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

Minutes of the 56th plenary meeting

Held on 11-13 December 2013, Parma

(Agreed on 5 February 2014)

Participants

- **Panel Members:** Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen[1], Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin (Chair), Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani[2], Anders Sjödin[3], Martin Stern, Sean Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen.
- **Hearing Experts:** None.
- **European Commission and/or Member States representatives:** Dora Szentpaly-Kleis and Francesco Carlucci[4].
- **EFSA:**
  - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Aurélie Zunino.
- **Observers:** None.
- **Others:** None.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Androniki Naska[5].

2. Adoption of agenda

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

Inge Tetens did not participate in agenda point 6.14.

[1] Present only on 11-12 December.
[2] Present only pm on 11 Dec, and present on 12-13 December.
[3] Present on 11-12 December and via teleconference on 13 December.
[4] Present only via teleconference for the item 7.2.1.
[5] Present only via teleconference on 13 December for the item 6.1.5.

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3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[7], EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

Oral DoIs were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 55th Plenary meeting held on 9-11 October 2013

The minutes of the 55th Plenary meeting were reviewed and agreed on 11 December 2013[8].

5. Report on written procedures since the 55th 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 ***Omikron Italia srl* - "Flavonoid Mixture containing Diosmin, Troxerutin and Hesperidin" and "maintaining venous-capillary permeability"** (Art 13.5, 0380_IT, EFSA-Q-2013-00353)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3511.pdf

6.2 ***Omikron Italia srl* - "Flavonoid Mixture containing Diosmin, Troxerutin and Hesperidin" and "maintaining venous tone"** (Art 13.5, 0381_IT, EFSA-Q-2013-00354)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3512.pdf

6.3 ***Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA*- "Oligofructose from chicory" and "reduction of postprandial blood glucose"** (Art 13.5, 0390_BE, EFSA-Q-2013-00615)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3513.pdf

[6] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[7] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[8] http://www.efsa.europa.eu/en/events/event/131009a-m.pdf

6.4 ***Specialised Nutrition Europe (formerly IDACE)*** **- "vitamin C" and "enhances non-haem iron absorption"** (Art. 14, 0096_FR, EFSA-Q-2008-176)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3514.pdf

6.5 ***Specialised Nutrition Europe (formerly IDACE)*****- "iron" and "blood formation"** (Art. 14, 0067_FR, EFSA-Q-2008-147)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3515.pdf

6.6 ***Specialised Nutrition Europe (formerly IDACE)*****- "iodine" and "thyroid hormone production"** (Art. 14, 0064_FR, EFSA-Q-2008-144)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3516.pdf

6.7 ***Specialised Nutrition Europe (formerly IDACE)*** **- "iodine" and "cognitive development"** (Art. 14, 0065_FR, EFSA-Q-2008-145)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3517.pdf

6.8 ***Institute of Cellular Pharmacology Ltd*****-"Padina pavonica–extract" and "maintenance of bone mineral density"** (Art. 13.5, 0378_MT, EFSA-Q-2013-00249)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3518.pdf

6.9 ***ITALSUR srl*** **- "Barley soup orzotto" and "contributes to the protection of blood lipids from oxidative damage"** (Art. 13.5, 0387_IT, EFSA-Q-2013-00578)

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: http://www.efsa.europa.eu/en/efsajournal/doc/3519.pdf

Food Allergy

6.10 Draft Opinion on the evaluation of allergenic foods for labeling purposes (EFSA-Q-2011-00760)

On 11 December, a draft opinion was presented (i.e. general sections 1 to 12). The structure, content and approach used by the Working Group to address the request from the Food Safety Authority of Ireland and to update EFSA existing opinions relative to food ingredients or substances with known allergenic potential listed in Annex IIIa of 2003/89/EC, as amended, were outlined and discussed. Feedback and comments received from the Panel were introduced. They will be further considered by the Working Group on Food Allergy in the preparation of a revised draft opinion in which specific sections addressing individual food allergens will be completed, prior to its submission to the February Plenary meeting for discussion.

Dietary Reference Values

6.11 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 Niacin (EFSA-Q-2011-01218)

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

6.12 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 iodine (EFSA-Q-2011-01213)

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

Post-meeting notes: Public consultation is open until 26 February 2014. Interested parties are invited to submit written comments via the following link http://www.efsa.europa.eu/en/consultations/call/140115.htm

6.13 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 B12 (EFSA-Q-2011-01227)

On 12 December, the proposed approach to use for setting DRVs for Vitamin B12 was presented and discussed. The Panel favoured in principle the approach based on biomarkers. The Panel recommended to the Working Group on DRV VIT to carefully argue why minimisation/maximisation of biomarkers is needed.

Novel Foods

6.14 *Lallemand SAS* - Draft Scientific Opinion on the safety of UV treated baker's yeast (EFSA-Q-2013-00335)

On 12 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: http://www.efsa.europa.eu/en/efsajournal/doc/3520.pdf

Other

6.15 Draft opinion on health benefits of fish consumption (EFSA-Q-2013-00167)

On 13 December, a draft opinion was presented. This opinion will address the health benefits of fish and shellfish consumption for the general population and specific population subgroups. This opinion will also advise on the extent to which available data will allow quantification of these benefits, and also on the uncertainties associated with such quantification. The structure, content and approach used were outlined and discussed. The terminology used for fish was clarified to avoid inconsistency with the terminology used in the opinion related to food allergy (section 6.10). Feedback and comments received from the Panel were introduced and will be further considered by the Working Group on Fish in the preparation of a revised draft opinion prior to its submission to a future Plenary meeting for discussion.

6.16 Draft opinion on Safety assessment of caffeine (EFSA-Q-2013-00220)

On 12 December, the structure and content of the draft opinion were presented, and the approach used by the Working Group for the safety assessment of caffeine was outlined and discussed. Feedback and comments received from the Panel will be further considered by the Working Group on Caffeine in the preparation of a revised draft opinion prior to its submission to a future Plenary meeting for possible discussion/endorsement for release for public consultation.

7. New Mandates

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

The Nutrition Unit informed the Panel about the status of claims applications since the last Plenary meeting.

- *Article 13.5 claims* (claims based on newly developed science and/or which include a request for the protection of proprietary data) – 7 new applications were received: Daily intake of supplemental olive leaf extract polyphenols, and, contributes to the reduction of the blood glucose rise after meals; Lutein together with zeaxanthin, and, helps to maintain clarity and contrast of sight in bright conditions; Pacran@, and, helps to inhibit the adhesion of P-fimbriated E. Coli to the urinary tract cells; Probiotic mix of Lactibiane Référence, and, improves intestinal comfort; Probiotic mix of Lactibiane Référence, and, improves stool frequency; PhaseLite™, and, helps to reduce body weight; Beta-alanine, and, increases performance during short-duration high intensity exercise.

- *Article 19 claims* (*conditions of use*) – 1 new application was received: Cocoa flavanols, and, help maintain the elasticity of blood vessels, which contributes to normal blood flow.

- *Article 14 claims* – No new applications received.

Rapporteurs have been appointed for the new applications received. EFSA NDA guidance documents on health claims will be taken into consideration for the evaluation of the new applications received.

7.2 Other mandates

7.2.1 Commission request for a scientific opinion on total diet replacement for weight control

EFSA received a request from the Commission for a scientific opinion on total diet replacement for weight control (EFSA-Q-2013-00994). The Commission representatives outlined the purpose of the mandate to the Panel.

EFSA is asked to revise the existing report of the Scientific Committee for Food (SCF) dated 1990 on foods intended for weight control diets[9] in the light of new evidence and to provide advice on the compositional criteria of products denominated as low calorie diets (LCD, providing a minimum of 800 kcal per day and a maximum of 1,200 kcal per day). In addition, EFSA is asked to provide advice on compositional criteria for total diet replacements providing less than 800 kcal per day (i.e. very low calorie diets (VLCD)), which are not regulated on a European level as yet, and advise on any potential restrictions or conditions of use of these products and the appropriate target

[9] http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_27.pdf

population. The Commission representatives clarified that meal replacement for a single or two occasions are not covered by this mandate.

In preparation for this task, EFSA has launched a call for an extensive literature search in order to retrieve all pertinent studies published since the SCF report was published in 1990. This mandate has been allocated to the NDA Working Group on Dietetic Products.

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

8.1 Scientific Committee and other Scientific Panels

Postponed to a future Plenary meeting.

8.2 Working groups

Postponed to a future Plenary meeting.

8.3 EFSA

Postponed to a future Plenary meeting.

8.4 European Commission

Postponed to a future Plenary meeting.

9. Other scientific topics for information and/or discussion

9.1 Feedback from the Technical meeting on reporting of human studies for health claims (20 November 2013, Parma)

Valeriu Curtui briefed the Panel about the fruitful and lively discussions which took place at the Technical meeting. An event report summarising suggestions and proposals expressed, as well as the outcome of the Technical meeting, will be published on EFSA's website. In addition, the Panel proposed that suggestions and views gathered from the Technical meeting be discussed at the meeting of the NDA Working Group on Claims.

10. Any Other Business

10.1 The next plenary meeting will be held on 5-7 February 2014.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[10]

In the SDoI filled for the present meeting, **Prof. I. Tetens** declared the following interest: draft opinion related to the safety of UV treated baker's yeast (EFSA-Q-2013-00335, agenda point 6.14). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, 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 the impossibility for the expert to be present when that item (agenda point 6.14) is discussed, voted on or in anyway processed by this scientific group.

[10] 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.