SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGY

(NDA)

Minutes of the 50th plenary meeting of the NDA Panel

Held on 28-30 November 2012, Parma

(Agreed on 24 January 2013)

Participants

- **Panel Members**:

  Roberto Berni Canani[1], Susan Fairweather-Tait, Marina Heinonen[1], Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska[1], Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Mikael Sjødin, Martin Stern, Sean Strain, Daniel Tomé, Dominique Turck, Hans Verhagen

- **Hearing Experts**:

  None

- **European Commission:**

  Christina Antoniou[2]

- **EFSA:**

  - **Nutrition Unit:** Juliane Kleiner, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Agnès de Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Amy Mullee, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez
  - **Other EFSA Directorates/Units**: Per Bergmann[3], Roy Kirby[4]

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair also welcomed Amy Mullee a new trainee in the Nutrition secretariat.

Apologies were received from Inge Tetens and Carlo Agostoni.

2. Adoption of agenda

The agenda was adopted without changes.

[1] Present only on 28 and 29 November 2012
[2] Present only on 29 and 30 November 2012
[3] Present only for agenda item 8.3
[4] Present only for agenda item 10.1

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[5] and the Decision of the Executive Director implementing this Policy[6], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoIs and SDoIs, as well as the Oral Declarations of Interest (ODoIs) at the beginning of the meeting, please refer to the Annex.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 49th Plenary meeting held on 12-14 September 2012, Parma

The minutes of the 49th Plenary meeting were reviewed and agreed on 28 November 2012[7].

5. Report on written procedures since the 49th Plenary meeting

5.1 *Glanbia Nutritionals plc* **– "Prolibra®"** and **"helps to reduce body fat while preserving lean muscle"** (Art. 13.5, 0318_IE, EFSA-Q-2012-00001) was adopted by written procedure on 30 October 2012. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/pub/2949.htm.

6. Scientific outputs submitted for discussion and possible adoption

6.1. *Nutrilinks* – "Grape seed extract" and "contributes to promote venous circulation in the legs" (Art. 13.5, 0342_BE, EFSA-Q-2012-00387)

On 28 November, 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/pub/2996.htm.

6.2. *Nutrilinks* – "Grape seed extract" and "helps to decrease swollen legs" (Art. 13.5, 0343_BE, EFSA-Q-2012-00388)

On 28 November, 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/pub/2997.htm.

6.3. *Nutrilinks* – "Grape seed extract" and "helps to drain the body in case of water accumulation" (Art. 13.5, 0347_BE, EFSA-Q-2012-00574)

On 28 November, 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/pub/2998.htm.

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[5] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[6] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[7] http://www.efsa.europa.eu/en/events/event/120912a-m.pdf

6.4. *Actina* – "OXY280 a combination of kidney bean extract (phaseolamins), olive extract (oleuropein) and rosemary extract (carnosic acid)" and "helps to lose weight" (Art. 13.5, 0348_BE, EFSA-Q-2012-00572)

On 28 November, 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/pub/2999.htm.

6.5. *Nutrilinks* – "Green tea including EGCG and Guarana including CAF extracts" and "helps to burn fat" (Art. 13.5, 0353_CY, EFSA-Q-2012-00590)

On 28 November, 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/pub/3000.htm.

6.6. *Nutrilinks* – "Lycopene, vitamin E, lutein, selenium" and "helps to prepare and activate tanning" (Art. 13.5, 0356_CY, EFSA-Q-2012-00593)

On 28 November, 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/pub/3001.htm.

6.7. *Nutrilinks* – "*Eff*$_{EXT}$™" and "contributes to support joint flexibility" (Art. 13.5, 0339_BE, EFSA-Q-2012-00384)

On 28 November, 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/pub/3002.htm.

6.8. *Nutrilinks* – "Krill oil" and "helps to improve the comfort of sensitive joints" (Art. 13.5, 0340_BE, EFSA-Q-2012-00385)

On 28 November, 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/pub/3003.htm.

6.9. *Roxlor Nutra LLC* – "Cynatine®" and "helps to support joint flexibility" (Art. 13.5, 0349_BE, EFSA-Q-2012-00570)

On 28 November, 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/pub/3004.htm.

6.10. *Nutrilinks* – "♀EFAX™" and "reduction of menstrual discomfort" (Art 13.5, 0354_CY EFSA-Q-2012-00591)

On 29 and 30 November, the draft opinion was discussed, and the Panel considered that the draft opinion needed to be returned to the Working Group on Claims for further clarification. The adoption of the opinion was postponed to the next Plenary meeting.

6.11. *Minami Nutrition Health BVBA*- "Eicosapentaenoic acid (EPA)" and "reduces the AA/EPA ratio in blood. A high AA/EPA ratio is a risk factor in the development of attention difficulties in children" (Art. 14, 0350_BE, EFSA-Q-2012-00573)

On 29 November, the draft opinion was presented and discussed. The Panel identified a number of issues for which additional information is needed from the applicant before the Opinion can be concluded. The stop the clock procedure will be applied.

6.11.1. *Merck Médication Familiale & Chr. Hansen A/S– Lactobacillus paracasei* LP-33® and "resistance to airborne allergens" (Art. 13.5, 0365_DK, EFSA-Q-2012-00816)

On 29 November, the draft opinion was presented and discussed. The Panel identified a number of issues for which additional information is needed from the applicant before the Opinion can be concluded. The stop the clock procedure will be applied.

Post-meeting notes: In the meantime the application has been withdrawn by the Competent Authority of Denmark.

Novel Foods

6.12. *Myrisana* – Cetyl Myristoleate Complex (EFSA-Q-2012-00649)

On 28 November, the Panel discussed the draft opinion on the safety of Cetyl Myristoleate Complex and considered that the draft opinion needs to be returned to the Working Group on Novel Food for further scrutiny of some of the data provided by the applicant.

Dietary Reference Values

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 energy (EFSA-Q-2008-465)

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 28 and 29 November and adopted on 29 November subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: http://www.efsa.europa.eu/en/efsajournal/pub/3005.htm.

6.14. Technical report: Outcome of a public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA) on the Dietary Reference Values for energy (EFSA-Q-2012-00696)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for energy, which summarises the comments received during the public consultation on this guidance (opened from 20 July 2012 to 28 September 2012), was presented and discussed on 28 November, and subsequently endorsed by the Panel on 29 November. The technical report will be published together with the Opinion related to the dietary reference values for energy (see also item 6.13) via the following link: http://www.efsa.europa.eu/en/supporting/pub/386e.htm.

7. New Mandates

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

The Secretariat 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) – four new applications pursuant to 13.5 claims were received: Combination of taurine, grape seed extract, green tea leaf extract, zinc and reducing hair loss by reducing hair telogen rate; *Lactobacillus rhamnosus* GG, and maintain normal defecation during antibiotic treatment; Natural extract of prickly pear cactus (TEX-OE) and physiological response to stress; Galactooligosaccharides from Bimuno® and reducing gastrointestinal discomfort; – Two applications were withdrawn: Food products with a reduced fat content and contributes to decrease the daily caloric intake; Short-chain fructo-oligosaccharides obtained from sucrose (scFOS) and reduce intestinal discomfort.

Article 14 claims – one new application was received related to a disease risk reduction claim: Limicol and reduction of LDL-cholesterol concentration. High LDL-cholesterol is a risk factor in the development of coronary heart disease. - One application was withdrawn: Almased Vitalkost, foods intended for use in energy-restricted diets for weight reduction" and "improves insulin resistance and glucose tolerance.

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 Safety of "Taxifolin" as a novel food ingredient

A new request was received from the European Commission asking EFSA to carry out an additional safety assessment related to "Taxifolin**"** (as a novel food ingredient) submitted in accordance with the Novel Foods Regulation 258/97/EC.

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

8.1 Scientific Committee and other Scientific Panels

The Vice-Chair of the Panel reported back regarding her participation at the most recent Scientific Committee (SC) plenary meeting. Feedback from the EFSA 10th year anniversary Scientific Conference held on 7-8 November 2012 was given. The Vice-Chair outlined the work programme of the SC and its various working groups (Compendium of botanicals; QPS for botanicals; Guidance review; Uncertainty in risk assessment; Environmental risk assessment; New risk assessment methodologies; Endocrine active substances), including activities related to other scientific panels which are of interest for the NDA Panel. The SC is currently preparing a scientific opinion on the human health and environmental risks associated with the possible presence of endocrine disruptors in the food chain; the opinion is expected to be delivered in March 2013.

8.2 Working groups

A first meeting of the WGs on DRVs for minerals and vitamins was held jointly on 26-27 November 2012. The work plans and the timeframe for delivering opinions covering 29 micronutrients by 2015 were discussed, and rapporteurs have been appointed. The group also discussed four draft opinions on DRVs for vitamin C, fluoride, manganese and molybdenum.

Chairs of various WGs also reported back regarding their respective latest meetings. Related to food allergy, a status report was given on the call for tender for literature searches and reviews of published and unpublished data related to the prevalence of food allergy in Europe, to the effects of food processing on the allergenicity of foods, and to the new analytical methods to analyse and detect food allergens in processed food. Related to novel food applications, the Novel Foods WG discussed and elaborated on the following draft opinions: Rooster Combs Extract, Cetyl Myristoleate Complex, Astaxanthin and Gantrez® (a novel chewing gum base ingredient). Concerning claims applications, the Claims WG discussed and elaborated on 17 draft opinions related to Article 13.5 claim applications, and on 1 opinion related to Article 14.

8.3 EFSA

Dr. Per Bergman, Director of Scientific Evaluation of Regulated Products, visited the Panel during its plenary meeting on 28 November and answered questions from the Panel related to declarations of interests and to cooperation between EFSA and National Agencies.

The Secretariat reminded the Panel about the two days statistical training on 23 January and 29 May 2013. The training will focus on statistical concepts and issues encountered rather that the mechanisms of calculation and analysis.

The Panel was also informed about specialised training courses on advanced aspects of risk assessment for panel members and scientific staff. The training is structured around EFSA guidance and practices covering three areas: evidence base for risk assessment; variability and uncertainty; and exposure assessment. Panel members were invited to send their expressions of interest as soon as possible (via the Karolinska website: http://ki.se/ki/jsp/polopoly.jsp?d=1666&l=en) and to inform the secretariat.

8.4 European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA-adopted scientific opinions on health claim applications, as well as regarding the Article 13.1 health claims that were placed on hold, including transitional measures for non-authorised claims. All the adopted Commission decisions related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/

The Commission also provided a six-monthly updated follow-up of various EFSA scientific opinions adopted during the period January-June 2013.

9. Other scientific topics for information and/or discussion

None.

10. Any Other Business

10.1. Quality Management System

Roy Kirby provided an update to the Panel about EFSA's objectives and processes for the implementation of quality management.

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

In the ADoI or in the SDoI filled for the present meeting, DR. ANDERS SJODIN declared the following interest: the application related to *Lactobacillus paracasei* LP-33® from Merck Médication Familiale & Chr. Hansen A/S (EFSA-Q-2012-00816, agenda item 6.11). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. The expert could therefore not be present at the meeting when this item (agenda point 6.11) was discussed, voted on or in anyway processed.