Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 83rd Plenary meeting

Held on 07-08 February 2018, Parma (Italy)

(Agreed on 18 February 2018)

Participants

- Panel Members

  Jean-Louis Bresson, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle[1], Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva[2], Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts.

- Hearing Experts[3]:

  Not applicable

- European Commission representatives:

  For item 8.1: Stephanie Bodenbach[1] and Fruzsina Nyemech[1] (DG SANTE);

  For items 8.2, 8.5, 8.6 and 8.7: Rafael Pérez-Berbejal[1] and Agnieszka-Anna Turek[1] (DG SANTE)

- EFSA:

  Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Janusz Ciok, Valeriu Curtui, 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.

- Observers:

  Not applicable

1. Welcome and apologies for absence

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

[1] Participated via web-conference

[2] Participated via web-conference on 07 February

[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 revised agenda was adopted with changes (with three new items added 8.5 to 8.7).

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest[5], 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[6].

4. Report on written procedures since 82nd Plenary meeting

The minutes of the 82nd Plenary meeting held on 12-14 December 2017 were agreed by written procedure on 21 December 2017[7].

5. Scientific outputs submitted for possible adoption/ endorsement

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

5.1. Specialised Nutrition Europe - "glycaemic carbohydrates and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise" (Art. 13.5, 0462_FR, EFSA-Q-2017-00621)

On 7 February, 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.2017.5191/abstract

5.2. TA-XAN AG - "xanthohumol and maintaining the integrity of DNA" (Art. 13.5, 0463_DE, EFSA-Q-2017-00663)

On 7 February, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full text

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[6] Before the meeting started, the Panel was asked to declare orally any interest related to three new items added: 8.5, 8.6 and 8.7, and no conflict of interest was identified.
[7] https://www.efsa.europa.eu/sites/default/files/event/171212-m.pdf

will be published in the EFSA Journal in the coming weeks via this link:
http://onlinelibrary.wiley.com/wol1/doi/10.2903/j.efsa.2017.5192/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: "Fibersol-2 contributes to a normal bowel function by increasing faecal bulk, stool frequency and by reducing colonic transit time" (EFSA-Q-2018-00017)".

One Article 14 application related to a risk reduction claim was received: "Symbiosal has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for hypertension" (EFSA-Q-2018-00002).

The Panel took note that the information collected from the grant (GP/EFSA/NUTRI/2014/01) has now become available and is published in a scientific report[8], the outcome of which helped to inform the NDA Panel and served as a basis for further guidance to applicants. The grant was launched in 2014, and was aimed at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The Panel agreed to self-task the updating of the existing guidance on the scientific requirements for health claims related to physical performance published in 2012[9].

These mandates will be assigned to the standing working group (SWG) on Claims.

- **Novel Foods**

A new request was received from the Commission asking EFSA for a scientific opinion related to: "the safety of whey protein isolate as a novel food ingredient" (EFSA-Q-2017-00836).

This request will be assigned to the standing working group (SWG) on novel foods.

The Panel took note that no notification for the placing on the market of a traditional food from a third country (pursuant to Article 14 of Regulation (EU) 2015/2283) has been received by EFSA.

[8] https://www.efsa.europa.eu/en/supporting/pub/1272e
[9] https://www.efsa.europa.eu/en/efsajournal/pub/2817

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 NDA Panel plenary meeting. The next SC Plenary meeting is scheduled to take place on 14-15 February 2018.[10]

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

The Chairs of respective WGs reported back to the Panel:

- WG on Claims – the WG discussed and elaborated on four draft opinions (3 Art. 13(5) claims and 1 Art. 19 claim). Two were submitted (items 5.1 and 5.2) to this Plenary for possible adoption. Two were subject to the stop-the-clock procedure for requesting supplementary information from the applicants.
- WG on Novel Foods - The WG discussed/elaborated on draft opinions related to: D-Ribose, shrimp peptides, and xylo-oligosaccharide. They were subject to the stop-the-clock procedure for requesting supplementary information from the applicants.
- WG on Infant Nutrition – The WG discussed and worked on the appraisal of the first batch of studies identified related to the outcome "growth". Selected sections of the draft opinion were presented to the Panel to get feedback and input (item 8.4).
- WG on DRVs for vitamins – The WG discussed further analyses of scientific evidence. The key information on the status of the assessment, to be presented to the NDA panel meeting, was also discussed (see item 8.1).
- WG on DRVs for minerals – Members of the WG and EFSA continued working on the screening/appraisal of studies identified for the assessment of the relationship between sodium intake and health outcomes.
- *Ad-hoc* WG on free sugars – The draft protocol has been released for public consultation (open until 4 March: https://www.efsa.europa.eu/en/press/news/180109).

  In addition, EFSA is holding a technical meeting in Brussels on 13 February to discuss the methodology that will be used in the assessment (https://www.efsa.europa.eu/en/events/event/180213). The meeting will focus on the methods for i) collecting data (i.e. which data to use for the assessment and how to identify and select them), ii) appraising the relevant evidence, and iii) analysing and integrating the evidence to draw conclusions that will form the basis of the EFSA Scientific opinion on free sugars.

[10] https://www.efsa.europa.eu/en/events/event/180214

7.3. European Commission

Not applicable

8. Other scientific topics for information and/or discussion

8.1. Draft Opinion on the tolerable upper intake level (UL) for vitamin D in infants (EFSA-Q-2017-00208)

The Panel was given a presentation on the current status of the draft opinion on the UL for vitamin D in infants. The approach and methodology used to address the mandate/terms of reference received from the Commission were outlined. Issues identified resulting from the extensive literature search and study appraisals, the statistical analysis, and intake assessment performed were depicted. Preliminary conclusions were presented.

The discussion focused on: the biomarkers to be used, cut-off for 25(OH)D, types of intake scenarios to consider for risk assessment, and the possibility of setting two levels for young and older infants.

The Panel took note of the preliminary conclusions, and agreed with the approach/methodology used for the opinion. 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 DRVs for Vitamins.

The Panel also agreed that the draft opinion will be submitted (by end of March) to the NDA Panel for endorsement by written procedure for release for public consultation (April-May 2018).

8.2. Dried aerial parts of *Hoodia parviflora* as a novel food pursuant to Art 26(2)(c) of Regulation (EU) 2015/2283 – proprietary data (EFSA-Q-2016-00091)

A scientific opinion on *Hoodia parviflora* as a Novel Food (NF) was adopted by the Panel on 20 September 2017[11].

Following the entry into force of the new NF Regulation (EU) 2015/2283, the European Commission requested EFSA to evaluate whether and if so, to what extent, the requirements of Article 26(2)(c) of the NF Regulation are fulfilled, i.e. whether the NF could not have been assessed by EFSA without the scientific evidence or data requested to be protected by applicants. The European Commission requests relate to the NF under agenda items 8.2, 8.5, 8.6 and 8.7.

The Panel noted that in elaborating its opinion on *Hoodia parviflora* as a NF the data from the report of the 90-day oral toxicity study (Desert Labs, 2012b, unpublished) served as basis for the Bench Mark Dose (BMD) analysis and for deriving safe intake levels for human.

[11] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5002/epdf

The Panel, therefore, considered that the conclusions on the safety of the NF, *Hoodia parviflora*, could not have been reached without the data from the unpublished report of the study by Desert Labs (2012b), which was requested to be protected by the applicant (the study, although not the full study report, was published by Lynch et al., 2013).

The request from the European Commission and the reply from EFSA in relation to *Hoodia parviflora* are available in the Register of Questions: EFSA-Q-2016-00091.

8.3. Draft Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources (EFSA-Q-2016-00150)

The Panel was informed about the status of the ANS Panel draft guidance related to nutrient sources. The draft guidance was released for public consultation until 11 February (https://www.efsa.europa.eu/en/press/news/171215)

In the light of the transfer of the evaluation of nutrient sources from the ANS Panel to the NDA Panel as of 1st July 2018,[12] the importance of consulting the NDA Panel on the draft guidance was highlighted. The Panel members were invited to provide comments on the draft guidance to the Nutrition Unit.

The guidance is foreseen for adoption by the ANS Panel (May 2018). The adopted guidance will form the basis for the NDA Panel assessment of nutrient sources starting from the 1st of July 2018.

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

Selected sections (i.e. 2.2.1. related to Assessment of the internal validity of relevant human studies, and 3.5.1 related to Growth) of the draft opinion were presented to the NDA Panel to collect their views and input 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.

8.5. 1-methylnicotinamide chloride, as a novel food pursuant to Article 26(2)(c) of Regulation (EU) 2015/2P283 – proprietary data (EFSA-Q-2016-00520)

A scientific opinion on 1-methylnicotinamide chloride (1-MNA) as a NF was adopted by the Panel on 20 September 2017[13].
As indicated under agenda item 8.2, the European Commission requested EFSA to evaluate whether the NF could not have been assessed by EFSA without the scientific evidence or data requested

[12] Commission Regulation (EU) 2017/228 of 9 February 2017 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority. OJ L 35, 10.2.2017, p. 10–11.

[13] https://www.efsa.europa.eu/en/efsajournal/pub/5001

to be protected by the applicant. The Panel noted that in elaborating its opinion on 1-MNA as a NF the information on the analytical methods (Annex F of the dossier) served as a basis to assess the specifications and composition of the NF.

The report of the *in vitro* micronucleus test (Stepnik, 2012, unpublished) was used by the Panel to conclude that there were no concerns with respect to genotoxicity of the NF.

The data from the report of the 90-day oral toxicity study (Ford, 2014, unpublished) were used by the Panel to establish a reference point and to assess whether the margin of exposure in relation to the proposed maximum intake of the NF by human is sufficient.

The Panel considered that the conclusions on the safety of the NF, 1-MNA, could not have been reached without the information on the analytical methods (Annex F of the dossier), the data from the unpublished reports of the *in vitro* micronucleus test (Stepnik, 2012) and the 90-day oral toxicity study (Ford, 2014), which were requested to be protected by the applicant.

The request from the European Commission and the reply from EFSA for 1-MNA are available in the Register of Questions: EFSA-Q-2016-00520.

8.6. Pyrroloquinoline quinone disodium salt, as a novel food pursuant to Article 26(2)(c) of Regulation (EU) 2015/2283 – proprietary data (EFSA-Q-2016-00659)

A scientific opinion on pyrroloquinoline quinone disodium salt (PQQ) as a NF was adopted by the Panel on 24 October 2017[14].

As indicated under agenda item 8.2, the European Commission requested EFSA to evaluate whether the NF could not have been assessed by EFSA without the scientific evidence or data requested to be protected by the applicant.

The Panel noted that in elaborating its opinion on PQQ as a NF the unpublished reports of the genotoxicity studies by Mitsubishi Gas Chemical Company Inc (i.e. bacterial reverse mutation test (2005b) and *in vivo* micronucleus test (2006c) were used by the Panel to conclude that there were no concerns with respect to genotoxicity of the NF (the studies, although not the full study reports, were published by Nakano et al., 2013).

The unpublished study reports of the 14-day dose finding study, the 28-day renal toxicity study and the 90-day toxicity study in rats (Mitsubishi Gas Chemical Company Inc, 2005a, c, 2006b) were used collectively by the Panel to assess the toxicity profile of the NF and establish the related NOAEL (the studies, although not the full study reports, were published by Nakano et al., 2014).

The Panel considered that the conclusions on the safety of the NF, PQQ, could not have been reached without the data from the

[14] https://www.efsa.europa.eu/en/efsajournal/pub/5058

unpublished reports of the genotoxicity studies (Mitsubishi Gas Chemical Company Inc, 2005b, 2006c) and the 14-day dose finding study, the 28-day renal toxicity study and the 90-day toxicity study in rats (Mitsubishi Gas Chemical Company Inc, 2005a, c, 2006b), which were requested to be protected by the applicant. The request from the European Commission and the reply from EFSA for PQQ are available in the Register of Questions: EFSA-Q-2016-00659.

8.7. Betaine, as a novel food pursuant to Article 26(2)(c) of Regulation (EU) 2015/2283 – proprietary data (EFSA-Q-2016-00287)

A scientific opinion on betaine as a NF was adopted by the Panel on 25 October 2017[15].

As indicated under agenda item 8.2, the European Commission requested EFSA to evaluate whether the NF could not have been assessed by EFSA without the scientific evidence or data requested to be protected by the applicant.

The Panel noted that in elaborating its opinion on betaine as a NF the data from the report of the combined chronic toxicity/carcinogenicity study (unpublished study report, 2002) served as a basis for the BMD analysis and for deriving safe intake levels for human.

The data from the report of the human study (unpublished study report, undated) served as a basis to derive the safe intake level of the NF (the study, although not the full study report was published by Schwab et al., 2011).

The reports of the genotoxicity studies (i.e. bacterial reverse mutation test (unpublished study report, 1989a) and *in vivo* micronucleus test (unpublished study report, 1989c) were used by the Panel to conclude that there were no concerns with respect to genotoxicity of the NF.

The Panel considered that the conclusions on the safety of the NF, betaine, could not have been reached without the data from the unpublished reports of the genotoxicity studies (unpublished study report, 1989a, c), the combined chronic toxicity/carcinogenicity study (unpublished study report, 2002) and the human study (unpublished study report, undated), which were requested to be protected by the applicant.

The request from the European Commission and the reply from EFSA for betaine are available in the Register of Questions: EFSA-Q-2016-00287.

[15] https://www.efsa.europa.eu/en/efsajournal/pub/5057

9. Any other business

- The Panel was informed about the status of the EFSA renewal of its ten Scientific Panels and its Scientific Committee. EFSA is currently proceeding with ADoI screening. The Management Board decision on the Panel/SC composition will take place by March 2018.
- In the framework of Regulation (EU) 2015/2283, the Panel was informed that the Art.36 tasking Grant for entrusting tasks for the preparatory work for the safety assessment of Novel Foods and Traditional Foods[16] was unsuccessful. EFSA will be exploring other outsourcing options.

  In relation to notification for the placing on the market of a traditional food (TF) from a third country (pursuant to Article 14), the Panel took note of the setting of an EFSA Working Group on TF (WG TF). The objective of the WG on TF is to support EFSA in performing the preparatory work in order to deliver efficiently and in timely fashion the requested scientific outputs in relation to TF notifications, which do not require adoption by the NDA Panel.
- The 84th NDA Plenary meeting will be held on 17-19 April 2018 in Parma.

[16] http://www.efsa.europa.eu/en/art36grants/article36/170714