

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 6<sup>th</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

Held on 2-3 March 2017

(Agreed on 3 March 2017)

#### Participants

##### ■ Working Group Members:

- David Gott, Claude Lambre, Alicja Mortensen (Chair), Peter Moldeus and Woutersen Ruud.
- Peter Moldeus participated via teleconference (on 3rd March).

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

Not present

##### ■ EFSA:

- FIP Unit: Federica Lodi
- AMU Unit: Laura Ciccolallo

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Riccardo Crebelli.

#### 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 and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>,

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Discussion on the additional data provided**

A general discussion took place on the final set of additional data provided from the Ramazzini Institute following request from EFSA.

#### **5. Scientific topic for discussion**

##### **5.1 Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

The Working Group discussed the draft opinion and agreed on the revisions proposed by the participants. The opinion will be discussed at a forthcoming ANS Plenary meeting.

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

None

#### **7. Agreement of the minutes**

The minutes of the 6<sup>th</sup> Working Group meeting held on 2-3 March 2017 were agreed.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 5<sup>th</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

**Held on 23-24 January 2017**

**(Agreed on 24 January 2017)**

#### **Participants**

■ **Working Group Members:**

- David Gott, Claude Lambre, Alicja Mortensen (Chair) and Woutersen Ruud.
- Peter Moldeus participated via teleconference (on 23rd January).

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

Not present

■ **EFSA:**

- FIP Unit: Federica Lodi
- AMU Unit: Laura Ciccolallo

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

The Chair welcomed the participants.

Apologies were received from Riccardo Crebelli and from David Gott (on the 23<sup>rd</sup> January).

## **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 and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## **4. Discussion on the additional data provided**

A discussion on the additional data provided from the Ramazzini Institute as a follow up of the technical hearing took place. The WG identified the need to ask for further data to the Ramazzini Institute.

## **5. Scientific topic for discussion**

### **5.1 Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

The Working Group discussed specific parts of the draft opinion and agreed on the revisions proposed by the participants. The opinion will be discussed at a forthcoming Working group meeting.

## **6. Any Other Business**

None

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>

## **7. Agreement of the minutes**

The minutes of the 5<sup>th</sup> Working Group meeting held on 23-24 January 2017 were agreed.

## **8. Next meetings**

The next meeting will be held in Parma on 2-3 March 2017.

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 4<sup>th</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

Held on 16 December 2016, by web-conference

(Agreed on 16 December 2016)

#### Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Claude Lambré, Peter Moldeus and Ruud Woutersen.

- **EFSA:**

FIP Unit: Paolo Colombo, Federica Lodi

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Riccardo Crebelli.

#### 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 and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Scientific topic for discussion**

##### **4.1 Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

The Working Group discussed specific parts of the draft opinion and agreed on the revisions proposed by the participants. The opinion will be discussed at a forthcoming Working group meeting.

#### **5. Any Other Business**

None

#### **6. Agreement of the minutes**

The minutes of the 4<sup>th</sup> Working Group meeting held by web-conference on 16 December 2016 were agreed.

#### **7. Next meetings**

The next meetings will be held in Parma on 23-24 January 2017 and 10 February 2017.

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<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 3<sup>rd</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

**Held on 22 November 2016, Parma (Italy)**

**(Agreed on 22 November 2016)**

#### **Participants**

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Claude Lambré and Ruud Woutersen.

- **EFSA:**

FIP Unit: Paolo Colombo, Federica Lodi

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

The Chair welcomed the participants.

Apologies were received by Riccardo Crebelli and Peter Moldeus.

#### **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 and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 2<sup>nd</sup> Working Group meeting held on 10 November 2016**

The minutes of the 2<sup>nd</sup> Working Group meeting held on 10 November 2016 were agreed.

#### **5. Scientific topic for discussion**

##### **5.1 Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

The Working Group discussed specific parts of the draft opinion and agreed on the revisions proposed by the participants. The opinion will be discussed at a forthcoming Working group meeting.

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

None

#### **7. Agreement of the minutes**

The minutes of the 3<sup>rd</sup> Working Group meeting held on 22 November 2016 were agreed.

#### **8. Next meeting**

The next meeting will be held via webconference on 16 December 2016.

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<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 2<sup>nd</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

**Held on 10 November 2016, Parma (Italy)**

**(Agreed on 22 November 2016)**

#### **Participants**

■ **Working Group Members:**

Alicja Mortensen (Chair), Riccardo Crebelli, David Gott, Claude Lambré, Peter Moldeus, Ruud Woutersen

■ **Hearing Experts**

Fiorella Belpoggi, Laura Falcioni, Isabella Manzoli, Eva Tibaldi

■ **European Commission**

Andreia Alvarez Porto, Guillermo Cardon (DG SANTE E2)

■ **EFSA:**

AMU Unit: Laura Ciccolallo

COMM Unit: Anthony Smith

FIP Unit: Paolo Colombo, Federica Lodi, Claudia Roncancio-Peña

#### **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 with a change: the item "adoption of minutes" was removed.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

### 4. Hearing experts

Dr Belpoggi, Dr Falcioni, Dr Manzoli and Dr Tibaldi were invited to elaborate on the specific questions they were called upon to answer for the specific topic on behalf of the Ramazzini Institute. They attended the meeting on 10 November 2016 from 13:00 to 14:45.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA invited Dr Belpoggi, Dr Falcioni, Dr Manzoli and Dr Tibaldi to submit an ADoI. Their participation was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework.

### 5. Scientific topic for discussion

#### **Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

Upon request from EFSA, representatives of Ramazzini Institute were given the opportunity to present at a technical hearing the experimental design of the study conducted in mice with sucralose, the results obtained and to elaborate about the additional information available. Following discussion during the hearing, a number of points requiring further clarification were identified. After the hearing was finished, and the hearing experts left the room, the WG briefly discussed the clarifications provided by Ramazzini Institute.

EFSA will follow up by providing the applicant with a written summary of the points discussed with the next steps and relative timelines.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>

## **6. Any Other Business**

None

## **7. Next meeting**

The next meeting will be held in Parma on 22 November 2016.

## Scientific Panel on Food Additives and Nutrient Sources added to Food

### Minutes of the 1<sup>st</sup> meeting of the Working Group on the assessment of a carcinogenicity study on sucralose

**Held on 18 October 2016, Parma (Italy)**

**(Agreed on 18 October 2016)**

#### **Participants**

- **Working Group Members:**

Alicja Mortensen (Chair), Riccardo Crebelli, Claude Lambré, Peter Moldeus, Ruud Woutersen.

- **EFSA:**

FIP Unit: Paolo Colombo, Federica Lodi

#### **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 and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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

##### **4.1. Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) (EFSA-Q-2016-00251)<sup>3</sup>**

Further to the review of the technical report submitted by Ramazzini Institute in support to its publication, a number of points were raised which would need to be followed-up with the authors to ensure a proper assessment of the results of the study.

For this reason the Working Group decided to request additional information and a technical hearing to be held with representatives of Ramazzini Institute.

The draft opinion will be scheduled for discussion and possible finalisation at a forthcoming meeting after the technical hearing takes place.

#### **5. Any Other Business**

The minutes of the meeting were agreed.

#### **6. Next meeting**

Next meeting will be held in Parma on 22 November 2016.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00251>