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

Minutes of the 63rd Plenary meeting

Held on 04-06 February 2015, Parma (Italy)

(Agreed on 9 February 2015)

Participants

- **Panel Members**

  Carlo Agostoni[1], Roberto Berni Canani[2], Susan Fairweather-Tait, Hannu Korhonen, Sébastien La Vieille[3], Rosangela Marchelli[2], Ambroise Martin (Chair), Androniki Naska[4], Monika Neuhäuser-Berthold, Grazyna Nowicka[3], Alfonso Siani[3], Anders Sjödin[5], Martin Stern, Sean (J.J.) Strain, Daniel Tomé, Dominique Turck and Hans Verhagen[2].

- **Hearing Experts[6]:**
  - Not Applicable
- **European Commission and/or Member States representatives:**
  - Marina Marini[2] and Olga Goulaki[7] (DG SANCO).
- **EFSA:**
  - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Céline Dumas, Lucia Fabiani, Wolfgang Gelbmann, Leng Heng, Christos Stefanidis, Emanuela Turla and Silvia Valtueña Martínez.
- **Observers:**
  - Not Applicable
- **Others:**
  - Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Marina Heinonen, Yolanda Sanz and Inge Tetens.

[1] Present on 5 February, and on the 6th via teleconference.
[2] Present on 5-6 February.
[3] Present on 4-5 February.
[4] Present on 4 (pm), 5 and 6 February.
[5] Present on 4-5 February, and on the 6th via teleconference.
[6] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.
[7] Present on 6 February via teleconference.

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2. Adoption of agenda

The agenda was adopted with changes in the order of items discussed.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[8] and the Decision of the Executive Director on Declarations of Interest[9], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

Anders Sjödin did not participate in agenda point 6.1.

Sean Strain did not participate in agenda point 6.12.

4. Agreement of the minutes of the 62nd Plenary meeting held on 9-12 December 2014, Parma (Italy)

The minutes of the 62nd Plenary meeting held on 9-12 December 2014 were agreed[10].

5. Report on written procedures since 62nd Plenary meeting

The technical report on the outcome of the public consultation on the discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00409) was endorsed by the NDA Panel by written procedure. The full text is available at this link: http://www.efsa.europa.eu/en/supporting/pub/758e.htm.

Post-meeting notes: The draft Guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms is open for public consultation until Monday 23 March 2015 and can be accessed via the following link: http://www.efsa.europa.eu/en/consultations/call/150209.htm.

[8] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[9] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[10] http://www.efsa.europa.eu/en/events/event/141209c.htm

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 *Synbiotec S.r.l.* - **"SYNBIO®, a combination of *Lactobacillus rhamnosus* IMC 501® and *Lactobacillus paracasei* IMC 502®"** and **"persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being"** (Art. 13.5, 0425_IT, EFSA-Q-2014-00567)

On 6th February, 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. A request for additional information will be sent to the applicant and a clock-stop procedure will be applied.

6.2 *Tchibo GmbH* **- Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body"** (Art. 13.5, 0428_DE, EFSA-Q-2014-00624)

On 6th February, the draft opinion was discussed. It was agreed to submit a revised draft to the Panel for adoption by written procedure.

6.3 *Lycotec Ltd* - **"L-tug lycopene"** and **"lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"** (Art.14, 0427_UK, EFSA-Q-2014-00590)

On 6th February, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4025.htm

6.4 *Han-Asiabiotech GmbH* - **"Symbiosal®"** and **"lowers the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for hypertension"** (Art. 14, 0415_DE, EFSA-Q-2014-00366)

On 6th February, 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. A request for additional information will be sent to the applicant and a clock-stop procedure will be applied.

6.5 *Dextro Energy GmbH & Co.* – **"Glucose contributes to the maintenance of normal brain function"** (Art. 13.5, 0420_DE, EFSA-Q-2014-00554); **"Glucose contributes to normal cognitive function"** (Art. 13.5, 0421_DE, EFSA-Q-2014-00555); **"Glycaemic carbohydrates contribute to the maintenance of normal brain function"** (Art. 13.5, 0422_DE, EFSA-Q-2014-00556)**; "Dextrose Tablets contribute to the maintenance of normal brain function"** (Art. 13.5, 0423_DE, EFSA-Q-2014-00557).

On 6th February, the draft opinions were discussed and adopted by the Panel subject to the incorporation of editorial changes. The full texts will be published in the EFSA Journal in the coming weeks via the following links: http://www.efsa.europa.eu/en/efsajournal/pub/4026.htm; http://www.efsa.europa.eu/en/efsajournal/pub/4027.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 cobalamin (vitamin B12) (EFSA-Q-2011-01227)

On 5th February, the draft opinion was introduced and discussed. This document proposes dietary reference values for cobalamin (vitamin B12) for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 5th February for release for public consultation, subject to incorporation of editorial comments.

The full text will be released for public consultation in the coming weeks.

6.7 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 A (EFSA-Q-2011-01226)

Following the public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see also item 6.8) was discussed and adopted by the Panel on 5th February subject to the incorporation of editorial changes.

The full text will be published in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4028.htm

6.8 Draft technical report on the outcome of the public consultation on the Draft Scientific Opinion on the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for vitamin A (EFSA-Q-2014-00790)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for vitamin A, which summarises the comments received during the public consultation on this opinion (which was open from 17 November 2014 to 07 January 2015), was presented and discussed, and subsequently endorsed by the Panel on 5th February.

The technical report will be published together with the Opinion related to the dietary reference values for vitamin A (see also item 6.7) in the coming weeks.

6.9 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 E (EFSA-Q-2011-01231)

On 5th February, the draft opinion was introduced and discussed. This document proposes dietary reference values for vitamin E for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 5th February for release for public consultation, subject to incorporation of editorial comments.

The full text will be released for public consultation in the coming weeks.

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 phosphorus (EFSA-Q-2011-01220)

On 5th February, the draft opinion was introduced and discussed. This document proposes dietary reference values for phosphorous for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel on 5th February for release for public consultation, subject to incorporation of editorial comments.

The full text will be released for public consultation in the coming weeks.

Novel Foods

6.11 *Technology Crops International* - ***Buglossoides arvensis*** **seeds oil** (EFSA-Q-2014-00444)

On 5th February, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4029.htm

6.12 *DSM Nutritional Products* – **Resveratrol** (EFSA-Q-2014-00232)

On 6th February, the draft opinion was discussed. It will be referred back to the WG on Novel Foods for further consideration. Adoption is postponed to a future Plenary meeting.

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.

One Article 14 application (disease risk reduction claim) was received: “Anxiofit-1-Echinacea angustifolia root dry extract has been shown to ameliorate sub-threshold and mild anxiety. Sub-threshold and mild anxiety are risk factors in the development of anxiety disorders and depression" (EFSA-Q-2015-00006).

One Article 13.5 application (claim based on newly developed science and/or which include a request for the protection of proprietary data) was received: "The combined ingestion of glucose and fructose improves performance in active individuals performing endurance exercise" (EFSA-Q-2014-00927).

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.

Three Article 14 children’s claim applications were withdrawn: “Dietary fibre, and, soften stools”; “DHA and ARA contribute to immune system development of infants and young children”; and “LC-PUFAs (DHA/ARA), and, visual development”.

7.2 Novel Foods

One new request was received from the European Commission in the context of Regulation (EC) No 258/97:

EFSA is asked to carry out additional assessment on 2'-O-Fucosyllactose as a novel food ingredient (EFSA-Q-2015-00052).

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

8.1 Scientific Committee

The Scientific Committee will set up a new Working Group on biological relevance[11].

8.2 Working Groups

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

WG on Claims - At the last meeting, 11 claim opinions were discussed and elaborated. Among these: 4 were put under the clock-stop procedure for requesting supplementary information from the applicants; the remainder were submitted to the Panel at this February Plenary meeting.

WG on Novel Foods (NF) – At the last meeting, the WG discussed and elaborated draft opinions on the following Novel Food applications: refined oil from the seeds of *Buglossoides arvensis*, synthetic trans-resveratrol, UV-treated bread, and Lacto-N-neotetraose. The WG also discussed sections of draft guidance documents for Novel Food applications and for notifications of Traditional Foods from third countries.

WG on Dietary Reference Values (DRVs) **–** The WGs are currently working on DRVs for the remaining micronutrients. The WG on DRVs for vitamins is working on vitamins B6, D, and choline, while the WG for minerals is preparing the opinions on iron, magnesium, copper, and chloride.

[11] http://www.efsa.europa.eu/en/events/event/141111-m.pdf

8.3 EFSA

Stakeholder meeting on the safety of caffeine: EFSA will present its draft opinion on the safety of caffeine at a scientific meeting on 5 March 2015 in Brussels**.** The meeting aims to bring together interested parties from national and international risk assessment bodies, academia, consumer organisations, and food sector operators**.** The meeting will allow for an exchange of scientific views on the draft scientific opinion before the end of the public consultation (i.e. 15 March 2015). Registration for participation at the meeting is open until 20 February via this link: http://www.efsa.europa.eu/en/events/event/150305.htm.

New templates for scientific outputs: The Panel was informed that starting 2015 all outputs (i.e. scientific opinions with a question number dated from 2015) will follow the new scientific templates. For scientific outputs for which work started before 2015, the old templates will still be used.

8.4 European Commission

The Commission representative provided an update on the status of its decision-making process related to EFSA-adopted scientific opinions.

9. Other scientific topics for information and discussion

9.1 Draft Guidance on Novel Foods and Traditional Foods (EFSA-Q-2014-00216)

On 4th February, the Panel was given an overview on the draft guidance documents on novel food applications and notifications of traditional foods from third countries that are being prepared by the Working Group on Novel Foods. The guidance documents are intended to assist applicants in preparing and presenting their applications for authorisation of Novel Foods and applicants who want to submit a notification under the framework provided by the new Regulation on Novel Foods.

10. Any Other Business

10.1 Biostatistics

A follow-up course on biostatistics applied to health claims was given.

10.2 Next NDA Panel Plenary meeting.

The Panel was informed that the next plenary meeting of the NDA Panel is scheduled to take place on 22-24 April 2015, most likely in Leuven, Belgium.

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting, Dr. A. Sjödin declared the following interest: "SYNBIO®, a combination of *Lactobacillus rhamnosus* IMC 501® and *Lactobacillus paracasei* IMC 502®" (**EFSA-Q-2014-00567,** agenda item 6.1**)**. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[12] and the Decision of the Executive Director on Declarations of Interest[13], 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 exclusion of the expert from any discussion, voting or other processing of item 6.1 by the concerned scientific group.

In the ADoI or in the SDoI filled for the present meeting by Prof. S. Strain, the following interest was identified: *DSM Nutritional Products* **–** Resveratrol **(EFSA-Q-2014-00232,** agenda item 6.12**)**. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[14] and the Decision of the Executive Director on Declarations of Interest[15], 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 exclusion of the expert from any discussion, voting or other processing of item 6.12 by the concerned scientific group.

[12] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[13] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[14] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[15] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf