

**Nutrition Unit (NUTRI UNIT)**

**Scientific Panel on Dietetic Products, Nutrition and Allergy (NDA)**

**Minutes of the 62<sup>nd</sup> Plenary meeting**

**Held on 09-12 December 2014, Parma (Italy)**

**(Agreed on 5 February 2015)**

**Participants**

• **Panel Members:**

Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait<sup>1</sup>, Hannu Korhonen, Sébastien La Vieille<sup>2</sup>, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz<sup>3</sup>, Alfonso Siani<sup>4</sup>, Anders Sjödin<sup>5</sup>, Martin Stern, Inge Tetens<sup>6</sup>, Daniel Tomé, Dominique Turck and Hans Verhagen<sup>7</sup>.

• **Hearing Experts<sup>8</sup>:**

- Not applicable.

• **European Commission representatives:**

- Basil Mathioudakis<sup>9</sup> and Olga Goulaki<sup>10</sup>.

• **EFSA:**

- Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Mieke Peters, Christos Stefanidis, Ariane Titz, Emanuela Turla and Silvia Valtueña Martínez

• **Observers:**

- Not applicable.

• **Others:**

- Not applicable.

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<sup>1</sup> Present on 9-11 December, and via teleconference on 12 December.

<sup>2</sup> Present on 9-11 December.

<sup>3</sup> Present on 10-12 December.

<sup>4</sup> Present on 9-11 December.

<sup>5</sup> Present on 10-11 December.

<sup>6</sup> Present via teleconference on 10, 11 and 12 December.

<sup>7</sup> Present on 9-10 December, and via teleconference on 11 and 12 December.

<sup>8</sup> As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:  
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>9</sup> Present on 10-11 December.

<sup>10</sup> Present on 10-12 December.

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Marina Heinonen and Sean Strain.

## 2. Adoption of agenda

The agenda was adopted with changes in the order of items discussed.

## 3. Declarations of Interest of Scientific Committee/Scientific Panel/Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>11</sup> and the Decision of the Executive Director on Declarations of Interest<sup>12</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Committee Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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 61<sup>st</sup> Plenary meeting held on 29-31 October 2014, Parma (Italy)

The minutes of the 61<sup>st</sup> Plenary meeting held on 29-31 October 2014 were agreed by written procedure<sup>13</sup>.

## 5. Report on written procedures since the 60<sup>th</sup> Plenary meeting

Two opinions were adopted by the NDA Panel on 8 December by written procedure. They related to "fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" ([EFSA-Q-2014-00126](#), [EFSA-Q-2014-00127](#)). The full text is published in the EFSA Journal via these links:

<http://www.efsa.europa.eu/en/efsajournal/pub/3948.htm>,  
<http://www.efsa.europa.eu/en/efsajournal/pub/3949.htm>.

## 6. Scientific outputs submitted for discussion and/or possible adoption

### *Applications pursuant to Article 14/13.5 of Regulation (EC) No 1924/2006*

#### 6.1 *Beneo* – "Orafti®Inulin" and "improves bowel function" (Art. 13.5, 0416\_BE, [EFSA-Q-2014-00403](#))

On 11 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3951.htm>.

#### 6.2 *Avesthagen Limited* – "Teestar™" and "lowers blood glucose levels" (Art. 13.5, 0414\_FR, [EFSA-Q-2014-00153](#))

On 11 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3952.htm>.

<sup>11</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>12</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

<sup>13</sup> <http://www.efsa.europa.eu/en/events/event/140918-m.pdf>

- 6.3** *BASF SE and Stepan Lipid Nutrition – “Clarinol® or Tonalin®” and “contributes to a reduction in body fat mass”* (Art. 13.5, 0426\_NL, [EFSA-Q-2014-00580](#))

On 11 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3953.htm>.

### **Dietary Reference Values**

- 6.4** **Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the dietary reference values for calcium** ([EFSA-Q-2011-01206](#))

On 12 December, the draft opinion was introduced and discussed. This document proposes dietary reference values for iron for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 12 December for release for public consultation, subject to incorporation of editorial comments.

*Post-meeting notes:* Public consultation is open until 28 February 2015 via this link: <http://www.efsa.europa.eu/en/consultations/call/150114.htm>.

- 6.5** **Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the dietary reference values for iron** ([EFSA-Q-2011-01214](#))

Postponed.

### **Novel Foods**

- 6.6** *Technology Crops International - Buglossoides arvensis seeds oil* ([EFSA-Q-2014-00444](#))

On 9 December, the draft opinion was discussed and the Panel considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. A draft letter requesting additional information was discussed and agreed by the Panel. This letter will be sent to the applicant and a stop the clock procedure will be applied.

- 6.7** *Euroandina Importaciones S.L. - Arracacia xanthorrhiza* ([EFSA-Q-2011-00918](#))

On 9 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3954.htm>.

- 6.8** *BASF/DSM/LycoRed - Post marketing studies on lycopene* ([EFSA-Q-2014-00301](#))

On 9 December, the draft statement was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3955.htm>.

- 6.9** *Avitop GmbH - Bacteroides xylanisolvens* ([EFSA-Q-2014-00295](#))

On 9-10 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3956.htm>.

## Others

### 6.10 Draft opinion on safety assessment of caffeine ([EFSA-Q-2013-00220](#))

On 10 December, the draft opinion was introduced and discussed. This document addresses concerns raised by national and international bodies in relation to caffeine consumption in the following circumstances and age groups:

- caffeine consumption during pregnancy, and adverse health effects on the fetus;
- acute and long-term effects of caffeine consumption on the central nervous system (e.g. sleep, anxiety, behavioural changes) in adults, adolescents, and children;
- long-term adverse effects of caffeine consumption on the cardiovascular system in adults;
- acute effects of caffeine consumption in “energy drinks” and risk of adverse health effects in adolescents and adults involving the cardiovascular and central nervous systems, particularly when consumed within short periods of time, at high doses, and in combination with alcohol and/or physical exercise;
- acute effects of caffeine in combination with synephrine on the cardiovascular system.

The document was endorsed by the Panel on 10 December for release for public consultation, subject to incorporation of editorial comments.

*Post-meeting notes:* Public consultation is open until 15 March 2015: <http://www.efsa.europa.eu/en/consultations/call/150115.htm>

### 6.11 Draft opinion on total diet replacements for weight control ([EFSA-Q-2013-00994](#))

On 11 December, the draft opinion was introduced and discussed. In this document, the Panel proposed a minimum protein content based on a Population Reference Intake for protein adjusted for the overweight or obese (75 g/day), a minimum carbohydrate content based on the obligatory glucose demands of the brain (30 g/day) and minimum contents of linoleic acid (11 g/day),  $\alpha$ -linolenic acid (1.4 g/day) and micronutrients based on reference values established either by the Panel or by other scientific or authoritative bodies. Derived from the minimum content of macronutrients, the Panel proposed a minimum energy content of total diet replacements for weight control of 2 510 kJ/day (600 kcal/day). The Panel also advised on potential conditions and restrictions of use for these products.

The full text is published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3957.htm>.

### 6.12 Draft guidance on scientific requirements for health claims related to gut and immune function ([EFSA-Q-2014-00353](#))

On 10 December, the updated draft guidance was introduced and discussed. This document takes into account the outcome of a public consultation on a discussion paper (which was open from 18 June to 10 September 2014) together with new scientific evidence available to the NDA Panel and the experience gained to date with the evaluation of health claim applications in the areas of the gastrointestinal tract, the immune system, and defence against pathogenic microorganisms. The structure of the guidance document has been changed to reflect the comments and the requests for clarification received during the public consultation. It was

endorsed by the Panel on 10 December for release for public consultation, subject to incorporation of editorial comments.

*Post-meeting notes:* Public consultation is open until 23 March 2015: <http://www.efsa.europa.eu/en/consultations/call/150209.htm>

### **6.13 Draft technical report on Outcome of the public consultation on the discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function ([EFSA-Q-2014-00409](#))**

A technical report on the outcome of a public consultation on a discussion paper for the revision of the guidance document on the scientific requirements for the substantiation of health claims related to gut and immune function, which summarises the comments received during the public consultation (open from 18 June to 10 September 2014) will be submitted to the Panel for endorsement by written procedure.

*Post-meeting notes:* The technical report was endorsed by written procedure. It will be published together with the updated draft guidance in the coming weeks via this link: <http://www.efsa.europa.eu/en/supporting/pub/758e.htm>

## **7. New Mandates**

### **7.1 Applications pursuant to Article 14/13.5 of Regulation (EC) no 1924/2006**

1 new Article 14 application has been received since the last Plenary meeting: "Vitamin D contributes to the normal function of the immune system" ([EFSA-Q-2014-00826](#)).

### **7.2 Novel Foods**

3 new mandates received since the last Plenary meeting:

Request for a scientific opinion on phytosterol esters (extension of use, cooking oils) as a novel food ingredient ([EFSA-Q-2014-00865](#));

Request for a scientific opinion on Lacto-TV-neotetraose (LNnT) as a novel food ingredient ([EFSA-Q-2014-00862](#));

Request for a scientific opinion on bread treated with UV light as a novel food ingredient ([EFSA-Q-2014-00836](#)).

## **8. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission**

### **8.1 Scientific Committee and Scientific Panels**

During its November Plenary meeting, the Scientific Committee (SC) was presented with the draft statement that will answer the question from the European Commission on the risk benefit of fish/seafood consumption as regards methylmercury (EFSA-Q-2014-00665). It is based on previous opinions from CONTAM on the risk for public health related to the presence of mercury and methylmercury in food and on the NDA opinion on health benefits of seafood (fish and shellfish) consumption in relation to health. The draft statement was proposed for written adoption by the end of December 2014. *Post-meeting notes:* The full text is published in the EFSA Journal via this link:

<http://www.efsa.europa.eu/en/efsajournal/pub/3982.htm>.

Following the public consultation (ended last 23<sup>rd</sup> July) on the draft **Guidance on Statistical Reporting**, the SC was presented with an updated version which takes into consideration relevant comments received. The guidance aims to assist EFSA's Scientific Committee, its Scientific Panels, working groups, units and stakeholders on harmonisation and standardisation in the reporting of statistical methodology, analyses and results to allow independent peer review and reproducibility. The SC endorsed the Guidance and took note of the Public Consultation Report. *Post-meeting notes*: The full text is published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3908.htm>.

With respect to the production and consumption of insects as food and feed, an outline of a draft table of contents for the opinion was discussed. A draft of the opinion is scheduled to be discussed for possible adoption at the SC Plenary in June 2015. A workshop with stakeholders is planned at the beginning of next year in order to get insights on production, processing and consumption of insects and products thereof.

## 8.2 Working Groups

Chairs of Working Groups (WG) reported back regarding their respective latest meetings.

*WG on Claims* - At the last meeting, 10 claims opinions were discussed and elaborated. Among these: 5 were put under the stop the clock procedure for requesting supplementary information from the applicants; 2 were submitted to the Panel for adoption by written procedure and 3 were submitted to the Panel at this December Plenary meeting. The WG also discussed the updated draft guidance document on scientific requirements for health claims related to gut and immune function, which has been re-structured based on comments received during the public consultation of the discussion paper.

*WG on Novel Foods (NF)* – The next meeting will be held on 15-16 January.

*WG on Dietary Reference Values (DRVs)* – The WGs are currently working on DRVs for the remaining micronutrients. The WG on DRVs for vitamins is working on vitamins B6, B12, E and D, while the WG for minerals is preparing the opinions on calcium, magnesium, copper, sodium and chloride.

## 8.3 EFSA

Following a request by the EFSA Management Board, EFSA prepared a paper on its role in the field of nutrition. The chair of the NDA Panel was invited to join the MB meeting of December 2014 to clarify the remit of EFSA in nutrition.

The Panel was informed that the next open plenary meeting of the NDA Panel meeting will be held on 22-24 April 2015 (the venue has yet to be confirmed).

## 8.4 European Commission

The European Representative informed the Panel about the meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, which took place on 22 and 24-28 November 2014. EFSA opinions on Dietary Reference Values on nutrients are very much appreciated by Member States, particularly non-European countries including Russia. They are looking forward for EFSA opinions to assist in setting their recommendations.

## **9. Other scientific topics for information and discussion**

### **9.1 Issues related to dietary reference values for micronutrients**

On 11 December, the approach used for setting dietary reference values for iron was introduced and discussed. The Panel agreed with the proposed approach. A draft opinion will be submitted to a future NDA Panel Plenary meeting for possible endorsement for release for public consultation.

### **9.2 Grant on “Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement” (GP/EFSA/NUTRI/20141/01)**

Postponed.

## **10. Any Other Business**

A follow-up course on biostatistics applied to health claims was given.

The NDA Panel was informed that Juliane Kleiner has been acting Head of the Scientific Evaluation of Regulated Products Department since 01 December 2014.

The next Plenary meeting will be held on 4-6 February 2015.