

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

Minutes of the 54th plenary meeting

Held on 10-12 July 2013, Parma

(Agreed on 10 October 2013)

Participants

- **Panel Members:** Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Yolanda Sanz¹, Alfonso Siani, Anders Sjödin, Martin Stern, Sean Strain, Daniel Tomé, Dominique Turck, and Hans Verhagen.
- **Hearing Experts:** None
- **European Commission and/or Member States representatives:** None
- **EFSA:**
 - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann², Leng Heng, Amy Mullee, Ariane Titz, Emanuela Turla, and Silvia Valtueña Martínez
- **Observers:** None
- **Others:** None

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Marina Heinonen and Grazyna Nowicka.

2. Adoption of agenda

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

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding

¹ Present only on 10-11 July.

² Present on 11 July via telephone conference, Agenda item 6.15

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests⁴, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process⁵. The 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 53rd Plenary meeting held on 30-31 May 2013

The minutes of the 53rd Plenary meeting were reviewed and agreed on 10 July 2013⁶.

5. Report on written procedures since the 53rd 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 Pharmatoka S.A.S –“Proanthocyanidins from Urell” and “contribute to support defence against bacterial pathogens in the lower urinary tract”
(Art. 13.5, 0358_FR, EFSA-Q-2012-00700)

On 10 July, 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/efsjournal/doc/3326.pdf>

6.2 Laboratoire Lescuyer –“Limicol” and “reduction of LDL-cholesterol concentration; high LDL-cholesterol is a risk factor in the development of coronary heart disease” (Art 14, 0370_FR, EFSA-Q-2012-00968)

On 12 July, 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/efsjournal/doc/3327.pdf>

6.3 Rank Nutrition Ltd –“Folic acid” and “raises maternal red blood cell folate” (Art. 14, 0379_UK, EFSA-Q-2013-00265)

On 10 July, 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/efsjournal/doc/3328.pdf>

6.4 Roquette Frères –“Food/drinks containing Nutriose instead of sugar” and “maintenance of tooth mineralisation” (Art 13.5, 0374_FR, EFSA-Q-2013-00040)

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

⁵ In the sDoI filled in for the present meeting and regarding an interest previously declared (see minutes of the 52nd plenary meeting) by Prof. Sue Fairweather-Tait in relation to the draft opinions on Dietary Reference Values for fluoride (EFSA-Q-2013-00318), molybdenum (EFSA-Q-2011-01217) and manganese (EFSA-Q-2011-01216), further assessment has established that this does not represent a conflict of interest since it relates to a past activity carried out on behalf of EFSA as part of a tender to provide evidence reports identifying health outcomes upon which DRVs could potentially be based for these minerals. It was therefore possible for the expert to participate in the meeting for these agenda items (6.10, 6.11, 6.12, 6.13, 6.14).

⁶ <http://www.efsa.europa.eu/en/events/event/130530a-m.pdf>

On 10 July, 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/search/doc/3329.pdf>

6.5 ICP Ltd –“Natural extract of prickly pear cactus (TEX-OE)” and “physiological response to stress” (Art. 13.5, 0373_MT, EFSA-Q-2013-00021)

On 10 July, 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/3330.pdf>

6.6 IDACE - “Vitamin A” and “helps support healthy immune function” (Art 14, 0080_FR, EFSA-Q-2008-00160)

On 10 July, 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/3334.pdf>

6.7 IDACE –“Magnesium” and “supports the development of strong/healthy bones” (Art 14, 0070_FR, EFSA-Q-2008-150)

On 11 July, 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/3331.pdf>

6.8 IDACE -“Iron” and “important for cognitive development” (Art 14, 0119_FR, EFSA-Q-2008-00199)

On 11 July, 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/3335.pdf>

Food Allergy

6.9 Scientific and technical guidance for the preparation and presentation of applications for labelling exemption pursuant to Article 6 Paragraph 11 of Directive 2000/13/EC, as amended (EFSA-Q-2013-00221)

On 11 July, the draft guidance document was introduced and discussed. The guidance presented in this document is intended to update the Commission guidelines in view of assisting applicants in the preparation and presentation of well-structured applications for exemption from labelling of allergenic foods. It was endorsed by the Panel for release for public consultation subject to incorporation of editorial comments.

Post-meeting notes: Public consultation was open from 26 July until 13 September 2013 via the following link:

<http://www.efsa.europa.eu/en/consultations/call/130726.htm>

Dietary Reference Values

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 fluoride (EFSA-Q-2011-01211)

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

discussed by the Panel on 11 July and adopted on 11 July subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsjournal/doc/3332.pdf>

6.11 Technical report: Outcome of the Public consultation on the draft Scientific Opinion on Dietary Reference Values for fluoride (EFSA-Q-2013-00318)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for fluoride, which summarises the comments received during the public consultation on this guidance (opened from 2 May 2013 to 14 June 2013), was presented and discussed on 11 July, and subsequently endorsed by the Panel on 11 July. The technical report will be published together with the Opinion related to the dietary reference values for fluoride (see also item 6.10) via the following link: <http://www.efsa.europa.eu/en/supporting/doc/476e.pdf>

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 molybdenum (EFSA-Q-2011-01217)

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received was thoroughly discussed by the Panel on 11 July and adopted on 11 July subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsjournal/doc/3333.pdf>

6.13 Technical report: Outcome of the Public consultation on the draft Scientific Opinion on Dietary Reference Values for molybdenum (EFSA-Q-2013-00320)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for molybdenum, which summarises the comments received during the public consultation on this guidance (opened from 26 April 2013 to 14 June 2013), was presented and discussed on 11 July, and subsequently endorsed by the Panel on 11 July. The technical report will be published together with the Opinion related to the dietary reference values for molybdenum (see also item 6.12) via the following link:

<http://www.efsa.europa.eu/en/supporting/doc/475e.pdf>

6.14 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 manganese (EFSA-Q-2011-01216)

On 12 July, the draft opinion was introduced and discussed. This document proposes dietary reference values for manganese 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 was open from 1 August until 13 September 2013. Interested parties are invited to submit written comments via the following link <http://www.efsa.europa.eu/en/consultations/call/130801.htm>

Novel Foods

6.15 Bioresco – Rapeseed protein (EFSA-Q-2013-00231)

On 11 July, the draft opinion was introduced and discussed. The Draft was referred back to the Working Group on Novel Foods for further consideration.

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) – **9** new applications were received: Black cabbage mix, and, contributes to the protection of blood lipids from oxidative damage; Black cabbage mix and maintains normal blood cholesterol concentrations; Mix of chard, chicory and spinach and contributes to the protection of blood lipids from oxidative damage; Mix of chard, chicory and spinach and maintains normal blood cholesterol concentrations; Barley soup orzotto and maintains normal blood cholesterol concentrations; Barley soup orzotto and contributes to the protection of blood lipids from oxidative damage; Foods/drinks containing oligofructose from chicory instead of sugars and induces a lower blood glucose rise; Transitech and improves bowel function; Caffeine and helps to increase alertness].
- *Article 14 claims* – **2** new applications on disease risk reduction were received: Plant sterol esters and lower/reduce blood (LDL) cholesterol. High cholesterol is a risk factor in the development of coronary heart disease; Cranberry extract named CranMax and prevents adhesion of E. Coli to the uroepithelial cells in women which are a risk factor for developing urinary tract infections.

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

No other new request was received from the European Commission.

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

8.1 Scientific Committee and other Scientific Panels

The Scientific Committee (SC) has carried out a review of its own cross-cutting risk assessment Guidance Documents to identify gaps requiring either the development of new guidance or the revision of existing guidance. The SC opinion on priority topics for the development of risk assessment guidance has been published (<http://www.efsa.europa.eu/en/efsajournal/pub/3345.htm>).

8.2 Working groups

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

WG on Food Allergy - At the last meeting on 18-19 June, different sections of the opinion related to the evaluation of allergenic foods for labelling purposes were discussed and amended as appropriate, including thresholds and minimal eliciting doses, structure of food allergens and methods of detection, and allergy to milk, fish, lupin, nuts, and gluten containing cereals. A draft on the Scientific and technical guidance for the preparation and presentation of applications for labelling exemption

pursuant to Article 6 Paragraph 11 of Directive 2000/13/EC, as amended, was also discussed, and was submitted to the July plenary for possible endorsement for release for public consultation (see also Agenda point 6.9).

WG on Novel Foods – At the last meeting, the WG discussed and elaborated on draft opinions related to the following Novel Food applications: Gantrez, novel chewing gum ingredient (EFSA-Q-2012-00653), Coriander Seed Oil (EFSA-Q-2013-00231), Rapeseed Protein (EFSA-Q-2013-00231; submitted to this July plenary-see Agenda item 6.15) and the most recent application on UV treated baker's yeast (EFSA-Q-2013-00335).

WG on Claims - The WG discussed and elaborated on 4 draft opinions related to Article 13.5 claim applications. Among these, 2 draft opinions were submitted to this July plenary meeting for discussion and possible adoption ("Proanthocyanidins from Urell" and "Food/drinks containing Nutriose instead of sugar"), and 2 were subject to the clock-stop procedure for requesting supplementary information from the applicant ("Padina pavonica - extract" and "Glycaemic carbohydrates"). The WG also discussed 2 draft opinions related to disease risk reduction claims ("Folic acid"; "Limicol"), which were also submitted to this July plenary meeting for discussion and possible adoption.

WG on DRVs for vitamins - The main work was on drafting the opinion on DRVs for vitamin C. Other vitamins, such as vitamins D and B12, will be tackled during the next WG meetings.

WG on DRVs for minerals – Outcomes of the public consultations on draft DRVs for fluoride and for molybdenum were discussed. Some sections of the draft opinions were discussed and amended. The related documents were submitted to the July plenary meeting (see Agenda items 6.10, 6.11, 6.12 and 6.13). The WG also discussed and elaborated on the draft opinion on DRVs for manganese, which was submitted to the July plenary for possible endorsement for public consultation (see Agenda item 6.14). Draft DRVs under preparation include iodine, calcium, chromium, and selenium.

WG on Dietetic products – During the meeting held on 11 -12 June, draft chapters on the dietary requirements of infants and young children for energy, water, carbohydrates and dietary fibre, fats, protein, biotin, calcium, chloride, choline, chromium, copper, folate, iodine, iron, magnesium, manganese, molybendum, niacin, pantothenic acid, phosphorus, potassium, selenium, sodium, vitamin A, vitamin B1, vitamin B12, vitamin B2, vitamin B6, vitamin C, vitamin D, vitamin E, vitamin K and zinc were discussed. Further tasks with respect to reviewing available data on dietary intakes of energy, macro- and micronutrients in infants and young children were distributed. A discussion on possible methodologies for defining insufficient nutrient intakes also took place.

WG on Fish – During the meeting held on 7 June, the discussions focused on the types of data available regarding the nutrient composition of fish, fish consumption data, dietary recommendations for fish consumption, and on key nutrients in fish. Criteria for the selection of studies on which to base the scientific assessment of the health benefits of fish consumption were also discussed. Some tasks were distributed among experts.

WG on Caffeine – The kick-off meeting was held on 21 June. The mandate was discussed, as well as the main questions to be addressed. Data and databases available to EFSA in order to assess exposure to caffeine from different sources in different age groups were presented. Strategies for identifying in the short timeframe available pertinent literature and previous risk assessments on caffeine and energy

drinks conducted by different bodies were discussed and agreed. Some tasks were distributed among experts.

8.3 EFSA

None

8.4 European Commission

None

9. Other scientific topics for information and/or discussion

Owing to scarcity of data for deriving DRVs for infants and children, scaling methods for extrapolation of data from adults to infants/children and different approaches used were compared and discussed (i.e. isometric versus allometric scaling). It was suggested that the method and approach used will be transparently outlined in the opinions if applicable. The Panel also discussed the optimal methodology for the assessment of dietary surveys with respect to the Commission request on growing up milks.

10. Any Other Business

The next plenary meeting will be held on 9-11 October 2013.