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

Minutes of the 53rd plenary meeting

Held on 30-31 May 2013, Parma

(Agreed on 10 July 2013)

Participants

- **Panel Members:** Carlo Agostoni[1], Susan Fairweather-Tait, Marina Heinonen[2], Hannu Korhonen, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Alfonso Siani, Anders Sjödin, Martin Stern, Sean Strain, Daniel Tomé, Dominique Turck, 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 Gelbmann, Leng Heng, Amy Mullee, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez
- **Observers:** None
- **Others:** None

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Roberto Berni Canani, Yolanda Sanz and Sébastien La Vieille.

2. Adoption of agenda

The agenda was adopted without changes.

[1] Present only on 30 May 2013 AM
[2] Present only on 30 May 2013

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3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[4], 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, as well as the Oral Declaration of Interest at the beginning of the meeting, please refer to Annexes I and II.

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.

A. Sjödin did not participate in agenda point 6.1.

M. Heinonen did not participate in agenda point 6.6.

4. Agreement of the minutes of the 52nd Plenary meeting held on 20-22 March 2013

The minutes of the 52nd Plenary meeting were reviewed and agreed on 30 May 2013[5].

5. Report on written procedures since the 52nd 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 *Fuko Pharma Ltd* - **"*Lactobacillus rhamnosus* GG"** and **"maintain normal defecation during antibiotic treatment"** (Art. 13.5, 0372_FI, EFSA-Q-2013-00015)

On 30 May, 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/3256.htm

6.2 *Gelita AG* - **"Collagen hydrolysate"** and **"maintenance of skin health"** (Art. 13.5, 0366_DE, EFSA-Q-2012-00839)

On 30 May, 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/3257.htm

6.3 *Vivatech* – **"Transitech"** and **"improves transit and durably regulates it"** (Art. 13.5, 0375_FR, EFSA-Q-2013-00087)

On 30 May, 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/3258.htm

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

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[5] http://www.efsa.europa.eu/en/events/event/130320.htm

On 30 May, 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.

6.5 *Clasado Ltd.* – **"Galactooligosaccharides from Bimuno®"** and **"reducing gastrointestinal discomfort"** (Art. 13.5, 0371_MT, EFSA-Q-2012-01007)

On 30 May, 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/3259.htm

Dietary Reference Values

6.6 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 C (EFSA-Q-2011-01229)

On 30-31 May, the draft opinion was introduced and discussed. This document proposes dietary reference values for vitamin C 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 31 August 2013. Interested parties are invited to submit on-line written comments via the following link http://www.efsa.europa.eu/en/consultations/call/130628.htm

Novel Foods

6.7 *Bioiberica* – **Rooster Combs Extract** (EFSA-Q-2012-00613)

On 31 May, 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/3260.htm

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

On 31 May, 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/3261.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 received 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: Flavonoid Mixture containing 300 mg of Diosmin, 300 mg of Troxerutin and 100 mg of Hesperidin and maintaining physiological venous-capillary permeability; Flavonoid Mixture containing 300 mg of Diosmin, 300 mg of Troxerutin and 100 mg of Hesperidin and maintaining physiological venous tone; Rosbacher Drive alcohol-free drink and helps concentration.

Article 14 claims – no new application was 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

Novel Foods **-** One new request was received from the European Commission asking EFSA to carry out additional assessment related to the safety of "**UV treated baker's yeast**", submitted in accordance with the Novel Foods Regulation 258/97/EC as a novel food ingredient.

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 of the Panel reported the main outcomes of the last Scientific Committee (SC) meeting held on 11-12 April[6].

The Scientific Committee's away day will be held on 17-18 July and all panel chairs will be participating. Strategic discussions will be focused on the sustainability of EFSA's operation and on mid- to long term perspectives for the SC. The SC was informed that the EC Services have in several recent mandates asked EFSA to derive tolerable upper intake levels (ULs) for chemical substances other than nutrients e.g. for caffeine and for some botanicals. The Scientific Committee underlined that the concept of deriving ULs was developed for vitamins and minerals which possess characteristics that distinguish them from other food chemicals. The SC recommended to reserve this term in principle for the risk assessment of essential nutrients.

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, the WG agreed on different chapters of the opinion on the evaluation of allergenic foods for labelling purposes (related to clinical symptoms, diagnosis, methods of detection of food allergens, management, and milk). The WG is currently working on chapters related to minimum observed eliciting doses (thresholds), structure of allergens, cross reactivity, effects of processing, fish, peanuts, and lupin. Prevalence, natural history and emerging allergens were also discussed; related chapters will be updated according to the results of the procurement project. The draft Scientific and technical guidance for the preparation and presentation of applications for labeling exemption pursuant to article 6 Paragraph 11 of Directive 2000/13/EC was discussed in details.

WG on Novel Foods – The WG discussed and elaborated on draft opinions on the following applications: Rooster Combs Extract (EFSA-Q-2012-00613) and Cetyl Myristoleate Complex, EFSA-Q-2012-00649), which were submitted to this May plenary meeting for discussion and possible adoption (see items 6.7 and 6.8). For two applications (Gantrez novel chewing gum ingredient, EFSA-Q-2012-00653) and Rapeseed Protein (EFSA-Q-2013-00231), the WG requested additional information/clarifications to be provided by the applicant, thus clock-stops were applied in the evaluation of these applications.

WG on Claims - The WG discussed and elaborated on 8 draft opinions related to Article 13.5 claim applications. Among these, 4 draft opinions were submitted to this May plenary meeting for discussion and possible adoption, and 4 were subject to the

[6] http://www.efsa.europa.eu/en/events/event/130411-m.pdf

clock-stop procedure in order to request supplementary information from the applicant.

WG on DRVs for vitamins - The WG discussed and elaborated on the draft opinions on DRVs for vitamin C, vitamin D, folate, vitamin B12 and niacin. The updated draft opinion on DRVs for vitamin C was submitted to this May plenary meeting for discussion and possible endorsement for public consultation (see item 6.6).

WG on DRVs for minerals - The WG discussed and elaborated on the draft opinions on DRVs for manganese, iodine, zinc and chromium. It was agreed to submit the draft opinion on DRVs for manganese for discussion and possible endorsement for public consultation to the 54th NDA Plenary meeting. The WG also discussed the DRVs for calcium and for iron.

WG on Dietetic products – In the framework of advice to be provided on milk based-drinks and similar products intended for infants and young children, draft chapters of the opinion on the dietary requirements of infants and young children for energy, water, carbohydrates and dietary fibres, fats and protein were discussed. The Chair of the WG informed the Panel that the WG has two new members, Tamás Decsi and Lotte Lauritzen[7].

WG on Fish – The discussion of the WG focused on the type of data available regarding the nutrient composition of fish, fish consumption data, and on key nutrients in fish. Questionnaires were sent to Member States to gather information on existing dietary recommendation in the EU.

WG on Caffeine – The Panel was informed about the composition of the WG on the safety of caffeine[8]. Anders Sjödin has been appointed as the Chair of the WG**.** EFSA has already begun work on the collection of data on the safety of caffeine, which is expected to be completed by the end of July 2013.

8.3 EFSA

Not applicable.

8.4 European Commission

Not applicable.

9. Other scientific topics for information and/or discussion

10. Any Other Business

10.1 Meeting dates for 2014

5-7 February;

9-11 April;

25-27 June;

17-19 September;

29-31 October;

10-12 December

[7] http://www.efsa.europa.eu/en/nda/ndawgs.htm
[8] http://www.efsa.europa.eu/en/nda/ndawgs.htm

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[9]

In the SDoI filled in for the present meeting, **Prof. A. Sjödin** declared an interest for the application on ***"Lactobacillus rhamnosus* GG"** (EFSA-Q-2013-00015, agenda point 6.1). 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 6.1) is discussed, voted on or in any way processed by this scientific group.

Annex II
Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

With regard to this meeting, Prof. **M. Heinonen** declared the following interest: draft opinion related to Dietary Reference Values for vitamin C (EFSA-Q-2011-01229, agenda point 6.6) (owing to a tender with EFSA to provide evidence reports identifying health outcomes upon which DRVs could potentially be based for this vitamin). 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. This results in the impossibility for the expert to be present when that item (agenda point 6.6) is discussed, voted on or in any way processed by that concerned scientific group.

[9] The Annual Declarations of Interests were 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.