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

Minutes of the 58th plenary meeting

Held on 8-11 April 2014, Parma

(Agreed on 25 June 2014)

Participants

- **Panel Members:** Carlo Agostoni[1], Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen[2], Hannu Korhonen, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka[2], Yolanda Sanz, Alfonso Siani[3], Anders Sjödin[3], Martin Stern, Sean Strain, Inge Tetens[2], Daniel Tomé and Dominique Turck[2].
- **Hearing Experts:** None.
- **European Commission and/or Member States representatives:** Basil Mathioudakis 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 Sébastien La Vieille[5] and Hans Verhagen.

2. Adoption of agenda

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

[1] Present on 9 and 11 April.
[2] Present on 9, 10 and 11 April.
[3] Present on 8, 9 and 10 April.
[4] Present on 9 April.
[5] Present only via teleconference on 8-9 April pm, for item 6.19.

European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • www.efsa.europa.eu

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.

Anders Sjödin did not participate in agenda point 6.9 and 6.10.

4. Agreement of the minutes of the 57th Plenary meeting held on 5-7 February 2014

The minutes of the 57th Plenary meeting were reviewed and agreed on 8 April 2013[8].

5. Report on written procedures since the 57th 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 *Biocodex* - "**Citrulline-malate**" and "**improved recovery from muscle fatigue**" (Art. 13.5, 0394_BE, EFSA-Q-2013-00659)

On 9 April, 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/3650.pdf.

6.2 *Specialised Nutrition Europe (formerly IDACE)* – **"Choline"** and **"development of brain"** (Art. 14, 0054_FR, EFSA-Q-2008-134)

On 10 April, 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/3651.pdf.

6.3 *Specialised Nutrition Europe (formerly IDACE)* – **"Complex carbohydrates"** and **"contribution to satiety"** (Art. 14, 0051_FR, EFSA-Q-2008-131)

On 9 April, 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/3652.pdf.

6.4 *Specialised Nutrition Europe (formerly IDACE)* **– "Zinc"** and **"normal function of the immune system"** (Art. 14, 0109_FR, EFSA-Q-2008-189)

On 10 April, 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/3653.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/140205-m.pdf

6.5 *Barry Callebaut Belgium NV* – **"Cocoa flavanol"** and **"help maintain the elasticity of the blood vessels which contributes to normal blood flow"** (Art. 19, 0398_BE, EFSA-Q-2013-00832)

On 10 April, 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/3654.pdf.

6.6 *Comvita New Zealand Limited* **– "Daily intake of supplemental olive leaf extract polyphenols"** and **"contributes to the reduction of the blood glucose rise after meals"** (Art. 13.5, 00397_UK, EFSA-Q-2013-00783)

On 10 April, 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/3655.pdf.

6.7 *Naturex SA* – **"Cranberry extract named Pacran"** and **"inhibition of adhesion of P-fimbriated *E. Coli* to urinary tract cells"** (Art. 13.5, 0400_FR, EFSA-Q-2013-00889)

On 10 April, 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/3656.pdf.

6.8 *Jemo-pharm A/S* – **"CranMax®"** and **"prevents adhesion of *E.coli* to uroepithelial cells which is a risk factor for developing urinary tract infections"** (Art. 14, 0391_DK, EFSA-Q-2013-00649)

On 10 April, 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/3657.pdf.

6.9 *PiLeJe* – **"A combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104"** and **"reducing intestinal discomfort"** (Art. 13.5, 0401_FR, EFSA-Q-2013-00892)

On 10 April, 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/3658.pdf.

6.10 *PiLeJe* – **"A combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104"** and **"improvement of stools frequency"** (Art. 13.5, 0402_FR, EFSA-Q-2013-00893)

On 10 April, 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/3659.pdf.

6.11 *Clasado Limited* – **"Regular daily consumption of 1.37g galactooligosaccharides from Bimuno®"** and **"may reduce abdominal discomfort"** (Art. 13.5, 0406_MT, EFSA-Q-2014-00022)

On 10 April, 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. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

Dietary Reference Values

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)

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see also item 6.13) was discussed and adopted by the Panel on 10 April subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/doc/3660.pdf.

6.13 Draft technical report on the comments received during the public consultation for the draft DRVs for iodine (EFSA-Q-2013-01017)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for iodine, which summarises the comments received during the public consultation on this opinion (opened from 15 January 2014 to 26 February 2014), was presented and discussed, and subsequently endorsed by the Panel on 10 April. The technical report will be published together with the Opinion related to the dietary reference values for iodine (see also item 6.12) via the following link: http://www.efsa.europa.eu/en/supporting/pub/589e.htm?wtrl=01.

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 zinc (EFSA-Q-2011-01233)

On 11 April, the draft opinion was introduced and discussed. This document proposes dietary reference values for zinc for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 11 April for release for public consultation subject to incorporation of editorial comments.

Public consultation is open until 8 July 2014:
http://www.efsa.europa.eu/en/consultations/call/140514.htm.

6.15 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 chromium (EFSA-Q-2011-01209)

On 11 April, the draft opinion was introduced. The criteria for essentiality of a trace element were discussed. It was concluded that no Average Requirement and no Population Reference Intake for chromium for the performance of physiological functions can be defined and that the setting of an Adequate Intake for chromium is also not appropriate. A revised draft incorporating comments received will be submitted to the Panel for possible endorsement by written procedure for release for public consultation.

Post meeting note: The draft opinion was endorsed for public consultation by written procedure on 21 May 2014. Public consultation is open until 3 August 2014: http://www.efsa.europa.eu/en/consultations/call/140606.htm.

6.16 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)

Postponed to a future plenary.

Novel Foods

6.17 Draft Opinion on the safety of astaxanthin-rich ingredients (AstaREAL A1010 and AstaREAL L10) as Novel Food ingredients (*Bioreal (Sweden) AB*) (EFSA-Q-2011-00990)

Postponed to a future Plenary meeting.

Others

6.18 Draft opinion on health benefits of fish and shellfish consumption in relation to health risks associated with exposure to methylmercury (EFSA-Q-2013-00167)

On 8 April, the draft opinion was introduced and discussed. The discussions focused on the evidence available for benefits of seafood (and nutrients in seafood) consumption, particularly in relation to children's neurodevelopmental outcomes.

The Panel agreed to delay adoption to a future plenary to allow consultation with the CONTAM Panel.

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

On 8 and 10 April, a draft opinion was presented and discussed. The document updates previous EFSA opinions on food ingredients or substances that are known to cause adverse reactions. These include: cereals containing gluten, milk and dairy products, eggs, nuts, peanuts, soy, fish, crustaceans, molluscs, celery, lupin, sesame, mustard, and sulphites. The opinion includes information on the prevalence of food allergy in unselected populations, on proteins identified as food allergens, on cross-reactivities, on the effects of food processing on allergenicity of foods and ingredients, on methods for the detection of allergens and allergenic foods, on doses observed to trigger adverse reactions in sensitive individuals, and on the approaches which have been used to derive individual and population thresholds for selected allergenic foods. On 10th April, the draft opinion was endorsed by the Panel for release for public consultation subject to incorporation of editorial comments.

Public consultation is open until 8 August 2014:
http://www.efsa.europa.eu/en/consultations/call/140523.htm**.**

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

On 8 April, the draft opinion was presented and different sections related to the safety assessment of caffeine were discussed.

Feedback and comments received from the Panel will be further considered by the Working Group (WG) 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.

In consultation with the Head of Unit, the Chair of the WG on Caffeine and the Panel Chair, it was proposed that two additional members are needed to support the WG on Caffeine. The additional members should have expertise in toxicology and experience is cross-cutting questions related to the risk assessment for caffeine. It was proposed that this expertise should come from members of the Scientific Committee (SC).

6.21 Draft opinion on the composition of milk based-drinks and similar products intended for infants and young children (EFSA-Q-2013-00264)

On 9 and 10 April, the draft opinion was presented and discussed. This Opinion reviews the Opinion provided by the Scientific Committee on Food in 2003 on the essential requirements of infant and follow-on formulae in light of more recent evidence and by considering the Panel's Opinion published in October 2013 on nutrient requirements and dietary intakes of infants and young children in the European Union[9]. This document considers which nutrients/substances can be considered as essential constituents of infant and/or follow-on formula and proposes minimum and maximum contents for these nutrients/substances. On 10 April, the draft opinion was endorsed by the Panel for release for public consultation subject to incorporation of editorial comments.

Post meeting note: Public consultation was closed on 29 May 2014 http://www.efsa.europa.eu/en/consultationsclosed/call/140424.pdf.

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) – 3 new applications were received: - "Fat-free-yoghurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars help to reduce body and visceral fat in the context of an energy restricted diet"; - "Fat-free-yoghurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars help to maintain lean body mass (muscle and bone) in the context of an energy restricted diet"; - "TEESTAR™ (Fenugreek fiber extract containing galactomannan) lowers blood glucose levels.

- *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

EFSA received a request from the European Commission for scientific and technical assistance to update and develop **scientific guidance for the preparation and presentation of applications for authorisation of novel foods and for the notifications and applications for authorisation of traditional foods from third countries** (EFSA-Q-2014-00216). This request is based on the Commission proposal for a Regulation of the European Parliament and of the Council on Novel Foods (COM(2013) 894 final)[10].

Three additional requests were also received from the European Commission in the context of Regulation (EC) No 258/97:

[9] http://www.efsa.europa.eu/en/efsajournal/pub/3408.htm

[10] http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-cloning_com2013-894_final_en.pdf

EFSA is asked to review its opinion on the safety of **Cetyl Myristoleate Complex** as a novel food ingredient in food supplements in light of submitted information from the applicant (EFSA-Q-2014-00166).

EFSA is asked to carry out additional assessment for the extension of use for **docosahexaenoic (DHA) and eicosapentaenoic acid (EPA) rich algal oil from *Schizochytrium*** as a novel food ingredient (EFSA-Q-2014-00218).

EFSA is asked to carry out additional assessment for **resveratrol** as a novel food ingredient (EFSA-Q-2014-00232).

These requests have been allocated to the NDA Working Group on Novel Foods.

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

8.1 Scientific Committee and other Scientific Panels

The Chair reported back from the Scientific Committee (SC) meeting held on 3-4 April 2014.

The SC discussed the draft proposal for the new structure of EFSA's opinions and statements. The SC proposed that Panels should test the new structure with an already published opinion to identify possible difficulties in the implementation of the revised format. The feedback on this testing will be collected before the format is finally adopted by the SC at its next plenary.

The SC identified the need to develop guidance on how to use the weight of evidence approach in risk assessments. A draft mandate was proposed. It was proposed to establish a Working Group (WG) on weight of evidence, which should work in close collaboration with the WG on Uncertainty and the WG on Biological Relevance, and to consider ongoing international activities while developing the detailed work-programme.

8.2 Working groups

Postponed to a future Plenary meeting.

8.3 EFSA

Members of the Panel were informed about the nomination by the EFSA Management Board of Bernhard Url as EFSA's next Executive Director. The next step in the procedure is the hearing of the designated Executive Director before the ENVI Committee of the European Parliament (EP), which will take place on 14th April in Strasbourg. The EP will formalise its opinion in a letter from the President of the European Parliament to the Chair of the Management Board. The Management Board will then proceed to the formal appointment of the Executive Director.

The Panel was informed about the EFSA call to renew membership of its Scientific Committee and eight Scientific Panels. The recruitment call is open to scientists from all Member States of the European Union. EFSA is looking for candidates with proven excellence in one or more of the scientific fields within EFSA's remit. Selection is carried out through an open, transparent procedure. Successful applicants will be appointed for a three-year term starting in July 2015. Applicants should apply online at:

http://www.efsa.europa.eu/en/scpanels/memberscall2011.htm. Members were kindly invite to help disseminating the call.

8.4 European Commission

The Commission representative provided an update on the status of its decision-making process related to EFSA-adopted scientific opinions. All the adopted Commission decisions related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

9. Other scientific topics for information and/or discussion

Following-up from the Technical meeting on reporting of human studies for health claims (20 November 2013, Parma), the Panel was informed about the publication of the Event Report, which summarises remarks made and the discussion points put forward during the Technical meeting (http://www.efsa.europa.eu/en/supporting/pub/569e.htm).

10. Any Other Business

10.1 The next plenary meeting will be held on 25-27 June 2014.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[11]

In the SDoI filled for the present meeting, **Dr. A. Sjödin** declared an interest for the applications from PiLeJe on "**a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and S*. thermophilus* LA 104**" (EFSA-Q-2013-00892, agenda item 6.9; EFSA-Q-2013-00893, agenda item 6.10). 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 those items of the meeting (agenda items 6.9 and 6.10) were discussed, voted on or in anyway processed by that concerned scientific group.

[11] 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.