



NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 5<sup>th</sup> MEETING OF THE WORKING GROUP ON THE UNCERTAINTY FACTOR FOR COPPER HBGVs

**Held on 31 January, via web-conference**

**(Agreed on 3 February 2020)**

### Participants

- Working Group Members:  
Harry McArdle (chair), Peter Aggett, Josef Schlatter
- Hearing Experts:  
Not Applicable
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
NUTRI Unit: Agnès de Sesmaisons-Lecarré, Charlotte Salgaard Nielsen  
SCER Unit: Jean-Lou Dorne  
PREV: Danièle Court Marques

### 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 Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### **4. Agreement of the minutes of the 4<sup>th</sup> Working Group meeting held on 23-24 January 2020 in Parma**

The **minutes of the 4<sup>th</sup> Working Group meeting** held on 23-24 January 2020 in Parma were adopted orally on 31 January 2020.

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

The final draft of the scientific output was reviewed by the WG. The work is expected to be shared with the NDA Panel for possible endorsement at the next Plenary on 25 February 2020.

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

The next meeting of the WG will take place on 20 April 2020 via web-conference.

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

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



NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 4<sup>th</sup> MEETING OF THE WORKING GROUP ON THE UNCERTAINTY FACTOR FOR COPPER HBGVs

**Held on 23-24 January, Parma**

**(Agreed on 31 January 2020)**

### Participants

- Working Group Members:  
Harry McArdle (chair), Peter Aggett, Josef Schlatter
- Hearing Experts:  
Dr Tomas Moeller (Federal Institute for Risk Assessment, Germany)
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
NUTRI Unit: Agnès de Sesmaisons-Lecarré, Charlotte Salgaard Nielsen  
SCER Unit : Jean-Lou Dorne  
PREV: Danièle Court Marques

### 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 Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### 4. Agreement of the minutes of the 3<sup>rd</sup> Working Group meeting held on 18 December 2019 via web-conference

The [minutes of the 3<sup>rd</sup> Working Group meeting](#) held on 18 December 2019 via web-conference were agreed by written procedure on 23 December 2019.

### 5. Scientific topics for discussion

The draft opinion was comprehensively reviewed by the WG. Hearing expert Dr Moeller from the Federal Institute for Risk Assessment (BfR), Germany, shared his comments with the WG.

The overall discussion and conclusions were revised in the light of newly identified evidence on copper homeostasis, retention and related effects.

The opinion will be finalised at the next web-meeting of the WG for submission to the NDA Panel at the next Plenary meeting scheduled on 25 February.

### 6. Next meeting(s)

The next meeting of the WG will take place on 31 January 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)



NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 3<sup>rd</sup> MEETING OF THE WORKING GROUP ON THE UNCERTAINTY FACTOR FOR COPPER HBGVs

**Held on 18 December, via web-conference**

**(Agreed on 23 December 2019)**

### Participants

- Working Group Members: Harry McArdle (chair),  
Peter Aggett  
Josef Schlatter
- Hearing Experts:  
Not Applicable
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
NUTRI Unit: Agnès de Sesmaisons Lecarré, Charlotte Salgaard Nielsen  
SCER Unit : Jean-Lou Dorne

### 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 Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### 4. Agreement of the minutes of the 2<sup>nd</sup> Working Group meeting held on 6 November 2019 in Parma

The [minutes of the 2<sup>nd</sup> Working Group meeting](#) held on 6 November 2019 via web-conference were agreed by written procedure on 18 November 2019.

### 5. Scientific topics for discussion

The latest developments of the draft opinion were considered by the WG. Evidence table regarding copper requirement, toxicokinetic and toxicodynamic were reviewed. The WG reviewed available data from human studies which investigated potential adverse effects of copper supplementation in different population groups, namely healthy adults, infants and the elderly. The WG agreed on a rationale to select an uncertainty factor to derive a HBGV for copper. Tasks were distributed to the WG members.

### 6. Next meeting(s)

The next meeting of the WG will take place on 23-24 January 2020 in Parma.

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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 THE UNCERTAINTY FACTOR FOR COPPER HBGVs

**Held on 6 November, Parma**

**(Agreed on 18 November 2019)**

### Participants

- Working Group Members:  
Harry McArdle (chair)  
Peter Aggett  
Josef Schlatter
- Hearing Experts:  
Not Applicable
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
NUTRI Unit: Agnès de Sesmaisons Lecarré  
SCER Unit : Jean-Lou Dorne

### 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 Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### **4. Agreement of the minutes of the 1st Working Group meeting held on 19-20 September 2019, Parma**

The minutes of the 1<sup>st</sup> Working Group meeting held on 19-20 September 2019 in Parma were agreed by written procedure on 26 September 2019.<sup>3</sup>

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

The last developments of the draft opinion were considered by the WG. Available data and data gaps in relation to the characterisation of copper toxicokinetics and toxicodynamics in the general population were discussed. The selection of appropriate uncertainty factors for micronutrients must consider potential effects in relation to both nutritional deficiency and toxicity. The two aspects will need to be integrated in the assessment. The principles set out in the SC Guidance on weight of evidence will be applied. Tasks were distributed among the WG members.

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

The next meeting of the WG will take place on the 18<sup>th</sup> of December (webmeeting).

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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> <http://www.efsa.europa.eu/sites/default/files/wqs/nutrition/wq-copper-uncertainty-factor.pdf>





NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 1<sup>st</sup> MEETING OF THE WORKING GROUP ON THE UNCERTAINTY FACTOR FOR COPPER HBGVs

**Held on 19-20 September, Parma**

**(Agreed on 26 September 2019)**

### Participants

- Working Group Members:  
Harry McArdle (chair)  
Peter Aggett  
Josef Schlatter
- Hearing Experts:  
Not Applicable
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
NUTRI Unit: Agnès de Sesmaisons Lecarré, Valeriu Curtui  
SCER Unit : Jean-Lou Dorne  
PREV Unit : Daniele Court Marques

### 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 Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### **4. Scientific topics for discussion**

The mandate was presented to the working group. The NDA Panel is requested to provide scientific advice on the uncertainty factor (UF) to be applied in deriving a HBGV for copper. The hazard identification and hazard characterisation should draw from existing safety assessments of copper. The assessment should focus on the last step of the process leading to derive a HBGV, namely the choice of the UF. The mandate is limited to risks associated with oral exposure.

Previous safety assessments of copper, by EFSA and other bodies, were presented, including the critical human and clinical studies used and the rationale applied to select an uncertainty factor in the respective assessments. An overview of the data available on copper kinetics was provided and options for selecting an UF were outlined.

The working group formulated the problem, taking into account that, specific to nutrients like copper, the application of an UF should also take into consideration the nutritional needs. Possible approaches, and related data requirements and methodologies were discussed. The possibility of modelling copper hepatic metabolism, in order to identify critical events on the path to toxicity and related dose-responses, was considered and will be explored further. A draft structure for the output was agreed and tasks were allocated.

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

The next meeting of the WG will take place on the 6<sup>th</sup> of November, in Parma.

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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)