

Nutrition Unit (NUTRI UNIT)

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

Minutes of the 60th Plenary meeting

Held on 18-19 September 2014, Parma (Italy)

(Agreed on 29 October 2014)

Participants

- Panel Members:

- Carlo Agostoni, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille¹, Rosangela Marchelli, Ambroise Martin (Chair), Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen².

- Hearing Experts³:

- Not applicable.

- European Commission and/or Member States representatives:

- Not applicable.

- 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:

- Not applicable.

- Others:

- Not applicable.

¹ Present on 18 September.

² Present on 18 September.

³ 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>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Roberto Berni Canani.

2. Adoption of agenda

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

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 ADol or the SDol, please refer to Annex I. 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 6.7.

Marina Heinonen did not participate in agenda point 6.2.

Sean Strain did not participate in agenda point 6.5.

4. Agreement of the minutes of the 60th Plenary meeting held on 25-27 June 2014, Parma (Italy)

The minutes of the 60th Plenary meeting held on 25-27 June 2014 were reviewed and agreed on 18 September 2014⁶.

5. Report on written procedures since the 60th 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** *British Specialist Nutrition Association - "Carbohydrate solutions" and "contribute to the maintenance of endurance performance during prolonged endurance exercise"* (Art. 13.5, 0408_UK, [EFSA-Q-2014-00058](http://www.efsa.europa.eu/en/efsajournal/pub/3836.htm))

On 18 September, 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/3836.htm>.

- 6.2** *Oy Karl Fazer Ab - "High-fibre sourdough rye bread" and "reduction of post-prandial glycaemic response accompanied by a reduced insulin response"* (Art. 13.5, 0405_FI, [EFSA-Q-2014-00012](http://www.efsa.europa.eu/en/efsajournal/pub/3836.htm))

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

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁶ <http://www.efsa.europa.eu/en/events/event/140918-a.pdf>

On 18 and 19 September, the draft opinion was discussed. It was adopted by the Panel on 19 September subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsajournal/pub/3837.htm>.

6.3 *Olygose* - “**AlphaGOS®**” and “**induces a lower blood glucose rise compared to sugar-containing foods or drinks**” (Art. 13.5, 0407_FR, [EFSA-Q-2014-00044](#))

On 18 September, 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/3838.htm>.

6.4 *Roquette Italia S.p.a.* - “**Nutriose®06**” and “**induces a lower blood glucose rise compared to high glycaemic carbohydrate-containing foods/drinks**” (Art. 13.5, 0410_IT, [EFSA-Q-2014-00073](#))

On 18 September, 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/3839.htm>.

6.5 *DSM Nutritional Products Ltd.* - “**Preformed DHA**” and “**contributes to brain development**” (Art. 14, 0409_UK, [EFSA-Q-2014-00059](#))

On 18 September, 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/3840.htm>.

6.6 *Specialised Nutrition Europe* - “**Lactase for comfortable digestion**” (Art. 14, 0068_FR, [EFSA-Q-2008-148](#))

On 18 September, 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/3841.htm>.

6.7 *E-piim production Ltd* - “**Lactobacillus plantarum TENSIA®** in the semi-hard Edam-type “**heart cheese**” of Harmony™” and “**maintenance of cardiovascular health through reduction of blood pressure**” (Art. 13.5, 0411_EE, [EFSA-Q-2014-00097](#))

On 18 September, 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/3842.htm>.

6.8 *Avesthagen Limited* - “**TEESTAR™**” and “**lowers blood glucose levels**” (Art. 13.5, 0414_FR, [EFSA-Q-2014-00153](#))

On 18 September, 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 stop the clock procedure will be applied.

6.9 *Cross Vetpharm Group UK Ltd* - “**Colief/lactase enzyme reduces the lactose load of the infant's feed**” and “**improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed**” (Art. 14, 0417_UK, [EFSA-Q-2014-00404](#))

On 18 September, 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 stop the clock procedure will be applied.

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 zinc ([EFSA-Q-2011-01233](#))

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see also item 6.11) was discussed and adopted by the Panel on 19 September subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsajournal/pub/3844.htm>.

6.11 Draft technical report on the comments received during the public consultation for the draft DRVs for zinc ([EFSA-Q-2014-00249](#))

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for zinc, which summarises the comments received during the public consultation on this opinion (opened from 14 May 2014 to 08 July 2014), was presented and discussed, and subsequently endorsed by the Panel on 19 September. The technical report was published together with the Opinion related to the dietary reference values for zinc (see also item 6.10) via the following link: <http://www.efsa.europa.eu/en/supporting/pub/672e.htm>.

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 chromium ([EFSA-Q-2011-01209](#))

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 18 September subject to the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsajournal/pub/3845.htm>.

6.13 Draft technical report on the comments received during the public consultation for the draft DRVs for chromium ([EFSA-Q-2014-00365](#))

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for chromium, which summarises the comments received during the public consultation on this opinion (opened from 06 June 2014 to 03 August 2014), was presented and discussed, and subsequently endorsed by the Panel on 18 September. The technical report was published together with the Opinion related to the dietary reference values for chromium (see also item 6.12) via the following link: <http://www.efsa.europa.eu/en/supporting/pub/669e.htm>.

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 selenium ([EFSA-Q-2011-01223](#))

Following the online public consultation of the above-mentioned draft Opinion, a revised draft document taking into consideration relevant comments received (see also item 6.15) was discussed and adopted by the Panel on 19 September subject to

the incorporation of editorial changes. The full text is published in the EFSA Journal: <http://www.efsa.europa.eu/en/efsajournal/pub/3846.htm>.

6.15 Draft technical report on the comments received during the public consultation for the draft DRVs for selenium ([EFSA-Q-2014-00469](#))

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for selenium, which summarises the comments received during the public consultation on this opinion (opened from 15 July 2014 to 19 August 2014), was presented and discussed, and subsequently endorsed by the Panel on 19 September. The technical report was published together with the Opinion related to the dietary reference values for selenium (see also item 6.14) via the following link: <http://www.efsa.europa.eu/en/supporting/pub/670e.htm>.

Novel Foods

6.16 DSM Nutritional Products-Draft Opinion on the extension of uses for DHA and EPA-rich algal oil from *Schizochytrium* sp. as a Novel Food ingredient ([EFSA-Q-2014-00218](#))

On 18 September, 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/3843.htm>

Others

6.17 Draft opinion on Safety assessment of caffeine ([EFSA-Q-2013-00220](#))

On 18 September, the draft opinion was presented and different sections related to the safety assessment of caffeine were discussed. The main changes introduced into the opinion since the last Plenary meeting were outlined and discussed. The current revised structure of the opinion was agreed.

The Panel was informed that new data on food consumption in a number of Member States had recently become available to EFSA. The NDA Panel considered it highly important to include these data in the intake assessment for caffeine, and therefore postponed the opinion's endorsement for public consultation. A revised draft which will take into account the new food composition data will be scheduled for discussion and possible endorsement for public consultation at the Plenary meeting in December 2014.

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) – 8 new applications were received: “Glucose contributes to the maintenance of normal brain function”; “Glucose contributes to normal cognitive function”; “Glycaemic carbohydrates contribute to the maintenance of normal brain function”; “Dextrose Tablets contribute to the maintenance of normal brain function”; “Combination of standardized pomegranate pomace extract and greater galangal rhizome powder increases the number of motile spermatozoa in semen”; “SYNBIO® persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being”;

“Clarinol® or Tonalin® contributes to a reduction in body fat mass”; “Coffee C21 contributes to the maintenance of DNA integrity in cells of the body”.

- *Article 14 claims* – 2 applications were received: “L-tug lycopene has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease”; and “Salt is essential for the electrolyte balance of the body”. Two applications were withdrawn: “Complex Carbohydrates and supply of metabolic energy”; and “Milk protein, and, growth and muscle development”.

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

Not applicable.

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

8.1 Scientific Committee and other Scientific Panels

At the last Scientific Committee (SC) meeting held on 8-9 July 2014, the vice chair of the NDA Panel presented to the SC an update on activities in the areas of nutrition.

The **adopted NDA Opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury (EFSA-Q-2013-00167)**⁷ was also presented to the SC. This opinion complements the CONTAM opinion on the risk for public health related to the presence of mercury and methylmercury in food that was adopted in 2012. The Scientific Committee discussed the original mandate received from the European Commission and underlined the difficulty of doing a formal risk-benefit assessment; indeed, the various type of data available would make a quantitative risk-benefit assessment very difficult. The Scientific Committee agreed to prepare a statement reviewing the outcome of the previous work done by the CONTAM and NDA Panels by the end of 2014.

During the meeting the SC endorsed the **Draft opinion on revised structure of EFSA’s opinions and statements** (EFSA-Q-2012-00786). The document will be published and then implemented by all the EFSA Panels for a period of about 10 months. After this testing phase, feedback from the Panels will be gathered and the new structure will be revised, if needed.

8.2 Working groups

Postponed to a future Plenary meeting.

8.3 EFSA

Per Bergman informed the Panel about the scope and status of the Matrix Project, which is an EFSA Organisational Development project aiming to develop an IT-based system for the electronic management of the applications received by EFSA for risk assessment in the area of regulated products. The Panels dealing with regulated

⁷ <http://www.efsa.europa.eu/en/efsajournal/doc/3761.pdf>

products were invited to review and confirm the completeness and correctness of data requirements, which have been retrieved and based on the Scientific Guidance Documents developed by EFSA and its Scientific Panels.

With respect to the evaluation process of application dossiers submitted to EFSA, the Panel was informed about initiatives undertaken by the REPRO department to increase Efficiency. The list of measures/actions for consideration include: how outsourcing can lead to increased efficiency and lower workload; greater use of hearing experts (if their written reply to stop-the-clock questions are unclear); update Guidance Documents for applicants on a regular basis or publish Explanatory Notes on Guidance documents (Technical Reports of EFSA); EFSA staff members to take greater part in drafting outputs; meetings with chair of panel/WG prior to meetings to resolve contentious issues, and to clarify procedural issues before meetings, etc. Panel members were invited to provide their feedback.

Per Bergman will leave EFSA to take up a new position as Head of the Risk and Benefit Assessment Unit at the Swedish National Food Agency on 01 December 2014. Juliane Kleiner will serve as *ad interim* Head of REPRO and Tobin Robinson will be *ad interim* Head of SCISTRAT.

8.4 European Commission

Not applicable.

9. Other scientific topics for information and/or discussion

Not applicable.

10. Any Other Business

10.1 The next plenary meeting will be held on 29-31 October 2014.

Annex I

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

In the SDoI filled for the present meeting, **Dr. A. Sjödin** declared the following interest: an application related to “**Lactobacillus plantarum TENSIA® in the semi-hard Edam-type “heart cheese”**” ([EFSA-Q-2014-00097](#), agenda item 6.7). In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁹, 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 6.7 by the concerned scientific group.

In the SDoI filled for the present meeting by **Prof. S. Strain**, the following interest was identified: an application from “DSM Nutritional Products Ltd. related to **Preformed DHA**” ([EFSA-Q-2014-00059](#), agenda point 6.5). In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁹, 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 6.5 by the concerned scientific group.

In the SDoI filled for the present meeting, **Prof. M. Heinonen** declared the following interest: an application from “*Oy Karl Fazer Ab* related to “**High-fibre sourdough rye bread**” ([EFSA-Q-2014-00012](#), agenda point 6.2). In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁹, 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 6.2 by the concerned scientific group.

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>