Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 84th Plenary meeting

Held on 17-19 April 2018, Parma (Italy)

(Agreed on 25 April 2018)

Participants

- Panel Members

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

- Hearing Experts[2]:

  Not applicable

- European Commission representatives:

  Not applicable

- EFSA:

  Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Janusz Ciok, Valeriu Curtui, Agnès De Sesmaisons-Lecarré, Céline Dumas, Lucia Fabiani, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Pauline LaChevre, Leonard Matijevic, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

- Observers:

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Harry J McArdle, Yolanda Sanz and Anders Sjödin.

2. Adoption of the Agenda

The agenda was adopted without changes.

[1] Attended on 18-19 April

[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. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], 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 83rd Plenary meeting

The minutes of the 83rd Plenary meeting held on 07-08 February 2018 were agreed by written procedure on 18 February 2018[5].

On 9 April the Draft opinion on the Tolerable Upper Intake Level of Vitamin D for infants was endorsed by the Panel by written procedure. The public consultation will be open from **18 April to 23 May 2018** via the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/consultation/doc/109.

5. Scientific outputs submitted for possible adoption/ endorsement

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

5.1. Unilever NV – "black tea and improvement of attention" (Art. 13.5, 0461_IE, EFSA-Q-2017-00606)

On 17 April, 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/wol1/doi/10.2903/j.efsa.2018.5266

Novel Foods

5.2. Bioenergy Life Science Inc. – Draft opinion on D-ribose (EFSA-Q-2017-00461)

On 18 April, 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/wol1/doi/10.2903/j.efsa.2018.5265

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[5] https://www.efsa.europa.eu/sites/default/files/event/180207-1-m.pdf

5.3. Medfiles Ltd on behalf of Marealis AS – Draft opinion on shrimp peptides (EFSA-Q-2017-00679)

On 18 April, 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/wol1/doi/10.2903/j.efsa.2018.5267

6. New Mandates

The Nutrition Unit updated the Panel members on new mandates which have been received since the last Plenary meeting.

- **Health Claims**

EFSA has agreed to self-task the NDA Panel regarding the updating of the existing guidance on the scientific requirements for health claims related to physical performance published in 2012 (EFSA-Q-2018-00243). This request has been assigned to the standing working group (SWG) on health claims.

Four applications pursuant to Article 13.5 on "Lignin hydrolyzed (Filtrum) reduces duration and severity of Acute Enteric Infections' symptoms" (EFSA-Q-2018-00006); "Lignin hydrolyzed (Filtrum) supports management of diarrhoea in Acute Enteric Infections" (EFSA-Q-2018-00007); Lignin hydrolyzed (Filtrum) supports management of vomiting in Acute Enteric Infections (EFSA-Q-2018-00008); "Lignin hydrolyzed (Filtrum) supports management of intoxication and dehydration in Acute Enteric Infections" (EFSA-Q-2018-00009) were withdrawn.

- **Novel Foods**

Fourteen new requests related to novel foods pursuant to Article 10 Regulation (EU) 2015/2283 were received from the Commission: "Egg Membrane" (EFSA-Q-2018-00103); "Vitalarmor® GF-100, a Basic Whey Protein Isolate" (EFSA-Q-2018-00104); "EPA rich oil from Phaeodactylum tricornutum" (EFSA-Q-2018-00105); "Tongkat ali root extract" (EFSA-Q-2018-00106); "Yarrowia lipolytica yeast biomass" (EFSA-Q-2018-00223); "Inulin-propionate ester" (EFSA-Q-2018-00225); "Allanblackia seed oil" (EFSA-Q-2018-00226); "Omega-3 fatty acid lysine complex" (EFSA-Q-2018-00248); "Dried mealworms" (EFSA-Q-2018-00262); "Dried crickets" (EFSA-Q-2018-00263); "Mycobacterium manresensis/Nyaditum resae" (EFSA-Q-2018-00278); "Hovenia Dulcis Fruit Extract" (EFSA-Q-2018-00279); "Phenylcapsaicin" (EFSA-Q-2018-00280); "Olive Leaf Extract" (EFSA-Q-2018-00281);

These requests will be assigned to the standing working group (SWG) on novel foods.

- **Traditional Foods**

Two notifications for the placing on the market of traditional foods from third countries pursuant to Article 14 of Regulation (EU)

2015/2283 were received from the Commission: "Haskap berries (*Lonicera caerulea* L.)" (EFSA-Q-2018-00145); "Fonio (*Digitaria Exilis*)" (EFSA-Q-2018-00144).

These requests have been assigned to the EFSA working group on traditional foods.

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

7.1. Scientific Committee (SC) and other Scientific Panels

The Chair of the panel reported back on his participation in the 88th SC open plenary meeting which was held on 11-12 April 2018[6].

The SC endorsed the draft guidance on communicating uncertainty in scientific assessment for release for public consultation.

The draft guidance on risk assessment of chemical mixtures was discussed and will be submitted to the May SC plenary meeting for endorsement for release for public consultation. In this context, the SC working group on Genotoxicity was asked to contribute on how to assess genotoxicity of chemical mixtures[7].

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

The Chairs of respective WGs reported back to the Panel:

- WG on Claims – the WG discussed and elaborated on four draft opinions (2 Art. 13(5) claims, 1 Art. 19 claim and 1 Art. 14 claim). One was submitted (items 5.1) to this Plenary for possible adoption. Two were subject to the stop-the-clock procedure for requesting supplementary information from the applicants. A preliminary outline of the draft guidance on the scientific requirements for health claims related to physical performance including muscle function was introduced and discussed (see item 6).

The Panel was informed about the Applicant's hearing related to an Article 19 health claim application (EFSA-Q-2017-00710), which was held on 14 March 2018[8]. Upon a request from EFSA, the applicant was given the opportunity to answer the questions elaborated by the WG on Claims.

- WG on Novel Foods - The WG discussed/elaborated on draft opinions related to: shrimp peptides, xylo-oligosaccharide, whey protein isolate and EPA-rich oil from Phaeodactylum tricornutum. Two were submitted (items 5.2 and 5.3) to this Plenary for possible adoption.

- WG on Infant Nutrition – The WG discussed the studies which were identified as related to overweight and obesity outcomes (see also item 8.3).

[6] https://www.efsa.europa.eu/en/events/event/180411
[7] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/genotoxicity20152018.pdf
[8] https://www.efsa.europa.eu/sites/default/files/wgs/nutrition/ndaclaims.pdf

- WG on DRVs for vitamins – The WG discussed/elaborated the scientific opinion on the tolerable upper intake level (UL) for vitamin D in infants in view of its submission to the panel for endorsement for release for public consultation (see item 4).
- WG on DRVs for minerals – The WG is currently implementing the systematic review on sodium intake and health outcomes (see protocol)[9].
- *Ad-hoc* WG on sugars[10] – The WG discussed the comments received from public consultation (closed on 4th March) and the feedback received from the participants to the related Technical meeting with stakeholders held in Brussels on 13th February[11]. The technical report that will address all the comments received during the public consultation process was discussed and elaborated. The working group also discussed which parts of the protocol will need to be revised based on the comments received (see item 8.2).

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1. Safety of Astaxanthin (EFSA-Q-2018-00247)

The mandate, which was received from the European Commission pursuant to Article 29(1) of Regulation (EC) No 178/2002, requesting from EFSA a scientific opinion on the safety of astaxanthin was presented to the Panel.

EFSA was asked to evaluate whether the safety of astaxanthin as a novel food used in food supplements at maximum levels of 8 mg/days is still in accordance with the requirements of Regulation (EU) 2015/2283, taking into account the overall, cumulative intakes of astaxanthin from all sources, including from its approved uses in foods. In doing so, EFSA should solicit and make use of the most recent toxicological and exposure evidence, which may be available to business operators and in the public domain.

Ways and approaches for EFSA to address the mandate were discussed. To this end, a public call for data will be launched by EFSA.

8.2. Outcome of the public consultation on the draft protocol for free sugars (EFSA-Q-2017-00828) and Protocol for the assessment of the mandate on free sugars (EFSA-Q-2017-00646)

Following the public consultation of the draft protocol for the assessment of the mandate on free sugars (closed on 4th March)

[9] https://zenodo.org/record/1116290#.WtXT1cNua02
[10] The Panel took note of the change in the naming of the "*Ad-hoc* WG on added sugars" to "*Ad-hoc* WG on sugars".
[11] https://www.efsa.europa.eu/en/events/event/180213

and the Technical meeting with stakeholders held in Brussels on 13th February, EFSA received about 370 comments from 46 interested parties.

An overview of comments received was presented to the Panel. The approach to address the comments received and to amend the protocol was outlined and discussed.

The technical report on the outcome of the public consultation and the amended protocol will be further discussed with the WG on Sugars. Both documents will be presented to the next NDA plenary meeting[12], for possible endorsement.

8.3. Draft Scientific Opinion on the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2016-00482)

Selected sections of the draft opinion on outcomes related to i.e. weight (5), length (6), head circumference (7), body mass index (8), overweight and obesity (9) were presented to the Panel to collect their views and input on the structure and approach used. The comments received will be incorporated in the next version of the opinion and will be discussed at the next meeting of the WG on Infant Nutrition.

9. Any other business

- The Panel was informed about the status of the EFSA renewal of its ten Scientific Panels and its Scientific Committee.
- An EFSA Conference 2018 will take place in Parma from 18 to 21 September 2018[13]. The Conference is constructed around the motto "contextualising risk assessment", reflecting on the future of risk assessment in food safety while acknowledging the social and political context within which it operates. Researchers, risk assessors, social scientists, risk managers and stakeholders from all over the world will gather to discuss issues around the complex interplay between science, food and society. Registrations will be accepted until the maximum venue capacity is reached, and in any case no later than 30 June 2018 (https://conference.efsa.europa.eu/register).
- The Panel was invited to contribute by 30 April 2018 to identify EFSA's research priorities to inform/help to shape the upcoming 9th Framework Programme (FP9) (i.e. the challenges in food safety for the coming 10 years that needs prioritising for research funding). The Panel's contributions will be presented for discussion by the SC Plenary in May 2018.
- Following the REFIT exercises carried out by the European Commission (EC) to review the General Food Law (Regulation 178/02) that includes EFSA's Founding Regulation, the Panel was informed about the

[12] The next meeting of the NDA Panel will be held on 27-29 June 2018.
[13] https://conference.efsa.europa.eu/

Commission's published proposals [14], which aim to further increase transparency in EU decision-making and risk assessment, and seek to strengthen long-term sustainability of EFSA. They include:

- Increased Member State involvement in EFSA's governance structure and scientific panels;
- More transparency of scientific studies by allowing citizens greater access to the information they contain;
- Creation of a common European Register of studies commissioned by companies as part of their application to EFSA;
- Empowerment of EFSA to request additional scientific studies, upon request of the Commission and financed by the EU budget;
- Strengthened risk communication to citizens through increased coordination with EU and national risk managers.

The Commission proposals will be presented to the European Parliament and the Council of the EU (Member States) to be further considered. The indicative timeframe for their adoption is in the first half of 2019**.**

- The 85th NDA Plenary meeting will be held on 27-29 June 2018 in Parma. The 28-29 June will be open to observers.

[14] Transparency and sustainability of the EU risk assessment in the food chain