

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 81st Plenary meeting

Held on 24-26 October 2017, Parma (Italy)
(Agreed on 3 November 2017)

Participants

■ Panel Members

Jean-Louis Bresson, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Kristina Pentieva¹, Yolanda Sanz, Alfonso Siani, Anders Sjödin², Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts.

■ Hearing Experts³:

Not applicable

■ European Commission:

Not applicable

■ EFSA:

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

SCER Unit: Nikolaos Georgiadis (for item 8.4)

PRAS Unit: Federica Crivellente (for item 8.3)

AFSCO Unit: Nicoline Le Gourierec (for item A.O.B)

LA Unit: Simone Gabbi (for item A.O.B)

■ Observers:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Barbara Burlingame and Grazyna Nowicka.

¹ Participated via teleconference on 24-25 October

² Participated on 24-25 October

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>

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 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.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Report on written procedures since 80th Plenary meeting

The minutes of the 80th Plenary meeting held on 19-21 September 2017 were agreed by written procedure on 27 September 2017⁶.

5. Scientific outputs submitted for possible adoption/endorsement

Novel Foods

5.1. DuPont Nutritional Biosciences ApS - Draft opinion on Betaine (EFSA-Q-2016-00287)

On 25 October 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/wol1/doi/10.2903/j.efsa.2017.5057/abstract>

5.2. Mitsubishi Gas Chemical Company Inc. - Draft Opinion on Pyrroloquinoline quinone disodium salt (EFSA-Q-2016-00659)

On 24 October 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/wol1/doi/10.2903/j.efsa.2017.5058/abstract>

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

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

⁶ <https://www.efsa.europa.eu/en/events/event/170919-1>

5.3. Ametis JSC - Draft statement on Taxifolin (EFSA-Q-2017-00554)

On 25 October 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/wol1/doi/10.2903/j.efsa.2017.5059/abstract>

5.4. Tetrahedron - Draft statement on L-ergothioneine (EFSA-Q-2017-00448)

On 25 October 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/wol1/doi/10.2903/j.efsa.2017.5060/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) were received: "Xanthohumol enriched roasted malt extract (XERME) helps to maintain the integrity of DNA and protects against oxidative damage in the cells of the body" (EFSA-Q-2017-00663).

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

One application pursuant to Article 13.5 related to "Dietary Menaquinone-7 (MK-7) helps promote cardiovascular health via the activation of matrix Gla protein (MGP), a natural inhibitor of vascular calcification" (EFSA-Q-2017-00235) was withdrawn.

- Novel Foods**

Two new requests were received from the Commission in the framework of Regulation (EC) No 258/97, asking EFSA for scientific opinions related to: xylo-oligosaccharide as a novel food ingredient (EFSA-Q-2017-00665); shrimp peptide concentrate as a novel food ingredient (EFSA-Q-2017-00679)

These requests have been 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

No SC plenary meeting took place since the last plenary meeting.

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

The Chairs of respective WGs reported back to the Panel:

- WG on Claims – No meeting took place since the last plenary meeting.
- WG on Novel Foods - The WG discussed/elaborated on draft opinions/statements related to: betaine (item 5.1), pyrroloquinoline quinone disodium salt (item 5.2), taxifolin (item 5.3), L-ergothioneine (item 5.4), and D-Ribose (item 8.2). Four draft documents were submitted to the Panel for possible adoption / for information and discussion.
- WG on Infant Nutrition – The WG discussed the appraisal of studies related to the outcome “food patterns/food preferences”. These studies were identified from the 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.
- WG on DRVs for vitamins – The outline of the work plan for the appraisal of the literature performed for the draft opinion on the tolerable upper intake level (UL) for vitamin D for infants, including the future structure of the opinion, was discussed.
- WG on DRVs for minerals - Public consultation on the scientific opinion on dietary reference values for sodium (intermediate draft) and related protocol is open until 12 November 2017: <https://www.efsa.europa.eu/en/consultations/call/170929>.
- *Ad-hoc* WG on added sugars – The WG discussed the new version of the draft protocol for the assessment (in line with the methodology described in the PROMETHEUS project), which incorporates all the contributions and comments received. The draft protocol was presented to the Panel for information and discussion (item 8.1).

7.3. European Commission

Not applicable

8. Other scientific topics for information and/or discussion

8.1. Draft protocol for added sugars (EFSA-Q-2017-00646)

The Panel was presented with the draft protocol for the assessment of the mandate request. The protocol is being discussed by the WG on Added Sugars and was presented to the NDA Panel members to

collect their views and inputs on the approach proposed. The comments received will be incorporated in the next version of the protocol and will be discussed at the next meeting of the WG on Added Sugars.

8.2. Bioenergy Life Science Inc - Draft opinion on D-Ribose (EFSA-Q-2017-00461)

The draft opinion was presented to the Panel for information. The Panel provided feedback on the issues that are still pending for the finalization of the assessment. The assessment of the dossier will continue at the next meeting of the WG on Novel Foods.

8.3. Scientific Opinion of the PPR Panel on the use of epidemiological studies linking exposure to pesticides and health effects (EFSA-Q-2014-00481)

The Panel was given a presentation on the approach and methodology proposed by the PPR Panel for an appropriate use of epidemiological data for pesticide risk assessment (<http://www.efsa.europa.eu/en/efsajournal/pub/5007>). The proposed recommendations on how to improve the quality and reliability of epidemiological studies on pesticides to overcome limitations and to facilitate appropriate use of epidemiological data for pesticide risk assessment were outlined. A methodological approach to integrate multiple lines of evidence, in particular how epidemiological studies can complement well-designed toxicological in vivo studies and mechanistic studies in the area of pesticide risk assessment, was also presented. Epidemiologic data can thus form part of the overall Weight of Evidence of available data. A contribution to establishing causation can be made by providing evidence of biological plausibility where this is available.

8.4. Scientific Committee guidance on the use of the weight of evidence approach in scientific assessments (EFSA-Q-2015-00007)

The Panel was given a presentation on the above-mentioned adopted SC guidance, which addresses the use of weight of evidence approaches in scientific assessments using both qualitative and quantitative approaches. Weight of evidence assessment is defined in the guidance as a process in which evidence is integrated to determine the relative support for possible answers to a question. Three basic steps considered for the weight of evidence assessment were introduced: (1) assembling the evidence into lines of evidence of similar type, (2) weighing the evidence, and (3) integrating the evidence. The guidance identifies reliability, relevance and consistency as three basic considerations for weighing evidence. Several case studies covering the various areas under EFSA's remit are annexed to the guidance document to

illustrate the applicability of the proposed approach (<https://www.efsa.europa.eu/en/efsajournal/pub/4971>).

9. Any other business

- The Panel was informed about new implementing rules on **Competing Interest Management** developed following the adoption of the EFSA Policy on Independence on 21 June 2017.
- The Panel was briefed about the **EU-FORA - The EUropean FOod Risk Assessment Fellowship Programme**, which aims at building the EU Risk Assessment capacity and knowledge community. Calls for applications from Hosting sites and Fellows will be published in October 2017.

EFSA is organising the Risk Assessment Research Assembly (RARA) on 7 February 2018 in Utrecht (NL), aiming at: (i) providing a platform for networking, especially to facilitate partnering on research ideas and identification of project funding mechanisms; and (ii) raising awareness of the importance of public funding for food safety to inform future food safety research agenda setting. The online registration for participation is open via the registration form until 13 November 2017: <http://www.efsa.europa.eu/en/events/event/180207>.

- In relation to Novel Foods, the Panel took note of the kick-off meeting of the EFSA Scientific Network on Novel Foods to be held on 8/9 November 2017 in Parma. In this context, a questionnaire was sent to members of the Network in order to (i) collect information on how NF applications have been assessed so far by Member States (MS) when preparing the initial assessment report and when providing comments by day 60; (ii) to gather information and ideas on the approach and methodologies MSs intend to apply for the assessment of Article 14 notifications of Traditional Foods within the 4 months.

The Panel also took note of the extension of the deadline until 17 November for applying to the Article 36 tasking Grant "GP/EFSA/NUTRI/2017/01-Entrusting preparatory work for the safety assessment on Novel Foods and Traditional Foods from third countries" published on the EFSA website: <https://www.efsa.europa.eu/en/art36grants/article36/170714>. Panel Members were invited to disseminate the information.

- Susan Fairweather-Tait reported back from the workshop in Rome on 21-22 September 2017 organised by the U.S. National Academies of Sciences, Engineering, and Medicine to explore issues related to global harmonisation of methodological approaches to nutrient intake recommendations.
- Androniki Naska reported back from the PROMETHEUS workshop held in EFSA on 9-10 October 2017. The main difficulties found in the implementation of the case studies across EFSA Units and

Panels were discussed, together with the possible solutions proposed by the workshop participants.

- The 82nd NDA Plenary meeting will be held on 12-14 December 2017 in Parma.