Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 70th Plenary meeting

Held on 9 – 11 December 2015, Parma (Italy)
(Agreed on 14 December 2015)

Participants

- Panel Members

  Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Mangelsdorf Inge, McArdle Harry, Androniki Naska [1] (Chair), Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva[2], Yolanda Sanz[3], Anders Sjödin[4], Alfonso Siani, Martin Stern, Daniel Tomé, Marco Vinceti and Peter Willatts.

- Hearing Experts[5]:

  Not Applicable

- European Commission:

  DG SANTE: Sirkku Heinimaa[6]

- EFSA:

  Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Anja Bronstrup, Janusz Ciok, Celine Dumas, Agnes De Sesmaisons-Lecarre, Wolfgang Gelbmann, Jelena Gudelj Rakic, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez and Olga Vidal Pariente.

- Observers:

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

[1] Present on 9-10 December; attending via teleconference on the 11 December.
[2] Present on 10-11 December.
[3] Present on 9-10 December.
[4] Present on 9-10 December.
[5] 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.
[6] Attending via teleconference on 9 December for items 5.7 and 5.8.

Apologies were received from Jean Louis Bresson, Dominique Turck[7] and Hendrick Van Loveren[8].

2. Adoption of the agenda

The agenda was adopted with changes in the order of discussion.

In accordance with the Rules of procedure of the Scientific Committee, Scientific Panels and of their Working Groups[9], in the absence of the chair/vice-chairs on 10 December (pm) and 11 December (am), the NDA Panel agreed that Harry McArdle should take over the chair for the following items: 5.1, 5.2, 5.9, 5.10, 5.11 and 5.12.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes [10] and the Decision of the Executive Director on Declarations of Interest [11], 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 69th Plenary meeting

The minutes of the 69th Plenary meeting held on 28-30 October 2015 were agreed on 6 November[12].

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. *Anxiofit Ltd.* – "Anxiofit-1" and "amelioration of sub-threshold and mild anxiety" (Art. 14, 0432_HU, EFSA-Q-2015-00006)

On 10 December, the draft opinion was discussed and adopted by the Panel subject to the incorporation of editorial changes. The full

[7] Attending via teleconference on 9 and 11 December.
[8] Attending via teleconference on the 11 December.
[9] http://www.efsa.europa.eu/sites/default/files/assets/paneloperation.pdf
[10] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[11] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[12] http://www.efsa.europa.eu/en/events/event/151028

text will be published in the EFSA Journal in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/4365

5.2. Beghin-Meiji ZI and Tereos Syral, ZI – "short chain FOS from sucrose" and "normal intestinal regularity" (Art. 13.5, 0436_FR, EFSA-Q-2015-00377)

On 10 and 11 December, the draft opinion was discussed. It was adopted on 11 December 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/4366

Guidance documents

5.3. Draft technical report on the outcome of the public consultation on the draft general scientific guidance for stakeholders on health claim applications (EFSA-Q-2015-00402)

A technical report on the Outcome of a public consultation on a draft general scientific guidance for stakeholders on health claim applications, which summarises the comments received from the public consultation (which was open from 17 July 2015 to 11 September 2015) and how the comments were addressed, was presented and discussed. It was endorsed by the Panel on 10 December subject to editorial changes.

The technical report will be published together with the guidance (see item 5.4) in the coming weeks via this link: http://www.efsa.europa.eu/en/supporting/pub/986e

5.4. Draft general scientific guidance for stakeholders on health claim applications (EFSA-Q-2015-00200) [updating the General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims]

The draft guidance, which takes into consideration relevant comments received from the public consultation (see item 5.3), was introduced and discussed. This guidance aims to explain the general principles which have been applied by the NDA Panel for the scientific evaluation of all health claims and the issues which should be considered by applicants for the compilation of applications. Once it is adopted, it will supersede the General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims and the pre-submission guidance on administrative and procedural questions for applicants intending to submit applications for authorisation of health claims made on foods.

The guidance was adopted by the Panel on 10 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://www.efsa.europa.eu/en/efsajournal/pub/4367

5.5. Draft technical report on the outcome of the public consultation on the draft guidance on the scientific requirements for health claims related to the immune system, the gastro-intestinal tract and defence against pathogenic microorganisms (EFSA-Q-2015-00017)

A technical report on the Outcome of a public consultation on a draft general scientific guidance on the scientific requirements for health claims related to the immune system, the gastro-intestinal tract and defence against pathogenic microorganisms summarises the comments received from the public consultation (which was open from 18 June to 10 September 2014) and how the comments were addressed. Many comments received were common to all health claims. They have been clarified in the general scientific guidance for stakeholders for health claim applications (see item 5.4), and further addressed in the technical report on the outcome of the public consultation on the draft general scientific guidance for stakeholders on health claim applications (see item 5.3). Specific comments have been referred to the updated version of the guidance on the immune system, gastro-intestinal tract and defence against pathogenic microorganisms (see item 5.6).

It was endorsed by the Panel on 10 December subject to the incorporation of editorial changes. The technical report will be published together with the guidance (see item 5.6) in the coming weeks via this link: http://www.efsa.europa.eu/en/supporting/pub/985e

5.6. Draft guidance on the scientific requirements for health claims related to the immune system, the gastro-intestinal tract and defence against pathogenic microorganisms (EFSA-Q-2014-00353)

On 10 December, the draft guidance which takes into consideration relevant comments received from the public consultation (see item 5.5) was introduced and discussed. The document has been structured to avoid overlapping with the general scientific guidance for stakeholders on health claim applications, which addresses general issues that are common to all health claims (see item 5.4). This guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms. Examples of claims evaluated

favourably by the Panel have been used to provide guidance to applicants on the scientific requirements for the substantiation of health claims in specific areas, whereas examples of claims evaluated unfavourably by the Panel have been used to illustrate the shortcomings that prevented the substantiation of these claims.

The guidance was adopted by the Panel on 10 December 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/4369

5.7. Draft guidance documents for the preparation and presentation of an application for authorisation of Novel Foods (EFSA-Q-2014-00216)

On 9 December, the draft guidance was introduced and discussed. The Guidance 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 application to demonstrate the safety of the Novel Food. Comments from the Panel were incorporated. The draft guidance will be submitted for internal comments to the EFSA Scientific Committee and Panels prior to its possible endorsement for public consultation by the NDA Panel in February 2016.

5.8. Draft guidance for the preparation and presentation of a notification of traditional foods from third countries (EFSA-Q-2015-00108)

On 9 December, the draft guidance was introduced and discussed. This guidance presents a common format for the organisation of the information to be presented in order to assist the applicants in the preparation of notifications for traditional foods from third countries. The draft opinion was referred back to the WG on Novel Foods for further elaboration, taking into account the Panel's comments

Novel Foods

5.9. DSM - Draft Opinion on resveratrol as a novel food ingredient (EFSA-Q-2014-00232)

On 11 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://www.efsa.europa.eu/en/efsajournal/pub/4368

5.10. **Dairy Crest Ltd. - Draft Opinion on pasteurised milk treated with UV-light as a novel food ingredient** (EFSA-Q-2015-00132)

On 10 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://www.efsa.europa.eu/en/efsajournal/pub/4370

Dietary Reference Values

5.11. Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Dietary Reference Values for vitamin B6 (EFSA-Q-2011-01228)

On 10 December, the draft opinion was introduced and discussed. This document proposes dietary reference values for vitamin B6 for adults, infants and children, and pregnant and lactating women. The draft opinion was endorsed by the Panel for release for public consultation, subject to the incorporation of editorial changes.

5.12. **Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Dietary Reference Values for choline** (EFSA-Q-2011-01208)

On 11 December, the draft opinion was introduced and discussed. This document proposes dietary reference values for **choline** for adults, infants and children, and pregnant and lactating women. A revised draft will be presented to the Panel in a future plenary meeting.

6. New Mandates

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

Postponed.

6.2. Other mandates

Postponed.

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

7.1. Scientific Committee and other Scientific Panels

Postponed.

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

The Chair of the WG on DRVs for vitamins informed the Panel about the progress on the Scientific Opinion related to the Dietary Reference Values for vitamin D.

Reporting from other working groups was postponed.

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

Not applicable.

9. Any other business

The 71st NDA Panel Plenary meeting will be held in Parma on 1-3 February 2016.