



# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens

## 39<sup>th</sup> Working Group meeting on Upper Tolerable Levels



10 September 2024

09:00-13:00

MINUTES – Agreed on XX 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Torsten Bohn, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Alfonso Siani, Marco Vinceti, Misha Vrolijk.
- EFSA:  
NIF Unit: Charlotte Marie Bercovici, Ionut Craciun, Agnès De Sesmaisons, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Vania Mendes, Silvia Valtueña Martinez.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received for Brandy Beverly and Maret Traber.

## 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.

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 of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 38<sup>th</sup> Working Group meeting held on 5 June 2024, via web-conference

The [minutes](#) of the 38th Working Group meeting were agreed by written procedure on 20 June 2024.

## 5. Scientific topic(s) for discussion

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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)



**a. Update of the scientific guidelines for the development of the Tolerable Upper Intake levels of vitamins and minerals, upon request of the European Commission ([EFSA-Q-2021-00364](#))**

The WG discussed the outcome of the public consultation and the changes in the guidance based on comments received. The guidance will be presented at the next plenary meeting of the NDA Panel, scheduled for the 24th and 25th of September, for possible adoption.

**b. Feedback from Task Forces**

The WG was informed about the status of the work by the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and was published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and was published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) on iron had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 30 April 2024 and was published on 12 June 2024.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and was published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) had 18 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 30 April 2024 and was published on 6 June 2024.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

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The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and was published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E met on 22 April 2024. The discussion focused on finalising the sections on priority outcomes, hazard characterization and recommendation for research. The TF reviewed the section on non-priority outcomes as well. The draft opinion was adopted at the NDA Panel plenary meeting on 28 June 2024 and published on 2 August 2024.

## **6. Any Other Business**

None.

## **7. Next meeting**

This meeting marks the conclusion of the UL Working Group's activities. No further meetings are scheduled.



## Annex

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

NO CONFLICT: With regard to this meeting, Susan Fairweather-Tait declared the following interest: Production of PowerPoint presentations and recordings on vitamins and minerals for Henry Stewart Talks (London), to be provided to universities, medical schools, and research institutes globally. The talks make significant use of the EFSA DRV opinions.

NO CONFLICT: With regard to this meeting, Harry J McArdle declared that his updated annual DoI is currently under evaluation and that no additional interests related to the activities of the WG were reported in the updated DoI.

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>, 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 experts concerned.

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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)

5 June 2024

09:00-11:00 | 14:00-17.30

MINUTES – Agreed on 20 June 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Alfonso Siani, Marco Vinceti, Misha Vrolijk.
- Hearing experts: Dominique Turck<sup>1</sup>, Monika Neuhäuser-Berthold<sup>1</sup>.
- EFSA:  
NIF Unit: Charlotte Marie Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Vania Mendes, Ariane Titz, Ermolaos Ververis, Silvia Valtueña Martinez.
- EC: Stephanie Bodenbach

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received for Torsten Bohn and Brandy Beverly.

## 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>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.

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 of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 37<sup>th</sup> Working Group meeting held on 22-29 April 2024, via web-conference

The [minutes](#) of the 37<sup>th</sup> Working Group meeting were agreed by written procedure on 13 May 2024.

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<sup>1</sup> Attended part of the meeting only, for the first agenda item, between 09:00 and 11:00.

<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)



## 5. Scientific topic(s) for discussion

### a. Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources, upon request of the European Commission ([EFSA-Q-2022-00856](#))

The WG discussed the outcome of the public consultation and the changes to the guidance document based on comments received. The opinion will be presented at the next plenary meeting of the NDA Panel taking place from the 26<sup>th</sup> to the 28<sup>th</sup> of June for possible adoption.

### b. Update of the scientific guidelines for the development of the Tolerable Upper Intake levels of vitamins and minerals, upon request of the European Commission ([EFSA-Q-2021-00364](#))

The WG resumed the discussion on the draft guidance from the previous meeting. The discussion focused primarily on two sections: evidence integration and conclusions, specifically the subsections on hazard characterization and on approaches when there are insufficient data to establish a UL, and the recommendations section, which was added to the document to enhance its comprehensiveness and practical applicability.

### c. Feedback from Task Forces

The WG was informed about the status of the work by the task forces (TF) of experts responsible for each nutrient.

#### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and was published on 13 November 2023.

#### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and was published on 8 December 2023.

#### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) on iron had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 30 April 2024 and will be published in the upcoming weeks.

#### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor.



The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and was published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) had 18 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 30 April 2024 and was published on 6 June 2024.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and was published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E met on 22 April 2024. The discussion focused on finalising the sections on priority outcomes, hazard characterization and recommendation for research. The TF reviewed the section on non-priority outcomes as well. The draft opinion was presented and endorsed at the NDA Panel plenary meeting on 30 April 2024.

## 6. Any Other Business

None.

## 7. Next meeting

The next meeting will be held on September 10<sup>th</sup> via web conference.

### Annex

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

NO CONFLICT: With regard to this meeting, Francesco Cubadda declared that his updated annual DoI is currently under evaluation and that no additional interests related to the meeting were reported in the updated DoI

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 experts 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)

22 April | 29 April 2024

14:00-18:00 | 09:00-13:00

MINUTES – Agreed on 13 May 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Torsten Bohn, Marta Crous-Bou, Francesco Cubadda<sup>1</sup>, Aymeric Dopter, Susan Fairweather-Tait, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Alfonso Siani, Maret Traber<sup>2</sup>, Marco Vinceti, Misha Vrolijk.
- EFSA:  
NIF Unit: Charlotte Marie Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Vania Mendes, Ariane Titz, Silvia Valtueña Martinez.
- MESE Unit: Horvath Zsuzsanna
- EC: Stephanie Bodenbach

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Francesco Cubadda for the meeting on 22 March 2024 and from Brandy Beverly.

## 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>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 and to the preparatory meetings reported under item E. 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 Androniki Naska before the beginning of one of the task force meetings on vitamin E. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of this meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 36<sup>th</sup> Working Group meeting held on 11-15 March 2024, via web-conference

The [minutes](#) of the 36<sup>th</sup> Working Group meeting were agreed by written procedure on 25 March 2024.

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<sup>1</sup> Attended only on 29 April.

<sup>2</sup> Attended only on 22 April.

<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)





## 5. Scientific topic(s) for discussion

**a. Update of the scientific guidelines for the development of the Tolerable Upper Intake levels of vitamins and minerals, upon request of the European Commission ([EFSA-Q-2021-00364](#))**

The WG thoroughly reviewed and discussed the draft guidance. The discussion focused on two sections, namely, evidence integration and conclusions, including its subsection on hazard identification and characterization; and intake assessment. The Working Group was informed that two new sections, aimed at defining eligibility criteria for evidence selection and identifying uncertainties, will be added to the guidance to improve clarity.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The WG discussed the outcome of the public consultation and the changes in the opinion based on comments received. The opinion will be presented at the next plenary meeting of the NDA Panel on 30<sup>th</sup> April for possible adoption.

**c. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Iron ([EFSA-Q-2021-00370](#))**

The WG discussed the outcome of the public consultation and the changes in the opinion based on comments received. The opinion will be presented at the next plenary meeting of the NDA Panel on 30<sup>th</sup> April for possible adoption.

**d. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The working group received an update on the current state of the assessment and discussed the conclusions regarding the identified target population and priority outcomes of this assessment, namely, impaired blood coagulation and risk of bleeding, cardiovascular disease and prostate cancer. Additionally, the WG reviewed the hazard and risk characterisation. The draft opinion will be presented at the plenary meeting of the NDA Panel on April 30<sup>th</sup>, for potential endorsement for public consultation.

**e. Feedback from Task Forces**

The WG was informed about the status of the work by the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/foleate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and has been published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

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The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 11 April 2024 to discuss and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Giovanni Passeri, Torsten Bohn, Georg Lietz) met on 18 April 2024 to review and address the comments received during the public consultation on the draft opinion. The opinion will be presented at the next NDA Plenary meeting on 30<sup>th</sup> April 2024 for possible adoption.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E met on 22 April 2024. The TF discussed updates and finalised sections on priority outcomes, hazard characterization, recommendations for research and non-priority outcomes. Exposure and ADME of alpha-tocopherol in infants, as well as the scaling methodology applicable to this population were thoroughly discussed during the meeting. The draft opinion will be presented at the NDA Panel plenary meeting on April 30<sup>th</sup> for possible endorsement for public consultation.

## 6. Any Other Business

None.

## 7. Next meeting

The next meeting will be held on June 5<sup>th</sup>, via web conference.

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## **Annex**

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

NO CONFLICT: With regard to a task force meeting on vitamin E, Androniki Naska declared the following interests: (a) chairing of the National Nutrition Committee of the Greek Ministry of Health and (b) coordinating the exchange of data relevant to foodborne outbreaks, a task assigned by the Hellenic Centre for Disease Control of the Ministry of Health.

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</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 experts concerned.

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<sup>5</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>6</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)

11 March | 15 March 2024

14:00-18:00 | 09:00-13:00

MINUTES – Agreed on 25 March 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Torsten Bohn, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Alfonso Siani, Maret Traber<sup>1</sup>, Marco Vinceti, Misha Vrolijk.
- EFSA:  
NIF Unit: Charlotte Marie Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Vania Mendes, Ariane Titz, Silvia Valtueña Martinez.
- FIP unit: Stefania Barmaz
- EC: Stephanie Bodenbach

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly.

## 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>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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 2<sup>nd</sup> part of the 35<sup>th</sup> Working Group meeting held on 21 February 2024, via web-conference

The [minutes](#) of the 2<sup>nd</sup> part of the 35<sup>th</sup> Working Group meeting were agreed by written procedure on 4 March 2024.

## 5. Scientific topic(s) for discussion

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<sup>1</sup> Present on 11 March.

<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)



**a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The WG had its first discussion on the draft opinion. Some background information, an overview of previously carried-out assessments, and the ADME of Vitamin E were presented. The WG discussed the intake assessment and two of the priority outcomes, namely, prostate cancer and cardiovascular-related outcomes. The draft opinion will be further discussed in upcoming meetings.

**b. Update of the scientific guidelines for the development of the Tolerable Upper Intake levels of vitamins and minerals, upon request of the European Commission ([EFSA-Q-2021-00364](#))**

The WG carefully reviewed the draft guidance and thoroughly discussed its overarching principles and key sections, including definitions, problem formulation and definition of methods. Particular focus was placed on two subsections, namely, identification of relevant endpoints and definition of assessment sub-questions and related methods. Finally, the WG members discussed the section on hazard identification and characterisation, with particular attention to the subsection addressing uncertainty analysis related to hazard identification and characterisation. The draft guidance will be further discussed in upcoming WG meetings.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and has been published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 12 January 2024 to finalise the draft opinion. The draft opinion was endorsed during the 144<sup>th</sup> NDA Panel Plenary meeting which took place from the 30 of January until the 1<sup>st</sup> of February. It was subsequently launched for public consultation on February 12<sup>th</sup> and will remain open for comments until 4 April 2024. Next TF meeting is scheduled for 11 April 2024 to discuss and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor.



The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Torsten Bohn, Georg Lietz, Giovanni Passeri and Androniki Naska) met on 15 January 2024 to finalise the draft opinion. The draft opinion was endorsed during the 144<sup>th</sup> NDA Panel Plenary meeting which took place from the 30 of January until the 1<sup>st</sup> of February. It was subsequently launched for public consultation on February 9<sup>th</sup> and will remain open for comments until 22 March 2024. Next TF meeting is scheduled for 17 and 18 April 2024 to discuss and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E met on 12-14 March 2024. On the first day, the discussion focused on non-priority outcomes, the body of evidence on bleeding and coagulation and the approach to follow in order to update the current UL. On the second day, the TF discussed on priority outcomes and appraised the body of evidence for one of the critical endpoints. The TF is scheduled to meet again on 9 April 2024.

## 6. Any Other Business

None.

## 7. Next meeting

The next meeting will be held on April 22<sup>nd</sup>, via web conference.

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait<sup>1</sup>, Torsten Bohn, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Misha Vrolijk, Alfonso Siani.
- EFSA:  
NIF Unit: Charlotte Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Silvia Valtueña Martinez, Vania Mendes, Ariane Titz.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly and Marco Vinceti.

## 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>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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 35<sup>th</sup> Working Group 1<sup>st</sup> part meeting held on 12 January 2024, via web conference

The [minutes](#) of the 35<sup>th</sup> Working Group 1<sup>st</sup> part meeting were agreed by written procedure on 24 January 2024.

## 5. Scientific topic(s) for discussion

- a. **Update of the scientific guidelines for the development of the Tolerable Upper Intake levels of vitamins and minerals, upon request of the European Commission ([EFSA-Q-2021-00364](#))**

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<sup>1</sup> Attended only the last 40 minutes of the meeting.

<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 had its first discussion on the draft guidance (published in 2022 for internal testing) following its piloting phase. The key topics of discussion included revisiting the definitions used throughout the guidance and the appropriateness of endpoints utilized for deriving ULs. Additionally, the WG also discussed the concept of a safe level of intake and its applicability. The draft guidance will be further discussed in upcoming WG meetings.

**b. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and has been published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 12 January 2024 to finalise the draft opinion. The draft opinion was endorsed during the 144<sup>th</sup> NDA Panel Plenary meeting which took place from the 30 of January until the 1<sup>st</sup> of February. It was subsequently launched for public consultation on February 12<sup>th</sup> and will remain open for comments until 4 April 2024. Next TF meeting is scheduled for 11 April 2024 to discuss and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Torsten Bohn, Georg Lietz, Giovanni Passeri and Androniki Naska) met on 15 January 2024 to finalise the draft opinion. The draft opinion was endorsed during the 144<sup>th</sup> NDA Panel Plenary meeting which took place from the 30 of January until the 1<sup>st</sup> of February. It was subsequently launched for public consultation on February 9<sup>th</sup> and will remain open for comments until 22 March 2024. Next TF meeting is scheduled for 17 and 18 April 2024 to discuss and address the comments received during the consultation.





**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E met on 23-24 January 2024 to discuss the drafting of the scientific opinion and the screening of the literature. The TF is scheduled to meet on 22 February 2024 to discuss the preparatory work done on one of the priority endpoints identified at Protocol level.

## 6. Any Other Business

None.

## 7. Next meeting

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

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12 January 2024

09.00-13:00

MINUTES – Agreed on 24 January 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Torsten Bohn, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk, Alfonso Siani.
- Hearing experts: Dominique Turck, Monika Neuhäuser-Berthold.
- EC representative: Stephanie Bodenbach
- EFSA:  
NIF Unit: Charlotte Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Georges Kass, Leonard Matijević, Silvia Valtueña Martinez, Vania Mendes, Ariane Titz, Ermolaos Ververis.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly.

## 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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 34<sup>th</sup> Working Group meeting held on 20 December 2023, via web-conference

The [minutes](#) of the 34<sup>th</sup> Working Group meeting were agreed by written procedure on 4 January 2024.

## 5. Scientific topic(s) for discussion

- a. **Update of the Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources, upon request of the European Commission ([EFSA-Q-2022-00856](#))**

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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 WG meticulously reviewed and deliberated on the initial five chapters of the draft guidance. These chapters encompassed the introduction, objectives and scope, structure of the guidance, general principles, and data requirements for dossiers. Following a thorough discussion, the WG members reached a consensus to seek endorsement for the draft guidance at the upcoming Panel meeting, which is scheduled from January 30<sup>th</sup> to February 1<sup>st</sup>.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#)), upon request of the European Commission**

The WG revisited the intake assessment results for both preformed vitamin A and  $\beta$ -carotene. The WG also engaged in a comprehensive discussion on the risk characterisation and conclusions presented in the draft opinion. The draft opinion is scheduled for endorsement at the forthcoming NDA Panel meeting, which will take place from 30<sup>th</sup> January to 1<sup>st</sup> February.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and has been published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 12 January 2024, to discuss the hazard characterisation section and derivation of safe levels of intake for iron. The opinion will be presented for endorsement at the Panel meeting scheduled from January 30<sup>th</sup> to February 1<sup>st</sup>.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**



The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) will meet on 15 January 2024 from 9:00 to 13:00 to finalise the discussion on intake assessment for both preformed vitamin A and beta-carotene. Additionally, the TF will discuss the risk characterisation and recommendation for research sections of the opinion.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E had two meetings to discuss the progress made on the screening of the evidence available regarding the relationship between vitamin E and two of the priority adverse health effects, namely, prostate cancer and impaired coagulation and risk of bleeding. The TF is scheduled to meet on 23-24 January 2024 to discuss the drafting of the scientific opinion and further discuss the screening of the literature.

## 6. Any Other Business

None.

## 7. Next meeting

The next meeting will be held on 21 February 2024, via web conference.

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20 December 2023

09.00-15:00

MINUTES – Agreed on 04 January 2024

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Aymeric Dopter, Susan Fairweather-Tait, Torsten Bohn, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk, Alfonso Siani<sup>1</sup>.
- Hearing experts: Dominique Turck<sup>1</sup>, Monika Neuhäuser-Berthold<sup>1</sup>.
- EFSA:  
NIF Unit: Charlotte Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Georges Kass, Leonard Matijević, Silvia Valtueña Martinez, Vania Mendes, Ariane Titz, Ermolaos Ververis.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly and Francesco Cubadda.

## 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>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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 33<sup>rd</sup> Working Group meeting held on 22-23 November 2023, via web-conference

The [minutes](#) of the 33<sup>rd</sup> Working Group meeting were agreed by written procedure on 5 December 2023.

## 5. Scientific topic(s) for discussion

- a. **Update of the Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources, upon request of the European Commission ([EFSA-Q-2022-00856](#))**

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<sup>1</sup> Attended part of the meeting only, for the first agenda item, between 09:00 and 10:45

<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 had its inaugural discussion of the draft guidance, during which the WG members were introduced to the guidance, its objectives and scope, and the overarching principles. The draft guidance will be rediscussed at the upcoming WG meeting.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#)), upon request of the European Commission**

The WG discussed the body of evidence concerning the priority adverse health effect, focusing on bone health, and agreed on the drawn conclusions. Additionally, the WG revisited the available evidence pertaining to adverse health effects associated with beta-carotene supplementation. Subsequently, the WG discussed the hazard characterisation section and consensus was reached on the proposal for deriving a UL for preformed vitamin A, as well as on the proposal related to beta-carotene. The WG will discuss the remaining parts of the draft opinion, namely the risk characterization and recommendations for research at the next WG meeting.

**c. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron, upon request of the European Commission ([EFSA-Q-2021-00370](#))**

The WG reviewed the feedback received from the 143<sup>rd</sup> NDA Plenary meeting, during which the draft opinion was presented. The focus of the discussion centred on the hazard characterisation section of the opinion and reassessing the proposal for establishing a safe level of intake, taking into account the feedback received from the NDA Panel in the process.

**d. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and has been published on 8 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 6 December 2023, to discuss a proposal regarding the hazard characterisation and derivation of safe levels of intake for iron. The draft Opinion was presented during the 143<sup>rd</sup> NDA plenary and the Panel provided feedback. The next meeting with the TF on iron to further work on the hazard characterisation and derivation of safe levels of intake for iron is scheduled for 12 January 2024.



**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) met on 13 December 2023 from 9:00 to 13:00 to discuss the hazard identification in relation to bone health, as well as the hazard characterisation. Moreover, the TF discussed the adverse health effects related to beta-carotene supplementation and the hazard characterisation section on beta-carotene. The next scheduled meeting for the task force is on 15 January 2024 to discuss the risk characterisation and recommendation for research sections of the opinion.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E ([EFSA-Q-2021-00368](#))**

The TF (Androniki Naska, Alfonso Siani, Misha Vrolijk, and Maret Traber) on vitamin E had two meetings to discuss the progress made on the screening of the evidence available regarding the relationship between vitamin E and two of the priority adverse health effects, namely, prostate cancer and impaired coagulation and risk of bleeding. The TF is scheduled to meet in January 2024 to discuss the drafting of the scientific opinion and further discuss the screening of the literature.

## 6. Any Other Business

The WG was informed that Reginald FitzGerald and Julia Bornhorst, who were previously members of the WG, had concluded their involvement in the WG's activities.

## 7. Next meeting

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

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**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Torsten Bohn, Rex FitzGerald, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk.
- EFSA:  
NIF Unit: Charlotte Bercovici, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Angeliki Sofroniou, Ariane Titz.
- MESE unit: Zsuzsanna Horvath

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly.

## 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.

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 of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 32<sup>nd</sup> Working Group meeting held on 6 October 2023, via web-conference

The [minutes](#) of the 32<sup>nd</sup> Working Group meeting were agreed by written procedure on 19 October 2023.

## 5. Scientific topic(s) for discussion

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron, upon request of the European Commission ([EFSA-Q-2021-00370](#))**

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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 WG examined the available evidence and discussed the conclusions on the relationships between high iron intake and gastrointestinal effects, as well as impaired growth in infants. The WG discussion focused on hazard characterisation, particularly on the selection of a critical effect for the derivation of the UL.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#)), upon request of the European Commission**

The WG reviewed EFSA's intake assessment for preformed vitamin A and  $\beta$ -carotene, along with the complementary data from national intake estimates and from Mintel GNPD. The WG also discussed the relationship between vitamin A and priority adverse health effects, namely, teratogenicity and hepatotoxicity. The available body of evidence on  $\beta$ -carotene supplementation and related adverse health effects was also discussed.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and has been published on 13 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) on manganese had 16 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The last meeting was held on 16 October 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 26 October 2023 and will be published in the upcoming weeks.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 19 September 2023 from 9:00 to 12:00 CET and on 6 November 2023 from 10:00 to 12:30 CET, to review the evidence synthesis on the relationship of high iron intake and gastrointestinal effects, as well as growth and development outcomes of infants. The TF discussed the Risk of Bias assessment of the pertinent studies related to these outcomes. The TF also focused on the editing of the draft text of all sections in the opinion and discussed the hazard characterisation section. The next meeting with the TF is scheduled on 6 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**



The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) met on 19 and 25 of October to further discuss the available evidence on bone health, adverse effects related to  $\beta$ -carotene and the intake assessment. The next TF meeting is scheduled for 13 December 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

## 6. Any Other Business

None.

## 7. Next meeting

The next meeting will be held on December 20<sup>th</sup>, via web conference.

### Annex

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

NO CONFLICT: With regard to this meeting, Francesco Cubadda declared the following interest: a pending DoI assessment related to his authorship of several publications on synthetic amorphous silica toxicology, a topic unrelated to the activities of the WG.

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>, 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 experts concerned.

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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)

# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens

## 32<sup>nd</sup> Working Group meeting on Upper Tolerable Levels



6 October 2023

14:00-17:30

MINUTES - Agreed on 19 October 2023

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Julia Bornhorst, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Rex FitzGerald, Georg Lietz, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk
- EFSA:  
NIF Unit: Charlotte Bercovici, Victor Bunea, Ionut Craciun, Agnès De Sesmaisons, Lucia Fabiani, Nena Karavasiloglou, Leonard Matijević, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly and Torsten Bohn.

## 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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 31<sup>th</sup> Working Group meeting held on 12 September 2023, via web-conference

The [minutes](#) of the 31<sup>st</sup> Working Group meeting were agreed by written procedure on 25 September 2023.

## 5. Scientific topic(s) for discussion

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for iron ([EFSA-Q-2021-00370](#))

The WG thoroughly discussed the available evidence on the relationship between high iron exposure and the priority adverse health effects, namely, gastrointestinal effects, and

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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)



impaired growth in infants. The WG discussed the conclusions on these relationships and how to proceed with the hazard characterisation step. The WG also discussed EFSA's intake assessment for iron as well as the complementary data from national intake estimates and from Mintel GNPD.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin E ([EFSA-Q-2021-00368](#))**

The discussion on the protocol for the vitamin E assessment has been postponed to a later meeting.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) had 14 meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 27 September 2023 and is foreseen to be published in November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) did not meet in the period since last WG meeting. Next TF meeting is scheduled for 16 October to discuss and address the comments received during the public consultation which will conclude on 10 October 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 19 July 2023 from 14:00 to 18:00 CET, to review the updated findings for the systematic reviews. The draft on the hazard identification sections in the scientific opinion was discussed. The next meeting with the TF on iron to discuss the conclusions from the hazard identification and related uncertainty analyses is scheduled for 6 November 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) met on 14 and 18 September 2023 from 9:00 to 13:00 to discuss the intake



assessment and the priority adverse health effects, namely the body of evidence on teratogenicity, hepatotoxicity and on fractures. The next TF meeting is scheduled for 19 and 25 of October to further discuss the available evidence on bone health and the intake assessment.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

## **6. Any Other Business**

The WG was informed that Anne Molloy and Susan Lanham-New, who were previously members of the WG, had concluded their involvement in the WG's activities. New WG meeting dates for 2024 were identified.

## **7. Next meeting**

The next meeting will be held on 22 and 23 November 2023, via web conference.

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# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens

## 31<sup>st</sup> Working Group meeting on Upper Tolerable Levels



12 September 2023

09:00-13:00

.....UTES - Agreed on 25 September 2023

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Rex FitzGerald, Georg Lietz, Susan Lanham New, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk
- EFSA:  
NIF Unit: Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Nena Karavasiloglou, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly, Torsten Bohn and Julia Bornhorst.

### 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. No further interests were declared orally at the start of the meeting.

### 4. Agreement of the minutes of the 30<sup>th</sup> Working Group meeting held on 15-16 June 2023, via web-conference

The [minutes](#) of the 30<sup>th</sup> Working Group meeting were agreed by written procedure on 28 June 2023.

### 5. Scientific topic(s) for discussion

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for folic acid/folate ([EFSA-Q-2021-00366](#))

The WG discussed the outcome of the public consultation. The opinion will be finalised and presented at the next plenary meeting of the NDA Panel on 26-27 September 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)



for possible adoption.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for iron ([EFSA-Q-2021-00370](#))**

The WG was presented with and discussed the available evidence regarding the relationship between high iron exposure and the priority adverse health effects, namely, GI effects, zinc absorption and status, T2DM, GDM, and adverse health effects in infants, young children, and pregnant women. Another point for discussion was the available evidence on the relationship between iron intake and serum ferritin concentrations.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF (Marta Crous-Bou, Anne Molloy, Kristina Pentieva) met on 13 July and 7 September to discuss and address the comments received during the consultation. The draft opinion will be presented at the next plenary meeting of the NDA Panel on 26-27 September 2023 for possible adoption. No further TF meetings are foreseen.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) met on 20 June from 14:00 to 18:00, as well as on 25 July from 14:00 to 18:00 to finalise the draft opinion. The draft opinion was also presented and discussed at the NDA Panel meetings on 22 June and 04-06 July, while it was endorsed, subject to the public consultations, on 03 August. The draft opinion was published for the public consultations on 29 August and it will remain open for the comments until 10 October. Next TF meeting is scheduled for 16 October to discuss and address the comments received during the consultations.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 11 and 19 July 2023 from 14:00 to 18:00 CET, to review the updated findings for the systematic reviews. The contractor had provided the final report of the preparatory work. The sections in the scientific opinion are starting to be drafted, and the next meeting with the TF on iron to discuss the scientific opinion incorporating the updates from the contractor, will be scheduled in September 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.





**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF (Androniki Naska, Georg Lietz, Giovanni Passeri, and Torsten Bohn) met on 17 July 2023 from 9:00 to 13:00 to discuss the intake assessment and the body evidence on bone health. The next TF meeting is scheduled for 14 and 18<sup>th</sup> of September to discuss the hazard identification section of the draft opinion and a further discussion on the intake assessment.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF (Androniki Naska, Giovanni Passeri, and Susan Lanham New) on vitamin D had nine meetings to review the preparatory work from the contractor and to discuss the drafting of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 5 July 2023 and has been published on 8 August 2023.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 6 October 2023, via web conference.

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# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens 30<sup>th</sup> Working Group meeting on Upper Tolerable Levels



15-16 June 2023

14:00-17:30 | 09:00-13:00

MINUTES - Agreed on 28 June 2023

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Marta Crous-Bou, Francesco Cubadda<sup>1</sup>, Aymeric Dopter, Susan Fairweather-Tait, Rex FitzGerald, Georg Lietz, Susan Lanham New, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk

- EFSA:

NIF Unit: Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Nena Karavasiloglou, Leonard Matijević Roanne Saad, Ariane Titz, Silvia Valtueña Martinez

MESE Unit: Zsuzsanna Horvath, Maryem Fateh

EC: Stephanie Bodenbach

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly, Torsten Bohn, Francesco Cubadda, and Julia Bornhorst.

## 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>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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 29<sup>th</sup> Working Group meeting held on 31 May 2023, via web-conference

The [minutes](#) of the 29<sup>th</sup> Working Group meeting were agreed by written procedure on 12 June 2023.

## 5. Scientific topic(s) for discussion

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin D ([EFSA-Q-2021-00367](#))  
The WG discussed the outcome of the public consultation. The opinion will be finalised and presented at the next plenary meeting of the NDA Panel on 4-6 July 2023 for

<sup>1</sup> Attended the first two hours of the second day meeting

<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)



possible adoption.

**b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for manganese ([EFSA-Q-2021-00371](#))**

The WG discussed the section of the opinion related to the ADME, with focus on the relationship between manganese and iron absorption. Other points of discussion were related to the available evidence coming from animal studies and the intake assessment. The WG then discussed the hazard characterisation and risk characterisation. The draft opinion will be discussed again at the upcoming task force meeting (20 June 2023) and at the next plenary meeting of the NDA Panel on 22 June 2023.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The draft opinion was endorsed by the NDA Panel on the 27<sup>th</sup> of April and was released for public consultation on the 22<sup>nd</sup> of May. The consultation will remain open until the 30<sup>th</sup> of June. A meeting of the TF on folate is scheduled on the 13<sup>th</sup> of July to review and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese**

The TF (Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) met on 06 June from 09:00 to 13:00 to review and discuss the draft opinion. Next TF meeting is scheduled for 20 June to finalise the draft opinion.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 11 May 2023 from 9:30 to 11:30 CET, to review and discuss the updated final draft report provided by the contractor. The contractor had provided an updated final report, and the next meeting to discuss these updates with the TF on iron, will be scheduled in July 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

No additional TF meetings took place since the last update at the previous WG meeting. The next TF meeting is scheduled for 19 June 2023.

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Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))

No additional TF meetings took place since the last WG meeting. The draft opinion will be presented at the 4-6 July NDA Plenary meeting for possible adoption.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 7, 8 and 12 September 2023, via web conference.

# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens 29<sup>th</sup> Working Group meeting on Upper Tolerable Levels



31 May 2023

09:00-13:00

MINUTES - Agreed on 12 June 2023

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J McArdle (Vice Chair), Peter Aggett, Julia Bornhorst, Marta Crous-Bou, Aymeric Dopter, Susan Fairweather-Tait, Susan Lanham New, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk

- EFSA:

NIF Unit: Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Leng Heng, Nena Karavasiloglou, Leonard Matijević Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez

MESE Unit: Horvath Zsuzsanna, Maryem Fateh

EC: Stephanie Bodenbach

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly, Torsten Bohn, Francesco Cubadda, Rex FitzGerald and Georg Lietz.

## 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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 28<sup>th</sup> Working Group meeting held on 20 April 2023, via web-conference

The minutes of the 28<sup>th</sup> Working Group meeting were agreed by written procedure on 1 May 2023.

## 5. Scientific topic(s) for discussion

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for manganese (EFSA-Q-2021-00371)

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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 WG was presented with, and discussed, the available evidence regarding the relationship between high manganese exposure and neurological symptoms in humans. Other points of discussion were the results of the intake assessment, and the ADME section, with focus on the relationship between manganese and iron absorption. Evidence from animal studies will be approached in more detail at the next WG meeting on 15 June 2023.

**b. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate (EFSA-Q-2021-00366)**

The draft opinion was endorsed by the NDA Panel on the 27<sup>th</sup> of April and was released for public consultation on the 22<sup>nd</sup> of May. The consultation will remain open until the 30<sup>th</sup> of June. A meeting of the TF on folate is scheduled on the 13<sup>th</sup> of July to review and address the comments received during the consultation.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese**

The TF (Julia Bornhorst, Aymeric Dopter, Francesco Cubadda, Rex FitzGerald and Marco Vinceti) has not met since the last WG meeting. The NDA Panel was informed about the work of the TF, as well as preliminary conclusions, in a form of presentation on 23/05/2023 (17:00-18:00 CET). The next TF meeting is scheduled for 06/06/2023 (09:00-13:00 CET) which will be used to discuss further improvements of the draft opinion.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron (EFSA-Q-2021-00370)**

The TF (Harry J McArdle, Peter Aggett and Susan Fairweather-Tait) met on 11 May 2023 from 9:30 to 11:30 CET, to review and discuss the updated final draft report provided by the contractor. The report is being discussed with the contractor, and the next meeting with the TF on iron will be scheduled.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 (EFSA-Q-2021-00369)**

The TF (Kristina Pentieva, Misha Vrolijk and Susan Fairweather-Tait) on vitamin B6 had seven meetings to review the preparatory work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and has been published on 17 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A (EFSA-Q-2021-00365) and  $\beta$ -Carotene (EFSA-Q-2021-00372)**

The TF (Georg Lietz, Torsten Bohn and Giovanni Passeri) last met on 10 May 2023 from 09:00 to 13:00 CET. The TF was presented the intake assessment work carried out by EFSA. The TF discussed the revised final technical report submitted by the contractor. The next TF meeting is scheduled for 19 June 2023.

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**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D (EFSA-Q-2021-00367)**

The TF (Androniki Naska, Susan Lanham-New and Giovanni Passeri) has not met since the last WG meeting and had no further updates. The TF is awaiting the outcome of the public consultation which is scheduled to end on 5 June 2023 and which will be presented at the next WG meeting.

## **6. Any Other Business**

Not applicable.

## **7. Next meeting**

The next meeting will be held on 15 and 16 June 2023, via web conference.

# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens 28<sup>th</sup> Working Group meeting on Upper Tolerable Levels

20 April 2023

09:00-13:00

MINUTES - Agreed on 1 May 2023



**Location:** Web conference

## **Attendees:**

- Working Group Members: Androniki Naska (Chair), Harry J Mcardle (Vice Chair), Peter Aggett, Torsten Bohn, Julia Bornhorst, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopfer, Susan Fairweather-Tait, Rex FitzGerald, Susan Lanham New, Georg Lietz, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk

- EFSA:

NIF Unit: Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Nena Karavasiloglou, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez

MESE Unit: Laura Ciccolallo

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

The Chair welcomed the participants. Apologies for absence were received from Brandy Beverly.

## **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. No further interests were declared orally at the start of the meeting.

## **4. Agreement of the minutes of the 27<sup>th</sup> Working Group meeting held on 14&16 March 2023, via web-conference**

The [minutes](#) of the 27<sup>th</sup> Working Group meeting were agreed by written procedure on 28 March 2023.

## **5. Scientific topic(s) for discussion**

- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for folate/folic acid ([EFSA-Q-2021-00366](#))

The WG was presented with, and discussed, the available evidence and uncertainty analyses related to the endpoints considered for the hazard identification and

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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)



characterisation. The draft opinion will be presented for possible endorsement for public consultation at the next plenary meeting of the NDA Panel on 27 April 2023.

**b. Feedback on the Scaling Workshop**

A workshop on Human-to-human scaling approaches for the derivation of tolerable upper intake levels was held on 28 February and 1 March, with the aim of defining criteria for the selection of the appropriate scaling method to adjust UL for a particular population group (e.g. adults) to other groups (e.g. infants, children). Due to time limitations, the discussion regarding the outcome of the workshop was postponed to a later meeting.

**c. Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF on folate had a meeting on 9 and 16 March 2023 to discuss the draft opinion. The task force reviewed the evidence regarding potential adverse effects associated with excess folic acid/folate intake and developed the hazard characterisation part of the assessment. The outcome of EFSA's intake assessment was also reviewed.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF on manganese had meetings on 31<sup>st</sup> March and 11<sup>th</sup> April to discuss the draft opinion, especially the sections on the lines of evidence from human and animal studies. New WG member (RF) was introduced and initial presentation on the PB-K modelling for Mn was given. The outcome of EFSA's intake assessment was also reviewed. The next TF meeting is scheduled for 21 April and 11 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF on iron met on 12 April 2023 to review and discuss the narrative reviews provided by the contractor. The report is being discussed with the contractor, and the next meeting with the TF on iron will be scheduled during May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF on vitamin B6 had seven meetings to review the work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. The opinion was adopted at the NDA Plenary meeting on 29 March 2023 and is being processed for publication.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

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The TF has not had any additional meetings since the last feedback to the WG and is still waiting for the updated technical report from the contractor. The next TF meeting is scheduled for 10 May 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF on vitamin D had its last meeting on 21<sup>st</sup> and 22<sup>nd</sup> March to review EFSA's intake assessment and discuss the risk characterisation. The draft opinion was presented to the NDA Panel and endorsed for public consultation on 29 March 2023. The public consultation will launch on 24 April and will run until 5 June 2023.

## **6. Any Other Business**

Not applicable.

## **7. Next meeting**

The next meeting will be held on 31 May 2023, via web conference.

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MEETING MINUTES – 20 April 2023  
28<sup>th</sup> Working Group meeting on Upper Tolerable Levels



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SCIENTIFIC PANEL ON  
Nutrition, Novel Foods, and Food Allergens  
27<sup>th</sup> Working Group meeting on Upper Tolerable Levels

14 & 16 March 2023

09:00-13:00

MINUTES - Agreed on 26 March 2023



Location: Web conference

Attendees:

- o Working Group Members: Androniki Naska (Chair), Henry Mcardle (Vice Chair), Peter Aggett, Brandy Beverly<sup>1</sup>, Torsten Bohn, Julia Bornhorst, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Susan Lanham New, Georg Lietz, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk
- o Hearing Experts<sup>2</sup>: Roger Bouillon<sup>3</sup> and Paul Lips<sup>4</sup>
- o EC: Carolin Bendadani
- o EFSA:  
NIF Unit: Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Nena Karavasiloglou, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez
- MESE Unit: Laura Martino<sup>5</sup>

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Henry McArdle and Brandy Beverly on 14 March 2023.

## 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>6</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>7</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. No further interests were declared orally at the start of the meeting.

## 4. Agreement of the minutes of the 26<sup>th</sup> Working Group meeting held on 23 February 2023, via web-conference

The ~~minutes~~ of the of the 26<sup>th</sup> Working Group meeting were agreed by written procedure on 6 March 2023.

## 5. Scientific topic(s) for discussion

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<sup>1</sup> Participated only for item 5c

<sup>2</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>3</sup> Participated only for item 5a

<sup>4</sup> Participated only for item 5a

<sup>5</sup> Participated only for item 5a

<sup>6</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>7</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)



- a. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin D ([EFSA-Q-2021-00367](#))

The WG was presented with, and discussed, the Body of Evidence (BoE), the meta-analyses and the uncertainty analysis conducted to derive a conversion factor for calcium and the derivation of the upper tolerable intake level for vitamin D. The draft opinion will be presented at the next plenary meeting of the NDA Panel on 28-30 March.

- b. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin B6 ([EFSA-Q-2021-00369](#))

The opinion and the technical report were finalised following the comments received from the public consultation and presented to the WG. The opinion will be finalised and presented at the next plenary meeting of the NDA Panel on 28-30 March for possible adoption.

- c. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for folate/folic acid ([EFSA-Q-2021-00366](#))

The WG was presented with, and discussed, the available evidence and uncertainty analyses related to the exacerbation of neurological manifestations and cognitive impairment in individuals with B12 deficiency, and colorectal cancer. The draft opinion will be presented at the next plenary meeting of the NDA Panel on 28-30 March.

- d. Feedback on the Scaling Workshop

A workshop on Human-to-human scaling approaches for the derivation of tolerable upper intake levels was held on 28 February and 1 March, with the aim of defining criteria for the selection of the appropriate scaling method to adjust UL for a particular population group (e.g. adults) to other groups (e.g. infants, children). Due to time limitations, the discussion regarding the outcome of the workshop was postponed for a later meeting.

- e. Feedback from Task Forces

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/ folate ([EFSA-Q-2021-00366](#))

The TF on folate had a meeting on 9<sup>th</sup> and 16<sup>th</sup> March 2023 to discuss the draft opinion. The task force reviewed the evidence regarding potential adverse effects associated with excess folic acid/folate intake and developed the hazard characterisation part of the assessment. The outcome of EFSA's intake assessment was also reviewed.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))

The TF on manganese had a meeting on 16<sup>th</sup> February to discuss the draft opinion, especially the sections on lines of evidence from animal studies. The discussion also took place on uncertainty factors and the need to conduct PBPK modelling for manganese. It was also concluded that the subject-matter-expert in the field of animal behavioural tests could be consulted. The next TF meeting is scheduled for the end of March 2023.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))

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The TF on iron had a meeting on 17 January to discuss the first draft of the final technical report (combining deliverables 3,4 and 5) where the contractor addressed meta-analyses conducted for outcomes for which a systematic review was conducted. The report is being discussed with the contractor, and the next meeting with the TF on iron is scheduled on 12 April 2023.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))

The TF on vitamin B6 had seven meetings to review the work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. Minor changes were made to the opinion with no changes to the conclusion. The opinion will be discussed at the NDA Plenary meeting on 29 March 2023 for possible adoption.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))

The TF on vitamin A had two meetings to discuss the chemistry and terminology for vitamin A and related compounds, the conversion factor for beta-carotene into retinol equivalents, and the mechanisms of toxicity for well-established adverse effects of high preformed vitamin A intakes. The TF is waiting for the updated technical report from the contractor, which will be discussed at the next meeting on 4 May 2023.

Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))

The TF on vitamin D had a meeting on 13th March 2023 to discuss the draft opinion. The TF has a meeting scheduled for 21<sup>st</sup> and 22<sup>nd</sup> March to review EFSA's intake assessment and discuss the risk characterisation. The opinion will be discussed at the NDA Plenary meeting on 29 March 2023 for possible endorsement for public consultation.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 19 April 2023, via web conference.

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# SCIENTIFIC PANEL ON Nutrition, Novel Foods, and Food Allergens 26<sup>th</sup> Working Group meeting on Upper Tolerable Levels



23 February 2023

09:00-13:00

MINUTES - Agreed on 6 March 2023

**Location:** Web conference

**Attendees:**

- Working Group Members: Androniki Naska (Chair), Henry Mcardle (Vice Chair), Peter Aggett, Brandy Beverly, Torsten Bohn, Julia Bornhorst, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopfer, Susan Fairweather-Tait, Susan Lanham New, Georg Lietz, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk
- Hearing Expert<sup>1</sup>: Roger Bouillon<sup>2</sup>
- EFSA:  
NIF Unit: Pedro Das Neves Ferreira, Lucia Fabiani, Nena Karavasiloglou, Heng Leng, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez  
MESE Unit: Laura Ciccolallo<sup>3</sup>, Laura Martino<sup>4</sup>

## 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>5</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>6</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 of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 2<sup>nd</sup> part of the 25<sup>th</sup> Working Group meeting held on 15 November 2022, via web-conference

The [minutes](#) of the 2<sup>nd</sup> part of the 25<sup>th</sup> Working Group meeting were agreed by written procedure on 22 November 2022.

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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 only for item 5.1

<sup>3</sup> Participated only for item 5.3

<sup>4</sup> Participated only for item 5.1

<sup>5</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>6</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)



## 5. Scientific topic(s) for discussion

- a. **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin D ([EFSA-Q-2021-00367](#))**

The WG was presented with, and discussed, the Body of Evidence (BoE), the meta-analyses and the uncertainty analysis conducted to derive a conversion factor for calcidiol and to re-assess the established relationship between high intakes of vitamin D and development of persistent hypercalcaemia and/or hypercalciuria.

- b. **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin B6 ([EFSA-Q-2021-00369](#))**

The WG was presented with, and discussed, the comments received by the public consultation of the draft scientific opinion on the revision of the UL for vitamin B6. The opinion will be finalised by the task force and presented to the WG in the next meeting.

- c. **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for folate/folic acid ([EFSA-Q-2021-00366](#))**

The WG was presented with the available body of evidence regarding the relationship between folate/folic acid intake and risk of colorectal cancer. The data will be presented to the NDA Panel for discussion at its plenary meeting on 27 February.

- d. **Feedback from Task Forces**

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF on folate accepted the final technical report from the contractor in December 2022 subject to editorial changes, particularly in the statistical report. Since then, the TF had two meetings to discuss the draft opinion, including the ADME, and sections on hazard identification regarding B12-dependent neuropathy and cancer risk. The next meetings of the TF are scheduled on 9 and 16 March 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF on manganese had a meeting on 16<sup>th</sup> February to discuss the draft opinion, especially the sections on lines of evidence from animal studies. The discussion also took place on uncertainty factors and the need to conduct PBKmodelling for manganese. It was also concluded that the subject-matter-expert in the field of animal behavioural tests could be consulted. The next TF meeting is scheduled for the end of March 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

The TF on iron had a meeting on 17 January to discuss the first draft of the final technical report (combining deliverables 3,4 and 5) where the contractor



addressed meta-analyses conducted for outcomes for which a systematic review was conducted. The report is being discussed with the contractor, and the next meeting with the TF on iron is scheduled on 22 March 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF on vitamin B6 had seven meetings to review the work from the contractor. The last meeting on vitamin B6 was held on 16 February 2023 where the TF reviewed and discussed the comments received via public consultation on the final draft of the scientific opinion. Minor changes were made to the opinion with no changes of the conclusion.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and  $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The TF on vitamin A had two meetings to discuss the chemistry and terminology for vitamin A and related compounds, the conversion factor for beta-carotene into retinol equivalents, and the mechanisms of toxicity for well-established adverse effects of high preformed vitamin A intakes. The TF is waiting for the updated technical report from the contractor, which will be discussed at the next meeting on 5 April 2023.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The TF on vitamin D accepted the final technical report from the contractor in December 2022 subject to editorial changes, particularly in the statistical report. Since then, the TF had three meetings to discuss the draft opinion, including the ADME, the conversion factor for calcidiol, and sections on hazard identification regarding hypercalcemia/hypercalciuria and musculoskeletal health. The next meeting of the TF is scheduled on 13 March 2023 to discuss sections on hazard characterisation.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 14 March 2023, via web conference.

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## Annex

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

NO CONFLICT: With regard to this meeting, Dr Marco Vinceti declared the following interest: receipt of two new research funds on “Epidemiologic investigation on the effects of selenium exposure through drinking water in the Reggio Emilia area on the risk of diabetes” (funded by: Fondazione Cassa di Risparmio di Reggio Emilia Pietro Manodori) and “Biocidal Nanocompounds implementation and production” (funded by: INAIL (Rome) - Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro). In accordance with EFSA’s Policy on Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</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>7</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>8</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)



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 25<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS, 2<sup>nd</sup> PART

Held on 15 November 2022 via web-meeting

(Agreed on 22 November 2022)

### Participants

Working Group Members:

Androniki Naska (Chair), Henry Mcardle (Vice Chair), Peter Aggett, Brandy Beverly, Marta Crous-Bou, Francesco Cubadda, Aymeric Dopter, Susan Fairweather-Tait, Susan Lanham New, Georg Lietz, Anne Molloy, Giovanni Passeri, Kristina Pentieva, Marco Vinceti, Misha Vrolijk

NIF Unit : Ionut Craciun, Pedro Das Neves Ferreira, Lucia Fabiani, Heng Leng, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña Martinez

MESE Unit : Rita Ferreira De Sousa, Zsuzsanna Horvath

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received by Julia Bornhorst and Torsten Bohn.

### 2. Adoption of agenda

Agenda item 3 was postponed to the first meeting of the WG on Upper levels in 2023.

### 3. Declarations of Interest of Working Group 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.

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<sup>1</sup> EFSA Policy on Independence

<sup>2</sup> Decision of the Executive Director on Competing Interest Management

#### 4. Agreement of the minutes of the 25<sup>th</sup> Working Group 1<sup>st</sup> part meeting held on 8 November 2022 via web-conference.

The **minutes** of the 1<sup>st</sup> part of the 25<sup>th</sup> Working Group meeting were agreed by written procedure on 10 November 2022.

#### 5. Scientific topics for discussion

##### 5.1 Intake assessment in the context of the derivation of Upper levels

The WG was presented with the overall approach for the assessment of the daily intake of vitamin B6, vitamin D, beta carotene, retinol, folate/folic acid and iron. Uncertainties and challenges around data on intake from different sources and the ways forward have been discussed.

##### 5.2 Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin B6 (EFSA-Q-2021-00369).

The WG discussed and agreed on the approach to the derivation of the tolerable upper level (UL) for vitamin B6. The opinion will be finalised by the task force and submitted to the NDA Panel for possible endorsement for public consultation at its plenary meeting in November.

##### 5.3 Feedback from Task Forces

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

##### Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate (EFSA-Q-2021-00366)

The TF on folic acid/folate had six meetings to review the work from the contractor. The contractor is preparing the submission of deliverable 5, the final technical report. The next meeting of the TF is scheduled on the 30 November 2022.

##### Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese (EFSA-Q-2021-00371)

The TF on manganese had five meetings to review the work from the contractor. The contractor has proceeded with the risk of bias appraisal for animal studies and statistical analyses for human studies. Evidence synthesis of human and animal data is expected to be finalised in the upcoming days. The next TF meeting is scheduled on the 25 November 2022, followed by the one on 1<sup>st</sup> December 2022 where the final deliverables from the contractor are expected to be reviewed.

##### Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron (EFSA-Q-2021-00370)

The TF on iron had two meetings to discuss deliverables 1 and 2 related to the implementation of the protocol, and search strategy and data extraction. The TF will review and discuss the 3<sup>rd</sup> deliverable from the contractor related to the evidence synthesis and meta-analyses at its next meeting, which is still to be determined. The contractor is in the process of drafting the statistical analysis (part of deliverable 3) in parallel to deliverable 4 after receiving revisions from EFSA staff.

##### Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 (EFSA-Q-2021-00369)

The TF on vitamin B6 had six meetings to review the work from the contractor. The last meeting on vitamin B6 was held on 19 October 2022 where the TF reviewed and discussed the draft of deliverable 5, related to the final technical report, provided by the contractor.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A (EFSA-Q-2021-00365) and  $\beta$ -Carotene (EFSA-Q-2021-00372)**

The TF on vitamin A has had six meetings to review the work from the contractor. The contractor has submitted the priority narrative reviews and a critical summary of the evidence and uncertainty analysis. Feedback has been provided by the task force experts on this deliverable and this feedback is to be implemented in the final technical report. The next meeting of the TF is scheduled for the 1 December 2022 to discuss the final technical report.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D (EFSA-Q-2021-00367)**

The TF on vitamin D has had five meetings to review the work from the contractor. The contractor has submitted a revision of deliverable 3 along with deliverable 4, which consists of the priority narrative reviews, critical summary of the evidence and the uncertainty analysis. The TF has provided feedback on this report which will be implemented in the final deliverable. The deadline to submit the final technical report is 24 November and this report will be discussed at the next meeting of the TF is scheduled for the 29 November 2022.

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will be held on 1 February 2023 as a web-meeting.



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 25<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS, 1<sup>ST</sup> PART

Held on 8 November 2022 via web-meeting

(Agreed on 10 November 2022)

### Participants

Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, Fairweather-Tait Susan<sup>1</sup>, McArdle Harry J., Vinceti Marco.

EFSA

NIF Unit : Ionut Craciun, Pedro Das Neves Ferreira, Agnès De Sesmaisons, Lucia Fabiani, Leonard Matijević, Roanne Saad, Angeliki Sofroniou, Ariane Titz

MESE Unit : Laura Ciccolallo

### 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 Group 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.

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<sup>1</sup> Observer

#### **4. Agreement of the minutes of the 24<sup>th</sup> Working Group meeting held on 11-12 October 2022 via web-conference.**

The [minutes](#) of the 24<sup>th</sup> Working Group meeting were agreed by written procedure on 20 October 2022.

#### **5. Scientific topics for discussion**

##### **5.1 Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))**

The draft technical report on the outcome of the public consultation on the draft Scientific opinion on the Tolerable Upper Intake Level for selenium was reviewed. Comments received by the public and corresponding changes to the draft Scientific opinion were discussed.

The final scientific opinion will be presented to the NDA Panel meeting on 24 November 2022 for discussion and possible adoption.

#### **6. Any Other Business**

Not Applicable.

#### **7. Next meeting**

The next meeting will be held on 15 November 2022 as a web-meeting.



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 24<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 11-12 October 2022 via web-meeting

(Agreed on 20 October 2022)

### Participants

Working Group Members:

Androniki Naska (Chair), Henry McARDLE (vice chair), Peter AGGETT, Brandy BEVERLY, Torsten BOHN, Julia BORNHORST, Marta CROUS-BOU, Francesco CUBADDA, Aymeric DOPTE, Susan FAIRWEATHER-TAIT, Susan LANHAM NEW, Georg LIETZ, Anne MOLLOY, Giovanni PASSERI, Kristina PENTIEVA, Marco VINCETI, Misha VROLIJK

EFSA

NIF Unit : Ionut CRACIUN, Agnès DE SESMAISONS, Lucia FABIANI, Leng HENG, Leonard MATIJEVIĆ, Silvia VALTUEÑA MARTINEZ, Angeliki SOFRONIOU, Ariane TITZ

MESE Unit : Laura CICCOLALLO, Laura MARTINO

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Kristina Pentieva.

Anne Molloy did not participate in agenda points 5.1, 5.2 and partly participated in 5.4.

Torsten Bohn partly participated in agenda points 5.4.

Brandy Beverly did not participate in agenda points 5.1, 5.2 and 5.3 and partly participated in 5.4.

Susan Fairweather-Tait did not participate in agenda point 5.3 due to a Conflict of Interest being identified for this agenda item.

Harry McArdle did not participate in agenda point 5.3 due to a Conflict of Interest being identified for this agenda item.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

### 4. Agreement of the minutes of the 23rd Working Group meeting held on 7-8 July 2022 via web-conference.

The [minutes of the 23rd Working Group meeting](#) were agreed by written procedure on 15 July 2022.

### 5. Scientific topics for discussion

#### 5.1. Feedback from Task Forces

The WG was informed about the status of the work by the contractor in charge of the preparatory work for the re-evaluation of tolerable upper intake levels (ULs) and of the task forces (TF) of experts responsible for each nutrient.

##### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF on folic acid/folate had five meetings to review the work from the contractor. The contractor has proceeded with the risk of bias appraisal, statistical analysis and uncertainty analysis of relevant evidence. Several narrative reviews are under preparation, as specified in the protocol. The next meeting of the TF is scheduled on the 27<sup>th</sup> of October 2022.

##### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The TF on manganese had four meetings to review the work from the contractor. The contractor has proceeded with the risk of bias appraisal for human studies, while for animal studies this work is still in progress. Statistical analyses are expected to be received by the end of October, while uncertainty analysis of relevant evidence is expected to be received by mid-November. The next TF meeting is scheduled on the 28<sup>th</sup> of October 2022.

##### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Iron ([EFSA-Q-2021-00370](#))**

The TF on iron had two meetings to discuss deliverables 1 and 2 related to the implementation of the protocol, and search strategy and data extraction. The TF will review and discuss the 3<sup>rd</sup> deliverable from the contractor related to the evidence synthesis and meta-analyses at its next meeting, which is still to be determined. The contractor is in the process of drafting the statistical analysis in parallel to finalising deliverable 2 after receiving revisions from EFSA staff.

##### **Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF on vitamin B6 had five meetings to review the work from the contractor. The TF on vitamin B6 will review and discuss the 5<sup>th</sup> and final deliverable from the contractor



related to the final technical report provided by the contractor at its next meeting, on the 19<sup>th</sup> of October 2022.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A (EFSA-Q-2021-00365) and  $\beta$ -Carotene (EFSA-Q-2021-00372)**

The TF on vitamin A had four meetings to review the work from the contractor. The contractor is in the process of finalising the statistical analysis and has finalised the risk of bias appraisal. Under preparation and to be discussed at the upcoming meetings is the uncertainty analysis of relevant evidence and a number of narrative reviews. The next meeting of the TF is scheduled for the 24<sup>th</sup> of October 2022.

**Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D (EFSA-Q-2021-00367)**

The TF on vitamin D had four meetings to review the work from the contractor. The contractor is in the process of finalising the statistical analysis and has finalised the risk of bias appraisal. Draft versions of several narrative reviews and uncertainty analyses of relevant evidence have been submitted by the contractor and will be discussed and reviewed with the TF at the upcoming meeting. The next meeting of the TF is scheduled for the 3<sup>rd</sup> of November 2022.

**5.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission, for vitamin B6 (EFSA-Q-2021-00369).**

The WG discussed the derivation of the tolerable upper level (UL) for vitamin B6 and the uncertainties around it. The opinion will be finalised by the TF and submitted to the Panel for possible endorsement for public consultation at its plenary meeting in November.

**5.3. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) submitted by the European Commission for vitamin D (EFSA-Q-2021-00367).**

The WG discussed the choices for data analysis on the conversion factor for calcidiol based on the evidence retrieved for the current assessment of the UL for vitamin D.

**5.4. Transversal scientific topics**

The WG discussed common topics in setting tolerable upper levels for all the vitamins and minerals currently under assessment. The topics included: the different consideration in setting a new UL versus updating an existing UL; the use of chronic disease endpoints to inform ULs for nutrients; feedback from using the OHAT tool to conduct risk of bias appraisals on the evidence collected for the derivation of ULs for nutrients; meta-analyses for non-well-established relationships between intake of the nutrients and adverse outcomes .

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will be held on 8 November 2022 as a web-meeting.

## Annex

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

**NO CONFLICT:** With regard to this meeting, Prof. Susan Lanham-New declared the following interest: plenary speaker on Vitamin D2 and Vitamin D3 at the 24th Vitamin D Workshop, Sept 6-9, 2022 (an open International Scientific Conference, organised by a non-profit organization). 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>, 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.

**NO CONFLICT:** With regard to this meeting, Prof. Peter Aggett declared the following interest: participation in 2015 in a meeting of a working group on Manganese Toxicity with Risk Sciences International, Ottawa. In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</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.

**CONFLICT OF INTEREST:** With regard to this meeting, Prof. Susan Fairweather-Tait declared the following interest: member of the UK FSA ACNFP, which is currently considering an application on calcidiol. In accordance with EFSA's Policy on Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.3 by the concerned scientific group.

**CONFLICT OF INTEREST:** With regard to this meeting, Prof. Henry McArdle declared the following interest: member of the UK FSA ACNFP, which is currently considering an application on calcidiol. In accordance with EFSA's Policy on Independence<sup>9</sup> and the Decision of the Executive Director on Competing Interest Management<sup>10</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.3 by the concerned scientific group.

<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> [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>6</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>7</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>8</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>9</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>10</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)



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 23<sup>rd</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 7-8 July 2022 via web-meeting

(Agreed on 15 July 2022)

### Participants

Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, Fairweather-Tait Susan<sup>1</sup>, McArdle Harry J., Vinceti Marco.

EFSA:

NIF Unit : Craciun Ionut, Fabiani Lucia, Heng Leng, Sofroniou Angeliki, Titz Ariane

MESE Unit : Rita de Sousa Ferreira<sup>2</sup>

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Kristina Pentieva.

### 2. Adoption of agenda

The agenda was adopted without changes.

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

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<sup>1</sup> Observer

<sup>2</sup> Only on 8 July 2022

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 22<sup>nd</sup> Working Group meeting held on 7-8 June 2022 via web-conference.**

The **minutes of the 22<sup>nd</sup> Working Group meeting** were agreed by written procedure on 15 June 2022.

#### **5. Scientific topics for discussion**

##### **5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))**

The WG revised sections of the draft selenium opinion related to hazard and risk characterisation, in particular the sub-section related to the derivation of the UL for adults and other population groups. In addition, revisions to the section on intake assessment were made and the conclusions of the opinion were finalised. The section on recommendations was discussed, particularly considerations for future research.

##### **5.2. Feedback from Task Force meetings**

Sub-groups of experts from the UL WG (Task Forces, TF) have been assigned to the preparation of the opinions on the individual micronutrients covered by the European Commission request for a scientific opinion on the Tolerable Upper Intake levels of vitamins and minerals (Mandate Nr. M-2021-00058). Preparatory work for these opinions is carried out by an external contractor (OC/EFSA//NUTRI/2021/01<sup>5</sup>). The WG was informed about the status of the work by the contractor and withing each TF.

##### **5.2.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic acid/folate ([EFSA-Q-2021-00366](#))**

The TF on folic acid/folate contractor continues working on the risk of bias appraisal and statistical analyses of included studies. The next meeting of the TF is scheduled on 9 August 2022.

##### **5.2.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

A meeting was held on 14 June 2022 to review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and the data extraction. Feedback was given to the contractor. The next meeting of the TF is scheduled for 28 August 2022.

##### **5.2.3. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron ([EFSA-Q-2021-00370](#))**

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

<sup>4</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)  
Accessible from Ted website for calls for tenders from the European institutions at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8872>

The 2<sup>nd</sup> deliverable from the contractor related to the search strategy and data extraction was discussed on 14 June 2022. The contractor has started working on deliverable 3 (risk of bias appraisal and statistical analyses) in parallel to finalising deliverable 2. The next meeting is scheduled on 9 September 2022.

#### **5.2.4. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin B6 ([EFSA-Q-2021-00369](#))**

The 2<sup>nd</sup> deliverable from the contractor related to the search strategy and data extraction was discussed on 9 June 2022. The contractor has started working on deliverable 3 (risk of bias appraisal and statistical analyses) in parallel to finalising deliverable 2. The next meeting is scheduled on 12 September 2022.

#### **5.2.5. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin A ([EFSA-Q-2021-00365](#)) and $\beta$ -carotene ([EFSA-Q-2021-00372](#))**

Deliverable 2 has been approved following implementation of some suggestions from EFSA. The next meeting is scheduled on 9 September 2022.

#### **5.2.6. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin D ([EFSA-Q-2021-00367](#))**

Deliverable 2 has been approved following implementation of some suggestions from EFSA staff. EFSA provided feedback on the tailoring of the risk of bias tool proposed by the contractor. The contractor also provided some examples of the forest plots to be created for the project. The next meeting is scheduled on 9 September 2022.

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will be held on 6 September 2022 as a web-meeting.



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 22<sup>ND</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 7-8 June 2022 via web-meeting

(Agreed on 15 June 2022)

### Participants

Working Group Members:

Naska Androniki (Chair)<sup>1</sup>, Aggett Peter, Crous Bou Marta, Cubadda Francesco, Fairweather-Tait Susan<sup>2</sup>, McArdle Harry J., Vinceti Marco.

EFSA:

NIF Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Matijevic Leonard, Sofroniou Angeliki, Titz Ariane

MESE Unit: Ciccolallo Laura<sup>3</sup>, Horvath Zsuzsanna<sup>3</sup>

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Kristina Pentieva.

The Chair, Androniki Naska was absent the afternoon of the 7<sup>th</sup> of June and was substituted by the the vice-chair, Harry McArdle.

### 2. Adoption of agenda

The agenda was adopted without changes.

<sup>1</sup> Present for the meeting on 7<sup>th</sup> June 2022, morning and 8<sup>th</sup> June 2022, morning.

<sup>2</sup> Observer

<sup>3</sup> Present for the meeting on 7<sup>th</sup> June 2022, morning only.

### 3. Declarations of Interest of Working Group 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 21<sup>th</sup> Working Group meeting held on 10-12 May 2022 via web-conference.

The **minutes of the 21<sup>th</sup> Working Group meeting** were agreed by written procedure on 24 May 2022.

### 5. Scientific topics for discussion

#### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (**EFSA-Q-2020-00618**)

The WG revised sections of the selenium draft opinion related to hazard identification, in particular the sub-section related to effects associated with selenium toxicity and selenosis, and the sub-section on the association between selenium exposure and risk of type 2 diabetes mellitus. In addition, the section on intake assessment was presented to the WG and feedback was collected.

#### 5.2. Feedback from Task Force meetings

Sub-groups of experts from the UL WG (Task Forces, TF) have been assigned to the preparation of the opinions on the individual micronutrients covered by the European Commission request for a scientific opinion on the Tolerable Upper Intake levels of vitamins and minerals (Mandate Nr. M-2021-00058). Preparatory work for these opinions is carried out by an external contractor (OC/EFSA//NUTRI/2021/016). The WG was informed about the status of the work by the contractor and withing each TF.

##### 5.2.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Folic acid/folate (**EFSA-Q-2021-00366**)

The TF on folic acid/folate awaits for the 3<sup>rd</sup> deliverable from the contractor related to the evidence appraisal and synthesis. The next meeting of the TF is scheduled on the 3<sup>rd</sup> of August 2022.

##### 5.2.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese (**EFSA-Q-2021-00371**)

The TF on manganese will review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and data extraction at its next meeting, on the 14<sup>th</sup> of June 2022.

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

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

Accessible from Ted website for calls for tenders from the European institutions at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8872>

#### **5.2.3. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Iron ([EFSA-Q-2021-00370](#))**

The TF on iron will review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and data extraction at its next meeting, on the 14<sup>th</sup> of June 2022.

#### **5.2.4. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The TF on vitamin B6 will review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and data extraction at its next meeting, on the 9<sup>th</sup> of June 2022.

#### **5.2.5. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

A meeting was held on the 1<sup>st</sup> of June 2022 to review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and the data extraction. Feedback was given to the contractor. The next meeting of the TF is scheduled for the 9<sup>th</sup> September 2022.

#### **5.2.6. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

A meeting was held on the 1<sup>st</sup> June 2022 to review and discuss the 2<sup>nd</sup> deliverable from the contractor related to the search strategy and the data extraction. Feedback was given to the contractor. The next meeting of the TF is scheduled for the 9<sup>th</sup> September 2022.

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will be held on 14 July 2022 as a web-meeting.





NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 21<sup>ST</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 10-12 May 2022 via web-meeting

(Agreed on 24 May 2022)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, Fairweather-Tait Susan<sup>1</sup>, McArdle Harry J., Vinceti Marco.

#### EFSA:

NIF Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, , Sofroniou Angeliki, Titz Ariane

MESE Unit: Ciccolallo Laura<sup>2</sup>, Costanzo Violetta<sup>3</sup>, Ferreira de Sousa Rita<sup>3</sup>, Horvath Zsuzsanna<sup>3</sup>

#### Others:

Hearing experts : Cappellani Daniele <sup>4</sup>, Sunde Roger<sup>3</sup>, Willatts Peter<sup>4</sup>

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Pentieva Kristina.

### 2. Adoption of agenda

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<sup>1</sup> Observer

<sup>2</sup> Present for the meeting on the 11 May 2022 only.

<sup>3</sup> Present for the meeting on the 12 May 2022 only.

<sup>4</sup> Present for the meeting on 10 May 2022 only.

The agenda was adopted without changes.

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

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</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 20<sup>th</sup> Working Group meeting held on 9 and 10 March 2022 via web-conference.

The **minutes of the 20<sup>th</sup> Working Group meeting** were agreed by written procedure on 15 March 2022.

### 5. Scientific topics for discussion

#### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (**EFSA-Q-2020-00618**)

The WG revised the sections of the selenium draft opinion related to hazard identification for the outcomes of chronic diseases, in particular the sub-sections thyroid function, prostate cancer, overall mortality and neuropsychological development in children. In addition, an update of the results of the dose-response analysis of prospective observational studies investigating the association between selenium exposure and risk of Type 2 diabetes mellitus (T2DM) was presented to the WG. The risk of bias appraisal and framework of the uncertainty analysis for the evidence related to the outcome of T2DM were discussed by the WG. Feedback on the section of the opinion related to the absorption, distribution, metabolism and excretion of selenium and the sections reporting on the intake assessment and clinical effects associated to selenosis was collected.

#### 5.2. Feedback from Task Force meetings

Sub-groups of experts from the UL WG (Task Forces, TF) have been assigned to the preparation of the opinions on the individual micronutrients covered by the European Commission request for a scientific opinion on the Tolerable Upper Intake levels of vitamins and minerals (Mandate Nr. M-2021-00058). Preparatory work for these opinions is carried out by an external contractor (OC/EFSA//NUTRI/2021/01<sup>7</sup>). The WG was informed about the status of the work by the contractor and withing each TF.

##### 5.2.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for folic Acid/folate (**EFSA-Q-2021-00366**)

The kick-off meeting of the TF on folic acid/folate was held on the 7<sup>th</sup> of April 2022. The protocol was presented to the experts of the TF and feedback was collected. A second meeting held on the 2<sup>nd</sup> of May 2022 was dedicated to discuss the deliverables from the

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<sup>5</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

Accessible from Ted website for calls for tenders from the European institutions at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8872>

contractor related to the search strategies and data extraction. The next meeting is scheduled on the 3<sup>rd</sup> of August 2022.

#### **5.2.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese ([EFSA-Q-2021-00371](#))**

The kick-off meeting of the TF on manganese was held on the 31<sup>st</sup> of March 2022. The protocol was presented to the experts of the TF and feedback was collected. Next meeting is scheduled on the 14<sup>th</sup> of June 2022 to review and discuss the deliverables from the contractor related to the search strategy and data extraction.

#### **5.2.3. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Iron ([EFSA-Q-2021-0037](#))**

The kick-off meeting of the TF on iron was held on the 12<sup>th</sup> of April 2022. The protocol was presented to the experts of the TF and feedback was collected. Next meeting is scheduled on the 10<sup>th</sup> of June 2022 to review and discuss the deliverables from the contractor related to the search strategy and data extraction.

#### **5.2.4. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin B6 ([EFSA-Q-2021-00369](#))**

The kick-off meeting of the TF on iron was held on the 11<sup>th</sup> of April 2022. The protocol was presented to the experts of the TF and feedback was collected. Next meeting is scheduled on the 9<sup>th</sup> of June 2022 to review and discuss the deliverables from the contractor related to the search strategy and data extraction.

#### **5.2.5. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin A ([EFSA-Q-2021-00365](#)) and $\beta$ -Carotene ([EFSA-Q-2021-00372](#))**

The review of the ULs of vitamin A and  $\beta$ -carotene will be addressed together. The kick-off meeting of the TF on iron was held on the 29<sup>th</sup> of April 2022. The protocol was presented to the experts of the TF and feedback was collected. The next meeting is scheduled for 1<sup>st</sup> June 2022 to review and discuss the deliverables from the contractor related to the search strategy and data extraction.

#### **5.2.6. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin D ([EFSA-Q-2021-00367](#))**

The kick-off meeting of the TF on vitamin D was held on the 20<sup>th</sup> of April 2022. The protocol was presented to the experts of the TF and feedback was collected. Next meeting is scheduled on the 1<sup>st</sup> of June 2022 to review and discuss the deliverables from the contractor related to the search strategy and data extraction.

## **6. Any Other Business**

Not Applicable.

## **7. Next meeting**

The next meeting will be held on 7-8 June 2022 as a web-meeting.



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 20<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 9 and 10 March 2022 via web-meeting

(Agreed on 15 March 2022)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J.<sup>1</sup>, Pentieva Kristina, Vinceti Marco.

#### EFSA:

NIF Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Matijevic Leonard, Neri Franco Maria<sup>2</sup>, Sofroniou Angeliki, Titz Ariane

MESE Unit: Ciccolallo Laura, Ferreira de Sousa Rita<sup>2</sup>, Horvath Zsuzsanna<sup>2</sup>

#### Others:

European Commission: Bendadani Carolin

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from McArdle Harry J. for the meeting on the 9 March 2022.

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<sup>1</sup> Present only on 10<sup>th</sup> March

<sup>2</sup> Present only on 9<sup>th</sup> March

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 19<sup>th</sup> Working Group meeting held on 3 and 4 February 2022 via web-conference.

The **minutes of the 19<sup>th</sup> Working Group meeting** were agreed by written procedure on 15 February 2022.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))

The WG was updated about the timelines foreseen for the finalisation of the scientific opinion on the revision of the UL for selenium. The structure of the scientific opinion was discussed. In addition, preliminary results of the dose-response analysis of the relationship between selenium exposure and the risk of Type 2 Diabetes Mellitus (T2DM) was presented to the WG. The outcomes of risk of bias appraisal of the eligible studies related to T2DM were also discussed. Lastly, the proposed approach for the intake assessment of selenium and the other micronutrients part of the on-going mandate on the revision of ULs<sup>5</sup> were presented to the WG. Feedback from the WG members was collected.

## 6. Any Other Business

Not Applicable.

## 7. Next meeting

The next meeting will be held on 10-12 May 2022 as a web-meeting.

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

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

<sup>5</sup> The mandate addresses iron ([EFSA-Q-2021-0037](#)), manganese ([EFSA-Q-2021-00371](#)), folate/folic acid ([EFSA-Q-2021-00366](#)), vitamin A ([EFSA-Q-2021-00365](#)), vitamin B6 ([EFSA-Q-2021-00369](#)), vitamin D ([EFSA-Q-2021-00367](#)), vitamin E ([EFSA-Q-2021-00368](#)) and beta-carotene ([EFSA-Q-2021-00372](#)).



NIF UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 19<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 3 and 4 February 2022 via web-meeting

(Agreed on 15 February 2022)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J., Vinceti Marco.

#### EFSA:

NIF Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Matijevic Leonard, Sofroniou Angeliki, Titz Arianne

MESE Unit: Ciccolallo Laura, Martino Laura

#### Others:

European Commission: Bendadani Carolin

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Kristina Pentieva.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 18<sup>th</sup> Working Group meeting held on 10 and 17 December 2021 via web-conference.**

The **minutes of the 18<sup>th</sup> Working Group meeting** were agreed by written procedure on 22 December 2021.

#### **5. Scientific topics for discussion**

##### **5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))**

The WG was informed about the most up to date results of the dose-response analysis for the relationship between plasma selenium concentrations and selenium intake. In addition, the WG discussed the results of the evidence related to thyroid function and skin cancer. Lastly, the WG members had an exchange of views about the tools used to appraise the eligible studies from the systematic review on selenium and chronic diseases for the outcome of Type 2 Diabetes Mellitus.

##### **5.2. Scientific Opinion on the revision of the Tolerable Upper Intake Level (UL) for Manganese, submitted by the European Commission ([EFSA-Q-2021-00371](#))**

Overall coordination aspects related to the organization of the work foreseen in relation to the UL mandate<sup>1</sup> was presented and discussed with the WG. The WG will be expanded to accommodate the workload and the needs for additional nutrient-specific and methodological expertise.

The 'high level' protocol for manganese was presented to the WG. The document is under revision by the contractor in charge of the preparatory work on this nutrient

##### **5.3. Scientific Opinion on the revision of the Tolerable Upper Intake Level (UL) for Iron, submitted by the European Commission ([EFSA-Q-2021-00370](#))**

The 'high level' protocol for iron was presented to the WG. The document is under revision by the contractor in charge of the preparatory work on this nutrient.

#### **6. Any Other Business**

Not Applicable.

#### **7. Next meeting**

The next meeting will be held on 9-10 March 2022 as a web-meeting.

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<sup>1</sup> The mandate addresses iron, manganese, folate/folic acid, vitamin A, vitamin B6, vitamin D, vitamin E and beta-carotene



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 18<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 10 and 17 December 2021 via web-meeting

(Agreed on 22 December 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J., Pentieva Kristina, Vinceti Marco.

#### EFSA:

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Sofroniou Angeliki, Titz Ariane, Valtueña Martinez Silvia

#### Others:

Not Applicable.

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 14<sup>th</sup> Working Group meeting held on 04 October 2021 via web-conference.

The [minutes of the 17<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 9 December 2021.

#### 5. Scientific topics for discussion

##### 5.1. Update of tolerable upper intake levels for vitamin B6 ([EFSA-Q-2021-00369](#))

The WG was updated about the workplan foreseen for the UL mandate. For each of the vitamins and minerals<sup>3</sup> which is part of the mandate request for an update of the tolerable upper intake levels, a high-level protocol will be developed to plan the scientific assessment. Hearing experts' meetings aiming to assist in the formulation of the risk assessment questions are being held during this month of December and will continue in January 2022. The draft of the high-level protocol for vitamin B6 was presented and discussed by the WG members and the document was amended. The protocol for vitamin B6 was foreseen to be presented in the 120th NDA plenary meeting, which was held on the 15th December 2021.

##### 5.2. Update of tolerable upper intake levels for folic acid/folate ([EFSA-Q-2021-00366](#))

In the second meeting day, the WG discussed the draft of the high-level protocol for folic acid/folate. The document was revised. Comments from the NDA Panel regarding methodological aspects of the protocol for vitamin B6 that could also apply to the protocol for folic acid/folate, were considered.

#### 6. Any Other Business

Not Applicable.

#### 7. Next meeting

The next meeting will be held on 3 February 2022 as a web-meeting.

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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> The mandate addresses iron, manganese, folate/folic acid, vitamin A, vitamin B6, vitamin D, vitamin E and beta-carotene



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 17<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 30 November 2021 via web-meeting

(Agreed on 9 December 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J., Pentieva Kristina, Vinceti Marco.

#### EFSA:

NUTRI Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Sofroniou Angeliki, Titz Arianne

AMU Unit: Ciccolallo Laura

#### Others:

European Commission: Bendadani Carolin

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Kristina Pentieva.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 14<sup>th</sup> Working Group meeting held on 04 October 2021 via web-conference.

The minutes of the 16<sup>th</sup> Working Group meeting were agreed by written procedure on 26 November 2021.

### 5. Scientific topics for discussion

#### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))

The WG was presented updated results of the dose-response analysis for the relationship between plasma and selenium intake. Feedback was collected and next steps were discussed. The WG discussed the collected evidence on selenium intake and markers of thyroid function, measures of glucose homeostasis and markers of liver dysfunction and damage.

### 6. Any Other Business

Not Applicable.

### 7. Next meeting

The next meeting will be held on 10 December 2021 as a web-meeting.

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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)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 16<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 16-17 November 2021 via web-meeting

(Agreed on 26 November 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J., Vinceti Marco.

#### Hearing Expert:

Schlatter Josef<sup>1</sup>

#### EFSA:

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Matijevic Leonard, Sofroniou Angeliki, Titz Ariane, Valtueña Martinez Silvia

AMU Unit: Martino Laura

#### Others:

European Commission: Bendadani Carolin

### 1. Welcome and apologies for absence

Pentieva Kristina has requested to suspend her participation in the WG on UL until further notice.

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<sup>1</sup> Present only for the meeting on 16 November 2021

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 14<sup>th</sup> Working Group meeting held on 04 October 2021 via web-conference.

The minutes of the 15<sup>th</sup> Working Group meeting were agreed by written procedure on 29 October 2021.

## 5. Scientific topics for discussion

### 5.1. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission (EFSAQ-2021-00364)

The draft of the revised guidance for establishing and applying ULs for vitamins and minerals was discussed by the WG and finalised. This document provides an updated framework based on the previous guidelines formulated by the Scientific Committee on Food (SCF) in 2000. The draft of the revised guidance will be presented and discussed in the 119<sup>th</sup> NDA Plenary meeting which will be held on 24<sup>th</sup> November 2021, for possible endorsement. It is foreseen that the document will be applied in EFSA's future assessments during a 1-year pilot phase and it will be revised and complemented as necessary after that period. The finalisation and public consultation on the document are expected in 2023.

## 6. Any Other Business

The WG was updated about the on-going appraisal of studies eligible for the re-evaluation of the UL for selenium.

## 7. Next meeting

The next meeting will be held on 30 November 2021 as a web-meeting.

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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)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 15<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 19-20 and 22 October 2021 via web-meeting

(Agreed on 29 October 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Aggett Peter, Crous Bou Marta, Cubadda Francesco, McArdle Harry J., Pentieva Kristina, Vinceti Marco.

#### Hearing Expert:

Flynn Albert<sup>1</sup>

#### EFSA:

NUTRI Unit: Ciok Janusz, Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Sofroniou Angeliki, Titz Ariane

AMU Unit: Ciccolallo Laura, Martino Laura

#### Others:

European Commission: Bendadani Carolin<sup>2</sup>

### 1. Welcome and apologies for absence

Apologies for absence were received from Marta Crous Bou and Peter Aggett for the last meeting day, 22 October 2021.

<sup>1</sup> Present for the discussion on the report of the workshop on data and methodologies for establishing tolerable upper intake levels (ULs)

<sup>2</sup> Present on 19 and 20 October

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 14<sup>th</sup> Working Group meeting held on 04 October 2021 via web-conference.

The **minutes of the 14<sup>th</sup> Working Group meeting** were agreed by written procedure on 11 October 2021.

## 5. Scientific topics for discussion

### 5.1. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission ([EFSA-Q-2021-00364](#))

The report of the workshop on data and methodologies for establishing tolerable upper intake levels (ULs) for vitamins and minerals, which was organised by EFSA on 28-29 September, was presented to the WG. It will be published as an Event report on EFSA's website.<sup>5</sup> The draft of the revised guidance on UL was discussed by the WG and elaborated. The draft guidance will be further discussed in the next WG meeting.

### 5.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))

Preliminary results of the analysis of the dose-response between selenium intake and plasma/serum selenium concentration was presented to the WG and feedback was collected. The status and next steps of the systematic reviews on selenium intake and selenosis-related outcomes and risk of chronic diseases were discussed.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 16-17 November 2021 as a web-meeting.

<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://www.efsa.europa.eu/en/publications>



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 14<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 4 October 2021 via web-meeting

(Agreed on 11 October 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco, McArdle Harry J.

#### Hearing Expert:

Flynn Albert<sup>1</sup>

EFSA: NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Matijevic Leonard, Sofroniou Angeliki, Titz Arianne

AMU Unit: Ciccolallo Laura, Martino Laura

#### Others:

European Commission: Bendadani Carolin

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted without changes.

<sup>1</sup> Present for discussion of item 5.1



### 3. Declarations of Interest of Working Group 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 13<sup>th</sup> Working Group meeting held on 23 September 2021 via web-conference.

The [minutes of the 13th Working Group meeting](#) were agreed by written procedure on 1 October 2021.

### 5. Scientific topics for discussion

#### 5.1. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission ([EFSA-Q-2021-00364](#))

The WG debriefed about the workshop on data and methodologies for establishing tolerable upper intake levels (ULs) for vitamins and minerals held on 28-29 September 2021. The input collected from the workshop and structure of the technical report of the event were discussed. The report will be published in November.

#### 5.2. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)

The WG discussed aspects related to the risk of bias appraisal of eligible studies and the workplan.

### 6. Any Other Business

Not applicable.

### 7. Next meeting

The next meeting will be held on 19-20 October 2021 as a web-meeting.

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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)



NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 13<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 23 September 2021 via web-meeting

(Agreed on 1 October 2021)

### Participants

Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco, McArdle Harry J.

EFSA:

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, De Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Matijevic Leonard, Sofroniou Angeliki, Titz Ariane

AMU Unit: Ciccolallo Laura

Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 12<sup>th</sup> Working Group meeting held on 1-2 September 2021 via web-conference.

The [minutes of the 12th Working Group meeting](#) were agreed by written procedure on 9 September 2021.

### 5. Scientific topics for discussion

#### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission ([EFSA-Q-2020-00618](#))

The WG was updated about the status of the selenium project. Preliminary results of the analysis of the dose–response relationship between plasma concentrations and selenium intake were presented to the WG and feedback was collected. The WG also discussed the risk of bias (RoB) appraisal on studies reporting on Type 2 Diabetes Mellitus (T2DM) incidence and reviewed the evidence on measures of glucose homeostasis, all-cause mortality and prostate cancer. In addition, an overview of the evidence collected on selenium intake and clinical symptoms of selenosis and/or markers of effect was presented to the WG and next steps were discussed.

### 6. Any Other Business

Not applicable.

### 7. Next meeting

The next meeting will be held on 04 October 2021 as a web-meeting.

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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)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 12<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 1-2 September 2021 via web-meeting

(Agreed on 9 September 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco, McArdle Harry J.

#### Hearing Expert:

Flynn Albert

#### EFSA:

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, De Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Sofroniou Angeliki, Titz Ariane, Valtueña-Martinez Silvia

AMU Unit: Ciccolallo Laura, Martino Laura

#### Others:

European Commission: Bendadani Carolin, Bodenbach Stephanie

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Group 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 10<sup>th</sup> Working Group meeting held on 20-21 July 2021 via web-conference.

The minutes of the 11th Working Group meeting were agreed by written procedure on 31 July 2021.

### 5. Scientific topics for discussion

#### 5.1. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission (EFSA-Q-2021-00364)

An update on the organisation of the workshop on data and methodologies for establishing tolerable upper intake levels (ULs) for vitamins and minerals (28-29 September 2021) was presented to the WG. Around 30 individuals have been invited to participate to the workshop discussions, including members of the NDA Panel, the WG on UL and external experts. Workshop participants were invited based on their experience in expert committees in charge of establishing DRVs and/or their expertise in areas such as nutrition, epidemiology, toxicology, food safety risk assessment. The input collected at the workshop will be used by the WG in its revision of the ULs guidelines. The discussion paper and the workshop programme were discussed and amended with the WG. These documents will be sent to the workshop participants as a preparatory material for the event.

### 6. Any Other Business

Not applicable.

### 7. Next meeting

The next meeting will be held on 23 September 2021 as a web-meeting.

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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)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 11<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 20-21 July 2021 via web-meeting

(Agreed on 31 July 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco, McArdle Harry J.

#### Hearing Expert:

Albert Flynn<sup>1</sup>

#### EFSA:

NUTRI Unit: De Matteu Monteiro Constanza, De Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Kalmpourtzidou Alik, Matijevic Leonard, Titz Ariane, Valtueña-Martinez Silvia<sup>1</sup>

AMU Unit: Ciccolallo Laura, Martino Laura<sup>1</sup>, Munoz-Guajardo Irene<sup>2</sup>

DATA Unit: Arcella Davide<sup>1</sup>, Gergelová Petra<sup>1</sup>

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

<sup>1</sup> Present for discussion of item 5.2

<sup>2</sup> Present for discussion of item 5.1

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 10<sup>th</sup> Working Group meeting held on 29 June 2021 via web-conference.

The **minutes of the 10th Working Group meeting** were agreed by written procedure on 6 July 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)

The WG was presented with an overview of the studies which have been identified as useful for the analysis of the dose–response relationship between plasma and selenium intake. Preliminary results of this modelling have also been presented. The WG discussed the inclusion/exclusion of studies for specific outcomes of interest, and the tools for the appraisal of risk of bias (RoB) for the studies on selenium and chronic diseases endpoints.

### 5.2. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission (EFSA-Q-2021-00364)

The WG discussed the data and strategy to inform the intake assessment of the vitamins and minerals under review. The discussion paper for the workshop on data and methodologies for establishing ULs (28-29 September 2021) was discussed and amended by the WG and the workshop programme was refined. It outlines the topics on which the WG would like to receive input from the workshop participants. The discussion paper will be further developed and will be finalised at the next WG meeting.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 1-2 September 2021 as a web-meeting.

<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)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 10<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 29 June 2021 via web-meeting

(Agreed on 06 July 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Flynn Albert<sup>1</sup>

#### European Commission and/or Member States representatives:

Bendadani Carolin

#### EFSA:

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, de Sesmaisons Lecarré Agnès, Heng Leng, Kalmpourtzidou Alik, Titz Ariane

AMU Unit: Ciccolallo Laura

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Marta Crous Bou.

<sup>1</sup> Present for discussion on item 5.2 only



## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 14 June 2021 via web-conference.

The **minutes of the 9th Working Group meeting** were agreed by written procedure on 19 June 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)

The WG was updated about the status of the selenium project. Feedback was received on the systematic review of chronic diseases and selenium for the outcome of Type 2 Diabetes Mellitus. Methodological issues related to the analysis of the dose-response relationship between plasma and selenium intake were discussed.

### 5.2. Update of the SCF guidelines on establishing tolerable upper intake levels for vitamins and minerals, submitted by the European Commission (EFSA-Q-2021-00364)

Article 6 of Regulation (EC) No 1925/2006<sup>4</sup>, on the addition of vitamins and minerals and of certain other substances to foods and Article 5 of Directive 2002/46/EC<sup>5</sup> on the approximation of the laws of the Member States relating to food supplements provide that maximum amounts of vitamins and minerals added to foods and to food supplements respectively, shall be set. In this context, the European Commission has requested EFSA to review the previous opinions of the Scientific Committee on Food (SCF) or the NDA Panel on the ULs for vitamin A, folic acid/ folate, vitamin D, vitamin E, Vitamin B6, iron, manganese and  $\beta$ -carotene to take into account recent scientific developments and evidence. Before conducting this task, the European Commission has requested EFSA to review the guidelines of the SCF for the development of tolerable upper intake levels for vitamins and minerals (adopted on 19 October 2000<sup>6</sup>) in the light of available recent scientific and methodological developments. EFSA will organise a workshop to discuss data and methodologies for establishing tolerable upper intake levels and collect feedback from

<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://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1925&from=EN>

<sup>5</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=DA>

<sup>6</sup> [https://www.efsa.europa.eu/sites/default/files/efsa\\_rep/blobserver\\_assets/ndatolerableuil.pdf](https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf)

**external experts regarding the update of the guidelines. The workshop will be held as a virtual meeting on the 28 and 29 September 2021. Topics to be addressed in the workshop were discussed and will be further refined in the next WG meeting.**

## **6. Any Other Business**

The Chair informed the working group that Harry McArdle, member of the NDA Panel and ex-member of the working group on dietary reference values for minerals, will join the working group as a member as of the next meeting. This is a valuable addition given his expertise in nutrient risk assessments and trace elements, given the new mandate on the revision of selected minerals and vitamins received from the European Commission (item 5.2).

## **7. Next meeting**

The next meeting will be held on 20 and 21 July 2021 as a web-meeting.



NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 9<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 14 June 2021 via web-meeting

(Agreed on 19 June 2021)

### Participants

**Working Group Members:**

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

**Hearing Expert:**

Not applicable

**European Commission and/or Member States representatives:**

Bendadani Carolin, Bodenbach Stephanie

**EFSA:**

NUTRI Unit: Craciun Ionut, De Matteu Monteiro Constanza, De Sesmaisons Lecarré Agnès, Fabiani Lucia, Heng Leng, Kalmpourtzidou Alik, Matijevic Leonard, Titz Ariane, Valtuena-Martinez Silvia<sup>1</sup>

AMU Unit: Cafaro Angelo<sup>1</sup>, Ciccolallo Laura, Da Costa Irene<sup>1</sup>, Ercolano Valeria<sup>1</sup>, Martino Laura<sup>1</sup>, Munoz-Guajardo Irene<sup>1</sup>

DATA Unit: Arcella Davide<sup>1</sup>, Gergelova Petra<sup>1</sup>

**Others:**

Not Applicable

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<sup>1</sup> Only for item 4

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 8<sup>th</sup> Working Group meeting held on 22 April 2021 via web-conference.

The **minutes of the 8th Working Group meeting** were agreed by written procedure on 26 April 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)

The WG was informed on the receipt of the mandate from the European Commission (EC) for the revision of the principles for establishing Tolerable Upper Intake Level (ULs) and the update of ULs for selected micronutrients. The work strategy developed by EFSA Staff in response to this mandate and the planning for the specific activities foreseen was presented. The WG was informed of the status of the systematic review of the literature conducted to inform the revision of ULs for Selenium. The screening and the data extraction of the literature on Type 2 Diabetes Mellitus (T2DM) was completed; the WG discussed the related strategy for the dose-response meta-analysis and the appraisal of risk of bias in eligible studies. The collection of evidence on the other health outcomes is in progress.

## 6. Any Other Business

Not applicable.

## 7. Next meeting

The next meeting will be held on 29 June 2021 as a web-meeting.

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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)



NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 8<sup>th</sup> MEETING OF THE WORKING GROUP ON TOLERABLE UPPER INTAKE LEVELS

Held on 22 April 2021 via web-meeting

(Agreed on 26 April 2021)

### Participants

**Working Group Members:**

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

**Hearing Expert:**

Not applicable

**European Commission and/or Member States representatives:**

Bendadani Carolin

**EFSA:**

NUTRI Unit: Craciun Ionut, de Sesmaisons Lecarré Agnès, Fabiani Lucia, Kalmpourtzidou Alik, Matijevic Leonard

**Others:**

Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 7<sup>th</sup> Working Group meeting held on 26 March 2021 via web-conference.

The **minutes of the 7th Working Group meeting** were agreed by written procedure on 06 April 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)

The WG was informed about the status of the systematic review of the literature conducted to inform the revision of the Tolerable Upper Intake Level (UL) for Selenium. The screening of the literature is in progress. The WG discussed inclusion/exclusion criteria of studies conducted in diseased populations. The WG was informed about the draft mandate received from the European Commission on the revision of the ULs for vitamins and minerals and discussed the strategy and the planning for the revision of the principles for establishing ULs. The WG was also informed about the activities of the International Liaison Group on Nutrient Reference Values Methodologies.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 14 June 2021 as a web-meeting.

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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)



NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

Held on 26 March 2021 via web-meeting

(Agreed on 06 April 2021)

### Participants

**Working Group Members:**

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

**Hearing Expert:**

Not applicable

**European Commission and/or Member States representatives:**

Bendadani Carolin

**EFSA:**

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia

AMU Unit: Ciccolallo Laura, Munoz Guajardo Irene

**Others:**

Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 6<sup>th</sup> Working Group meeting held on 09 March 2021 via web-conference.

The **minutes of the 6th Working Group meeting** were agreed by written procedure on 15 March 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the Upper Level (UL) for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)<sup>3</sup>

The WG discussed the strategy for the characterisation of a quantitative relationship between selenium intake and serum/plasma levels and possible approaches for addressing infants, children, pregnant and lactating women in the risk assessment. The process of appraising the internal validity of individual studies, related critical appraisal tools and their tailoring to specific research questions was presented to the WG. The WG also received an update on the status of the upcoming mandate on the revision of the ULs for vitamins and minerals.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 22 April 2021 as a web-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)

<sup>3</sup> Please be aware that EFSA's Register of Questions is unavailable from 21 January. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)





NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

Held on 09 March 2021 via web-meeting

(Agreed on 15 March 2021)

### Participants

Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

Hearing Expert:

Not applicable

European Commission and/or Member States representatives:

Not applicable

EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia

AMU Unit: Ciccolallo Laura, Munoz Guajardo Irene

Others:

Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 5<sup>th</sup> Working Group meeting held on 11-12 February 2021 via web-conference.

The **minutes of the 5th Working Group meeting** were agreed by written procedure on 17 February 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the UL for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)<sup>3</sup>

The Working Group (WG) was informed about the feedback received from the **NDA Panel during its 111<sup>st</sup> Plenary on 25 February 2021** on the approach proposed for the revision of the tolerable upper intake levels for selenium and the main sections of the draft protocol. The WG continued the discussion on the development of the draft protocol. The following aspects were addressed: problem formulation, dietary selenium and intake assessment, selection of health outcomes to be considered in the risk assessment, and eligibility criteria for the literature search. Preliminary results of the literature search strategy were also presented to the WG. The protocol will be further elaborated by EFSA staff and further discussed by the WG at its next meeting.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 26 March 2021 as a web-meeting

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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> Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

Held on 11-12 February 2021 via web-meeting

(Agreed on 17 February 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Not applicable

#### European Commission and/or Member States representatives:

Bendadani Carolin, Bodenbach Stephanie

#### EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia<sup>1</sup>

AMU Unit: Ciccolallo Laura, Martino Laura, Munoz Guajardo Irene

DATA Unit: Arcella Davide<sup>1</sup>

#### Others:

Not Applicable

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<sup>1</sup> Only on 11 February

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 4<sup>th</sup> Working Group meeting held on 25 January 2021 via web-conference.

The **minutes of the 4th Working Group meeting** were agreed by written procedure on 31 January 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the UL for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)<sup>4</sup>

The Working Group (WG) continued the discussion on the development of the protocol for the review of the tolerable upper intake levels for selenium. The following aspects were addressed: biomarkers of selenium intake and status, prioritisation of health outcomes to be considered in the risk assessment, and eligibility criteria for the literature search. The protocol will be elaborated by EFSA staff and further discussed by the WG at its next meeting.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 9 March 2021 as a web-meeting.

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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> Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 4<sup>th</sup> MEETING OF THE WORKING GROUP ON UPPER LEVELS

Held on 25 January 2021 via web-meeting

(Agreed on 31 January 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Not applicable

#### European Commission and/or Member States representatives:

Bodenbach Stephanie

#### EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia

AMU Unit: Martino Laura, Munoz Guajardo Irene

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 3<sup>rd</sup> Working Group meeting held on 21 December 2020 via web-conference.

The **minutes of the 3<sup>rd</sup> Working Group meeting** were agreed by written procedure on 4 January 2021.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the UL for Selenium, submitted by the European Commission (EFSA-Q-2020-00618)<sup>3</sup>

The Working Group (WG) pursued the development of the protocol for the review of the tolerable upper intake levels for selenium. The following aspects were addressed: formulation of the risk assessment questions regarding the hazard identification and hazard characterisation (conceptual framework); evidence needs to answer the risk assessment questions and eligibility criteria related to study characteristics. The protocol will be elaborated by EFSA staff and further discussed by the WG at its next meeting.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 11-12 February 2021 as a web-meeting.

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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> Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

Held on 21 December 2020 via web-meeting

(Agreed on 4 January 2021)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Not applicable

#### European Commission and/or Member States representatives:

Bodenbach Stephanie

#### EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia, Craciun Ionut

AMU Unit: Ciccolallo Laura, Martino Laura

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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 1<sup>st</sup> and 2<sup>nd</sup> Working Group meeting held on 11 and 14 December 2020 via web-conference.

The minutes of the 1<sup>st</sup> and 2<sup>nd</sup> Working Group meeting were agreed by written procedure on 18 December 2020.

## 5. Scientific topics for discussion

### 5.1. Scientific opinion on the revision of the UL for Selenium, submitted by *the European Commission* (EFSA-Q-2020-00618)

The Working Group (WG) pursued the development of the protocol for the review of the tolerable upper intake levels for selenium (EFSA, 2020). The following aspects were addressed: data and methods to estimate selenium intake in European populations (exposure assessment); formulation of the risk assessment questions regarding the hazard identification and hazard characterisation; identification of relevant types of data that could inform the risk assessment. The protocol will be elaborated by EFSA staff and reviewed and refined by the WG at its next meeting.

## 6. Any Other Business

Not applicable

## 7. Next meeting

The next meeting will be held on 25 January 2021 as a web-meeting.

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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)





## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

Held on 14 December 2020 via web-meeting

(Agreed on 18 December 2020)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Not applicable

#### European Commission and/or Member States representatives:

Bodenbach Stephanie

#### EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia

AMU Unit: Martino Laura

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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. Scientific topics for discussion

### 4.1 Scientific opinion on the Tolerable Upper Intake Level for Selenium (EFSA-Q-2020-00618)

The secretariat presented the risk assessment by the [SCF \(2000\)](#) for setting the tolerable upper intake level (UL) for selenium, which EFSA is requested to update. The mandate was triggered following the NDA Panel's assessment of a selenium rich novel ingredient ([NDA Panel, 2020](#)). The secretariat provided an overview of risk assessments of selenium conducted by other authoritative bodies and of the epidemiological evidence on adverse effects related to selenium excess consumption which have become available since 2000. In line with EFSA's principles for carrying out the scientific assessment process,<sup>3</sup> a protocol for the risk assessment will be developed ([EFSA, 2020](#)). The Working Group (WG) discussed the problem formulation and the risk assessment questions which will inform the drafting of the protocol.

## 5. Any Other Business

Not applicable

## 6. Next meeting

The next meeting will be held on 21 December 2020 as a web-meeting.

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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/methodology/evidence>



## NUTRITION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## MINUTES OF THE 1<sup>st</sup> MEETING OF THE WORKING GROUP ON UPPER LEVELS

Held on 11 December 2020 via web-meeting

(Agreed on 18 December 2020)

### Participants

#### Working Group Members:

Naska Androniki (Chair), Cubadda Francesco, Pentieva Kristina, Crous Bou Marta, Aggett Peter, Vinceti Marco

#### Hearing Expert:

Not applicable

#### European Commission and/or Member States representatives:

Bodenbach Stephanie

#### EFSA:

NUTRI Unit: de Sesmaisons Lecarré Agnès, Fabiani Lucia

#### Others:

Not Applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Group 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. Round of presentations.

All participants introduced themselves to the Working Group.

## 5. How we work

The secretariat provided the WG with information on the responsibilities of WG coordinators, WG members and the Panel and practical information on meeting organisation and on the management of meeting and scientific documents.

## 6. Scientific topics for discussion

### 6.1. Scientific opinion on the UL for Selenium (EFSA-Q-2020-00618)

The secretariat introduced the background and terms of references of the Mandate from the European Commission on the revision of the tolerable upper intake levels (ULs) for selenium. The first meeting of the WG was dedicated to introductory presentations in which the secretariat introduced EFSA's framework for setting Dietary Reference Values (DRVs). In 2000, the Scientific Committee on Food (SCF) – EFSA's predecessor – issued [guidelines for the development of ULs for vitamins and minerals](#). These guidelines outline general principles which have served as the basis for the evaluation of the adverse effects of micronutrients on humans and the setting of ULs carried out by the SCF and EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA). The secretariat presented some of the challenges faced in setting ULs, based on past assessments, and relevant methodological developments at EFSA. Conceptual and methodological developments in other authoritative bodies in charge of establishing nutrient reference values were also presented.

The WG discussed the work programme. The deadline for the publication of the scientific opinion on the UL for selenium is March 2022. Meeting dates for the first half of 2021 were agreed.

## 7. Any Other Business

Not Applicable

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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)

## 8. Next meeting

The next meeting will be held on 14 December 2020 as a web-meeting.