NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 104TH PLENARY MEETING

Held on 30 June – 01 July 2020 via web conference
(Agreed on 07 July 2020)

Participants

- Panel Members:

  Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.

- Hearing Experts:

  Not Applicable

- European Commission:

  Yvette Azzopardi,[1] Ivona Babic,[2] Stella D'Amore,[2] Olga Goulaki[1]

- EFSA:

  NUTRI Unit: Janusz Ciok, Valeriu Curtui, Agnès Desesmaisons-Lecarré, Céline Dumas, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Leng Heng and Ariane Titz

- Others:

  Not Applicable

[1] Attended on 01 July 2020
[2] Attended on 30 June 2020

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence[3] and the Decision of the Executive Director on Competing Interest Management[4], EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. The minutes of the 103rd Plenary meeting held on 11 June 2020

The minutes of the 103rd Plenary meeting held on 11 June 2020 were agreed by written procedure on 18 June 2020.

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

5.1 Novel Food - Draft opinion on Hovenia Dulcis Fruit Extract (NF 2018/0328) - *Applicant: Hovenia Dulcis AB* (EFSA-Q-2018-00279)

The draft opinion was presented. The Panel reviewed and discussed the sections regarding composition, production process, specifications, proposed uses and use levels, anticipated daily intake, nutritional information, toxicology and allergenicity of the Novel Food. The opinion was adopted by the Panel on 30 June subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/efsajournal/pub/6196

5.2 Novel Food – Draft opinion on rapeseed powder from Brassica rapa L and Brassica napus L. (NF 2018/0768) - *Applicant: Avena Nordic Grain Oy* (EFSA-Q-2019-00213)

The draft opinion was presented. The Panel reviewed and discussed the sections regarding composition, production process, specifications, proposed uses and use levels, anticipated daily intake, nutritional information, toxicology and allergenicity of the Novel Food. The opinion was adopted by the Panel on 30 June subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/efsajournal/pub/6197

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5.3 Health Claim – Draft opinion on Bifidobacterium animalis subsp. lactis Bi-07 contributes to the improvement of lactose digestion in individuals who have difficulty digesting lactose - *Applicant: DuPont Nutrition Biosciences ApS (0492_IE - Art. 13.5 Claim, Reg. (EC) No 1924/2006,* EFSA-Q-2020-00024)

The draft opinion was presented. The Panel reviewed and discussed the sections on the characterisation of the food/constituent, relevance of the claimed effect to human health, and the scientific substantiation of the claimed effect taking into consideration the data submitted in the present application including the applicant's reply to EFSA's stop-the-clock letter. The opinion was adopted by the Panel on 1 July 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/6198

6. New mandates

A new mandate was received related to the safety of alpha-lipoic acid in food (EFSA-Q-2020-00457). In accordance with Article 8(2) of the Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, the European Commission (EC) asks EFSA to assess the available information on the safety of alpha-lipoic acid intentionally added to food including food supplements, specifically on the possible link between the intake of alpha-lipoic acid and the Insulin Autoimmune Syndrome (IAS). EFSA is also requested to provide advice on a dietary intake of alpha-lipoic acid intentionally added to foods that does not give rise to concerns about IAS for the general population, and as appropriate, for vulnerable subgroups of the population. For information on the mandate and the status, please refer to EFSA Register of Questions.

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

Scientific Committee (SC) – The Chair updated the Panel about the latest activities of the SC that are relevant to the NDA Panel.

- EFSA guidance on technical requirements to establish the presence of small particles including nanoparticles was endorsed by the SC for release for public consultation. These requirements apply to particles requiring specific assessment at the nanoscale in conventional materials that do not meet the definition of engineered nanomaterial as set out in the Novel Food Regulation (EU) 2015/2283.
- The draft statement on EFSA approaches for the Derivation of Health Based Guidance Values (HBGV) for food additives, other regulated products and nutrients was also endorsed by the SC for release for public consultation. The document provides recommendations on how EFSA Panels should derive HBGV in a harmonised/consistent manner for these substances, including a decision tree with regard to the need to revise established HBGV.
- Draft guidance on appraising and integrating evidence from epidemiological studies (chapter 4.1, 4.2 and 4.3) was endorsed by the SC for testing in EFSA's assessment during a one-year pilot phase. The guidance describes key epidemiological concepts relevant for evidence appraisal for use in EFSA's scientific assessments.
- The SC received a new mandate from EC on an Acceptable Daily Intake (ADI) for exposure to copper (EFSA-Q-2020-00399). The work completed by the NDA Panel for reviewing the scientific

basis to derive the uncertainty factor to establish a health-based guidance value for copper (EFSA-Q-2019-00385) will be handed over to the SC to be used in responding to this new mandate.

The Chairs of respective NDA Panel/EFSA Working Groups (WG) reported back to the Panel:

- *WG on Claims* - The WG discussed one Art 13(5) and one Art 14 claim applications, one of which was submitted to this plenary for adoption (see item 5.3).
- *WG on Novel Foods* - The WG discussed and elaborated several draft opinions, two of which were submitted to this plenary for possible adoption (items 5.1 and 5.2).
- *WG on Sugars* - The WG Chair briefed the Panel on the work done so far in relation to this mandate regarding the Tolerable Upper Intake Level of dietary sugars. The WG discussed data available for dental caries, data analysis of observational studies, the body of evidence available for metabolic diseases (intervention and observational studies) and the conceptual framework for the integration of the evidence.
- *WG on Food Allergy* – No ongoing mandates. A post-adoption telephone conference took place between EFSA staff and the applicant following the publication of the scientific output on application from Lyckeby Starch AB on barley starch Lyckeby Starch AB, represented by Oy Medfiles Ltd (EFSA-Q-2019-00389). Please refer to EFSA Register of Questions.
- *WG on Protein hydrolysate-based formula* – Five applications are under evaluation, 2 of which are under stop-the-clock procedure for requesting additional information and clarification to the applicant.
- *EFSA WG on Traditional Foods from Third Countries (TF)* – No ongoing mandates.

8. Other scientific topics for information and/or discussion

Not applicable.

9. Any Other Business

The Panel was informed about the setting of an International Liaison Group on nutrient reference values methodologies. The objectives of the Group will be to exchange information on activities related to reference values, to share experience on methodological approaches for establishing reference values, to identify potential areas of international collaboration and to foster global harmonisation in these fields. EFSA will be exchanging the draft Terms of Reference with representatives of authoritative bodies in charge of nutrient reference values at international/regional level (US FDA, Health Canada, New Zealand Ministry of Health, FSANZ, FAO and WHO).

The next plenary meeting of the NDA Panel is scheduled on 31 August 2020 via web conference.