

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 82nd Plenary meeting

Held on 12-14 December 2017, Parma (Italy)

(Agreed on 21 December 2017)

Participants

■ Panel Members

Jean-Louis Bresson, Susan Fairweather-Tait¹, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf², Harry J McArdle¹, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin², Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts¹.

■ Hearing Experts³:

Not applicable

■ European Commission:

Not applicable

■ EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Mathias Amundsen, 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: Bernard Bottex⁴

■ Observers:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Barbara Burlingame and Tara Dean.

¹ Participated via web-conference

² Participated on 12-13 December

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>

⁴ For item 8.1 and 8.2

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 Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, 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 81st Plenary meeting

The minutes of the 81st Plenary meeting held on 24-26 October 2017 were agreed by written procedure on 03 November 2017⁷.

5. Scientific outputs submitted for possible adoption/endorsement

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

5.1. Draft Technical report on the outcome of a public consultation on the draft guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00534)

The technical report on the outcome of a public consultation on the draft guidance, which summarises the comments received from the public consultation (open from 12 July to 3 September 2017) and how the comments were addressed, was presented and discussed. EFSA received comments from 8 interested parties. The technical report was endorsed by the Panel on 13 December, subject to editorial changes. It will be published together with the updated guidance document (see agenda item 5.2) in the coming weeks via this link:

<http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1364/abstract>

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

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁷ <http://www.efsa.europa.eu/sites/default/files/event/171024-m.pdf>

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

The draft guidance, which took into consideration relevant comments received from the public consultation, was presented and discussed (see agenda item 5.1). The 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 the human intervention studies which can provide evidence for the scientific substantiation of specific claims addressed in the guidance (e.g. appropriate outcome variables and methods of measurement, suitable study group(s), appropriate duration of the study, suitable controls).

The guidance was adopted by the Panel on 13 December, 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.2017.5136/abstract>

5.3. Lonza Ltd. - "L-carnitine and normal lipid metabolism" (Art. 13.5, 0460_DE, EFSA-Q-2017-00564)

On 13 December, 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.2017.5137/abstract>

5.4. Unilever NV - "Tea flavanols" and "improvement of endothelium-dependent vasodilatation" (Art. 13.5, 0458_IE, EFSA-Q-2017-00419)

On 13 December, 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.2017.5138/abstract>

5.5. Newtricious R&D B.V. - "NWT-02 and reduces loss of vision" (Art. 13.5, 0459_IE, EFSA-Q-2017-00539)

On 13 December, 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.2017.5139/abstract>

Dietary Reference Values

5.6. Draft technical report on the outcome of a public consultation on the scientific opinion on Dietary Reference Values (DRVs) for sodium (intermediate draft) and related protocol ([EFSA-Q-2015-00673](#))

The draft technical report on comments received on the scientific opinion (intermediate draft of sections 1 to 5.4 and protocol developed for sections 5.5 and 6) on DRVs for sodium was presented and discussed. EFSA received comments from 10 interested parties. The draft report summarises the comments received from the public consultation (open from 29 September to 12 November 2017) and how the comments were addressed. In particular, the report describes the revisions of the draft scientific opinion and of the protocol that have been applied in the light of the comments received.

The protocol that will be implemented for the assessment of the relationship between sodium intake and pre-specified health outcomes, including dose-response relationships (section 5.5), and for the integration of different lines of evidence for setting DRVs for sodium (section 6), was finalised.

The technical report and the revised protocol were endorsed by the NDA Panel on 12 December 2017.

The final protocol will be published in the EFSA knowledge junction. The protocol will be implemented in order to finalise the scientific opinion (section 5.5 and 6). Another public consultation will be organised once the scientific opinion is complete (Spring 2019).

Link: <http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1356/abstract>

5.7. Draft protocol for the Scientific Opinion on free sugars from all sources ([EFSA-Q-2017-00646](#))

The draft protocol for the assessment of the mandate on free sugars from all sources was presented. This protocol has been developed following the principles and processes illustrated in the EFSA PROMETHEUS project with the aim of defining beforehand the strategy that will be applied for collecting data (i.e. which data to use for the assessment and how to identify and select them), appraising the relevant evidence, and analysing and integrating the evidence in order to draw conclusions that will form the basis for the Opinion.

The Panel reviewed and discussed different sections of the protocol, including the sub-questions identified, the methods applied to answer the sub-questions, the methods to be used for integrating and weighing the evidence, and how to evaluate the uncertainty in the body of the evidence.

The draft protocol was endorsed by the NDA Panel on 12 December for release for public consultation to gather input from the scientific community. The public consultation will be launched on 9th January 2018 via the following link:

https://ec.europa.eu/eusurvey/runner/Freesugars_nutri_public_consul.

In addition before the end of the public consultation, EFSA will be organising a stakeholder meeting on 13 February 2018.

6. New Mandates

Postponed.

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

7.1. Scientific Committee (SC) and other Scientific Panels

The NDA Panel was informed of the adoption by the SC of the Guidance on Uncertainty Analysis in Scientific Assessments (new concise guidance).

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

Postponed.

7.3. European Commission

Not applicable

8. Other scientific topics for information and/or discussion

8.1. Update: Guidance on the use of the benchmark dose approach in risk assessment⁸

The Panel was given a presentation on the SC updated guidance on the use of the benchmark dose approach (BMD) in risk assessment, in which the SC reconfirms that the BMD approach is a scientifically more advanced method compared to the NOAEL approach for deriving a Reference Point (RP). In this update (2017), most of the modifications made to the SC guidance of 2009 concern the section providing guidance on how to apply the BMD approach. Model averaging is recommended as the preferred method for calculating the BMD confidence interval. The set of default models to be used for BMD analysis has been reviewed, and the Akaike information

⁸ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4658/epdf>

criterion (AIC) has been introduced to characterise the goodness of fit of different mathematical models to a dose-response data set. A new flow chart and template provide a step-by-step guide for performing and reporting a BMD analysis in a complete and transparent manner. It is recommended to report the BMD confidence interval rather than the value of the BMD. The lower bound (BMDL) is needed as a potential RP, and the upper bound (BMDU) is needed for establishing the BMDU/BMDL per ratio reflecting the uncertainty in the BMD estimate. It was noted that the updated guidance does not call for a general re-evaluation of previous assessments where the NOAEL approach was used, or where the BMD approach as described in the 2009 SC guidance was used.

8.2. EFSA Compendium of Botanicals - database

The Panel was given an overview of EFSA's [Compendium of Botanicals](#), a hazard database of plants reported to contain naturally occurring substances of possible concern for human health when present in food. It contains about 2,700 plant species and includes information related to the botanical family/species/plant parts, toxicity information (oral intake only) and relevant composition data (qualitative and quantitative if available). The criteria and approach used for the searching/screening of scientific literature, and for how the data collected are reviewed and validated for transferring to the database, were outlined. The Panel noted with interest the criteria and approach applied for literature search, and the useful information contained in the Compendium that could be used to inform EFSA for the assessment of notifications for Traditional Foods from third countries.

8.3. Scientific Opinion on the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2016-00482)

Selected sections of the draft opinion were presented to the NDA Panel members to collect their views and inputs on the structure and approach used. The comments received will be incorporated in the next version of the opinion and will be discussed at the next meeting of the WG on Infant Nutrition.

8.4. The assessment of notifications for Traditional Foods (TF) from third countries

Following the [EFSA Scientific Network on Novel Foods meeting of 8-9 November 2017](#), EFSA's Nutrition Unit sought views and inputs from the Panel about the approach for the assessment of notifications for TF from third countries.

Given the tight legal deadline of four months from the date of receipt of a valid notification from the Commission, and considering that neither a full risk assessment nor a scientific opinion by the

NDA Panel is requested/feasible, EFSA suggests a stepwise risk-based approach (i.e. taking into account available information on hazard identification and characterisation, health-based guidance values and exposure) but not to perform a full risk characterisation. The proposal foresees that EFSA would not limit its assessment to the information provided in the notifications, but also look for additional data for comprehensive hazard identification. The comments received from the Panel will be discussed at the next meeting of the WG on Novel Foods.

In this context, the Panel took note of the setting of an EFSA Working Group on Traditional Foods (WG TF). The objective of the WG TF is to support EFSA in performing the preparatory work in order to deliver efficiently and timely the requested scientific outputs in relation to notifications for the placing on the market of a traditional food from a third country, submitted pursuant to Article 14 of Regulation (EU) 2015/2283. The outputs delivered by the WG TF will not require adoption by the NDA Panel.

The Panel also took note of the existing International/European guidelines and different databases that are relevant for the safety evaluation of edible insects and products thereof.

9. Any other business

- The Panel was informed about the NDA work-plan for 2018 and the upcoming increased workload in relation to Novel Foods as of January 2018, outlining the shortage of available resources.
- The Panel was also informed about the status of the EFSA renewal of its ten Scientific Panels and its Scientific Committee. EFSA is currently proceeding with ADoI screening (until January 2018). The Management Board decision on the Panel/SC composition will take place by March 2018.
- A [virtual issue on DRVs](#) has been published in the EFSA Journal⁹. It collects all DRV opinions published so far in a single place, as well as the DRV summary report. Panel members are invited to disseminate further this information. Please also see the related [news](#)¹⁰.
- The draft "Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources" (EFSA-Q-2016-00150) was endorsed by the ANS Panel for release for public consultation: <https://www.efsa.europa.eu/en/consultations/call/171215>
- The 83rd NDA Plenary meeting will be held on 07-08 February 2018 in Parma.
- The NDA Panel plenary meeting of 27-29 June will be open to observers (venue: Parma).

⁹ [http://efsa.onlinelibrary.wiley.com/hub/issue/10.1002/\(ISSN\)1831-4732.021217](http://efsa.onlinelibrary.wiley.com/hub/issue/10.1002/(ISSN)1831-4732.021217)

¹⁰ <http://www.efsa.europa.eu/en/press/news/171211>