plenary on 29 May 2024 for discussion.

##### **b. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the opinion sections on bone health, thyroid effects and biomarkers of fluoride exposure. Specific input on the opinion section on effects on thyroid was provided by the hearing experts. The WG continued the evaluation of the additional literature reporting on prioritised endpoints captured through the targeted and the extended (prior 2005) literature searches. Moreover, the WG completed the screening of the outcome of the literature search for hazard assessment repeated in January 2024 to capture literature published since the first search in 2022.

##### **c. Review of available evidence on Fluoride Toxicity: Animal studies**

The WG members continued the discussion on the opinion sections on (D)NT, bone health and thyroid effects. Specific discussion was held on the evaluation of (D)NT histopathological data. The WG completed the screening of the outcome of the literature search for hazard assessment repeated in January 2024 to capture literature published since the first search in 2022. The evidence from *in vitro* studies on (D)NT and the integration of lines of evidence were also discussed.

##### **d. Exposure Assessment Uncertainty Analysis**

A preliminary discussion on the uncertainty analysis related to the fluoride exposure assessment was held. The WG agreed to schedule two dedicated preparatory meetings to perform Expert Knowledge Elicitation (EKE) on the exposure assessment.

##### **e. Analytical Methods**

The WG members discussed and agreed on additional refinements to the opinion section on analytical methods.

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## **f. Discussion on Risk Characterisation Approach**

The WG continued the discussions initiated at previous WG meetings on the Weight of Evidence approach for the integration of all lines of evidence for all prioritized endpoints and on the approach for risk characterization of fluoride. Further discussions will be held at next meetings toward the finalization of the assessment.

## **VI. Any Other Business**

### **○ Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The WG agreed to schedule a preparatory meeting on 18 April 2024, two preparatory meetings to perform EKE on exposure assessment on 15 April and 23 May 2024 and additional WG meetings on 24 May and on 4-5 June 2024.

## **VII. Next meetings**

Next meetings are scheduled for:

- 15 and 18 April 2024 (preparatory meetings)
- 23 May 2024 (preparatory meeting)
- 24 May 2024
- 4 and 5 June 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024

### **Annex**

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

With regard to this meeting, WG member Heather Wallace declared the following interest: evaluator of grants in the context of European Commission Horizon Europe. In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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, the annual Declaration of Interests of WG member Evangelia Ntzani was under assessment but no new interests were declared orally.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC COMMITTEE

## 21<sup>st</sup> Working Group meeting on Fluoride

19 and 25 March 2024  
08:30-15:30 and 13:00-19:00  
MINUTES - Agreed on 12 April 2024



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Karlien Cheyns  
Keyvin Darney  
Jean-Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing experts<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Laura Cicolallo, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Pesticides Peer Review (PREV) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants and the new WG expert on Analytical Chemistry. Apologies for absence were received by Martin Paparella on 19 March 2024. Jean-Charles Leblanc attended online. The hearing expert Svante Twetman participated on 25 March 2024.

## II. Adoption of agenda

The agenda was adopted with some changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 20<sup>th</sup> Working Group meeting held on 20 and 21 February 2024, via web-conference**

The [minutes of the 20th Working Group Meeting](#) were agreed by written procedure on 12 March 2024.

#### **V. Scientific topics for discussion**

##### **a. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the opinion sections on bone health, thyroid effects and biomarkers of fluoride exposure. As foreseen by the protocol, an extended literature search prior 2005 on the prioritised endpoints of developmental neurotoxicity, thyroid toxicity and bone health was launched. The WG is currently in the process of evaluating the outcome of the extended literature search.

##### **b. Exposure Assessment**

Minor refinements to the opinion section on Exposure Assessment, addressing comments received from Scientific Committee (SC) members at the last SC Plenary were agreed. Due to lack of time at the February SC Plenary, this section will be presented at the next SC Plenary on 11<sup>th</sup> April for possible endorsement.

##### **c. Analytical Methods**

The opinion section on analytical methods was revised and updated, considering input provided by the new WG expert on analytical chemistry. Feedback on the reliability of analytical methods used to measure fluoride concentrations in different matrices in human epidemiological studies was also provided.

##### **d. Discussion on Risk Characterisation Approach**

A preliminary discussion on following the Weight of Evidence approach for the integration of the different lines of evidence was held. In addition, the methodology for the risk characterization of fluoride was discussed. These discussions will continue at the next meetings toward the finalization of the assessment.

##### **e. Uncertainty Analysis**

The WG continued the discussion of the uncertainty analysis, which will be integrated with the outcome of the risk of bias assessment and weight of evidence approach.

#### **VI. Any Other Business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The WG agreed to reschedule the April WG meeting on 12, 23 and 24 April 2024 and to organise an additional preparatory meeting on 18 April 2024.

#### **VII. Next meetings**

Next meetings are scheduled for:

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MEETING MINUTES – 19 and 25 March 2024  
21<sup>st</sup> Working Group meeting on Fluoride



- 12, 23 and 24 April 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024



# SCIENTIFIC COMMITTEE

## 20<sup>th</sup> Working Group meeting on Fluoride



20 and 21 February 2024  
14:00-18:00 and 09:00-16:00  
MINUTES - Agreed on 12 March 2024

**Location:** Parma and online

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing experts<sup>1</sup>:

Svante Twetman

Robert Thomas Zoeller

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Laura Ciccolallo, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Pesticides Peer Review (PREV) Unit: Luna Greco, Anna Lanzoni, Andrea Terron

## I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received. Jean Charles Le Blanc attended online. The hearing expert Robert Thomas Zoeller participated to agenda item Va. The hearing expert Svante Twetman participated to agenda items Vb and Vc.

## II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### **IV. Agreement of the minutes of the 19<sup>th</sup> Working Group meeting held on 11 and 12 January 2024, via web-conference**

The [minutes of the 19th Working Group Meeting](#) were agreed by written procedure on 1 February 2024.

#### **V. Scientific topics for discussion**

##### **a. Consultation with the Hearing Expert on Thyroid effects**

The WG continued the discussion on the interpretation of the evidence on thyroid effects in animal studies with input from the hearing expert. The WG is currently in the process of evaluating the outcome of the targeted literature search for human and animal studies on fluoride exposure and thyroid effects in females during pregnancy that may be associated with potential developmental effects in offspring. The WG agreed to conduct an additional targeted literature search on *in vitro* studies, including high-throughput (HTS) assays, reporting on endpoints relevant to thyroid function.

##### **b. Review of available evidence on Fluoride Toxicity: Animal studies**

The WG members continued the discussion on the assessment of the evidence, with emphasis on the histopathological evaluation of studies assessing potential DNT and thyroid effects of fluoride.

##### **c. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the feasibility of a meta-analysis of (D)NT cohort studies based on access to pertinent data requested from study authors. The sections on biomarkers of fluoride exposure and on reported fluoride effects on the thyroid were discussed and refinements in these sections were agreed.

##### **d. Opinion section on Kinetic**

The opinion section on kinetics was discussed and some refinements were agreed.

##### **e. Feedback from the 117th Scientific Committee Plenary**

The WG members were informed about the outcome of the discussion held at the 117<sup>th</sup> Scientific Committee Plenary on 6<sup>th</sup> February 2024. The feedback received from the Scientific Committee on the sections that were discussed was considered and addressed by the WG. Due to lack of time at the Plenary, it was not possible to discuss all tabled sections of the opinion and the possible endorsement of the section on Analytical Methods and Exposure Assessment was postponed to the next SC Plenary on 10<sup>th</sup> and 11<sup>th</sup> April 2024.

#### **VI. Any Other Business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The WG agreed to schedule an additional preparatory subgroup meeting before the next WG meeting.

#### **VII. Next meetings**

Next meetings are scheduled for:

- 19 and 25 March 2024
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MEETING MINUTES – 20 and 21 February 2024  
20<sup>th</sup> Working Group meeting on Fluoride



- 25 April 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024



# SCIENTIFIC COMMITTEE

## 19<sup>th</sup> Working Group meeting on Fluoride



11 and 12 January 2024  
09:00-16:00 and 11:00-18:00  
MINUTES - Agreed on 1 February 2024

**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Laura Cicolallo, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Jean Charles Le Blanc, Keyvin Darney, Martin Paparella and Heather Wallace (WG experts) participated to agenda items Vc, Vd, Ve. Svante Twetman (hearing expert) participated to agenda items Vb, Vd, Ve.

## II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 18<sup>th</sup> Working Group meeting held on 1 and 6 December 2023, via web-conference**

The [minutes of the 18th Working Group Meeting](#) were agreed by written procedure on 22 December 2023.

#### **V. Scientific topics for discussion**

##### **a. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the strength of the available evidence, focusing on the endpoints of neurotoxicity (NT), developmental neurotoxicity (DNT) and thyroid effects from human epidemiological studies. Refinements in these sections of the draft opinion were agreed.

##### **b. Discussion on meta-analysis for human cohort studies**

The WG continued the discussion on the feasibility of a meta-analysis of (D)NT cohort studies. For this purpose, an updated literature search on (D)NT cohort studies will be conducted, to capture and include any relevant studies published after the date of the systematic literature search run for this assessment.

##### **c. Review of available evidence on Fluoride Toxicity: Animal studies**

The WG members continued the discussion on the assessment of the evidence on (D)NT, with emphasis on the integration of the evidence and consistency among the reported endpoints from behavioral and biochemical/histopathological endpoints, together with the evidence on thyroid effects. The WG agreed to conduct an additional targeted literature search on *in vitro* studies and results from high-throughput (HTS) assays for these endpoints.

##### **d. Exposure assessment**

The WG finalised the sections on Methods of Fluoride Analysis and Exposure Assessment to be presented at the 117<sup>th</sup> Scientific Committee Plenary on 6 February 2024 for endorsement.

##### **e. Uncertainty Analysis**

A preliminary discussion on the Uncertainty Analysis was held.

#### **VI. Any other business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

#### **VII. Next meetings**

Next meetings are scheduled for:

- 20 and 21 February 2024
  - 19 and 25 March 2024
  - 25 April 2024
  - 10 and 11 July 2024
  - 30 and 31 July 2024
  - 27 and 28 August 2024
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# SCIENTIFIC COMMITTEE

## 18<sup>th</sup> Working Group meeting on Fluoride

1 and 6 December 2023  
09:00-16:00 and 14:00-18:00  
MINUTES - Agreed on 22 December 2023



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing experts<sup>1</sup>:

Svante Twetman  
Robert Thomas Zoeller

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Jean Charles Le Blanc (WG expert), Francesca Riolo, Maria Anastassiadou, Luna Greco and Jean Lou Dorne (EFSA) did not participate on 6 December 2023 (agenda item V.d). The Hearing Expert Robert Thomas Zoeller only participated on 6 December 2023 (agenda item V.d).

## II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 17<sup>th</sup> Working Group meeting held on 8 November 2023, via web-conference**

The [minutes of the 17th Working Group Meeting](#) were agreed by written procedure on 28 November 2023.

#### **V. Scientific topics for discussion**

##### **a. Review of available evidence on Fluoride Toxicity: Human studies**

The WG members continued the discussion on the strength of the available evidence, focusing on the endpoints of neurotoxicity (NT), developmental neurotoxicity (DNT) and thyroid effects from human epidemiological studies. Refinements of these sections of the draft opinion were agreed. A preliminary discussion to investigate the feasibility of a meta-analysis of (D)NT cohort studies was held. With regards to the endpoint of bone effects, the WG has conducted a more targeted literature search on bone fractures and bone mineral density and is currently in the process of reviewing the new literature collected.

##### **b. Review of available evidence on Fluoride Toxicity: Animal studies**

The WG members continued the discussion on the assessment of the evidence on (D)NT with emphasis on the integration of the evidence and consistency among the reported endpoints from behavioral and biochemical/histopathological endpoints. Evidence of thyroid effects was also discussed.

##### **c. Update on exposure assessment**

The WG was updated on recent additions and revisions in the section on exposure assessment. The WG agreed to conduct an additional targeted literature search on fluoride concentrations in human breast milk to identify any additional relevant data pertinent to the exposure assessment.

##### **d. Consultation with the Hearing Expert on Thyroid effects**

A dedicated discussion was held on the interpretation of the evidence on thyroid effects in human and animal studies with input from the hearing expert. The WG agreed to conduct an additional targeted literature search for human and animal studies on fluoride exposure during pregnancy and thyroid effects in offspring.

#### **VI. Any other business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting. The draft opinion will be presented at the 117<sup>th</sup> Scientific Committee Plenary in February 2024 for a second reading and endorsement of the section on Exposure Assessment.

#### **VII. Next meetings**

Next meetings are scheduled for:

- 11 and 12 January 2024
  - 20 and 21 February 2024
  - 19 and 25 March 2024
  - 25 April 2024
  - 10 and 11 July 2024
  - 30 and 31 July 2024
-

MEETING MINUTES – 1 and 6 December 2023  
18<sup>th</sup> Working Group meeting on Fluoride



- 27 and 28 August 2024



# SCIENTIFIC COMMITTEE

## 17<sup>th</sup> Working Group meeting on Fluoride

8 November 2023

08:30-15:30

MINUTES - Agreed on 27 November 2023



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Martin Paparella only participated to agenda item Vb.

## II. Adoption of agenda

The agenda was adopted with minor changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### **IV. Agreement of the minutes of the 16<sup>th</sup> Working Group meeting held on 5 and 11 October 2023, via web-conference**

The [minutes of the 16th Working Group Meeting](#) were agreed by written procedure on 30 October 2023.

#### **V. Review of available evidence on Fluoride Toxicity**

##### **a. Human studies**

The WG members continued the discussion on the strength of the evidence available for the endpoints of neurotoxicity (NT), developmental neurotoxicity (DNT), thyroid and bone effects from human epidemiological studies. A dedicated discussion on biomarkers of exposure and biomarkers of effect was held.

##### **b. Animal studies**

The WG members continued the discussion on the available evidence on NT and DNT from animal studies and focused on specific elements of the structure of the section on hazard assessment and characterisation. A preliminary discussion on how to integrate the different lines of evidence was held.

#### **VI. Update on exposure assessment**

The WG was updated on recent additions and revisions in the section on exposure assessment and had a dedicated discussion about data availability for fluoride concentrations applicable to more specific food subcategories for better accuracy and clarity in the exposure assessment and in the text of the opinion.

#### **VII. Any other business**

##### **o Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting and agreed on WG meetings calendar in 2024.

#### **VIII. Next meetings**

Next meetings are scheduled for:

- 1 and 6 December 2023
- 11 and 12 January 2024
- 20 and 21 February 2024
- 19 and 25 March 2024
- 25 April 2024
- 10 and 11 July 2024
- 30 and 31 July 2024
- 27 and 28 August 2024



# SCIENTIFIC COMMITTEE

## 16<sup>th</sup> Working Group meeting on Fluoride

5 and 11 October 2023

14:00-18:00

MINUTES - Agreed on 30 October 2023



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Francesca Riolo  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Martin Paparella. Luna Greco only partially participated in the first part of the meeting held on 5 October 2023.

## II. Adoption of agenda

The agenda was adopted with minor changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 15<sup>th</sup> Working Group meeting held on 1 September 2023, via web-conference

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



The [minutes of the 15th Working Group Meeting](#) were agreed by written procedure on 21 September 2023.

## **V. Feedback from the 115<sup>th</sup> Scientific Committee Plenary**

The WG members were informed on the outcome of the discussion held at the 115<sup>th</sup> Scientific Committee (SC) Plenary on 20 and 21 September 2023, where the draft opinion on fluoride was presented for the first reading. The feedback and the input for improvement received from SC members were addressed during the present meeting. The draft opinion will be tentatively presented for the second reading at the February 2024 SC Plenary.

## **VI. Review of available evidence on Fluoride Toxicity**

### **a. Human studies**

The WG members continued the discussion on the available evidence for the endpoints of neurotoxicity (NT), developmental neurotoxicity (DNT), thyroid and bone effects from human epidemiological studies. WG members discussed and agreed on specific elements of the structure of the opinion section on hazard assessment and characterization. The WG was informed that the outsourced data extraction of the other endpoints reported in the remaining literature selected in the context of the systematic review has been completed. The narrative review of this body of literature will follow upon completion of the assessment of the prioritised endpoints.

### **b. Animal studies**

The WG members continued the discussion on the available evidence on NT and DNT from animal studies and focused on specific elements of the structure of the opinion section on hazard assessment and characterization, including the application of different RoB scoring criteria for the appraisal of neurobehavioural and histopathological/biochemical endpoints compared to the criteria applied for the appraisal of the behavioural evaluations. As a next step, the WG will complete the RoB for studies reporting on thyroid and bone effects. The narrative review of the literature on other endpoints will follow, for which the outsourced data extraction has been completed.

## **VII. Update on exposure assessment**

The WG was updated on recent additions and revisions in the section on exposure assessment and agreed on minor refinements in the section on aggregated exposure assessment. The section was also updated with consideration of the possible contribution of water contact materials that are subject to the remit of the European Chemicals Agency (ECHA).

## **VIII. Update on analytical methods**

The WG was updated on recent additions and revisions in the section on analytical methods for the measurement of fluoride concentration in food, drinking water and other matrices. The reporting of methods that might overestimate the content of free fluoride in the samples in the literature on fluoride hazard will be addressed in the uncertainty analysis.

## **IX. Any other business**

### **○ Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

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## **X. Next meetings**

Next meetings are scheduled for:

- 8 November 2023
- 1 and 6 December 2023



**SCIENTIFIC COMMITTEE**  
15<sup>th</sup> Working Group meeting on Fluoride



1 September 2023

09:00-16:00

MINUTES - Agreed on 21 September 2023

**Location:** in Parma and online

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Francesca Riolo

Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies for absence were received. Jean Charles Leblanc, Keyvin Darney, Martin Paparella and Marco Vinceti participated online.

## **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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 14<sup>th</sup> Working Group meeting held on 5 and 8 June 2023, via web-conference**

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



The [minutes of the 14th Working Group Meeting](#) were agreed by written procedure on 28 June 2023.

## **V. Review of available evidence on Fluoride Toxicity**

### **a. Human studies**

The WG completed the risk-of-bias assessment (RoB) for the prioritised endpoints of neurotoxicity (NT) and developmental neurotoxicity (DNT) and continued with the RoB of studies reporting on thyroid and bone effects. Other endpoints reported in the literature will be reviewed narratively upon completion of data extraction which has been outsourced and is expected to be completed in October. Text on the study appraisal and assessment of the evidence is included in the draft opinion, that will be presented at the next EFSA Scientific Committee Plenary on 20 and 21 September 2023 for the first reading.

### **b. Animal studies**

The WG members continued the discussion on the available evidence on neurotoxicity from animal studies and focused specifically on the application of the RoB scoring criteria due to the special requirements for the conduct of the behavioural tests. The WG started conducting the RoB for studies reporting on thyroid and bone effects. Literature on other endpoints will be reviewed narratively upon completion of data extraction which has been outsourced and is expected to be completed in October. Text on the study appraisal and assessment of the evidence is also included in the draft opinion, that will be presented at the next EFSA Scientific Committee Plenary on 20 and 21 September 2023.

## **VI. Update on exposure assessment**

The WG was updated on recent additions and revisions in the section on exposure assessment. The section on the aggregated exposure assessment was updated with incorporation of information on the use of oral tablets as dental health preventive treatment. This information was received from national authorities of EU countries through a brief survey disseminated in coordination with the European Medicines Agency (EMA).

## **VII. Update on kinetics**

The WG continued the discussion on the available evidence regarding the fluoride crossing of the blood brain barrier (BBB) and integrated the outcome of the discussion in the draft opinion section on Kinetics.

## **VIII. Any other business**

### **o Extention of the mandate**

Due to the size of the body of literature identified and the workload and time needed for a systematic literature review, and in agreement with the Scientific Committee at its 113<sup>th</sup> Plenary held on 15-16 February 2023, an extension of the deadline was requested from the European Commission DG SANTE. An extension was granted until 30 September 2024.

### **o Planning of next steps**

In light of the extension of the mandate's deadline, the WG members agreed on the updated workplan and on subdivision of tasks in preparation to the SC Plenary.

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## **IX. Next meetings**

Next meetings are scheduled for:

- 5 and 11 October 2023
- 8 November 2023
- 1 and 6 December 2023



# SCIENTIFIC COMMITTEE

## 14<sup>th</sup> Working Group meeting on Fluoride

5 and 8 June 2023

09:00-13:00

MINUTES - Agreed on 28 June 2023



**Location:** web conference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Jean Charles Leblanc and Svante Twetman participated only on 5 June 2023.

## II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 13<sup>th</sup> Working Group meeting held on 4 and 5 May 2023, via web-conference

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





The [minutes of the 13th Working Group Meeting](#) were agreed by written procedure on 29 May 2023.

## **V. Feedback from the NTP Board of Scientific Counselors WG Report on the Draft State of the Science Monograph and the Draft Meta-Analysis Manuscript on Fluoride**

The WG members were informed of the outcome of the public meeting organised on 4 May 2023 by the Working Group of the National Toxicology Program (NTP) Board of Scientific Counsellors (BSC) in charge of the scientific review of the “Draft NTP Monograph on Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects”. The WG took note of the literature reviewed by the NTP for comparison with the literature reviewed for the present assessment.

## **VI. Review of available evidence on Neurotoxicity from Tier 1 and Tier 2 studies**

### **a. Human studies**

The WG members continued the discussion on the available evidence on neurotoxicity from human cross-sectional studies ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis, focusing specifically on how to group and weigh the studies. Further considerations on Tier 3 studies will follow in the next meetings.

### **b. Animal studies**

The WG members continued the discussion on the available evidence on neurotoxicity from animal studies, ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis. The WG further worked on the reporting of results on different endpoints obtained from animal studies. Further considerations on Tier 3 studies will follow in the next meetings.

## **VII. Update on exposure assessment**

The WG was updated on recent developments in the draft opinion section on exposure assessment. The WG finalised the collection of results from the exchange established with the European Medicines Agency (EMA) to obtain information on the use of oral tablets as dental health preventive treatment in EU countries.

## **VIII. Update on kinetics**

The WG discussed the available evidence regarding the fluoride crossing of the blood brain barrier (BBB), considering specifically the appropriateness of the analytical methods used to obtain fluoride brain concentrations. Further discussion and collection of additional evidence will follow in the next meetings.

## **IX. Update on analytical methods**

The WG members were informed on new additions and revisions, addressing all the internal comments received, in the draft section on Analytical Methods of the opinion. A discussion on the influence of high temperatures used in sample extraction methods on the stability of the fluoride-carbon covalent bonds was started and will be continued in the next meeting.

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## **X. Any other business**

### **○ Planning of next steps**

The WG members agreed on the updated workplan and on subdivision of tasks for the next meeting.

## **XI. Next meetings**

Next meetings are scheduled for:

- 1 September 2023
- 5 and 11 October 2023
- 8 November 2023
- 1 and 6 December 2023



# SCIENTIFIC COMMITTEE

## 13<sup>th</sup> Working Group meeting on Fluoride

4 and 5 May 2023  
14:00-18:00 and 09:00-13:00  
MINUTES - Agreed on 29 May 2023



**Location:** Parma and via web conference (hybrid)

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Keyvin Darney  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing expert<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Working Group members Jean Charles Leblanc, Evangelia Ntzani and Marco Vinceti participated online. Hearing expert Svante Twetman participated online.

## II. Adoption of agenda

The agenda was adopted with minor changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the ad hoc Working Group meeting held on 28 and 31 March 2023, via web-conference**

The [minutes of the ad hoc Working Group Meeting](#) were agreed by written procedure on 25 April 2023.

#### **V. Feedback from the 113<sup>th</sup> Scientific Committee Plenary**

The WG members were informed on the outcome of the discussion of the draft opinion on fluoride held at the 113<sup>th</sup> Scientific Committee (SC) Plenary that took place on 19 and 20 April in Athens. EFSA provided the WG with a list of questions raised and suggestions made by SC members. These were addressed during the present meeting and will be reported to the SC at the next Plenary on 27 and 28 June 2023.

#### **VI. Review of available evidence on Neurotoxicity from Tier 1 and Tier 2 studies**

##### **a. Human studies**

The WG members continued the discussion on the available evidence on neurotoxicity from human studies ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis. A draft assessment of the evidence from observational cohort studies was included in the draft opinion. The WG members started assessing the available data from cross sectional studies. In parallel, the WG started performing RoB consistency check.

##### **b. Animal studies**

The WG members continued the discussion on the available evidence on neurotoxicity from animal studies, ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis. A draft assessment of the evidence on neurobehavioral and biochemical endpoints was included in the draft opinion. A preliminary discussion on the best format for presenting the data in the opinion was held.

#### **VII. Update on analytical methods**

The WG members were informed on the recent progress in the Analytical Methods section in the draft opinion. A more focused discussion on this section will be organised at the next WG meeting.

#### **VIII. Update on exposure assessment**

The WG reviewed the draft opinion section on fluoridated dental care products and fluoridated salt, and updated the aggregated overall exposure assessment. The WG was also updated on the progress from the exchange established with the European Medicines Agency (EMA) and was informed that a brief survey was disseminated among Member States to obtain information on the use of oral tablets as dental health preventive treatment in EU countries. The outcome of the survey will be discussed at the next WG meeting.

#### **IX. Any other business**

##### **○ Planning of next steps**

The WG members agreed on the updated workplan and on tasks subdivision for the next meeting.

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## **X. Next meetings**

Next meetings are scheduled for:

- 5 and 8 June 2023
- 1 September 2023
- 5 and 11 October 2023
- 8 November 2023
- 1 and 6 December 2023



# SCIENTIFIC COMMITTEE

## Ad hoc Working Group meeting on Fluoride

28 and 31 March 2023  
12:00-13:00 and 09:00-13:00  
MINUTES - Agreed on 25 April 2023



**Location:** Webconference

**Attendees:**

○ Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

○ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

Working Group members Martin Paparella and Heather Wallace participated on 28 March 2023 (agenda item V.a). WG members Thorhallur Halldorsson, Jacqueline Castenmiller, Evangelia Ntzani and Marco Vinceti, participated on 31 March 2023 (Agenda items V.b and VI). WG member Jean Charles Leblanc participated on 31 March 2023 (Agenda item VI).

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 12<sup>th</sup> Working Group meeting held on 9 March 2023, via web-conference

The [minutes of the 12th Working Group Meeting](#) were agreed by written procedure on 29 March 2023.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## **V. Review of available evidence on Neurotoxicity from Tier 1 and Tier 2 studies**

### **a. Animal studies**

The WG members continued the discussion on the available evidence on neurotoxicity from animal studies, ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis. The WG members agreed on the workplan and tasks distribution to summarise the evidence on neurobehavioral and biochemical endpoints to be included in the draft opinion that will be presented for information at the next Scientific Committee Plenary on 19 and 20 April 2023. Further discussion and elaboration will follow at the next meetings.

### **b. Human studies**

The WG members continued the discussion on the available evidence on neurotoxicity from human studies ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis, prioritising observational cohort studies over other study designs. The WG members agreed on the workplan and tasks distribution to draft text with description and preliminary interpretation assessment of the evidence in the draft opinion to be presented at the next Scientific Committee Plenary on 19 and 20 April 2023. Further discussion and elaboration will follow at the next meetings.

## **VI. Update on exposure assessment**

The WG was updated on the outcome of the aggregated exposure assessment including fluoridated dental care products based on information on their use obtained from the literature. The WG was also informed on the established exchange between EFSA and the European Medicines Agency (EMA) to obtain information on the consumption of oral tablets as dental health preventive treatment in EU countries.

## **VII. Next meetings**

Next meetings are scheduled for:

- 4 and 5 May 2023
- 5 and 8 June 2023
- 1 September 2023



# SCIENTIFIC COMMITTEE

## 12<sup>th</sup> Working Group meeting on Fluoride

9 March 2023

09:00-16:00

MINUTES - Agreed on 29 March 2023



**Location:** Parma

**Attendees:**

○ Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

○ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received by the hearing expert Svante Twetman. WG members Jean Charles Leblanc, Evangelia Ntzani and Heather Wallace participated online.

## II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>2</sup> 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 Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I.

## IV. Agreement of the minutes of the ad hoc Working Group meeting held on 31 January 2023, via web-conference

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





The [minutes of the ad hoc Working Group Meeting](#) were agreed by written procedure on 20 February 2023.

## **V. Feedback from the Scientific Committee Plenary**

The Working Group (WG) was updated on the outcome of the discussion held at the Scientific Committee (SC) Plenary, on 15 and 16 February 2023, after the presentation of draft sections of the opinion. The SC recognised the extent of work that has been completed to date by the WG and acknowledged the complexity of the mandate and the time needed for a systematic literature review. The SC underlined the importance of an independent assessment of the evidence by this WG and recommended engaging with the experts involved in the US National Toxicology Program (NTP) report<sup>3</sup> on fluoride once the EFSA assessment is completed to exchange views on the available evidence. The SC also recommended obtaining information from the European Medicines Agency (EMA) on the use of oral tablets used as dental health preventive treatment to understand the contribution of such products to the total fluoride exposure in the population or subgroups. The WG discussed and addressed comments and feedback received and agreed on actions to be taken and next steps.

## **VI. Review of Neurotoxicity available evidence from Tier 1 and Tier 2 studies**

The WG members started a discussion on the available evidence on neurotoxicity from the human and animal studies, ranked in Tier 1 and Tier 2 in the Risk of Bias (RoB) analysis. It was agreed to structure the evidence into lines of evidence to be assessed according to the Weight of Evidence approach. The review of the evidence will continue at the next meeting.

## **VII. Update on exposure assessment: Dental care products**

The WG was updated on the information obtained in the literature on the use of fluoridated dental care products and was presented with the outcome of the exposure assessment performed for different population groups from use of dental care products. The estimated contribution of such products to the total fluoride exposure will be included in the assessment.

## **VIII. Update on analytical methods**

The WG was updated on the progresses of the draft section on analytical methods for the measurement of fluoride concentration in food and drinking water. The WG was presented with data showing that extraction methods that can release all fluoride from the matrix (bound and unbound) overestimate the content of free fluoride in the sample.

## **IX. Update on ADME**

The WG discussed specific parameters needed as inputs to run the human physiologically-based pharmacokinetic (PBPK) model to derive fluoride concentrations in tissues and target organs related to fluoride exposure. It was specifically noted that data needed to estimate distribution of fluoride to the brain compartment are limited.

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<sup>3</sup><https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/ongoing/fluoride/index.html#:~:text=The%20report%20underwent%20two%20peer,ognitive%20neurodevelopmental%20hazard%20for%20humans.>



## **X. Update on the status of the literature screening and data extraction**

EFSA informed the WG that the completion of the activity of data extraction from the remaining human and animal studies on health effects of fluoride will be outsourced. Further discussion on the data extraction templates to be used will be held at the next meeting.

## **XI. Any Other Business**

### **o Additional meetings**

The WG agreed to schedule additional WG meetings on 28 and 31 March 2023.

## **XII. Next meetings**

Next meetings are scheduled for:

- 28 and 31 March 2023
- 4 and 5 May 2023
- 5 and 8 June 2023
- 1 September 2023

## **Annex I**

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

With regard to this meeting, Thorhallur Halldorsson declared that he was asked to update the ADOI due to invitation to participate in an EFSA CONTAM WG meeting on arsenic. No changes in the ADOI were made and the same ADOI was resubmitted. In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



**SCIENTIFIC COMMITTEE**  
*Ad hoc* Working Group meeting on Fluoride



31 January 2023

09:00-16:00

MINUTES - Agreed on 20 February 2023

**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by the hearing expert Svante Twetman.

## **II. Adoption of agenda**

The agenda was adopted with minor changes in the timeschedule.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 11<sup>th</sup> Working Group meeting held on 16 January 2023, via web-conference**

The [minutes of the 11th Working Group Meeting](#) were agreed by written procedure on 6 February 2023.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## **V. Discussion on a first draft of the opinion**

The WG members had a discussion on the outline of the draft opinion on fluoride in food and drinking water and commented the priority sections of the opinion drafted to be presented for information and discussion at the Scientific Committee (SC) Plenary, on 15 and 16 February 2023.

### **a. Section on Analytical Methods**

The WG was presented with the draft section on analytical methods for the measurement of fluoride concentration in food and drinking water. The WG agreed on the structure of the section and commented on additional information and clarifications to be added to the list of analytical methods for the measurement of fluoride in different matrices, including additional elements of uncertainty.

### **b. Section on Exposure Assessment**

The WG was presented with the draft section on fluoride Exposure Assessment. The assessment was conducted based on the data of fluoride concentration retrieved from the EFSA Occurrence database for water and the EFSA Composition database for food and data of food consumption from the EFSA Food Consumption Database. Four exposure scenarios were examined based on different levels of possible fluoride concentrations (using the mean and 95% values of occurrence data, and two scenarios using legal limit values). A preliminary discussion on the results obtained from the four exposure scenarios compared to the current upper level for fluoride was held. The WG agreed to add in the text further clarification on the uncertainties related to the assessment.

### **c. Section on ADME**

The WG agreed on the proposed structure of the section. The section provides a preliminary description of the kinetics of the fluoride ion and the human physiologically-based pharmacokinetic (PBPK) model to derive fluoride concentrations in tissues and target organs related to fluoride exposure. Further details will be included and additional discussion on the PBPK model will be held at the next meetings.

## **VI. Discussion on first draft of the opinion: review of neurotoxicity data extraction tables and available evidence from Tier 1 and 2 studies**

A general discussion was held on how to structure the draft opinion sections on hazard identification and characterisation for the toxicological endpoint of neurotoxicity for presentation to the SC. The WG agreed to include summary tables within the main text body to describe pertinent details of the human and animal studies, ranked in Tier 1 and Tier 2 according to the Risk of Bias (RoB) analysis. Further discussion on the available evidence of neurotoxicity on animal and human studies will be held at the upcoming meetings. The studies will be assessed according to the Weight of Evidence approach.

## **VII. Finalisation screening and RoB neurotoxicity studies in Distiller**

In the context of the RoB analysis performed on the toxicological endpoint of neurotoxicity, the WG discussed the process of consistency checks of the scores assigned by experts according to the scoring criteria agreed during previous meetings. Consistency checks have been made and will be completed in the following weeks.

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## **VIII. Any Other Business**

### **○ Hybrid format for next meetings**

The WG agreed to schedule the 9 March and 4-5 May 2023 meetings as hybrid meetings.

## **IX. Next meetings**

Next meetings are scheduled for:

- 9 March 2023
- 4 and 5 May 2023
- 5 and 8 June 2023
- 1 September 2023



# SCIENTIFIC COMMITTEE

## 11<sup>th</sup> Working Group meeting on Fluoride

16 January 2023

09:00-16:00

MINUTES - Agreed on 2 February 2023



**Location:** Webconference

**Attendees:**

- Working Group Members:

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace

- Hearing Experts<sup>1</sup>:

Svante Twetman

- EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Plant Health (PLANTS) Unit: Luna Greco

## I. Welcome and apologies for absence

The Chair welcomed the participants.

Evangelia Ntzani did not participate in agenda points VIII, IX, X, XI.

Jean Charles Leblanc only participated in part of the agenda point IX and in the agenda points X, XI.

## II. Adoption of agenda

The agenda was adopted with changes.

An additional point under Any Other Business (AOB) was added to discuss the planning of an additional WG *ad hoc* meeting on 31<sup>st</sup> January 2023.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 10<sup>th</sup> Working Group meeting held on 2 and 8 December 2022, via web-conference**

The [minutes of the 10th Working Group Meeting](#) were agreed by written procedure on 5 January 2023.

#### **V. Discussion on first draft of the opinion**

The WG members had a discussion on the outline of the draft opinion on fluoride in food and drinking water and identified the priority sections of the opinion to be presented for information and discussion at the Scientific Committee (SC) Plenary which will be held on 15 and 16 February 2023. WG members agreed on tasks allocation for proceeding in drafting the opinion.

#### **VI. Update on Neurotoxicity Risk of Bias (RoB) Analysis of Human and Animal Studies and conflicts resolution**

The WG members finalised the resolution of conflicts that emerged from the RoB Analysis of human and animal studies for the toxicological endpoint of neurotoxicity. The resolution of conflicts was carried out according to the application of general scoring rules previously agreed by WG experts. As a result, human and animal studies were categorised into three Tiers (1, 2 or 3), which indicate the internal validity of eligible studies. The initial RoB analysis will be followed by additional consistency checks. The selected studies will be assessed according to the Weight of Evidence approach for assembling, integrating and weighing the evidence in the risk assessment process.

#### **VII. Review of Neurotoxicity data extraction tables and available evidence from Tier 1 and 2 studies**

The WG members were updated on the status of the data extraction from human and animal studies on health effects of fluoride performed by an external contractor selected through the EFSA Individual Scientific Advisor (ISA) mechanism. The contractor is progressing with all the allocated tasks using the data extraction forms agreed by the WG members. A preliminary discussion on the available evidence on developmental neurotoxicity endpoints from animal studies was held. Further discussion on the available evidence on animal and human studies will be held at the next meetings.

#### **VIII. Update on ADME**

The WG was updated on the status of the human physiologically-based pharmacokinetic (PBPK) model to derive fluoride concentrations in tissues and target organs related to fluoride exposure. Additional inputs needed to refine the model were noted, such as data on chronic exposure to fluoride stratified by age and parameters for incorporation of the brain compartment into the model to enable the modelling of toxicodynamics. Additional details will be presented at next meetings.

#### **IX. Exposure assessment – Data and calculations evaluation**

The WG was updated on the status of the preliminary exposure assessment, using data from the EFSA Occurrence and Consumption Databases. The WG reviewed additional details on fluoride concentrations in specific food commodities and agreed on the approach proposed for conducting the assessment.

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## **X. Any Other Business**

### **o Additional *ad hoc* meeting**

The WG agreed to schedule an additional ad hoc meeting on 31st January 2023 to progress with the sections of the Opinion to be presented for information and discussion at the EFSA SC Plenary on 15 and 16 February 2023.

## **XI. Next meetings**

Next meetings are scheduled for:

- 31 January 2023
- 9 March 2023
- 4 and 5 May 2023
- 5 and 8 June 2023
- 1 September 2023





METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 10<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 2 and 8 December 2022**

**(Agreed on 5 January 2023)**

#### Participants

- Working Group Members:  
Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Keyvin Darney  
Jean Charles Leblanc  
Evangelia Ntzani  
Martin Paparella  
Marco Vinceti  
Heather Wallace
- Hearing expert<sup>1</sup>:  
Svante Twetman (for items 7 and 8)
- European Commission and/or Member States representatives:  
Veerle Vanheusden (DG SANTE)
- EFSA:  
Methodology and Scientific Support (MESE) Unit: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Francesca Riolo, Silvia Tangianu  
Feed and Contaminants (FEEDCO) Unit: Maria Anastassiadou  
Pesticides Residues & Plant Health (PLANTS) Unit: Luna Greco

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<sup>1</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by Martin Paparella on 2 December and by the hearing expert Svante Twetman on 8 December.

## **2. Adoption of agenda**

The agenda of the meeting was adopted with slight changes in the time scheduled for each item to dedicate more time for discussion to the agenda item "Finalisation of the template for data extraction".

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

## **4. Agreement of the minutes of the 9<sup>th</sup> Working Group meeting held on 24 October 2022, by TELE-conference**

The minutes of the 9<sup>th</sup> Working Group (WG) meeting held on 24 October 2022 were agreed by written procedure on 14 November 2022.

## **5. Hearing Expert**

Prof. Svante Twetman was invited to present his views for items 7 and 8 of the present meeting.

## **6. DistillerSR Support**

EFSA provided to WG members a brief technical training on using the software DistillerSR for performing Risk of Bias (RoB) analysis, focusing especially on how to resolve differences between reviewers in scoring questions of RoB of human and animal studies on fluoride health effects.

## **7. Update on analytical methods search**

EFSA updated the WG on the status of the search of analytical methods used to detect the occurrence of fluoride ion in foods. An evaluation of literature reviews as well as other peer-reviewed original research studies was presented. The WG discussed and agreed on which among the analytical methods retrieved can be considered appropriate and valid for the purpose of the risk assessment of this mandate. The WG agreed on next steps and elements of uncertainty related to analytical methods to be considered in the context of the Opinion.

## **8. Risk of Bias Analysis of Human Studies and conflicts resolution**

The WG members finalised the RoB analysis of human and animal studies prioritised for one toxicological endpoint, using a template of the Risk of Bias Tool (OHT-OHAT<sup>4</sup>) customised for fluoride hazard assessment in humans and experimental animal. During the meeting conflicts among reviewers emerged from the RoB analysis were discussed and addressed according to general scoring rules agreed by the WG experts.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>4</sup> [https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019_508.pdf)

## 9. Exposure assessment – Data and calculations evaluation

The WG was updated on the status of the literature search on exposure to fluoride as foreseen by specific sub questions in the protocol. Consistency between fluoride concentration data in specific food items from the literature and the EFSA composition database was checked. Some elements of uncertainty of the consumer exposure assessment were identified and discussed so that they are properly assessed in the text of the Opinion. Further results of the preliminary exposure assessment and developments will be presented at the next meetings.

## 10. Template for data extraction

EFSA announced that the activity of data extraction from human and animal studies on health effects of fluoride will be performed by an external contractor selected through the EFSA Individual Scientific Advisor (ISA) mechanism. The WG presented and discussed two templates for data extraction, one for animal and one for human studies. Between the two half day meetings of the WG, the contractor was provided with the two draft data extraction templates to test them in a pilot phase with a small number of selected studies. Based on the outcome of the pilot phase the WG further refined the templates during the second half day of the meeting to improve clarity and make them fit for purpose for this mandate. The data extraction completion is expected by end of February 2023.

## 11. Update on ADME

The WG was updated on the completed status of the human physiologically-based pharmacokinetic (PBPK) model to derive fluoride concentrations in tissues and target organs related to fluoride acute exposure, while the PBPK model for chronic exposure conditions is in progress. Both human and animal toxicokinetic data retrieved will be considered respectively for dose-response modelling and forward-dosimetry modelling. Further updates will be presented at the next meetings.

## 12. AOB

### 12.1. Status update

The WG agreed on next steps and task allocation to finalise conflicts resolution of the RoB analysis of human and animal studies and start working on a first draft of the Opinion.

## 13. Next meeting(s)

Next meetings are tentatively scheduled for:

- 16<sup>th</sup> January 2023
- 9<sup>th</sup> March 2023
- 4<sup>th</sup> and 5<sup>th</sup> May 2023
- 5<sup>th</sup> and 8<sup>th</sup> June 2023
- TBD September 2023



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 9<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 24 October 2022**

**(Agreed on 14 November 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Martin Paparella, Marco Vinceti, Heather Wallace.
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Luna Greco, Francesca Riolo, Silvia Tangianu.

## 1. Welcome and apologies for absence

The Chair welcomed the participants and the new WG member Marco Vinceti. Apologies for absence were received by the hearing expert Svante Twetman.

## 2. Adoption of agenda

The agenda of the meeting was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## 4. Agreement of the minutes of the 8<sup>th</sup> Working Group meeting held on 26 and 30 September 2022, by TELE-conference

The minutes of the 8<sup>th</sup> Working Group (WG) meeting held on 26 and 30 September 2022 were agreed by written procedure on 19 October 2022.

## 5. Discussion on Risk of Bias (RoB) analysis

The WG members had a discussion on the ongoing RoB analysis of human and animal studies for one relevant toxicological endpoint judged to likely be most influential on the HBGV at doses that might challenge the current Upper Level (EFSA NDA Panel, 2005)<sup>3</sup>. RoB analysis is performed using a template of the Risk of Bias Tool (OHT-OHAT<sup>4</sup>), customised for fluoride hazard assessment in humans and experimental animal. The WG discussed in detail the application of scoring criteria and refined tasks allocation to complete the RoB analysis on the selected endpoint by the next WG meeting. Possible conflicts on the RoB rating for this first endpoint reviewed will be addressed during the next WG meeting.

## 6. Update on Developmental Neurotoxicity (DNT) in vitro and High-Throughput Screening (HTS) search

The WG was updated on the agreed search terms of the additional literature search that will be conducted to retrieve relevant *in vitro* studies on fluoride developmental neurotoxicity.

## 7. Update on Exposure data and search

The WG was updated on the status of fluoride concentration data in foods and results of the preliminary exposure assessment on four identified scenarios were presented. Additional data will be integrated in the assessment and further results and developments will be presented at the next meetings.

The WG was informed on the outcome of the Exposure literature search on specific sub questions as foreseen by the protocol.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/192>

<sup>4</sup> [https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019_508.pdf)

## 8. Update on ADME

The WG will be updated on the progress and developments of the selected kinetic model at the next meeting.

## 9. AOB

### 9.1. Next meeting

The 10<sup>th</sup> WG meeting is tentatively scheduled as two half-days meeting on 2<sup>nd</sup> and 8<sup>th</sup> December 2022.



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 8<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 26 and 30 September 2022**

**(Agreed on 19 October 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Martin Paparella, Heather Wallace.
- Hearing Expert: Svante Twetman<sup>1</sup>.
- European Commission: Verlee Vanheusden (DG SANTE)<sup>2</sup>.
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Maria Anastassiadou, Luna Greco, Francesca Riolo.

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<sup>1</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

<sup>2</sup> Absent for agenda items 8, 9 and 10

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received by Evangelia Ntzani on 26 September and by Heather Wallace on 30 September.

## 2. Adoption of agenda

The agenda of the meeting was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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.

## 4. Agreement of the minutes of the *ad hoc* Working Group meeting held on 2 September 2022, by TELE-conference

The minutes of the *ad hoc* Working Group (WG) meeting held on 2 September 2022 were agreed by written procedure on 21 September 2022.

## 5. Discussion on the systematic literature review status and Risk of Bias (RoB) analysis

EFSA updated the WG members on the completion of the screening process of the literature on health effects in animals and humans using the software Distiller, after resolution of conflicts on inclusion-exclusion of papers. As agreed in the "Protocol for human health risk assessment of fluoride in food and drinking water taking into account all sources of exposure"<sup>5</sup>, the WG will now proceed with conducting a RoB analysis of the studies relevant to endpoints judged to be most influential of the HBGV at doses that might challenge the current Upper Level (EFSA NDA Panel, 2005)<sup>6</sup>. RoB analysis will be performed using the template of the Risk of Bias Tools, customised for human studies and for animal studies. The WG members will conduct a RoB analysis for one relevant endpoint before the next WG meeting. The WG reviewed the tool and discussed adjustments before proceeding. Possible conflicts on the RoB rating for the first endpoint reviewed will be addressed during the next WG meeting.

## 6. Additional literature search on Fluoride *In vitro* Neurodevelopmental Toxicity studies

The WG agreed on performing an additional literature search to retrieve relevant *in vitro* studies on Fluoride Developmental Neurotoxicity.

## 7. Update on Exposure data and search

The WG was updated on the status of the fluoride concentration data and the exposure assessment. New data availability was described and specific considerations on the fluoride concentration data were

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>5</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Uc2/pc0148>

<sup>6</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/192>



discussed. Four possible exposure scenarios were discussed, and preliminary assessment results will be presented at the next WG meeting.

## **8. Update on ADME**

After a discussion on the selected published kinetic model to be used to compare predicted and observed kinetics parameters, it was agreed to improve and update the model and to include the brain compartment.

## **9. Update on Analytical Methods search**

The WG was updated on the status of the literature search on Analytical Methods used to identify the more appropriate methods to detect fluoride concentrations. The screened papers by title and abstract are currently under full-text evaluation. Further developments will be presented at the next WG meeting.

## **10. AOB**

### **10.1. Next meeting**

The 9<sup>th</sup> WG meeting is tentatively scheduled on 24<sup>th</sup> of October 2022.



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE *ad hoc* MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 2 September 2022**

**(Agreed on 21 September 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- Hearing Expert: Svante Twetman<sup>1</sup>
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Luna Greco, Francesca Riolo.

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<sup>1</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received by Martin Paparella.

## **2. Adoption of agenda**

The agenda of the meeting was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

## **4. Agreement of the minutes of the 7<sup>th</sup> Working Group meeting held on 14-15 July 2022, by TELE-conference**

The minutes of the 7<sup>th</sup> Working Group (WG) meeting held on 14-15 July 2022 were agreed by written procedure on 3 August 2022.

## **5. Update since last Working Group meeting**

EFSA updated the WG on the recruitment of the new WG member with specific expertise in developmental neurotoxicity and clarified which tasks will be allocated to him.

A brief update on the status of exposure data search and ADME search was provided; further details will be discussed at the next WG meeting.

## **6. Discussion on the systematic literature review status**

EFSA updated the WG members on the status of the screening process of the literature on health effects in animals and humans using the software Distiller. The literature selected through title and abstract screening (Level 1) is currently undergoing full-text screening process (Level 2): each paper will be screened by two screeners from the WG. It was agreed that any conflicts on inclusion-exclusion of paper that may emerge will be addressed and solved by screeners in bilateral meetings. Following the outcome of the Level 2 screening process, a preliminary high-level assessment will be carried out to prioritise literature on toxicological endpoints that will be appraised through a systematic review, as foreseen in the protocol.

## **7. Risk of Bias (RoB) planning**

The WG will proceed with using the template of the Risk of Bias Tools (RoB) for conducting a Risk of Bias Analysis before the next WG meeting. The two RoB tools, one for human studies and one for animal studies, were previously customised and refined for the context of the mandate and were tested through a pilot phase with a few selected studies. General common decision criteria for scoring were agreed upon during previous meetings. The progress, questions and adjustments needed, if any, will be discussed at the next meeting before completing the RoB analysis.

## **8. Discussion on other literature searches**

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

The WG agreed to screen the literature retrieved from database searches as envisaged in the draft protocol<sup>4</sup> and discussed division of screening tasks.

## **9. AOB**

### **9.1. Next meeting**

The 8<sup>th</sup> WG meeting is tentatively scheduled as half-day meetings on 26<sup>th</sup> and 30<sup>th</sup> of September 2022.

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<sup>4</sup> <https://connect.efsa.europa.eu/RM/sfc/servlet.shepherd/document/download/0697U000001IC98QAE>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 7<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 14 and 15 July 2022**

**(Agreed on 3 August 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- Hearing Expert: Svante Twetman<sup>1</sup>
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Maria Anastassiadou, Francesca Riolo.

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<sup>1</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

## **1. Welcome and apologies for absence**

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

## **2. Adoption of agenda**

The agenda of the meeting was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

## **4. Agreement of the minutes of the 6<sup>th</sup> Working Group meeting held on 20 May 2022, by TELE-conference**

The minutes of the 6<sup>th</sup> Working Group meeting held on 20 May 2022 were agreed by written procedure on 6 June 2022.

## **5. Mandate timeline review**

According to the current state of the Working Group (WG) on Fluoride activities, the WG members internally updated and reviewed the timeline of the mandate; a tentative agenda for the next actions and milestones to be achieved was discussed and approved.

## **6. Additional WG expert (DNT) recruitment**

EFSA updated the WG on the recruitment process of an additional WG member with specific expertise in neurodevelopmental toxicity.

## **7. Discussion on the systematic literature review approach**

EFSA communicated to the WG members that screening at title and abstract level of the literature on health effects in animals and humans using the software Distiller had been completed. The literature, retrieved through search strings set up to address relevant subquestions according to the protocol, was screened by a two-screener process, including an external contractor selected through the Individual Scientific Advisor (ISA) mechanism, by WG experts for a minimum number of article titles necessary to generate a training set and subsequently by the Artificial Intelligence function in Distiller. The results of the screening process were reviewed and discussed by the WG members to plan the full text level screening.

## **8. Critical studies on Fluorosis from NDA Opinion 2005**

The WG members reviewed and commented on the critical studies reporting on skeletal (Riggs et al., 1990 and 1994) and dental (Dean, 1942; Fejerskov et al., 1996) fluorosis that were considered by the EFSA Scientific Panel on Nutrition, Novel Foods and Food Allergens (NDA) Panel in 2005 to be the pivotal studies upon which to set Upper Levels for Fluoride, for adults and children, respectively.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

## 9. Literature search

### 9.1. Status of exposure data and search

EFSA presented results of a preliminary exposure assessment performed with data obtained from the Occurrence and the Composition Databases. Consistency Data reported in the scientific literature will be assessed for consistency with the data in these databases. As a next step, exposure assessments will be performed for specific scenarios (i.e. dental care products, infant formulas). Data reported in the literature relevant to these assessments will be taken into consideration.

### 9.2. Status of ADME search

The WG members were updated on results of the literature screening relevant to Fluoride Kinetics that was conducted through the databases PubMed, Web of Science and Scopus. The main Kinetics parameters were extracted from the selected studies, collected in a database and observed parameters will be compared to predicted values reported in published kinetic models. A further literature search on Fluoride concentration in bone will be conducted.

### 9.3. Status of Analytical Methods search

EFSA updated the WG on the status of the literature screening relevant to Analytical Methods of Analysis of Fluoride concentrations. During the screening process, specific attention has been given to fit-for-purpose methods for a specific matrix, validation criteria of the method and uncertainty related to the Fluoride concentration determination. Further updated will be provided at the next WG meeting.

## 10. AOB

### 10.1. Next meeting

The next *ad hoc* WG meeting is tentatively scheduled as half-day meeting on 2<sup>nd</sup> of September 2022.



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 6<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 20 May 2022**

**(Agreed on 6 June 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc<sup>1</sup>, Evangelia Ntzani, Heather Wallace<sup>2</sup>.
- Hearing Expert: Svante Twetman<sup>3</sup>
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Maria Anastassiadou, Luna Greco, Francesca Riolo.

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<sup>1</sup> Present from agenda item 6.2

<sup>2</sup> Absent from agenda item 6.3

<sup>3</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)



## 1. Welcome and apologies for absence

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

## 2. Adoption of agenda

The agenda of the meeting was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

## 4. Agreement of the minutes of the 5<sup>th</sup> Working Group meeting held on 11 and 21 April 2022, by TELE-conference

The minutes of the 5<sup>th</sup> Working Group meeting held on 11 and 21 April 2022 were agreed by written procedure on 9 May 2022.

## 5. Risk of Bias (RoB) tool for human studies

The Working Group (WG) experts reviewed the draft template of the Risk of Bias Tool to be applied to human studies, based on the OHT-OHAT<sup>6</sup> tool for conducting a Risk of Bias Analysis. The tool was further refined for the context of the mandate and tested through a pilot phase with a few selected studies. The WG experts compared the assigned scores for each section of the tool and agreed on general common decisional criteria for scoring.

## 6. Literature search

### 6.1. Update on literature search terms and literature screening

Maria Bastaki updated the working group on the literature search strings set up to address relevant subquestions according to the protocol and which were refined with the assistance of the EFSA Library staff. She also provided an update on the status of screening of the health effects literature using the software Distiller. Due to the size of the literature retrieved, the screening has been outsourced through the mechanism of Individual Science Assistance (ISA) contract. The contractor selected by EFSA is currently proceeding with the screening of the human and animal studies in Distiller. WG experts agreed to contribute as second screeners for a minimum number of article titles necessary to train the software. The outcome of the screening process is expected by the end of June 2022.

### 6.2. Fluoride Kinetics

Keyvin Darney reported the results of the literature screening relevant to fluoride kinetics that was conducted through the databases PubMed, Web of Science and Scopus. A more refined selection of the relevant studies will follow.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>6</sup> [https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019_508.pdf)

### **6.3. Exposure assessment**

Francesca Riolo presented the available Fluoride concentration data in foods retrieved from the Occurrence and the Composition Databases. The WG members suggested to look for additional data concerning infant formula and drinking water characteristics through a literature search to complement the data available in these databases.

## **7. AOB**

### **7.1. Next meeting**

The 7<sup>th</sup> WG meeting is tentatively scheduled as two half-day meetings on 14<sup>th</sup> and 15<sup>th</sup> of July 2022. The meeting previously scheduled on 10<sup>th</sup> June 2022, was cancelled due to the timing and status of the WG activities.



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 5<sup>th</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 11 and 21 April 2022**

**(Agreed on 9 May 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- Hearing Expert: Svante Twetman
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Maria Anastassiadou, Luna Greco, Francesca Riolo.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence on the 21<sup>st</sup> April 2022 were received from the working group members Heather Wallace and Evangelia Ntzani and from the hearing expert Svante Twetman.

## 2. Adoption of agenda

The agenda of the 11 April meeting was adopted without changes. The agenda of the 21 April meeting was adopted after deleting the item “Data extraction tool review” due to the absence of the expert Evangelia Ntzani.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA’s Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## 4. Agreement of the minutes of the 4<sup>th</sup> Working Group meeting held on 22 and 24 March 2022, by TELE-conference

The minutes of the 4<sup>th</sup> Working Group meeting held on 22 and 24 March 2022 were agreed on by written procedure on 12 April 2022.

## 5. Review of the Risk of Bias (RoB) tools

The WG members reviewed a draft template of the OHT-OHAT<sup>3</sup> tool for conducting a Risk of Bias Analysis and adapted it to both human and animal studies. The tool for each stream of literature was customised for the context of the mandate and further refinement is expected before the next meeting. The customised tools will be tested through a pilot phase with a few selected studies.

## 6. Literature search

### 6.1. Exposure assessment

The WG proceeded with the refinement of the list of search terms and strings for the exposure assessment literature search with the support of the EFSA Library. In order to reduce the number of irrelevant results and the background noise of the search, the search terms will be further adjusted in consultation with the library experts.

### 6.2. Kinetic

Keyvin Darney presented a first proposal for the search terms and search strings to be used to identify literature on fluoride kinetics.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> [https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookmarch2019_508.pdf)

### **6.3. Updates on literature screening outsourcing**

Maria Bastaki updated the WG members on the status of outsourcing the literature screening of the human and the animal studies. Outsourcing will be done through a mechanism of Individual Science Assistance (ISA) contract and the outcome of the screening process is expected by the end of May.

## **7. Protocol amendments**

Maria Bastaki updated the WG members that the public consultation of the Protocol for human health risk assessment of fluoride in food and drinking water taking into account all sources of exposure<sup>4</sup> closed on the 18<sup>th</sup> of April 2022 and no comments were received. Nevertheless, minor amendments to the published protocol were suggested by the WG members to improve clarity, as needed. All the amendments to the protocol will be recorded and will be published as an Annex to the final Scientific Opinion.

## **8. AOB**

### **8.1. Next meeting**

The 6<sup>th</sup> WG meeting is tentatively scheduled as a full day meeting on 20<sup>th</sup> of May 2022.

### **8.2. Work plan**

The WG members reviewed the initial work plan and reassessed the milestones in the context of the current state of the work.

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<sup>4</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Uc2/pc0148>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 4th MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 22 and 24 March 2022**

**(Agreed on 12 April 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- Hearing Expert: Svante Twetman
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Maria Anastassiadou, Luna Greco, Francesca Riolo.

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received from Heather Wallace on the 24<sup>th</sup> March 2022 meeting.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## **4. Agreement of the minutes of the ad hoc Working Group meeting held on 28 February 2022, by TELE-conference**

The minutes of the ad hoc Working Group meeting held on 11 February 2022 were agreed by written procedure on 28 February 2022.

## **5. Public consultation of draft Protocol**

Maria Bastaki updated the WG on the status of the public consultation of the Protocol for human health risk assessment of fluoride in food and drinking water taking into account all sources of exposure<sup>3</sup> launched by EFSA on the 18<sup>th</sup> of March 2022. The WG was requested to disseminate the information among the relevant network of experts. The public consultation will remain open for four weeks until the 18<sup>th</sup> of April 2022.

## **6. Literature search screen**

The WG discussed details on how to conduct the literature search presented in the protocol, refining the list of search terms for the initial screening and the list of search strings for human and animal studies. Due to the very high number of hits, the WG discussed on the possibility of using software or outsource the search to conduct the first screening.

## **7. Exposure data**

Francesca Riolo and Jean Charles Leblanc presented the current status of the available data from the Occurrence and the Consumption EFSA's databases. Together with the WG members agreed on providing a specific list of search terms for the exposure assessment literature search.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Uc2/pc0148>

## 8. Draft outline of the opinion

The WG prepared a draft outline of the Scientific Opinion based on the published protocol for public consultation. A first task allocation was defined according to WG members' specific expertise.

## 9. Systematic literature review instrument – RoB tool

The WG further elaborated the strategy for conducting a systematic literature review. Moreover, the WG discussed the plans for conducting a Risk of Bias Analysis, including customising the available OHT-OHAT tool for human studies and animal studies.

## 10. Kinetic Modelling

Keyvin Darney presented characteristics and limitations of two available kinetic models (Rao et al., 1995<sup>4</sup> and Jean et al., 2019<sup>5</sup>) to derive fluoride concentrations in tissues and target organs. The WG agreed on the use of the model by Rao et al., 1995, considering the limitations and uncertainties in the Jean et al., 2019 model.

## 11. AOB

### 11.1. Next meeting

The 5<sup>th</sup> WG meeting is tentatively scheduled as two half-days meetings on 11<sup>th</sup> and 21<sup>st</sup> of April 2022.

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<sup>4</sup> <https://doi.org/10.1006/rtp.1995.1065>

<sup>5</sup> <https://doi.org/10.3390/ijerph15071358>





METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE *ad hoc* MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 11 February 2022**

**(Agreed on 28 February 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- EFSA: Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Luna Greco, Francesca Riolo.

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received from the hearing expert Svante Twetman.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## **4. Feedback from the 107<sup>th</sup> SC Plenary on the Protocol**

Maria Bastaki updated the WG on the comments received from the Scientific Committee (SC) members on the draft protocol during the 107<sup>th</sup> SC Plenary, held on 9 and 10 February 2022. At the end of the discussion, the SC formally endorsed the protocol for public consultation conditionally upon addressing the changes discussed.

## **5. Protocol finalisation**

The WG revised the draft Protocol for fluoride risk assessment, following the draft framework for Protocol development for EFSA's scientific assessments<sup>3</sup>, incorporating adjustments and comments provided by the Scientific Committee during the SC Plenary. Additional revisions will be made by written procedure. The final draft will be published for public consultation in the following weeks.

## **6. Next meeting(s)**

The 4<sup>th</sup> WG meeting is tentatively scheduled as two half-days meetings on 22<sup>nd</sup> and 24<sup>th</sup> of March 2022.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1843>



## SCIENTIFIC COMMITTEE

### MINUTES OF THE *ad hoc* MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 28 January 2022**

**(Agreed on 16 February 2022)**

#### Participants

- Working Group Members: Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- European Commission: Veerle Vanheusden
- EFSA: Maria Anastassiadou, Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Luna Greco, Francesca Riolo.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from the hearing expert Svante Twetman.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## 4. Update on EFSA-ECHA cooperation

Maria Bastaki updated the WG on the ongoing cooperation EFSA-ECHA on Fluoride risk assessment. A specific meeting with ECHA was organised to promote inter-agencies collaboration and join the effort under the context "one substance one assessment". ECHA will provide the WG with the relevant information and possibly data if available that could be useful to the EFSA risk assessment of fluoride. It was agreed to continue mutual updates between the two agencies.

## 5. Protocol development

The WG worked further on drafting the Protocol for fluoride risk assessment, following the draft framework for Protocol development for EFSA's scientific assessments<sup>3</sup>, also considering inputs provided by the European Commission. A final draft of the protocol was agreed to be shared with the EFSA Scientific Committee after proposed revisions and reorganisation. The protocol will be presented for discussion at the next Scientific Committee Plenary on February 9, 2022.

## 6. Next meeting(s)

The 4<sup>th</sup> WG meeting is tentatively scheduled as two half-days meetings on 22<sup>nd</sup> and 24<sup>th</sup> of March 2022. An additional meeting will be scheduled if needed on the 11<sup>th</sup> of February to address comments received after the Scientific Committee Plenary.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1843>



## SCIENTIFIC COMMITTEE

### MINUTES OF THE 3<sup>rd</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

Held by teleconference on 11 and 14 January 2022

(Agreed on 28 January 2022)

#### Participants

- **Working Group Members:** Thorhallur Halldorsson (Chair), Jacqueline Castenmiller, Keyvin Darney, Jean Charles Leblanc, Evangelia Ntzani, Heather Wallace.
- **Hearing expert:** Svante Twetman
- **European Commission:** Veerle Vanheusden
- **EFSA:** Maria Anastassiadou, Maria Bastaki, Irene Cattaneo, Jean-Lou Dorne, Luna Greco, Francesca Riolo.

#### 1. Welcome and apologies for absence

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

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

## 4. Planning of WG meetings

The plan for WG meetings in 2022 was reviewed for possible adjustments and further discussion on this topic to finalise dates is foreseen for the next meetings.

## 5. Protocol development

The WG further worked on drafting the Protocol for fluoride risk assessment, following the draft framework for Protocol development for EFSA's scientific assessments<sup>3</sup>. The draft protocol will then be presented and discussed at the next EFSA Scientific Committee Plenary to be held on 9<sup>th</sup> and 10<sup>th</sup> February. Written comments on the protocol provided by WG members were discussed and agreed during the meeting. Further revisions of the draft protocol are envisaged, and finalisation completion draft is foreseen by next week.

## 6. Next meeting(s)

An additional half-day meeting is planned on 28<sup>th</sup> of January to finalise the Protocol. The 4<sup>th</sup> WG meeting is tentatively scheduled as two half-days meetings on 22<sup>nd</sup> and 24<sup>th</sup> of March 2022.

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<sup>3</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1843>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 2<sup>nd</sup> MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 15 November 2021**

**(Agreed on 03 December 2021)**

#### Participants

■ **Working Group Members:**

Thorhallur Halldorsson (Chair)  
Jacqueline Castenmiller  
Jean Charles Leblanc  
Evangelia Ntzani  
Heather Wallace

■ **EFSA:**

SCER Unit: Jean-Lou Dorne, Maria Bastaki, Irene Cattaneo  
CONTAM Unit: Maria Anastassiadou  
PRES Unit: Luna Greco  
NUTRITION Unit: Leng Heng  
DATA Unit: Francesca Riolo

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the hearing expert Svante Twetman.

#### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

### 4. Planning of WG meetings and milestones

The WG discussed and agreed on the timeline of WG meetings, activities, and milestones to achieve the final adoption of the Opinion by the Scientific Committee on the 30 September 2023 Plenary Meeting, to meet the deadline requested by the European Commission Mandate.

### 5. Inputs for exposure assessment

The WG had a preliminary discussion on the quality and quantity of the available exposure assessment data. Additional data collection from databases and literature retrieve is foreseen for the next meeting.

### 6. Protocol development

The WG prepared a draft version of the Protocol, intended to be finalised at the next WG meeting, following the Draft framework for Protocol development for EFSA's scientific assessments<sup>3</sup>. WG experts and EFSA staff were invited to provide input in the protocol in their respective areas of expertise.

### 7. Next meeting(s)

The 3<sup>rd</sup> WG meeting has been scheduled in two separated days of meetings, a full day-meeting on Tuesday 11<sup>th</sup> January 2022 and a half-day meeting on Friday 14<sup>th</sup> January 2022.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1843>





SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 1st MEETING OF THE WORKING GROUP ON FLUORIDE

**Held by teleconference on 21 October 2021**

**(Agreed on 05 November 2021)**

#### Participants

- Working Group Members:
  - Thorhallur Halldorsson (Chair)
  - Jacqueline Castenmiller
  - Jean Charles Leblanc
  - Evangelia Ntzani
  - Heather Wallace
- EFSA:
  - SCER Unit: Jean-Lou Dorne, Maria Bastaki, Irene Cattaneo
  - CONTAM Unit: Marco Binaglia, Maria Anastassiadou
  - PRES Unit: Luna Greco
  - DATA Unit: Francesca Riolo, Davide Arcella

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from the hearing expert Svante Twetman.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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.

## **4. Presentation of the mandate and interpretation of the Terms of Reference**

The Chair presented to the WG the Terms of Reference (ToR) and the deadline of the mandate, which was received from the European Commission in February 2021 and accepted from the Scientific Committee and Emerging Risk Unit (SCER) in April 2021. The WG proceeded with initial discussion on the interpretation of the ToR. The WG coordinators presented a summary of the current state of the art of the scientific literature with regard to the Terms of Reference.

## **5. Protocol development**

The WG had a preliminary discussion on the need for a protocol development and the method to be followed for drafting it. A brief overview of the draft guidance for protocol development was presented. A further detailed discussion on this topic is foreseen for the next meeting.

## **6. Next meeting(s)**

The 2<sup>nd</sup> WG meeting on Fluoride has been scheduled for Monday 15<sup>th</sup> November 2021.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

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