



#### NUTRITION AND FOOD INNOVATION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

# MINUTES OF THE 15th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 04th April 2022 via web-meeting

(Agreed on 07 April 2022)

#### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives: Carolin Bendadani, Fruzsina Nyemecz
- EFSA:

NIF Unit: Ariane Titz , Angeliki Sofroniou

Others:

Anne Molloy as a hearing expert

# 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 14th Working Group meeting

The minutes of the 14th Working Group meeting were agreed by written procedure on 8 March 2022.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The Working Group, together with the hearing expert, discussed and consolidated the conclusions of the scientific opinion and associated uncertainties. The Working Group also consolidated the final DFE conversion factors derived and their application.

# **6. Any Other Business**

Not applicable.

# 7. Next meeting

No further meetings are foreseen.

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf





#### NUTRITION AND FOOD INNOVATION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

# MINUTES OF THE 14th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 03<sup>rd</sup> March 2022 via web-meeting

(Agreed on 08 March 2022)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives: Carolin Bendadani
- EFSA:

NIF Unit: Janusz Ciok, Heng Leng, Angeliki Sofroniou, Ariane Titz

MESE Unit: José Cortiñas Abrahantes

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 13th Working Group meeting

The minutes of the 13th Working Group meeting were agreed by written procedure on 16 February 2022.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The Working Group discussed the statistical report and final adjustments that need to be made, the conclusions of the scientific opinion and associated uncertainties to be described. The Working Group also consolidated on the extrapolation of the findings to specific population groups.

# 6. Any Other Business

Not applicable.

# 7. Next meeting

This was the final WG meeting.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf





#### NUTRITION AND FOOD INNOVATION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

# MINUTES OF THE 13th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 8th February 2022 via web-meeting

(Agreed on 16 February 2022)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives: Fruzsina Nyemecz
- EFSA:

NIF Unit: Janusz Ciok, Heng Leng, Angeliki Sofroniou, Ariane Titz

MESE Unit: José Cortiñas Abrahantes

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 12th Working Group meeting

The minutes of the 12th Working Group meeting were agreed by written procedure on 20 January 2022.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The Working Group discussed the uncertainties associated with the approach taken to derive a conversion factor for 5 methyl-tretrahydrofolate (5MTHF) into Dietary Folate Equivalents (DFE), the possibility to extrapolate the findings obtained in specific population groups to other groups of the general population, and the way in which data from animal and in-vitro studies as well as from single-dose studies could support the results of repeated dose studies in humans.

# **6. Any Other Business**

Not applicable.

## 7. Next meeting

The next meeting will be held on 03 March 2022 as a web-meeting.

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf





#### NUTRITION AND FOOD INNOVATION UNIT

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

# MINUTES OF THE 12th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 14th January 2022 via web-meeting

(Agreed on 20 January 2022)

### **Participants**

Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda

- European Commission and/or Member States representatives:
   Franziska Beese, Carolin Bendadani, Stephanie Bodenbach, Fruzsina Nyemecz
- EFSA:

NIF Unit: Ester Artau Cortacans, Janusz Ciok, Céline Dumas, Heng Leng, Angeliki Sofroniou,

Ariane Titz

AMU Unit: José Cortiñas Abrahantes

Others:

Not applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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 11th Working Group meeting

The minutes of the 11th Working Group meeting were agreed by written procedure on 9 December 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed the outcome on an ad-hoc literature search on red blood cell folate concentrations in infants. Furthermore, the WG agreed on the interpretation of data from repeated-dose studies in humans regarding comparative bioavailability of 5MTHF with folic acid. The WG discussed the corresponding section in the draft opinion.

# **6. Any Other Business**

Not applicable.

# 7. Next meeting

The next meeting will be held on 08 February 2021 as a web-meeting.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 7<sup>th</sup> December 2021 via web-meeting

(Agreed on 09 December 2021)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Heng Leng, Angeliki Sofroniou, Ariane Titz AMU Unit: José Cortiñas Abrahantes, Valeria Ercolano

Others:

Not applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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 10th Working Group meeting

The minutes of the 10th Working Group meeting were agreed by written procedure on 1 December 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed the draft of the statistical report and agreed on the approach to be taken regarding human repeated-dose studies and infant data. Furthermore, the WG discussed the data received via the call for data.

# 6. Any Other Business

Not applicable.

# 7. Next meeting

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

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 19<sup>th</sup> and 22<sup>nd</sup> November 2021 via web-meeting (Agreed on 01 December 2021)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- Hearing Expert: Anne Molloy
- European Commission and/or Member States representatives:
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Heng Leng, Angeliki Sofroniou AMU Unit: José Cortiñas Abrahantes, Valeria Ercolano

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 9th Working Group meeting

The minutes of the 9th Working Group meeting were agreed by written procedure on 27 October 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed the interpretation of the statistical analysis based on aggregated data collected from human repeated-dose studies. The WG also discussed how to calculate total amount of DFE based on these results. Furthermore, the WG discussed the approach for the statistical analysis regarding infants. Possible approaches regarding foods for specific medical purposes in the context of the mandate were also discussed.

## 6. Any Other Business

Not applicable.

#### 7. Next meeting

The next meeting will be held on 7 December 2021 as a web-meeting.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

#### Held on 21 October 2021 via web-meeting

(Agreed on 27 October 2021)

### **Participants**

- Working Group Members:
   Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
   Carolin Bendadani, Fruzsina Nyemecz
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Giovanni Iacono, Heng Leng, Ariane Titz AMU Unit: José Cortiñas Abrahantes, Valeria Ercolano

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

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 8th Working Group meeting

The minutes of the 7th Working Group meeting were agreed by written procedure on 30 September 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed the statistical report on the results of the analysis conducted on data collected from human repeated-dose studies. The WG also discussed the possible interpretations of these results to answer the mandate and how to possibly calculate total amount of DFE based on these results.

# 6. Any Other Business

Not applicable.

# 7. Next meeting

The next meeting will be held on 15 November 2021 as a web-meeting.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 8th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

## Held on 20 September 2021 via web-meeting

(Agreed on 30 September 2021)

#### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
   Carolin Bendadani, Stephanie Bodenbach
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Heng Leng

AMU Unit: José Cortiñas Abrahantes, Valeria Ercolano

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

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 7th Working Group meeting

The minutes of the 6th Working Group meeting were agreed by written procedure on 30 July 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed the first results of the analysis conducted on data collected from human repeated-dose studies, in particular some graphical representations of the results, and discussed possible interpretations. The WG also discussed some of the drafted sections of the opinion regarding their content and structure.

# **6. Any Other Business**

Not applicable.

# 7. Next meeting

The next meeting will be held on 21 October 2021 as a web-meeting.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 7th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 19 July 2021 via web-meeting

(Agreed on 30 July 2021)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
   Stephanie Bodenbach, Fruzsina Nyemecz
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Heng Leng, Ariane Titz

AMU Unit: Valeria Ercolano

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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 6th Working Group meeting

The minutes of the 6th Working Group meeting were agreed by written procedure on 7 July 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed possible approaches for presenting and discussing data from the various study types (i.e. human, animal and in-vitro gastrointestinal systems) in the draft opinion. The WG also discussed and solved minor discrepancies between reviewers on some questions included in the appraisal of studies and then discussed the tiers (per study and outcome) of overall risk of bias.

# 6. Any Other Business

Not applicable.

# 7. Next meeting

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

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 6th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

# Held on 28 June 2021 via web-meeting

(Agreed on 7 July 2021)

### **Participants**

- Working Group Members:
   Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Ariane Titz

AMU Unit: José Cortiñas Abrahantes, Valeria Ercolano

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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 5th Working Group meeting

The minutes of the 5th Working Group meeting were agreed by written procedure on 25 May 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG discussed and agreed on the content of a call for data that will be launched by mid-July. It was decided that the NDA Panel members will be informed during the 116<sup>th</sup> Plenary meeting (6-8 July 2021). The WG was presented with visualisation plots of the biomarkers investigated in chronic studies in humans. The next steps of the data analysis were discussed and agreed.

# 6. Any Other Business

Not applicable.

# 7. Next meeting

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

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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

# MINUTES OF THE 5th MEETING OF THE WORKING GROUP ON

# DIETARY FOLATE EQUIVALENT

Held on 18 May 2021 via web-meeting

(Agreed on 25 May 2021)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives:
   Carolin Bendadani, Stephanie Bodenbach
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Leng Heng, Ariane Titz

AMU Unit: Valeria Ercolano

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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

# 4. Agreement of the minutes of the 4th Working Group meeting

The minutes of the 4<sup>th</sup> Working Group meeting were agreed by written procedure on 26 April 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG had an initial discussion on a draft structure of the opinion. The criteria to be considered for the appraisal of the studies on in-vitro gastrointestinal systems were discussed. The WG also discussed an update on the approach to be taken for the analysis of the data from the included longitudinal studies in healthy humans, missing data and the possible approach to fill the gaps, as well as the next steps for this analysis.

# 6. Any Other Business

Not applicable.

#### 7. Next meeting

The next meeting will be held on 28 June 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/competing\_interest\_management\_17.pdf





# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

# DIETARY FOLATE EQUIVALENT

Held on 19 April 2021 via web-meeting

(Agreed on 26 April 2021)

### **Participants**

- Working Group Members:Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Leng Heng, Ariane Titz

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

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 3rd Working Group meeting

The minutes of the 3<sup>rd</sup> Working Group meeting were agreed by written procedure on 30 March 2021.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-0-2020-00542)

The WG discussed the data extracted from the animal studies included after literature search. Possible criteria for appraisal of the risk of bias of the animal studies were also further discussed. A preliminary proposal of the approach to be taken for the analysis of the data from the included chronic studies in humans and the possible next steps for this analysis were also discussed.

# 6. Any Other Business

Not applicable.

#### 7. Next meeting

The next meeting will be held on 18 May 2021 as a web-meeting.

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

# **DIETARY FOLATE EQUIVALENT**

# Held on 23 March 2021 via web-meeting

(Agreed on 30 March 2021)

### **Participants**

- Working Group Members:
   Kristina Pentieva (Chair), Francesco Cubadda
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Leng Heng, Ariane Titz

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

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 safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)<sup>3</sup>

The WG discussed the data extracted from the acute studies in humans and the in-vitro studies included after literature search. Appraisal of the risk of bias of the included studies, considering various types/designs, was also further discussed.

# 5. Any Other Business

Not applicable.

# 6. Next meeting

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

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;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





# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

# DIETARY FOLATE EQUIVALENT

# Held on 18 February 2021 via web-meeting

(Agreed on 22 February 2021)

### **Participants**

- Working Group Members:Kristina Pentieva, Francesco Cubadda
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Céline Dumas, Leng Heng, Charlotte Salgaard Nielsen, Ariane Titz

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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> Working Group meeting held on 6 November 2020 via web conference.

The minutes of the 1<sup>st</sup> Working Group meeting were agreed by written procedure on 6 November 2020.

# 5. Scientific topics for discussion

# 5.1. Scientific opinion on the safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)<sup>3</sup>

The WG discussed the data extracted from the chronic studies in humans included after literature search, and further discussed on the sections on the appraisal of the risk of bias of the studies and the approach for evidence synthesis in the draft protocol.

# 6. Any Other Business

Not applicable.

#### 7. Next meeting

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

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;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





# Scientific Panel on Nutrition, Novel Foods and Food Allergens

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

# DIETARY FOLATE EQUIVALENT

## Held on 06 November 2020 via web-meeting

(Agreed on 06 November 2020)

### **Participants**

- Working Group Members: Kristina Pentieva, Francesco Cubadda
- European Commission and/or Member States representatives:Fruzsina Nyemecz
- EFSA:

NUTRI Unit: Ester Artau Cortacans, Janusz Ciok, Céline Dumas, Leng Heng, Charlotte Salgaard Nielsen, Ariane Titz

Others:

Not Applicable

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

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 safety of Dietary Folate Equivalent, submitted by the European Commission (EFSA-Q-2020-00542)

The WG was provided with background information on the mandate on the assessment of the scientific evidence on the conversion factor of calcium-L-methylfolate and (6S)-5-methyltetrahydrofolic acid, glucosamine salt into dietary folate equivalent. The WG also discussed a draft protocol for the assessment, including the type of evidence that will be used. The protocol will be further discussed in the next WG meeting. The secretariat informed the WG about the status of the screening of the literature.

# 5. Any Other Business

Not applicable.

# 6. Next meeting

The next meeting will be held on 07 December 2020 as a web-meeting.

<sup>&</sup>lt;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/competing\_interest\_management\_17.pdf