

**Nutrition Unit (NUTRI UNIT)**

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

**Minutes of the 61<sup>st</sup> Plenary meeting**

**Held on 29-31 October 2014, Parma (Italy)**

**(Agreed on 12 November 2014)**

**Participants**

• **Panel Members:**

Carlo Agostoni, Susan Fairweather-Tait, Marina Heinonen<sup>1</sup>, Hannu Korhonen, Sébastien La Vieille<sup>2</sup>, Rosangela Marchelli, Ambroise Martin<sup>3</sup>, Androniki Naska, Monika Neuhäuser-Berthold, Yolanda Sanz<sup>4</sup>, Alfonso Siani, Anders Sjödin<sup>5</sup>, Martin Stern, Sean Strain (Chair), Inge Tetens, Daniel Tomé and Dominique Turck.

• **Hearing Experts<sup>6</sup>:**

- Not applicable.

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

- Not applicable.

• **EFSA:**

- Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Christos Stefanidis, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez
- REPRO Department: Per Bergman<sup>7</sup>

• **Observers:**

- Not applicable.

• **Others:**

- Not applicable.

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<sup>1</sup> Present via Teleconference on 31 October.

<sup>2</sup> Present on 29-30 October.

<sup>3</sup> Present via Teleconference on 31 October.

<sup>4</sup> Present on 29-30 October.

<sup>5</sup> Present on 29-30 October; on 31 October, present via teleconference.

<sup>6</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>7</sup> For Agenda item 10.2 only.

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Roberto Berni Canani and Grazyna Nowicka.

Anders Sjödin did not participate in agenda points 6.5 and 6.6 (see Annex I).

## 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>8</sup> and the Decision of the Executive Director on Declarations of Interest<sup>9</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting.

For further details on the outcome of the screening of the ADol or the SDol, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## 4. Agreement of the minutes of the 60<sup>th</sup> Plenary meeting held on 18-19 September 2014, Parma (Italy)

The minutes of the 60<sup>th</sup> Plenary meeting held on 18-19 September 2014 were agreed.<sup>10</sup>

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

There were no written procedures to report to the Panel.

## 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 *Specialised Nutrition Europe (formerly IDACE) – “Non-digestible Oligo- and Polysaccharides” and “calcium absorption”* (Art. 14, 0060\_FR, [EFSA-Q-2008-140](#))

On 30 October, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3889.htm>.

#### 6.2 *Specialised Nutrition Europe (formerly IDACE) – “Selenium” and “has an antioxidant functionality”* (Art. 14, 0079\_FR, [EFSA-Q-2008-159](#))

On 30 October, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3890.htm>.

<sup>8</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>9</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

<sup>10</sup> <http://www.efsa.europa.eu/en/events/event/140918-m.pdf>

**6.3 Specialised Nutrition Europe (formerly IDACE) – “Zinc” and “is essential for growth”** (Art. 14, 0110\_FR, [EFSA-Q-2008-190](#))

On 30 October, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3891.htm>.

**6.4 Specialised Nutrition Europe (formerly IDACE) - “Prunes” and “normal bowel function”** (Art. 14, 0113\_FR, [EFSA-Q-2008-193](#))

On 30 October, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3892.htm>.

**6.5 Federacion Nacional de Industrias Lácteas (FeNIL) – “Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars” and “help reduce body and visceral fat in the context of an energy restricted diet”** (Art. 13.5, 0412\_ES, [EFSA-Q-2014-00126](#))

On 30 October, the draft opinion was presented and discussed. The Panel was informed that the applicant had been requested to provide additional information. Pending the applicant’s reply, a revised draft will be discussed by WG Claims prior to its submission to the NDA Panel for possible adoption by written procedure.

**6.6 Federacion Nacional de Industrias Lácteas (FeNIL) – “Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars” and “maintenance of lean body mass (muscle and bone)”** (Art. 13.5, 0413\_ES, [EFSA-Q-2014-00127](#))

On 30 October, the draft opinion was presented and discussed. The Panel was informed that the applicant was requested to provide additional information. Pending the applicant’s reply, a revised draft will be discussed by WG Claims prior to its submission to the NDA Panel for possible adoption by written procedure.

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

On 30 September, the draft opinion was presented and discussed. The adoption will be postponed to a future NDA Panel Plenary meeting.

### ***Dietary Reference Values***

**6.8 Draft technical report on the comments received during the public consultation for the draft DRVs for folate** ([EFSA-Q-2014-00470](#))

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for folate, which summarises the comments received during the public consultation on this opinion (opened from 22 July to 14 September 2014), was presented and discussed, and subsequently endorsed by the Panel on 31 October. The technical report will be published together with the Opinion related to the dietary reference values for folate (see also item 6.9) in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/supporting/pub/694e.htm>.

**6.9 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 folate** ([EFSA-Q-2011-01212](#))

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see

also item 6.8) was discussed and adopted by the Panel on 31 October subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/3893.htm>.

**6.10 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 vitamin A (EFSA-Q-2011-01226)**

On 30 October, the draft opinion was introduced and discussed. This document proposes dietary reference values for vitamin A for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 31 October for release for public consultation, subject to incorporation of editorial comments. The full text will be released for public consultation via this link: <http://www.efsa.europa.eu/en/consultations/call/141117.htm>.

**Others**

**6.11 Draft technical report on the comments received during the public consultation for the Draft opinion on the evaluation of allergenic foods for labelling purposes (EFSA-Q-2014-00248)**

A technical report on the Outcome of a public consultation on a draft Opinion on the evaluation of allergenic foods for labelling purposes, which summarises the comments received during the public consultation on this opinion (opened from 23 May to 8 August 2014), was presented and discussed, and subsequently endorsed by the Panel on 30 October. The technical report will be published together with the Opinion on the evaluation of allergenic foods for labelling purposes (see also item 6.12) in the EFSA Journal via this link: <http://www.efsa.europa.eu/en/publications/supporting.htm>.

**6.12 Draft opinion on the evaluation of allergenic foods for labelling purposes (EFSA-Q-2011-00760)**

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see also item 6.11) was discussed and adopted by the Panel on 31 October subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsajournal/pub/3894.htm>.

**6.13 Draft opinion on total diet replacements for weight control (EFSA-Q-2013-00994)**

The approach and methodology proposed for use by the WG on Dietetic Products in order to advise on the essential composition of total diet replacements for weight control was presented to the Panel and discussed on 31 October 2014. A draft opinion taking into account the comments made by the Panel will be submitted to the Plenary in December 2014 for discussion/possible adoption.

**7. New Mandates**

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

There were no new claims applications received since the last Plenary meeting.

**7.2 Foods for special medical purposes (FSMP)**

A new request was received from the Commission asking EFSA to develop a scientific and technical guidance related to the type of data that will be needed to provide advice to the European Commission on specific products notified as foods

for special medical purposes (FSMPs) in the framework of Article 3 of Regulation (EU) No 609/2013 (EFSA-Q-2014-00736). The deadline for finalisation of the guidance is October 2015. To carry out the preparatory work, the Panel agreed on the creation of an *ad-hoc* Working Group (WG) consisting of four members with expertise relevant to the task, i.e. experts in inborn errors of metabolism, clinical nutrition, gastroenterology, nutritional requirements of patients and vulnerable population groups (such as infants and young children). The Panel also agreed to appoint Dominique Turck as the Chair of this *ad-hoc* WG.

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

### 8.1 Scientific Committee and Scientific Panels

Related to the European Commission mandate for a preliminary opinion on the risks arising from the production and consumption of insects as food/feed ([EFSA-Q-2012-00578](#)), EFSA sent its acceptance letter for this mandate to the EC, including the interpretation of the Terms of Reference. The Focal Points have been asked to forward to EFSA national risk assessments on insects, if and when available. The WG is being established by the SC. A workshop with stakeholders and representatives from the WG is foreseen in order to get insights on production, processing and consumption of insects and products thereof.

With respect to the mandate on the Risk benefit of fish/seafood consumption as regards methylmercury ([EFSA-Q-2014-00665](#)), the Scientific Committee will use the previous opinions from CONTAM on mercury, as well as the recently published NDA opinion on the health benefits of seafood consumption, in relation to health risks associated with exposure to methylmercury. The draft statement will be presented at the next Plenary meeting (11-12 November 2014) for discussion. The objective is to adopt the statement by the end of December 2014.

The SC standing WG on Genotoxicity had a kick-off meeting on 10 October. The mandate of this WG is to provide ad hoc assistance to the Panels in the interpretation of the existing SC guidelines on assessing genotoxicity. Ad hoc requests to the WG should be put forward by the chair of the Panel requesting the advice.

### 8.2 Working Groups

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

*WG on Claims* - At the last meeting, 11 claims opinions were discussed and elaborated. Among these: 7 were put under the stop the clock procedure for requesting supplementary information from the applicants; 4 were submitted to the Panel at this October Plenary meeting. The WG was also given an overview of comments received during the public consultation for the revision of the guidance on scientific requirements for health claims related to gut and immune function.

*WG on Novel Foods (NF)* – The next meeting will be held on 6-7 November.

*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 and magnesium.

*WG on Food Allergy* – Several meetings took place to review and address extensive comments received from stakeholders during the public consultation and to revise the Draft opinion on the evaluation of allergenic foods for labelling purposes within a very tight timeframe in order to submit these documents to the Panel at this October Plenary meeting (see items 6.11 and 6.12).

### **8.3 EFSA**

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 to be confirmed).

### **8.4 European Commission**

Not applicable.

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

### **9.1 SACN Draft Report on Carbohydrates and Health**

The Panel considered the SACN draft carbohydrates and health report (released on 26 June 2014) and also the WHO draft guidelines on sugars intake (released on 25 March 2014).

The mandate for the EFSA (2010) opinion on Dietary Reference Values for carbohydrates and fibre was to derive Reference Ranges (lower and upper bound levels)<sup>11</sup>. Sugars were considered as a component of dietary carbohydrates. The terms of reference of the WHO guideline on sugars intake for adults and children was to provide recommendations on the consumption of free sugars to reduce the risk of non-communicable diseases in adults and children. The terms of reference of the UK Scientific Advisory Committee on Nutrition (SACN) report on carbohydrates and health was to provide clarification of the relationship between dietary carbohydrate and health and make public health recommendations. In relation to sugars, all three reports focussed on dental caries and body weight/weight gain. EFSA concluded that the available data did not allow the setting of an adequate intake or reference intake range. WHO recommended that the intake of free sugars should not exceed 10% of total energy and that there should be a reduced intake of free sugars throughout the life-course. SACN recommended that free sugars should be limited to no more than 10% of total energy intakes at an individual level, and set a dietary reference value of 5% of total energy intake.

The Panel noted that different terms of references were given to the three committees, that slightly different methodologies were applied, and that therefore the outcomes are not directly comparable. The EFSA opinion only covered risk assessment, whereas the WHO and SACN also included risk management.

## **10. Any Other Business**

### **10.1 Biostatistics**

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

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<sup>11</sup> <http://www.efsa.europa.eu/en/efsajournal/doc/1462.pdf>

## **10.2 New implementing rules for declarations of interests**

Per Bergman informed the Panel about the new Decision of the Executive Director on Declarations of Interest.<sup>12</sup>

## **10.3 Next NDA Panel Plenary meeting**

The December Plenary meeting will be extended by an extra day, i.e.: 9-12 December 2014.

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<sup>12</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



## Annex I

### Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)<sup>13</sup>

In the ADoI or in the SDoI filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the applications from *Federacion Nacional de Industrias Lácteas (FeNIL)* 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](#), agenda item 6.5 and [EFSA-Q-2014-00127](#), agenda item 6.6). In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes<sup>14</sup> and the Decision of the Executive Director on Declarations of Interest<sup>15</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.

This results in exclusion of the expert from any discussion, voting or other processing of items 6.5 and 6.6 by the concerned scientific group.

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<sup>13</sup> The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.

<sup>14</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>15</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>