

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 75th Plenary meeting

Held on 25–27 October 2016, Parma (Italy)

(Agreed on 1 November 2016)

Participants

■ Panel Members

Jean-Louis Bresson, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska¹, Monika Neuhäuser-Berthold, Kristina Pentieva, Yolanda Sanz², Alfonso Siani, Anders Sjödin³, Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts.

■ Hearing Experts⁴:

Not Applicable

■ European Commission:

Rafael Perez Berbejal⁵, Francesco Carlucci⁶ (DG SANTE)

■ EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Krizia Ferrini, 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.

Apologies were received from Barbara Burlingame and Grazyna Nowicka.

¹ Participation on 25-26 October

² Participation on 26-27 October

³ Participation on 25 October

⁴ 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>

⁵ Participation via teleconference on 26 October for items 5.1-5.3.

⁶ Participation via teleconference on 27 October for item 8.2.

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 Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, 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 74th Plenary meeting

The minutes of the 74th Plenary meeting held on 21-23 September 2016 were agreed by written procedure on 29 September 2016⁹.

5. Scientific outputs submitted for possible adoption

Novel Foods

5.1. Tetrahedron - Draft opinion Draft opinion on synthetic L-ergothioneine (EFSA-Q-2015-00613)

On 26 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: <https://www.efsa.europa.eu/en/efsajournal/pub/4629>

5.2. DSM Food Specialties - Draft opinion on Tolerase® (EFSA-Q-2015-00763)

On 26 October, the draft opinion was discussed. Feedback from the Panel was received. The draft opinion will be referred back to the WG on Novel Foods for further elaboration. It will be submitted to a future plenary meeting¹⁰ for possible adoption.

5.3. Ametis JCS – Draft opinion on Taxifolin (EFSA-Q-2012-00961)

On 26 October, the draft opinion was discussed. Feedback from the Panel was received. The draft opinion will be referred back to the

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁹ <http://www.efsa.europa.eu/en/events/event/160921a-m.pdf>

¹⁰ The next NDA Panel Plenary meeting will be held on 13-15 December 2016.

WG on Novel Foods for further elaboration. It will be submitted to a future plenary meeting¹¹ for possible adoption.

Dietary Reference Values

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

On 25 October, the draft opinion was introduced and discussed. This document proposes dietary reference values for vitamin K 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>

Others

5.5. Draft technical report on the outcome of the public consultation on the draft scientific opinion on the energy conversion factor of D-tagatose for labelling purposes (EFSA-Q-2016-00423)

A technical report on the Outcome of the public consultation on the draft scientific opinion on the energy conversion factor for D-tagatose for labelling purposes, which summarises the comments received during the public consultation (open from 18 July to 12 September 2016), was presented and discussed, and subsequently endorsed by the Panel on 25 October.

The full text will be available in the EFSA Journal via the following link: <https://www.efsa.europa.eu/en/efsajournal/pub/4630>

5.6. Draft scientific opinion on the energy conversion factor of D-tagatose for labelling purposes (EFSA-Q-2009-00227)

On 25 October, a draft opinion, which takes into consideration relevant comments received from the public consultation (see item 5.5), was introduced and discussed. This document provides advice on the energy conversion factor of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling. 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: <http://www.efsa.europa.eu/en/publications/supporting>

5.7. Dupont Nutrition Biosciences Aps - Behenic acid to be used in the manufacturing of emulsifiers pursuant to

¹¹ The next NDA Panel Plenary meeting will be held on 13-15 December 2016.

Article 21(2) of Regulation (EU) No 1169/2011 – for permanent exemption from labelling (EFSA-Q-2015-00844)

On 25 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: <https://www.efsa.europa.eu/en/efsajournal/pub/4631>

6. New Mandates

- Since the last Plenary meeting, one Article 14 application (a reduction of disease risk claim) was received: “Condensyl®” and “decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility” (EFSA-Q-2016-00665). This new request has been assigned to the standing working group (SWG) on Claims.
- A new request was received from the European Commission in the framework of Regulation (EC) No 258/97, asking EFSA for a scientific opinion related to Pyrroloquinoline Quinone Disodium Salt as a novel food ingredient (EFSA-Q-2016-00659). This new request has been assigned to the SWG on Novel Foods.

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

7.1. Scientific Committee (SC) and other Scientific Panels

No Scientific Committee (SC) meeting took place since the last NDA Plenary meeting.

Of relevance to the NDA remit, members were briefed about the ongoing activities of the SC’s Working Groups dealing with: weight of evidence, biological relevance, and 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 – No meeting took place since the last NDA plenary meeting. The next meeting will be held on 15-17 November 2016.
- WG on Novel Foods – The WG discussed and elaborated on draft opinions on the following Novel Food applications: Tolerase®

(item 5.2), Taxifolin (item 5.3), synthetic L-ergothioneine (item 5.1), and Hydroxytyrosol. In addition, new applications received were introduced to the WG.

- WG on DRVs for vitamins – The WG has been working on vitamin K (see item 5.4), and riboflavin.
- WG on DRVs for minerals – The WG has been working on the draft protocol (applying PROMETHEUS approach¹²) for the opinion on DRVs for sodium.
- *WG on Food Allergy* – The WG discussed and elaborated on the 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 (see item 5.7).
- *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 8.2), 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 8.1).

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. 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 (EFSA-Q-2016-00276)

Postponed.

8.2. Nestlé Nutrition - 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 27 October, the draft opinion was introduced. The approach proposed to address the Terms of Reference, the data used and methodologies applied were discussed and agreed by the Panel. The draft will be referred back to the Working Group on Infant Nutrition for further elaboration.

¹² <http://www.efsa.europa.eu/en/efsajournal/pub/4121>

9. Any other business

- Following the Panel discussion¹³ on the request from the National food safety authorities in the five Nordic countries to provide scientific assistance in assessing DRVs for sugar with particular attention to added sugar (EFSA-Q-2016-00414), the Nutrition Unit provided feedback from the discussion by the Advisory Forum meeting which was held in Bratislava (Slovakia) on 18-19 September 2016. The Panel was informed that clarification on the mandate has been sought from the requestor.
- The Panel provided feedback on the application of EFSA's new approach to authorship¹⁴ for EFSA's scientific outputs.
- The Nutrition Unit informed the Panel of a post-adoption teleconference with an applicant (the minutes of the teleconference are published via this link EFSA-Q-2015-00696), and a Commission request to EFSA for scientific assistance on comments pursuant to Article 16(6) of Regulation (EC) N°1924/2006 related to application 0441_SE (EFSA-Q-2015-00696).
- To further assist applicants, EFSA is planning to organise an Info session on Novel Food applications on 6 March 2017 in Parma.
- As of 2017, open plenary meetings of the EFSA Scientific Committee/Panel will be held in Parma.
- The 76th NDA Panel Plenary meeting will be held on 13-15 December 2016 in Parma.

¹³ <http://www.efsa.europa.eu/en/events/event/160921a-m.pdf>

¹⁴ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.e14091/full>