

## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 71<sup>st</sup> Plenary meeting

**Held on 1 – 3 February 2016, Parma (Italy)  
(Agreed on 8 February 2016)**

#### Participants

##### ■ Panel Members

Jean Louis Bresson, Barbara Burlingame<sup>1</sup>, Susan Fairweather-Tait<sup>2</sup>, Marina Heinonen<sup>3</sup>, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva, Yolanda Sanz<sup>4</sup>, Anders Sjödin, Alfonso Siani, Martin Stern, Daniel Tomé, Dominique Turck<sup>5</sup>, Henk Van Loveren, Marco Vinceti and Peter Willatts.

##### ■ Hearing Experts<sup>6</sup>:

Not Applicable

##### ■ European Commission:

Not Applicable

##### ■ EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup<sup>7</sup>, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Wolfgang Gelbmann, Jelena Gudelj Rakic, Leng Heng, Joaquim Maia, Emanuela Turla, Silvia Valtueña Martínez and Olga Vidal Pariente.

##### ■ Observers:

Not applicable

---

<sup>1</sup> Not Present on 1 February; attended via teleconference on 2-3 February.

<sup>2</sup> Present on 2-3 February.

<sup>3</sup> Present on 2-3 February.

<sup>4</sup> Present on 1-2 February.

<sup>5</sup> Attended via teleconference on 1-3 February.

<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> Attended via teleconference on 1-3 February.

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

The Chair welcomed the participants.

Apologies were received from Tara Dean.

The plenary was co-chaired by the Vice-Chairs, Androniki Naska and Henk Van Loveren.

Harry McArdle did not participate in agenda point 5.6.

## **2. Adoption of the agenda**

The agenda was adopted with changes in the order of discussion.

## **3. Declarations of Interest of 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 Scientific Panel Members invited for the present meeting. For further details on the outcome of the screening of the ADoIs or the SDoIs, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## **4. Report on written procedures since 70<sup>th</sup> Plenary meeting**

The minutes of the 70<sup>th</sup> Plenary meeting held on 9-11 December 2015 were agreed on 14 December 2015<sup>10</sup>.

There were no other written procedures to report to the Panel.

---

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

<sup>9</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>10</sup> <http://www.efsa.europa.eu/en/events/event/151209.htm>

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

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

#### **5.1. AlzChem AG - 'Creatine' and 'contributes to the maintenance of muscle function in the elderly' (Art. 13.5, 0437\_AT, EFSA-Q-2015-00437)**

On 2 February, 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/4400>

#### **5.2. Ecopharma BVBA - 'Fabenol Max' and 'reduces the absorption of carbohydrates' (Art. 13.5, 0433\_BE, EFSA-Q-2015-00123)**

On 2 February, 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/4401>

### ***Guidance documents***

#### **5.3. Draft guidance document on Novel Foods (EFSA-Q-2014-00216)**

On 1 February, the draft guidance was introduced and discussed. The document provides guidance on the data needed to carry out the safety assessments of Novel Foods and their presentation in a structured format.

It was endorsed by the Panel for release for public consultation subject to editorial comments. The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

#### **5.4. Draft guidance document on Traditional Foods from Third Countries (EFSA-Q-2015-00108)**

On 2 February, the draft guidance was introduced and discussed. The guidance presents a common format for the organisation of the information to be presented in order to assist the applicants in the preparation of notifications for traditional foods from third countries.

It was endorsed by the Panel for release for public consultation subject to editorial comments. The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

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

#### **5.5. 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 choline (EFSA-Q-2011-01208)**

On 1 February, the draft opinion was introduced and discussed. This document proposes dietary reference values for **choline** for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to editorial comments. The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

#### **5.6. 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 D (EFSA-Q-2011-01230)**

On 3 February, the draft opinion was introduced and discussed. This document proposes dietary reference values for **vitamin D** for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to editorial comments. The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

## **6. New Mandates**

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

Since the last Plenary meeting, one Article 13.5 application (claims based on newly developed science and/or which include a request for the protection of proprietary data) was received: "V0137, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function (EFSA-Q-2016-00071)".

One Article 14 Children claim was received: "Nutrimune supports the immune defence in the gastrointestinal and upper-respiratory tract of young children (EFSA-Q-2016-00008)".

These new requests will be assigned to the standing working group (SWG) on Claims. EFSA NDA guidance documents on health claims will be taken into consideration for the evaluation of the new applications received.

Two Article 13.5 applications were withdrawn: "collagen peptide mixture (FORTIGEL®P) that contributes to the maintenance of joint function (EFSA-Q-2015-00360)", "collagen peptide mixture (FORTIGEL®B) that contributes to the maintenance of joint function (EFSA-Q-2015-00762)".

## **6.2. Other mandates**

A new request was received from the Commission for a scientific opinion on dried aerial parts of Hoodia parviflora as a novel food ingredient (EFSA-Q-2016-00091). This new request will be assigned to the standing working group (SWG) on novel foods.

## **7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission**

### **7.1. Scientific Committee and other Scientific Panels**

The Scientific Committee (SC) has developed a draft guidance document on how to characterise, document and explain uncertainty arising in EFSA's scientific assessments. It provides a framework and principles for uncertainty analysis, with the flexibility for assessors to select different methods to suit the needs of each assessment. The guidance will be submitted to the SC for endorsement for a testing phase for each EFSA Panel. The outcomes of this pilot phase will be used to further revise the guidance document before its finalisation.

The Panel was also briefed about on-going activities of various Working Groups of the SC dealing with: Guidance on the Weight of Evidence approach, Biological Relevance, Guidance on Risk Assessment of substances in foods intended for infants, and Genotoxicity.

## 7.2. EFSA including its Working Groups (WG) /Task Forces

The Chairs of respective WGs reported back to the Panel:

- *WG on Claims* – Draft opinions related to seven Art 13(5) claims were discussed. The “stop-the clock” procedure for requesting clarifications/supplementary information from the applicant was applied for four applications. Three opinions were submitted to the Plenary: two for possible adoption (see items 5.1 and 5.2) and one for discussion (see item 8.1).
- *WG on Novel Foods* – At the last meeting, the WG discussed and elaborated draft guidance documents for novel food applications and for traditional foods from third countries, and the opinions on the following NF applications: phytosterol esters (EFSA-Q-2014-00865), Alginate-Konjac-Xanthan Polysaccharide Complex (EFSA-Q-2015-00469), and an extract of three herbal roots (EFSA-Q-2015-00249).
- *WG on DRVs for vitamins* – The WG was working on vitamin D (see item 5.6) and choline (see item 5.5). The WG will be continuing to work on vitamin K, thiamine, and riboflavin.
- *WG on DRVs for minerals* – The WG was working on sodium, potassium and chloride. A questionnaire has been sent to Member States to gather data on urinary excretion of Sodium and Chloride in the EU.
- *WG on Food Allergy* – The WG is working on behenic acid (from mustard) used for the manufacturing of a series of emulsifiers (EFSA-Q-2015-00844).

## 7.3. European Commission

Not applicable.

## 8. Other scientific topics for information and/or discussion

### 8.1. DSM Nutritional Products - ‘DHA’ and ‘contributes to improved memory function’ (Art. 13.5, 0438\_UK, EFSA-Q-2015-00456)

On 2 February, the draft opinion was presented and discussed. The Panel was informed that additional information has been requested from the applicant in order to proceed with the scientific assessment of this application. Adoption of the opinion was postponed.

## **9. Any other business**

### **9.1 EFSA Prometheus projects**

EFSA Prometheus project (Promoting Methods for evidence use in scientific assessments)<sup>11</sup> aims at further improving EFSA's methods for "dealing with data and evidence" (i.e. for collecting/extracting, validating/appraising, analysing and integrating data and evidence) and increasing their consistency. An impact analysis on the implementation of the PROMETHEUS process will be carried out.

The panel was asked to provide feedback by completing a Questionnaire on EFSA's methodological needs for evidence use in scientific assessment.

### **9.2 EFSA webinar**

Following the publication of the General scientific guidance on health claim applications, and to further assist applicants in preparing health claim applications, EFSA will be holding a webinar on 10<sup>th</sup> March on "Practical examples on scientific aspects to consider when preparing a health claim application".

### **9.3 Next NDA Plenary meeting**

The 72<sup>nd</sup> NDA Panel Plenary meeting will be held on 20-22 April 2016 in Parma.

The 73<sup>rd</sup> NDA Panel Plenary meeting, which is open to observers, will be held on 28-30 June 2016 in Brussels.

---

<sup>11</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4121>

## Annex I

### Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

**CONFLICT OF INTEREST:** In the SDoI filled for the present meeting, Dr Harry McArdle declared the following interest: Vitamin D (EFSA-Q-2011-01230, *agenda item 5.6*). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>12</sup> and the Decision of the Executive Director on Declarations of Interest<sup>13</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 item 5.6 by the concerned scientific group.

---

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

<sup>13</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>