Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 77th Plenary meeting

Held on 31 January 2017 – 2 February 2017, Parma (Italy)

(Agreed on 8 February 2017)

Participants

- Panel Members

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

- Hearing Experts[2]:

  Not Applicable

- European Commission:

  Rafael Perez Berbejal[3] (DG SANTE)

- EFSA:

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

  FIP Unit: Camilla Smeraldi (for item 8.6)

- Observers:

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Barbara Burlingame and Peter Willatts.

[1] Participation via tele-conference
[2] 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] Participation via tele-conference for items 5.5 and 5.6

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 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.

4. Report on written procedures since 76th Plenary meeting

The minutes of the 76th Plenary meeting held on 13-15 December 2016 were agreed by written procedure on 20 December 2016[6].

5. Scientific outputs submitted for possible adoption

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

5.1. Laboratoires Nutrition et Cardiométabolisme - "Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors" (Art. 13.5, 0488_FR, EFSA-Q-2016-00319)

On 31 January, 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.2017.4723/abstract

Novel Foods

5.2. Seprox Biotech. - Draft opinion on hydroxytyrosol (EFSA-Q-2015-00749)

On 31 January, 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.2017.4728/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/sites/default/files/event/161213-m.pdf

Infant Nutrition

5.3. 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 (EFSA-Q-2016-00864)

Following a request from the Commission asking EFSA to update its opinion on the appropriate age for introduction of complementary feeding of infants published in 2009 (EFSA-Q-2008-311)[7], a systematic literature review will be conducted to retrieve data on health outcomes related to the age of introduction of complementary food. To this end, a draft protocol for the systematic review was developed.

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.

The Panel agreed on the need to seek the external views and input of the public on the draft protocol, and on 1 February endorsed the document for release for public consultation. The public consultation will be launched in the next few weeks via the following link: http://www.efsa.europa.eu/en/calls/consultations.

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 applications (claims based on newly developed science and/or which include a request for the protection of proprietary data) were received: "Curcumin contributes to the normal functioning of joints" (EFSA-Q-2016-00856); "Vibigaba germinated brown rice contributes to the maintenance of normal blood cholesterol level" (EFSA-Q-2017-00030); "Vibigaba germinated brown rice contributes to the maintenance of normal blood pressure (EFSA-Q-2017-00031); "Vibigaba rice in the context of an energy restricted diet contributes to weight loss (EFSA-Q-2017-00032); "Vibigaba germinated brown rice contributes to the maintenance of normal blood glucose levels (EFSA-Q-2017-00033).

  One Article 14 Risk reduction claim was received: "Sugar-free hard confectionery sweetened with at least 90% Zerose erythritol (ERY) has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries" (EFSA-Q-2017-00002).

[7] https://www.efsa.europa.eu/en/efsajournal/pub/1423

The Panel agreed to self-task the updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health[8]

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

- **Novel Foods**

  A new request was received from the Commission asking EFSA to review additional information in relation to the scientific opinion on the safety of an extract of three herbal roots (EstroG-100TM) as a novel food ingredient (EFSA-Q-2017-00040). This request will be assigned to the standing working group (SWG) on novel foods.

- **Other mandates**

  With reference to the request for EFSA's scientific assistance in setting dietary reference values for sugars, with particular attention to added sugars (EFSA-Q-2016-00414), the NDA Panel took note of the reply letter from five Nordic Competent Authorities dated 2 February, which has addressed the points raised by the Panel in the minutes of its 74th plenary meeting[9]. The Panel agreed to set up an *ad-hoc* working group to assist the Panel in undertaking all necessary preparatory tasks in relation to draft the scientific output for this mandate. The setting of the ad-hoc WG will be 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 groups[10] and the Decision of the Executive Director on selection of experts[11]. The full composition of the *ad-hoc* WG, once established, will be published on the EFSA website.

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

7.1. Scientific Committee (SC) and other Scientific Panels

No plenary meeting of the Scientific Committee took place since the last NDA Plenary. The upcoming plenary will take place on 13 February.[12]

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

The Chairs of respective WGs reported back to the Panel:

- WG on Claims – Draft opinions related to three Art 13(5) and one Art 14 claims were discussed/elaborated. The "stop-the clock" procedure for requesting supplementary information from the applicant was

[8] Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health: https://www.efsa.europa.eu/en/efsajournal/pub/2474
[9] https://www.efsa.europa.eu/sites/default/files/event/160921a-m.pdf
[10] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/paneloperation.pdf
[11] http://www.efsa.europa.eu/sites/default/files/assets/expertselection.pdf
[12] http://www.efsa.europa.eu/en/events/event/170213

applied for two applications. One opinion was submitted to this Plenary for possible adoption (Agenda item 5.1) and one was deferred to the next meeting of WG Claims for further elaboration/discussion. The WG discussed a case study using a published health claim opinion to illustrate the approach applied by the NDA Panel for the weight of evidence assessment on the substantiation of a health claim (Agenda item 8.4). A sub-group of the working group discussed the case study related to 'soy isoflavones and maintenance of bone mineral density (ID 1655)' for the uncertainty exercise (Agenda item 8.3).

- WG on Novel Foods - The WG discussed/elaborated on draft opinions on the following Novel Food applications: Hydroxytyrosol (see item 5.2), Hoodia parviflora (see item 8.1), Cranberry extract (see item 8.2), Ecklonia cava phlorotannins, Tocotrienol-rich extract from Annatto seeds. New applications received were presented. The WG also discussed the agenda and the content of the topics to be presented for the Info Session on Novel Foods (6 March 2017).
- 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 (Agenda item 5.3).
- WG on DRVs for vitamins – The WG has been working on riboflavin.
- WG on DRVs for minerals – The WG has been working on the draft protocol (applying the PROMETHEUS approach[13]) for the opinion on DRVs for sodium.

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

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

The draft scientific opinion was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

8.2. Ocean Spray Cranberries, Inc. - Draft opinion on cranberry extract (EFSA-Q-2016-00325)

The draft scientific opinion was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application.

[13] http://www.efsa.europa.eu/en/efsajournal/pub/4121

Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

8.3. Testing applicability of the Guidance on uncertainty in EFSA scientific assessment (EFSA-Q-2013-00738)

The Panel was informed about the uncertainty exercise carried out by a sub-group of the WG on Claims on the case study using a published health claim opinion related to 'soy isoflavones and maintenance of bone mineral density (an Article 13(1) claim ID 1655)'.

The exercise is applying the EFSA SC-revised guidance on uncertainty[14].

The Panel agreed to the publication of a written report on the case study, which could be appended to the EFSA SC guidance document. The written report will be elaborated by the WG and will be submitted to a future plenary meeting[15] for discussion.

8.4. Weight of evidence assessment applied to the scientific substantiation of health claims

The Panel noted that a published opinion on a health claim related to vitamin D and risk of falling[16] pursuant to Article 14 of Regulation (EC) No 1924/2006 was used as a case study to illustrate the approach applied by the NDA Panel for the weight of evidence assessment on the substantiation of a health claim.

This case study will be shared with the Scientific Committee Working Group in the framework of EFSA's use of the weight of evidence approach in scientific assessments[17].

8.5. Check list for appraisal of human intervention studies

Postponed.

8.6. ANS Panel's draft guidance for the safety evaluation of sources of nutrients[18]

The draft guidance for the safety evaluation of sources of nutrients was presented. The background, scope, data requirements and proposed approach used by the ANS Panel for assessing the safety and bioavailability of nutrient sources were outlined and discussed.

The Panel was invited to provide comments on the draft guidance prior to the meeting of the ANS Working Group on Nutrient Sources to be held on 15-16 February.

[14] http://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf
[15] The next NDA Panel Plenary meeting will be held on 4-6 April 2017
[16] https://www.efsa.europa.eu/it/efsajournal/pub/2382
[17] http://www.efsa.europa.eu/sites/default/files/assets/useofweight.pdf
[18] http://www.efsa.europa.eu/sites/default/files/wgGuidanceNutrientSources.pdf

The draft is foreseen for endorsement for release for public consultation by the ANS Panel in March 2017.

It was agreed to add this item to the Agenda of a future NDA Panel plenary meeting[12] for discussion.

8.7. Draft opinion on Dietary Reference Values for Riboflavin

The Panel was provided with an update on the status of the draft opinion on DRVs for riboflavin. Questions addressed by the WG related to the use of biomarkers for setting DRVs, and the influence of frequent polymorphisms and of energy/physical exercise on requirements. The possible approaches to apply for deriving DRVs were presented. The draft opinion will be further elaborated by the WG and will be submitted to a future plenary meeting[12] for possible endorsement for release for public consultation.

9. Any other business

- Valeriu Curtui outlined the 2017 work programme for the NDA Panel. In addition to the on-going activities related to DRVs (vitamin K, riboflavin, sodium and chloride), to the update of the opinion on the appropriate age for introduction of complementary feeding (see item 5.3) and new mandates received (see item 6), the Panel will be finalising the guidance for applications on infant and follow-on formulae manufactured from protein hydrolysates (EFSA-Q-2016-00276) and an opinion on follow-on formulae with lower protein content (EFSA-Q-2016-00275). The Panel noted the increasing workload related to Novel Food applications.
- The 78th NDA Panel Plenary meeting, which is open to observers, will be held on 4-6 April 2017 in Parma[19].
- A technical meeting with stakeholders on Novel Food applications will be held on 6 March 2017 in Parma[20].

[19] Further information on open plenaries available via: http://www.efsa.europa.eu/en/stakeholders/observers
[20] https://www.efsa.europa.eu/it/events/event/170306