Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 74th Plenary meeting

Held on 21–23 September 2016, Parma (Italy)

(Agreed on 29 September 2016)

Participants

- Panel Members

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

- Hearing Experts[2]:

  Not Applicable

- European Commission:

  Siret Surva[3] (DG SANTE – Unit E2, for items 5.3-5.7)

- EFSA:

  Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Wolfgang Gelbmann, Krizia Ferrini, Leng Heng, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Olga Vidal Pariente.

- Observers:

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Tara Dean and Marina Heinonen.

[1] Participation via teleconference on 23 September
[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 teleconference on 21 September

2. Adoption of the Agenda

The agenda was adopted with an additional item (8.3) included in the Agenda and 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 (including additional item 8.3) 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 73rd Plenary meeting

The minutes of the 73rd Plenary meeting held on 28-30 June 2016 were agreed by written procedure on 11 July 2016[6].

5. Scientific outputs submitted for discussion and/or possible adoption

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

5.1. Specialised Nutrition Europe (SNE, formerly IDACE) – "Calcium is important for the development of bones" (Art. 14, 0048_FR, EFSA-Q-2008-128)

On 21 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: https://www.efsa.europa.eu/en/efsajournal/pub/4587

5.2. Specialised Nutrition Europe (SNE, formerly IDACE) – "With Vitamin E for protection of cells against oxidative damage" (Art. 14, 0099_FR, EFSA-Q-2008-179)

On 21 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: https://www.efsa.europa.eu/en/efsajournal/pub/4588

[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/160628a

Novel Foods

5.3. Naturalendo Tech Co., Ltd - Draft opinion on an extract of three herbal roots (EstroG-100) (EFSA-Q-2015-00249)

On 21 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: https://www.efsa.europa.eu/en/efsajournal/pub/4589

5.4. Draft technical report on the outcome of the public consultation on the draft guidance on Novel Food applications (EFSA-Q-2016-00113)

A technical report on the Outcome of the public consultation on the draft guidance for Novel Food applications, which summarises the comments received during the public consultation on this guidance (which was open from 18 February 2016 to 21 April 2016), was presented and discussed, and subsequently endorsed by the Panel on 21 September.

The full text will be available in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/publications/supporting

5.5. Draft guidance on the preparation and presentation of an application for authorisation of a Novel Food (EFSA-Q-2014-00216)

On 21 September, a draft guidance, which takes into consideration relevant comments received from the public consultation (see item 5.4), was introduced and discussed. This document provides guidance on the data needed to carry out the safety assessment of Novel Foods and their presentation in a structured format. The draft guidance was adopted by the Panel subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: https://www.efsa.europa.eu/en/efsajournal/pub/4594

5.6. Draft technical report on the outcome of the public consultation on the guidance on the preparation and presentation of the notification and application for authorisation of Traditional Foods from third countries (EFSA-Q-2016-00114)

A technical report on the Outcome of a public consultation on a draft guidance for the notification and application of Traditional Foods from third countries, which summarises the comments received during the public consultation on this guidance (which was open from 18 February 2016 to 21 April 2016), was presented and discussed, and subsequently endorsed by the Panel on 22 September.

The full text will be available in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/publications/supporting

5.7. Draft guidance on the preparation and presentation of the notification and application for authorisation of Traditional Foods from third countries (EFSA-Q-2015-00108)

On 22 September, a draft guidance, which takes into consideration relevant comments received from the public consultation (see item 5.6), was introduced and discussed. This document presents a common format for the organisation of the information to be presented in order to assist the applicant in the preparation of a well-structured notification and application. The draft guidance was adopted by the Panel subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: https://www.efsa.europa.eu/en/efsajournal/pub/4590

Dietary Reference Values

5.8. Draft technical report on the outcome of the public consultation on the draft opinion on Dietary Reference Values for potassium (EFSA-Q-2015-00672)

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for potassium, which summarises the comments received during the public consultation on this opinion (which was open from 13 July 2016 to 24 August 2016), was presented and discussed, and subsequently endorsed by the Panel on 22 September.

The full text will be available in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/publications/supporting

5.9. Draft opinion on the Dietary Reference Values for potassium (EFSA-Q-2011-01221)

On 22 September, a draft opinion, which takes into consideration relevant comments received from the public consultation (see item 5.8), was introduced and discussed. This document proposes dietary reference values for potassium for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: https://www.efsa.europa.eu/en/efsajournal/pub/4594

5.10. Draft opinion on the Dietary Reference Values for thiamin (EFSA-Q-2011-01225)

On 22 September, the draft opinion was introduced and discussed. This document proposes dietary reference values for thiamin for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to editorial comments.

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

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

Since the last Plenary meeting, one Article 13(5) application (claim based on newly developed science and/or which include a request for the protection of proprietary data) was received: "Product formulated with a carbohydrate: protein ratio< 1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (EFSA-Q-2016-00436).

This new request has been assigned to the standing working group (SWG) on Claims.

6.2. Other mandates

- Four new requests were received from the European Commission in the framework of Regulation (EC) No 258/97, asking EFSA for scientific opinions related to: N-Acetyl-D-neuraminic acid (EFSA-Q-2016-00488), Ecklonia cava phlorotannins (EFSA-Q-2016-00518), tocotrienol-rich extract derived from the seeds of the Annatto shrub (Bixa orellana L.) (EFSA-Q-2016-00519) and 1-Methylnicotinamide chloride (EFSA-Q-2016-00520) as novel food ingredients. These new requests have been assigned to the SWG on novel foods.

- EFSA has also received a request from the European Commission for an update of the scientific opinion on the appropriate age for the introduction of complementary feeding of infants (EFSA-Q-2016-00482). This request has been assigned to the SWG on Infant Nutrition.

- A request was received from five Nordic Competent Authorities 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 discussed the mandate received by EFSA on 22 June 2016 from the National Food Agencies of Sweden, Finland, Denmark, Norway, and Iceland requesting "scientific assistance in line with Regulation (EC) No 178/2002 in assessing if a dietary reference value for sugar with particular attention to added sugar can be set".

  The Panel considered that further information would be needed from the requestor in order to define EFSA's task (i.e. definition of the Terms of Reference) in relation to the exposure of interest (dietary component(s)), the type of value(s) to be derived and the target population for the assessment.

  In relation to the **exposure of interest**, it is important to define whether the scientific assessment should address one or more of the following:

  - total sugars from all sources,
  - added sugars from all sources,
  - total or added sugars from solid foods,
  - total or added sugars from liquid foods,
  - specific food source(s) containing (added) sugars,
  - other.

  It should also be clarified whether different types of sugars (e.g. glucose, fructose, sucrose, lactose) should be considered separately.

  In relation to the **type of values to be derived**, the Panel understands that the Dietary Reference Values (DRV) of interest to the requestor is the tolerable upper intake level (UL). This could be assessed if the request relates to a nutrient (e.g. total sugars from all sources, added sugars from all sources). If the available data does not allow setting a UL, the Panel could consider providing advice on a daily intake of total or added sugars from all sources which is not associated with adverse health effects. The latter approach could also be applied to a request in relation to specific food source(s) containing (added) sugars or to sugars (total or added) in different food forms (solids vs. liquids).

  In relation to the **target population**, it should be clarified whether the request applies to the general healthy population, and if so, to which specific subgroups thereof (e.g. infants,

children, adolescents, adults, the elderly, pregnant and lactating women), since different health outcomes may be relevant to the assessment for each specific subgroup.

The Panel also discussed the possibility that the request refers to an update of the EFSA's Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre published in 2010 only in relation to the section on sugars. In that Opinion, the NDA Panel addressed the effects of total and added sugars on nutrient density of the diet, glucose tolerance and insulin sensitivity, serum lipids, other cardiovascular risk factors (blood pressure), body weight, type 2 diabetes, and dental caries in adults and children.

The Panel noted that the time and resources needed for the assessment will very much depend on the scope and the Terms of Reference for this task.

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

7.1. Scientific Committee (SC) and other Scientific Panels

Dominique Turck, Chair of the NDA Panel, provided feedback on the 80th plenary meeting of the SC, which was held on 14-15 September, highlighting activities which are relevant to the NDA Panel[7].

The Panel was briefed on the activities of the SC working group on the risk assessment of substances present in Food Intended for Infants.

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 one Art 13(5) and four Art 14 claims were discussed. The "stop-the clock" procedure for requesting clarifications/supplementary information from the applicant was applied for three applications. Two opinions were submitted to this Plenary for discussion and/or for possible adoption (see items 5.1-5.2). The WG also discussed regarding the case study on the health claim selected for the uncertainty exercise.
- *WG on Novel Foods* – The WG reviewed and considered comments received during public consultation of the draft guidance document for Novel Food applications and the draft

[7] https://www.efsa.europa.eu/en/events/event/160914a

guidance for notifications and applications of Traditional Foods from third countries. Both guidance documents have been amended taking into account relevant comments received (see items 5.3-5.7). The WG also discussed and elaborated on draft opinions on the following Novel Food applications: extract of three herbal roots (EstroG-100) (see item 5.3), Taxifolin, synthetic L-ergothioneine, Tolerase, Hydroxytyrosol, Alginate-Konjac-Xanthan Polysaccharide Complex, Hoodia parviflora, and Cranberry extract.

- *WG on DRVs for vitamins* – The WG has been working on thiamin (see item 5.10), vitamin K (see item 8.1), and riboflavin.
- *WG on DRVs for minerals* – The WG has been working on potassium (see items 5.8-5.9), and will be continuing with sodium and chloride.
- *WG on Food Allergy* – The WG will be discussing on draft opinion related to the use of behenic acid in the manufacturing of emulsifiers pursuant to Article 21(2) of Regulation (EU) No 1169/2011 for permanent exemption from labelling.
- *WG on Infant Nutrition* - The WG discussed and elaborated on: draft opinion on the safety and suitability for use by infants of a follow-on formula with a protein content of at least 1.61 g/100 kcal (see item 8.3), and on draft Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (see item 8.2). The WG also discussed about the new request from the Commission for an update of the scientific opinion on the appropriate age for introduction of complementary feeding of infants (see item 6.2).

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. Draft opinion on the Dietary Reference Values for vitamin K (EFSA-Q-2011-01232)

On 22 September, the Panel was provided with an update on the status of the draft opinion on DRVs for vitamin K. The approach applied by the Working Group (WG) for deriving DRVs was presented. The draft opinion will be submitted to a future plenary

meeting [8] for possible endorsement for release for public consultation.

8.2. Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (EFSA-Q-2016-00276)

On 23 September, the draft guidance was presented and discussed. Feedback from the Panel was received. The draft guidance will be further elaborated by the WG on Infant Nutrition. It will be submitted to a future plenary meeting[9] for possible endorsement for release for public consultation.

8.3. Nestlé - Scientific Opinion on the safety and suitability for use by infants of a follow-on formula with a protein content of at least 1.61 g/100 kcal (EFSA-Q-2016-00275)

On 23 September, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion was referred back to the WG on Infant Nutrition for further elaboration, taking into account the Panel's comments.

9. Any other business

9.1. Open Plenary meeting in Brussels

The Panel was provided with the feedback received from observers and Panel members attending the Open Plenary on 29-30 June in Brussels.

9.2. EFSA's new approach to authorship

The Panel was informed about EFSA's new approach to authorship which was recently endorsed by the Scientific Committee and is described in an editorial[10] published in the EFSA Journal, which will be applied to all EFSA scientific outputs.

9.3. Next NDA Plenary meeting

The 75th NDA Panel Plenary meeting will be held on 25-27 October 2016 in Parma.

[8] The next NDA Panel Plenary meeting will be held on 25-27 October 2016.
[9] The next NDA Panel Plenary meeting will be held on 25-27 October 2016.
[10] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.e14091/full