

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 79th Plenary meeting

Held on 27-29 June 2017, Parma (Italy)

(Agreed on 6 July 2017)

Participants

■ Panel Members

Jean-Louis Bresson, Barbara Burlingame, Harry J McArdle, Tara Dean¹, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Androniki Naska, Monika Neuhäuser-Berthold¹, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti² and Peter Willatts.

■ Hearing Experts³:

Not applicable

■ European Commission:

Fruzsina Nyemecz (DG SANTE, for Agenda items 5.10-5.11)

■ EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

■ Observers:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Anders Sjödin did not participate in agenda item 5.5.

2. Adoption of the Agenda

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

¹ Participated on 27-28 June

² Participated on 28-29 June

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>

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 Scientific 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 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 76th Plenary meeting

The minutes of the 78th Plenary meeting held on 4-6 April 2017 were agreed by written procedure on 13 April 2017⁶.

5. Scientific outputs submitted for possible adoption/endorsement

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

5.1. Loc Troi Group - "Vibigaba germinated brown rice and contributes to the maintenance of normal blood cholesterol level" (Art. 13.5, 0453_NL, EFSA-Q-2017-00030)

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4913/abstract>

5.2. Loc Troi Group - "Vibigaba germinated brown rice and contributes to the maintenance of normal blood pressure" (Art. 13.5, 0454_NL, EFSA-Q-2017-00031)

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4914/abstract>

5.3. Loc Troi Group - "Vibigaba germinated brown rice and contributes to weight loss" (Art. 13.5, 0455_NL, EFSA-Q-2017-00032)

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

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

⁶ <https://www.efsa.europa.eu/sites/default/files/event/170404-0m.pdf>

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4915/abstract>

5.4. Loc Troi Group - "Vibigaba germinated brown rice and contributes to the maintenance of normal blood glucose levels" (Art. 13.5, 0456_NL, EFSA-Q-2017-00033)

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4916/abstract>

5.5. Biosearch Life - "Lactobacillus fermentum CECT5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (Art. 14, 0447_FR, EFSA-Q-2016-00318)

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4917/abstract>

5.6. Cargill R&D Centre Europe - "Zerose® erythritol sugar-free hard confectionary and reduction of dental plaque which reduces the risk of caries" (Art. 14, 0452_BE, EFSA-Q-2017-00002)

On 27 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4923/abstract>

5.7. Draft guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094)

The draft guidance document, which updates the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health published in 2011, was presented and discussed. This guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to antioxidants, oxidative damage and cardiovascular health. It focuses on key issues, particularly:

- claimed effects which are considered to be beneficial physiological effects, and
- characteristics of human intervention studies which can provide evidence for the scientific substantiation of specific claims addressed in this guidance (e.g. appropriate outcome

variables and methods of measurement, suitable study group(s), appropriate duration of the study, suitable controls).

The draft guidance was endorsed by the Panel on 28 June for release for public consultation subject to editorial changes. The public consultation will be launched in the next few weeks via the following link:

[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)2397-8325](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2397-8325)

DRVs

5.8. Draft technical report on the outcome of a public consultation on Dietary Reference Values for riboflavin (EFSA-Q-2016-00079)

A technical report on the outcome of a public consultation on a draft Opinion related to the dietary reference values for riboflavin was presented and discussed. EFSA received comments from 5 interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from 21 April to 28 May 2017) and how the comments were addressed. It was subsequently endorsed by the Panel on 27 June.

The full text of the technical report will be available in the coming weeks in the EFSA Journal, under the related opinion, via the following link:

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4919/abstract> (see also item 5.9).

5.9. Draft opinion on Dietary Reference Values for riboflavin (EFSA-Q-2011-01222)

Following the public consultation on the above-mentioned draft Opinion, relevant comments received (as outlined and discussed under item 5.8) were taken into consideration in a revised draft document. This document proposes dietary reference values for riboflavin for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel on 27 June subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4919/abstract>

Complementary Feeding

5.10. Draft technical report on the outcome of a public consultation on the draft protocol for a systematic review on health outcomes for the scientific assessment of the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2017-00068)

A technical report on the outcome of a public consultation on the draft protocol for a systematic review on health outcomes related to

the age of introduction of complementary food for the scientific assessment of the appropriate age of introduction of complementary feeding into an infant's diet was presented and discussed. EFSA received comments from 2 interested parties. The report summarises the comments received during the public consultation on this output (which was open from 16 February to 23 March 2017) and how the comments were addressed. It was subsequently endorsed by the Panel on 27 June.

The full text of the technical report will be available in the coming weeks via the following link: [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)2397-8325](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2397-8325) (see also item 5.11).

5.11. Draft protocol for a systematic review on health outcomes for the scientific assessment of the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2016-00864)

Following the public consultation on the above-mentioned draft protocol, relevant comments received (as outlined and discussed under item 5.10) were taken into consideration in a revised draft document. The draft protocol, which specifies the approach used for identification of relevant studies, data extraction from relevant studies, and assessment of the reliability of studies, was presented and discussed. It was subsequently endorsed by the Panel on 27 June subject to the incorporation of editorial changes.

The full text will be published via the following link: [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1831-4732](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1831-4732)

Novel Foods

5.12. Glycom A/S - Draft opinion on N-acetyl-D-neuraminic acid (EFSA-Q-2016-00488)

On 28 June 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.4918/abstract>

6. New Mandates

The Nutrition Unit updated the Panel members on new mandates received since the last Plenary meeting.

- **Health claims**

One Article 13.5 application (claims based on newly developed science and/or which include a request for the protection of proprietary data) was received: "Tea flavanols improve endothelium-dependent vasodilation which contributes to healthy blood flow" (EFSA-Q-2017-00419).

This mandate has been assigned to the standing working group (SWG) on Claims.

- **Novel Foods**

In the framework of Regulation (EC) No 258/97, a new request was received from the Commission asking EFSA for a scientific opinion related to: the safety of D-ribose as a novel food ingredient (EFSA-Q-2017-00461).

A request was also received from the Commission asking EFSA to carry out a supplementary dietary exposure and safety assessment of L-ergothioneine (EFSA-Q-2017-00461).

These requests will be assigned to the standing working group (SWG) on novel foods.

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

7.1. Scientific Committee (SC) and other Scientific Panels

The 83rd Plenary meeting of the Scientific Committee took place on 26 April 2017.⁷ The guidance on risk assessment of substances present in food intended for infants below 16 weeks of age was adopted by the SC and published: <http://www.efsa.europa.eu/en/efsajournal/pub/4849> (see Agenda item 8.3).

The Panel was informed of a public consultation (open until 28th July: <https://www.efsa.europa.eu/en/consultations/call/170612>) on a draft opinion on the use of epidemiological studies in risk assessment of pesticides. The document examines the methodological limitations that affect the quality of such studies and makes recommendations on how to improve their quality and reliability and thus facilitate an appropriate use of epidemiological data in the risk assessment of pesticides.

The SC standing working group on Genotoxicity has been working on the development of an opinion addressing the Commission's mandate asking for clarification on specific aspects of genotoxicity assessment. The draft opinion will be tabled for possible endorsement by the SC for public consultation at the July plenary.

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

The Chairs of respective WGs reported back to the Panel:

- WG on Claims – Six draft opinions were discussed/elaborated, and were submitted to this Plenary for possible adoption (Agenda items 5.1-5.6). The WG also discussed the draft guidance document, which updates the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health published in 2011. The draft guidance was

⁷ <https://www.efsa.europa.eu/en/events/event/170426-0>

submitted to the Panel for possible endorsement for release for public consultation (item 5.7).

- WG on Novel Foods - The WG discussed/elaborated on draft opinions on the following Novel Food applications: N-acetyl-D-neuraminic acid (item 5.12.), Betaine, methylnicotinamide chloride, pyrroloquinoline quinone disodium salt. A new application (D-Ribose) was presented.

On 15 June, EFSA held a webinar to present key scientific issues regarding the required compositional and toxicological data as outlined in its guidance document on the preparation and presentation of a novel food application (<https://www.efsa.europa.eu/en/events/event/170615>). While Marina Heinonen and Inge Mangelsdorf gave the presentation, questions submitted by participants during the webinar were answered by a team from EFSA's Nutrition Unit.

Following publication of two EFSA opinions related to novel foods, post-adoption teleconferences/meetings between EFSA staff and the applicants were held for: Alginate-Konjac-Xanthan Polysaccharide Complex (PGX) (EFSA-Q-2015-00469); EstroG-100TM as a novel food (EFSA-Q-2015-00249).

- WG on Infant Nutrition - The WG discussed/elaborated on: the draft protocol for a systematic review on health outcomes related to the age of introduction of complementary food for the scientific assessment of the appropriate age of introduction of complementary feeding into an infant's diet, taking into consideration comments received from the public consultation (items 5.10-5.11).
- WG on DRVs for vitamins – The WG has been working on riboflavin, taking into consideration comments received from the public consultation (items 5.8-5.9). A joint meeting of the WGs on DRVs for vitamins and on Infant Nutrition was held to discuss the draft Opinion on the tolerable upper intake level (UL) for vitamin D in infants (EFSA-Q-2017-00208).
- WG on DRVs for minerals - The WG has been working on the draft protocol (applying the PROMETHEUS approach) for DRVs for sodium, i.e. to certain sections of the opinion related to sodium and health consequences (see item 8.1).
- *Ad-hoc* WG on added sugars - The Panel was informed about the composition of the *ad-hoc* WG which 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 Groups⁸ and the Decision of the Executive Director on selection of experts⁹. The composition of the *ad-hoc* WG is published on the EFSA website¹⁰.

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/paneloperation.pdf

⁹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

¹⁰ <https://www.efsa.europa.eu/en/nutrition/working-groups>

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. Dietary Reference Values for sodium (EFSA-Q-2011-01224)

The Chair of the WG on DRVs for minerals provided an overview on the state of play of the on-going preparatory work undertaken on DRVs for sodium. The context, the framework and the status of different chapters of the draft opinion, and issues identified (e.g. for estimation of sodium intake based on 24-hour urinary excretion vs. dietary questionnaires, use of balance studies) were outlined.

The Panel was also given an overview on the status of the draft protocol which applies the PROMETHEUS (Promoting Methods for evidence use in scientific assessments) approach to section 5.5 (the assessment of possible relationships between sodium intake and health outcomes, including dose-response relationship(s), where applicable) and section 6 of the opinion (the integration of different lines of evidence for setting DRVs).

The draft opinion and the draft protocols will be submitted to the Panel in the upcoming Plenary meeting¹¹ for discussion and possible release for public consultation.

8.2. ANS Panel's draft guidance for the safety evaluation of sources of nutrients (EFSA-Q-2016-00150)

The Panel discussed the above-mentioned draft guidance, particularly regarding data requirements and the proposed approach applied for the bioavailability of nutrient sources.

A revised draft incorporating the comments discussed will be circulated to the Panel for further comments before submitting it to the ANS Panel's working group.

8.3. Scientific Committee guidance on the Risk Assessment of Substances Present in Food Intended for Infants¹²

The Panel was given a presentation on the SC-adopted guidance on risk assessment of substances present in food intended for infants below 16 weeks of age. The approach used to develop this guidance and the decision tree proposed to enable a risk assessment of substances present in food intended for infants below 16 weeks of age were outlined. The Panel took note that additional information is needed when testing substances present in food for infants below 16 weeks of age, and that the approach to be taken for the risk assessment is on a case-by-case basis, depending on whether the substance is added intentionally to food and is systemically available.

¹¹ Plenary meeting of 19-21 September 2017

¹² <http://www.efsa.europa.eu/en/efsajournal/pub/4849>

9. Any other business

- Further to a request from the Commission seeking clarification regarding an EFSA opinion (EFSA-Q-2012-00968)¹³, the Panel reiterated its conclusion that all three studies submitted by the applicant and claimed as proprietary (i.e. Barrat et al., 2012, Barrat et al., 2013 and Ogier et al., 2013) were needed to come to a favourable opinion on the health claim related to a combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate and the reduction of blood LDL-cholesterol concentrations.
- The Panel was provided with feedback from the Uncertainty Workshop which was held on 22-23 June.
- The Panel took note of the EFSA Scientific Network on Novel Foods (see the Terms of Reference endorsed by the Advisory Forum on 8 June: <https://www.efsa.europa.eu/en/events/event/170608>).
- The Panel also took note of the EFSA call for the renewal of its ten Scientific Panels and its Scientific Committee, which was launched on 1 June (<https://www.efsa.europa.eu/en/careers/experts>). The call will be closed on 8 September 2017. EFSA is looking for independent experts who will carry out scientific assessments and develop related assessment methodologies. The application tool was introduced to the Panel. Panel members were invited to publicize the call.
- The Panel was informed about the Management Board decision changing the way EFSA's Scientific Committee, its Scientific Panels and Working Groups are established and operate (<https://www.efsa.europa.eu/sites/default/files/paneloperation170601.pdf>).
- The 80th NDA Plenary meeting will be held on 19-21 September 2017 in Parma.
- The Panel was informed of the meeting scheduled for 2018:
 - 83rd NDA Plenary: 06-08 February 2018
 - 84th NDA Plenary: 17-19 April 2018
 - 85th NDA Plenary: 05-06 June 2018 (tbc)
 - 86th NDA Plenary: 27-29 June 2018
 - 87th NDA Plenary: 02-04 July 2018 (tbc)
 - 88th NDA Plenary: 25-27 September 2018
 - 89th NDA Plenary: 23-25 October 2018
 - 90th NDA Plenary: 11-13 December 2018

¹³ <https://www.efsa.europa.eu/en/efsajournal/pub/3327>

Annex I

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

Dr Anders Sjödin had the following interest: "*Lactobacillus fermentum* CECT5716" (EFSA-Q-2016-00318, agenda item 5.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁴ and the Decision of the Executive Director on Declarations of Interest¹⁵, 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 resulted in the exclusion of the expert from any discussion, voting or other processing of item 5.5 by the concerned scientific group.

¹⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

¹⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>