

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 72nd Plenary meeting

**Held on 20 – 21 April 2016, Parma (Italy)
(Agreed on 25 April 2016)**

Participants

■ Panel Members

Jean Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Androniki Naska, Monika Neuhäuser-Berthold, Kristina Pentieva, Yolanda Sanz, Anders Sjödin, Alfonso Siani, Martin Stern, Daniel Tomé, Dominique Turck (Chair), Marco Vinceti and Peter Willatts¹.

■ Hearing Experts²:

Not Applicable

■ European Commission:

Not Applicable

■ EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Wolfgang Gelbmann, Jelena Gudelj Rakic, Leng Heng, Joaquim Maia, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Olga Vidal Pariente.

■ Observers:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ Present on the first day only.

² 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>

Apologies were received from Harry McArdle, Grazyna Nowicka and Henk Van Loveren.

Anders Sjödin did not participate in agenda points 5.2 and 8.6.

2. Adoption of the 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 Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. For further details on the outcome of the screening of the ADoIs or the SDIs, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Report on written procedures since 71st Plenary meeting

The minutes of the 71st Plenary meeting held on 1-3 February 2016 were agreed on 8 February 2016⁵.

The opinion related to 'DHA and contributes to improved memory function' (Art. 13.5, 0438_UK, EFSA-Q-2015-00456) was adopted by written procedure on 30/03/2016. 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/4455>

5. Scientific outputs submitted for discussion and/or possible adoption

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

5.1. Tate & Lyle PLC – "Polydextrose contributes to an improved bowel function by increasing stool bulk" (Art. 13.5, 0440_UK, EFSA-Q-2015-00550)

On 20 April, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁵ <http://www.efsa.europa.eu/it/events/event/160201>

will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/4480>

5.2. Probi AB – “*Lactobacillus plantarum 299v increases non-haem iron absorption*” (Art. 13.5, 0441_SE, EFSA-Q-2015-00696)

On 20 April, the draft opinion was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will apply.

Dietary Reference Values

5.3. 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 choline (EFSA-Q-2011-01208)

On 21 April, a draft opinion, which takes into consideration relevant comments received from the public consultation (see item 5.4), was introduced and discussed. This document proposes dietary reference values for **choline** for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/efsajournal/pub/4484>

5.4. Draft technical report on the outcome of the public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for choline (EFSA-Q-2015-00670)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for **choline**, which summarises the comments received during the public consultation on this opinion (which was open from 22 February 2016 to 21 March 2016), was presented and discussed, and subsequently endorsed by the Panel on 21 April.

The full text will be available in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/publications/supporting>

5.5. 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 B6 (EFSA-Q-2011-01228)

On 21 April, a draft opinion, which takes into consideration relevant comments received from the public consultation (see item 5.6), was

introduced and discussed. This document proposes dietary reference values for **vitamin B6** for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel subject to the incorporation of editorial changes.

The full text will be available in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/efsjournal/pub/4485>

5.6. Draft technical report on the outcome of the public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for vitamin B6 (EFSA-Q-2015-00675)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for **vitamin B6**, which summarises the comments received during the public consultation on this opinion (which was open from 3 February 2016 to 16 March 2016), was presented and discussed, and subsequently endorsed by the Panel on 21 April.

The full text will be available in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/publications/supporting>

6. New Mandates

6.1 Applications pursuant to Article 14/13.5 of Regulation (EC) No 1924/2006

Since the last Plenary meeting, one Article 14 Children claim was received: "Calcium is important for the development of bones (EFSA-Q-2008-128)".

These new requests will be assigned to the standing working group (SWG) on Claims. EFSA NDA guidance documents on health claims will be taken into consideration for the evaluation of the new application received.

6.2 Other mandates

- A new request was received from the Commission for a scientific opinion on betaine as a novel food ingredient (EFSA-Q-2016-00287). This new request will be assigned to the standing working group (SWG) on novel foods.
- Two additional requests were received from the Commission for scientific opinions on: 1) scientific and technical guidance for the assessment of formulae manufactured from protein hydrolysates (EFSA-Q-2016-00276); 2) the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.60 g/100 kcal (EFSA-Q-2016-00275).

The Panel agreed to set up a standing working group (SWG) on Infant Nutrition to assist the Panel in undertaking all necessary preparatory tasks in relation to draft scientific outputs for these two mandates. The appointed Chair is Dominique Turck. The setting of the SWG has been processed in accordance with the Decision of the EFSA Management Board concerning the establishment and operation of the Scientific Committee, Scientific Panels and of their working groups⁶ and the Decision of the Executive Director on selection of experts⁷. The full composition of the SWG, once established, will be published on the EFSA website.

- The NDA Panel is requested by EFSA (a self-task mandate) to update the scientific and technical guidance for the preparation and presentation of an application for authorization of a health claim published in 2011⁸ (EFSA-Q-2016-00285, see also agenda point 8.3). This self-task mandate has been assigned to the standing working group (SWG) on claims.

7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

7.1 Scientific Committee (SC) and other Scientific Panels

Androniki Naska, vice-Chair of the NDA Panel, provided feedback on the 78th plenary meeting of the SC, which took place concomitantly with the 71st NDA Plenary meeting on 20-21 April 2016, highlighting activities which are relevant to the NDA panel⁹.

The SC WG on Guidance review is working on a scientific opinion on priority topics for the development of risk assessment guidance by EFSA's Scientific Committee in 2016-2018.

7.2 EFSA including its Working Groups (WG)/Task Forces

The Chairs of respective WGs reported back to the Panel:

- *WG on Claims* – Draft opinions related to six Art 13(5) and two Art 14 claims were discussed. The “stop-the clock” procedure for requesting clarifications/supplementary information from the applicant was applied for five applications. Four opinions were submitted to this Plenary for discussion and/or for possible adoption.
- *WG on Novel Foods* – At the last meeting, the WG discussed and elaborated draft opinions on the following NF applications:

⁶ http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/paneloperation.pdf

⁷ <http://www.efsa.europa.eu/sites/default/files/assets/expertselection.pdf>

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/2170>

⁹ <http://www.efsa.europa.eu/sites/default/files/event/160420a-a.pdf>

fermented soybean extract (Nattokinase), phytosterol esters (extension of use), synthetic L-ergothioneine, hydroxytyrosol, and proline-specific oligopeptidase from *Aspergillus niger*.

- *WG on DRVs for vitamins* – The WG has been working on vitamin B6 and choline. The WG will be reviewing comments received from public consultation (open until 16 May 2016) on vitamin D, and continuing to work on vitamin K, thiamine, and riboflavin.
- *WG on DRVs for minerals* – The WG has been working on sodium, potassium and chloride.

7.3 European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1 Draft Scientific Opinion on the energy conversion factor of D-tagatose for labelling purposes (EFSA-Q-2009-00227)

On 20 April, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion will be amended, taking into account the Panel's comments. Its endorsement for release for public consultation will be deferred to a future plenary meeting¹⁰.

8.2 Pierre Fabre Medicament – “V0137, a DHA-enriched fish oil, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function” (Art. 13.5, 0446_FR, EFSA-Q-2016-00071)

On 20 April, the draft opinion was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will apply.

8.3 Updating the scientific and technical guidance for the preparation and presentation of an application for authorization of a health claim (EFSA-Q-2016-00285)

Over the last years, considerable experience in the evaluation of health claim applications has been gained. The NDA Panel has translated the lessons learnt from these experiences into a revised General scientific guidance for stakeholders on health claim applications¹¹, which was recently published and represents a step

¹⁰ The next NDA Panel Plenary meeting will be held on 28-30 June 2016.

¹¹ <http://www.efsa.europa.eu/it/efsajournal/pub/4367>

forward in assisting applicants in the compilation of their applications for health claim authorisation. In this context, note is taken of the need to adapt the existing scientific and technical guidance for stakeholders¹² published in 2011 to the new scientific and technical developments in this area.

On 20 April, a revised structure of the guidance was presented and discussed. The draft guidance was referred back to the WG on Claims for further elaboration. Its endorsement for release for public consultation will be deferred to a future plenary meeting¹³.

8.4 Japan Bio Science Laboratory - Fermented soybean extract (Nattokinase-NSKSD®) (EFSA-Q-2015-00294)

On 20 April, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion was referred back to the WG on Novel Foods for further elaboration, taking into account the Panel's comments.

8.5 Unilever PLC and Unilever N.V. - Phytosterol esters (extension of use, cooking oils) (EFSA-Q-2014-00865)

On 21 April, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion was referred back to the WG on Novel Foods for further elaboration, taking into account the Panel's comments.

8.6 Granarolo Spa - "Consumption of *L. rhamnosus* GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" (Art. 13.5, 0439_IT, EFSA-Q-2015-00488)

On 21 April, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion was referred back to the WG on Claims for further elaboration, taking into account the Panel's comments.

9. Any other business

9.1 Report back from EFSA Webinar on Scientific aspects to consider when preparing a health claim application (10 March 2016)

The webinar presented practical examples to illustrate key scientific issues to be considered when preparing health claim applications, following the recently released General scientific guidance for stakeholders on health claim applications. The examples focused on

¹² Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim <http://www.efsa.europa.eu/en/efsajournal/pub/2170>

¹³ The next NDA Panel Plenary meeting will be held on 28-30 June 2016.

health claims based on the essentiality of nutrients and claims other than those based on the essentiality of nutrients, and were presented by Sean Strain and Alfonso Siani. Around 207 people attended the online event. Participants could submit questions via the Q&A box throughout the webinar and a team of NUTRI scientific officers provided answers to each question received. The recording of the webinar is published in the dedicated event page on the EFSA website together with the final presentation.

9.2 Report back from the EFSA stakeholder meeting on Novel Foods (11 April 2016)

A meeting with stakeholders was held on 11 April in Brussels to explain the guidance documents on applications for Novel Foods and notifications for Traditional Foods from third countries, and to get feedback before the end of the public consultation period¹⁴ (closing 21 April). More than 80 people attended the meeting. The meeting gave stakeholders such as Member States, international organisations, academic institutions, NGOs and representatives of the private sector the opportunity to exchange views with EFSA experts on both documents. See EFSA news story here: <http://www.efsa.europa.eu/en/press/news/160415>

9.3 Next NDA Plenary meeting

The 73rd NDA Panel Plenary meeting, which is open to observers, will be held on 28-30 June 2016 in Brussels.

¹⁴ <http://www.efsa.europa.eu/en/press/news/160218b>

Annex I

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

In the SDoI filled for the present meeting, **Dr Anders Mikael Sjödin** declared an interest for the application related to: '*Lactobacillus plantarum* 299v' (EFSA-Q-2015-00696, agenda item 5.2), and '*Lactobacillus rhamnosus* GG (ATCC 53103) and fructooligosaccharides (FOS)' (EFSA-Q-2015-00488, agenda item 8.6). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on 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 the exclusion of the expert from any discussion, voting or other processing of agenda items 5.2 and 8.6 by the concerned scientific group.