Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 69th Plenary meeting

Held on 28 - 30 October, 2015, Parma (Italy)

(Agreed on 6 November 2015)

Participants

- Panel Members

  Jean Louis Bresson, Barbara Burlingame, Susan Fairweather-Tait, Marina Heinonen[1], Karen Ildico Hirsch-Ernst, Androniki Naska (Chair), Monika Neuhäuser-Berthold[2], Grazyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Hendrik Van Loveren, Marco Vinceti and Peter Willatts.

- Hearing Experts[3]:

  Not Applicable

- European Commission:

  Francesco Carlucci and Dora Szentpaly-Kleis (DG SANTE)[4]

- EFSA:

  Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Wolfgang Gelbmann, Jelena Gudelj Rakic, Leng Heng, Emanuela Turla and Silvia Valtueña Martínez.

- Observers:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Inge Mangelsdorf, Harry McArdle, Tara Dean and Dominique Turck.

[1] Present on 28-29 October.
[2] Present on 29-30 October.
[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] Present on 28 October via Teleconference for items 5.2, 5.3 and 5.4.

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[5] and the Decision of the Executive Director on Declarations of Interest[6], 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 68th Plenary meeting

The minutes of the 68th Plenary meeting held on 23-25 September 2015 were agreed on 28 October[7].

There were no other written procedures to report to the Panel.

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) - 'vitamin C' and 'helps to support a healthy immune system' (Art. 14, 0097_FR, EFSA-Q-2008-177)

On 28 October, 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://www.efsa.europa.eu/en/efsajournal/pub/4298.

Novel Foods

5.2. Draft statement on the safety of 2'-O-fucosyllactose and lacto-N-neotetraose as novel food ingredients in food supplements for children pursuant to Regulation (EC) No 258/97 (EFSA-Q-2015-00594, EFSA-Q-2015-00595)

[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/en/events/event/150923b

On 28 October, the draft statement 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://www.efsa.europa.eu/en/efsajournal/pub/4299.

Other

5.3. Draft technical report on the outcome of the public consultation on the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)'s draft scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (EFSA-Q-2015-00400)

A technical report on the Outcome of a public consultation on a draft guidance related to foods for special medical purposes (FSMPs), which summarises the comments received from the public consultation (which was open from 17 July to 11 September 2015) and how the comments were addressed, was presented and discussed. It was endorsed by the Panel on 28 October.

The technical report will be published together with the guidance (see also item 5.4) in the coming weeks via this link: http://www.efsa.europa.eu/en/nda/ndascdocs.

5.4. Draft scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (EFSA-Q-2014-00736)

On 28 October, the draft guidance which takes into consideration relevant comments received from the public consultation (see item 5.3) was introduced and discussed. The guidance presented in this document is for assisting in the preparation and presentation of well-structured dossiers. It presents a common format for the organisation of the information and outlines the information and scientific data which could be included in the dossier, as well as the key issues which should be addressed in the dossier in order to assess the extent to which a food product notified as FSMP falls under the scope of Regulation (EU) No 609/2013, under the proposed use. The guidance was adopted by the Panel subject to the incorporation of editorial changes.

The full text will be published in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4300.

5.5. Draft statement on the conditions of use for health claims related to meal replacements for weight control (EFSA-Q-2015-00579)

On 28 October, the draft statement was presented and discussed. The statement provides scientific advice on the conditions of use for health claims related to meal replacements for weight control, and

in particular advises on whether a change in the conditions of use for claims on meal replacements for weight control regarding their micronutrient composition (i.e. referring to 30 % of the Nutrient Reference Values (NRVs) laid down in Part A of Annex XIII of Regulation (EU) 1169/2011 instead of 30% of the NRVs laid down in Annex I of Directive 96/8/EC) would affect the conclusions reached by the NDA Panel in its Scientific Opinion with respect to the scientific substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and the reduction of body weight (ID 1417) and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. The statement was 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://www.efsa.europa.eu/en/efsajournal/pub/4287.

6. New Mandates

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

As of 28 October 2015, **8** claim applications are in progress. No new claim application was received since the last Plenary meeting.

6.2. Other mandates

Three new requests were received from the Commission:

- Request to assess the safety of 2'-O-fucosyllactose and lacto-N-neotetraose as novel food ingredients in food supplements for children pursuant to Regulation (EC) No 258/97 (EFSA-Q-2015-00594, EFSA-Q-2015-00595) (see Agenda item 5.2).
- Request for scientific advice in relation to the Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (EFSA-Q-2015-00579) (see Agenda item 5.5)
- Request for a scientific opinion on non-allergenicity of behenic acid used for the manufacturing of certain emulsifiers.
- In order to fulfil this mandate and other future mandates in relation to allergen labelling in the framework of Regulation (EU) No 1169/2011, the Panel agreed to establish a Standing Working Group on Food Allergy. The procedure for appointing chairs of WGs and selection of members of WGs will follow the Decision of the EFSA Management Board concerning the establishment and operation of the Scientific Committee,

Scientific Panels and of their working groups[8] and the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work[9].

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

7.1. Scientific Committee and other Scientific Panels

No plenary meeting of the Scientific Committee (SC) was held since the last NDA Plenary meeting. The 11-12 November SC Plenary meeting will be open to observers[10].

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

- *WG on Claims* – Draft opinions related to four Art 13(5) claims and one Art. 14 children claim 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 the Plenary: one for possible adoption (see item 5.1) and another one for discussion (see item 8.1).
- *WG on Novel Foods* – At the last meeting, the WG discussed and elaborated draft opinions on the following NF applications: Taxifolin, fermented soybean extract (Nattokinase) (see item 8.3), and UV treated pasteurised milk.
- *WG on DRVs for vitamins* – The WG was working on vitamin B6, vitamin D, vitamin K, and choline.
- *WG on DRVs for minerals* – The WG was working on sodium, potassium and chloride. The WG appealed for data on non-sodium sources of chloride intake in various population groups.

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. DSM Nutritional Products - 'DHA' and 'contributes to improved memory function' (Art. 13.5, 0438_UK, EFSA-Q-2015-00456)

[8] http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf
[9] http://www.efsa.europa.eu/it/keydocs/docs/expertselection.pdf
[10] http://www.efsa.europa.eu/en/events/event/151111a

On 29 October, the draft 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. Japan Bio Science Laboratory - Novel food application on fermented soybean extract (Nattokinase) (EFSA-Q-2015-00294)

On 29 October, the draft opinion was presented and discussed. Feedback from the Panel was received. The draft opinion was referred back to the WG on Novel Foods for further elaboration, taking into account the Panel's comments.

8.3. Draft guidance on Novel Foods (EFSA-Q-2014-00216) **– discussion paper on section "Nutritional Information"**

On 29 October, a discussion paper related to a section on "Nutritional information" of the draft guidance was presented and discussed. Feedback from the Panel was received. The paper was referred back to the WG on Novel Foods for further elaboration of the guidance section on "nutritional information".

9. Any other business

- **Federation of European Nutrition Societies (FENS) meeting, European Nutrition Conference, 20-23 October 2015, Berlin, Germany**

The Panel was provided with feedback from the FENS Conference, particularly from the EFSA session on DRVs of 22 October 2015. EFSA's DRV session was attended by about 150 participants of the FENS conference. The audience used the opportunity to raise questions after each presentation and at the very end. Issues discussed were, among others, the definition of the reference person and whether DRVs should aim at being as close as possible to "reality", on the usefulness of deriving food-based dietary guidelines at EU level, on the quality of studies used to derive DRVs for various nutrients and on the role of other projects at EU level (e.g. EURRECA) for the setting of DRVs by the EFSA NDA Panel.

For further information, see www.fensberlin2015.org. Abstracts can be found here: http://www.karger.com/Article/Pdf/440895. Abstracts for the DRV session are on pages 22-23.

Presentations from the DRV's session will be published on the EFSA webpage in the future via this link: http://www.efsa.europa.eu/en/publications.

- **Feedback from EFSA EXPO 2015 Conference**

The Panel was provided with feedback from EFSA's scientific conference, which was held in Milan on 14-16 October in the context of EXPO 2015. Around 1100 participants attended the conference to discuss pressing issues that are facing food safety experts in the 21st century – nutrition, open data, weighing evidence, and finding the experts of the future. The conference was also webcasted online, and questions and answers to dedicated sessions were organised through Twitter.

A parallel session on nutrition challenges ahead was held on 15 October. The session started with an opening speech on Nutrition in the 21st century facing an aging population and an obesity epidemic, then considered the concept of metabolic programming and implications for feeding infants/children in view of improving later metabolic health and reducing obesity risk, and followed by personalised nutrition based on gut microbiome. The second part of the session attempted to promote sustainable provision of nutritious food for the growing population of the planet, such as use of novel foods including insects, exploring under-used food sources of key nutrients, and using agri-biodiversity for healthier diets within sustainable food systems. These sessions were closed with lively discussions with Q&A from the audiences to speakers.

Lessons learned from the conference will be gathered and a report will be published. The presentations as well as the recorded sessions of the conference will be made available in the coming weeks via the conference website.

- **Functioning of the NDA Panel**

The Panel was given a presentation about the NDA Panel's role and operation, outlining its remit in the framework of EFSA's founding regulation and in particular possible activities related to human nutrition.

The next NDA Panel Plenary meeting will be held on 9-11 December 2015 in Parma.