

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 80th Plenary meeting

Held on 19-21 September 2017, Parma (Italy)

(Agreed on 27 September 2017)

Participants

■ Panel Members

Jean-Louis Bresson, Barbara Burlingame, Marina Heinonen¹, Karen Ildico Hirsch-Ernst, Androniki Naska, Monika Neuhäuser-Berthold, Kristina Pentieva, Yolanda Sanz², Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts.

■ Hearing Experts³:

Not applicable

■ European Commission:

Panagiotis Daskaleros (for items 5.3, 5.4 and 5.5)

■ 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.

SCER Unit: Nikolaos Georgiadis (for item 8)

■ Observers:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Susan Fairweather-Tait, Inge Mangelsdorf, Harry J McArdle and Alfonso Siani.

2. Adoption of the Agenda

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

¹ Participated on 19 and 20 September

² Participated on 20 and 21 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>

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 79th Plenary meeting

The minutes of the 79th Plenary meeting held on 27-29 June 2017 were agreed by written procedure on 6 July 2017⁶.

5. Scientific outputs submitted for possible adoption/endorsement

DRVs

5.1. Draft opinion on Dietary Reference Values for sodium – selected sections (EFSA-Q-2011-01224)

On 19 September, the draft opinion addressing DRVs for sodium was presented and discussed. The approach used for the assessment follows the established principles for deriving and applying DRVs⁷. However, owing to the complexity of how sodium intake associates with certain health outcomes, parts of the assessment (i.e. sections 5.5 and 6 of the draft opinion) were undertaken by applying the PROMETHEUS approach⁸ on principles and process for dealing with data and evidence. To this end, a draft protocol was developed for Section 5.5 and 6 of the scientific opinion (see item 5.1.1).

The Panel agreed to endorse the draft opinion, i.e. sections 1 to 5.4, for public consultation, in order to receive early input from stakeholders.

The draft opinion will be released for public consultation together with the draft protocol by the end of September via the following link: <https://www.efsa.europa.eu/en/consultations/call/170929>

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/sites/default/files/event/170627-m.pdf>

⁷ Scientific Opinion on principles for deriving and applying DRVs: <https://www.efsa.europa.eu/en/efsajournal/pub/1458>

⁸ PROMoting METHods for Evidence Use in Scientific assessments

5.1.1. Draft Protocol on Dietary Reference Values for sodium

To promote quality in its scientific processes and to realise the strategic objectives related to evidence and methods for scientific assessments, a draft protocol was developed applying PROMETHEUS methodology for selected sections of the scientific opinion on DRVs for sodium. The protocol only applies to sections 5.5 and 6 of the scientific opinion, namely: i) the assessment of possible relationships between sodium intake and selected health-related outcomes in the general population, including a quantitative assessment of the dose-response, where applicable (Section 5.5), and ii) the integration of the different lines of evidence to derive DRVs for sodium (Section 6). Systematic reviews will be conducted on the relationship between sodium intake and selected health outcomes. The protocol describes the steps to be followed. It specifies the problem formulation, sub-questions to be answered for achieving the objective of section 5.5, method for answering the individual sub-question, and method for combining the evidence and setting DRVs (section 6).

The draft protocol was presented and discussed. It was endorsed by the Panel on 20 September for release for public consultation to receive input from stakeholders.

The draft protocol and draft opinion (see item 5.1) will be released together for public consultation by the end of September via the following link: <https://www.efsa.europa.eu/en/consultations/call/170929>.

Novel Foods

5.2. Pharmena S.A. – Draft Opinion on 1-methylnicotinamide chloride (EFSA-Q-2016-00520)

On 20 September, 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.2017.5001/abstract>

5.3. Desert Labs Ltd. - Draft opinion on Hoodia parviflora (EFSA-Q-2016-00091)

On 20 September, 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.2017.5002/abstract>

5.4. Botamedi Inc. - Draft opinion on Ecklonia cava (EFSA-Q-2016-00518)

On 20 September, 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.2017.5003/abstract>

6. New Mandates

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

- **Health claims**

Five Article 13.5 application (claims based on newly developed science and/or which include a request for the protection of proprietary data) were received: "Consumption of NWT-02 reduces loss of vision" (EFSA-Q-2017-00539); "L-carnitine contributes to normal lipid metabolism" (EFSA-Q-2017-00564); Black tea improves attention (EFSA-Q-2017-00606); Glycaemic carbohydrate intake during a high-intensity and long-lasting physical exercise contributes to the improvement of physical performance (EFSA-Q-2017-00621); 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)

These mandates have been assigned to the standing working group (SWG) on Claims.

- **Novel Foods**

A request was also received from the Commission asking EFSA to carry out a supplementary dietary exposure and safety assessment of taxifolin (EFSA-Q-2017-00554).

This request has 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

The Chair reported back from the 85th Plenary meeting of the Scientific Committee which took place on 13-14 September 2017.

Of relevance to the Panel, the draft guidance on risk assessment of nanosubstances was endorsed by the SC for release for public consultation.

The SC working group on Genotoxicity had been working on comments received from public consultation on the draft opinion on "Reflection on interpretation of some aspects related to genotoxicity assessments". A revised draft is foreseen for submission to the SC for possible adoption before the end of 2017.

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

The Chairs/Vice-Chair (in the absence of the Chair) of respective WGs reported back to the Panel:

- WG on Claims – Comments received from the public consultation on the draft guidance related to health claims on antioxidants and cardiovascular health were presented. They will be further reviewed and discussed at the next WG meeting. Four draft opinions were discussed/elaborated. It was considered that additional information from the applicants is needed in order to proceed with the scientific assessment of these applications. Therefore, requests for additional information will be sent to the applicants and stop the clock procedures will be applied.
- WG on Novel Foods - The WG discussed/elaborated on draft opinions related to: 1-methylnicotinamide chloride (item 5.2), Hoodia parviflora (item 5.3), Ecklonia cava phlorotannins (item 5.2), D-Ribose, and pyrroloquinoline quinone disodium salt. Three draft opinions were submitted to the Panel for possible adoption.
- WG on Infant Nutrition – The WG worked on the approach for appraising human studies 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. To this end, a sample of publications was appraised by all experts of the WG during the meeting, the outcome of this appraisal was discussed, and the approach towards the appraisal was refined.
- WG on DRVs for vitamins – The WG undertook appraisal of the studies identified and performed data extraction for the Opinion on the UL for vitamin D in infants.
- WG on DRVs for minerals - The draft opinion (item 5.1) and protocol on DRVs for sodium (item 5.1.1) were discussed and elaborated. They were submitted to the Panel for possible endorsement for release for public consultation.

- *Ad-hoc* WG on added sugars – The members of the WG discussed the terms of reference for the activities, and the proposed methodology and tools to address the mandate. The approach used to address the mandate applying PROMETHEUS methodology was agreed by the WG. The initial focus of the WG activities will be on the development of a protocol for the assessment in line with the PROMETHEUS methodology. The draft protocol is foreseen for submission to the Panel in December 2017 for possible endorsement for release for public consultation.

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. Scientific Committee's Guidance on the assessment of the biological relevance of data in scientific assessments

The Panel was given a presentation on the SC-adopted guidance on Biological relevance⁹. The document provides general concepts and criteria to consider biological relevance of an observed effect, i.e. whether it is an adverse (or a beneficial) health effect or not. Biological relevance is considered at three main stages when dealing with evidence: 1) development of the assessment strategy (i.e. specification of agents, effects, subjects and conditions in relation to the assessment question(s)); 2) collection and extraction of data; 3) appraisal and integration of the relevance of the agents, subjects, effects and conditions (i.e. reviewing dimensions of biological relevance for each data set). A decision tree is developed to assist in the collection, identification and appraisal of relevant data for a given specific assessment question to be answered. Case studies relevant to the Panel remits were used for illustration. Trainings will be provided to the Panel and EFSA staff in due course.

8.2. EFSA's Summary report on Dietary Reference Values for nutrients

The Panel was informed about the publication of the Summary report on Dietary Reference Values (DRVs) for nutrients. The summary report puts together the summaries of the individual opinions published by EFSA over 7 years (**covering water, fats, carbohydrates and dietary fibre, protein, energy, as well as 14 vitamins and 13 minerals**), together with synthetic tables and annexes. It provides an overview about the outcome of EFSA's scientific deliberations, for easy reference by end-users. This report is not meant to replace the original opinions. For the detailed reasoning behind individual values, the reader is invited to consult

⁹ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4970/epdf>

the full opinions. The report is published [here](https://www.efsa.europa.eu/en/topics/topic/dietary-reference-values-and-dietary-guidelines) on EFSA DRVs webpage: <https://www.efsa.europa.eu/en/topics/topic/dietary-reference-values-and-dietary-guidelines>.

The Summary of Tolerable Upper Intake Levels (ULs) is also available [here](#) on the same EFSA DRVs webpage.

9. Any other business

- The Panel took note of 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.
- In relation to Novel Foods, the Panel was informed about the kick-off meeting of the EFSA Scientific Network on Novel Foods (the Terms of Reference¹⁰ endorsed by the Advisory Forum on 8 June) to be held on 8/9 November 2017 in Parma.

EFSA launched in July 2017 a call using an Art 36 tasking Grant for entrusting tasks for the preparatory work for the safety assessment of Novel Foods and Traditional Foods¹¹. The deadline for application is 13 October 2017.

- The Panel was also informed of the closing date 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 next steps will be screening/evaluation of applications until November 2017, followed by aDoI screening (until January 2018). The Management Board decision on the Panel/SC composition will take place by March/April 2018.
- The 81st NDA Plenary meeting will be held on 24-26 October 2017 in Parma.

¹⁰ <https://www.efsa.europa.eu/en/events/event/170608>

¹¹ <http://www.efsa.europa.eu/en/art36grants/article36/170714>