NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 109TH PLENARY MEETING

Held on 17 December 2020 via web conference
(Agreed on 23 December 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:

  Ivona Babic, Stephanie Bodenbach, Stella D'Amore, and Fruzsina Nyemecz.

- EFSA:

  NUTRI Unit: Valeriu Curtui, Paolo Colombo, Agnès de Sesmaisons-Lecarré, Wolfgang Gelbmann, Leng Heng, Annamaria Rossi, Roman Svejstil, Ariane Titz and Emanuela Turla.

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted with an additional item included (8.3).

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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 108th Plenary meeting held on 24-26 November 2020

The minutes of the 108th Plenary meeting held on 24-26 November 2020 were agreed by written procedure on 09 December 2020.

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

5.1 Draft opinion on the safety of a change in the conditions of use of galacto-oligosaccharides as a novel food ingredient in food supplements. *Applicant: Yakult Pharmaceutical Industry Co., Ltd* (EFSA-Q-2020-00211)

The draft opinion was presented. The Panel reviewed and discussed the sections regarding composition, proposed uses and use levels, anticipated daily intake, nutritional information and allergenicity of the Novel Food. The opinion was adopted by the Panel on 17 December 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/6384

6. New mandates

The Panel was informed of the new mandate received from the European Commission requesting EFSA for a scientific advice on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. It will be further discussed in a future plenary meeting.

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

Postponed.

8. Other scientific topics for information and/or discussion

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

8.1 Draft Scientific opinion on the Assessment of the relationship between intake of alpha-lipoid acid (thioctic acid) and the risk of insulin autoimmune syndrome (EFSA-Q-2020-00457)

The Panel re-discussed the principles developed for evidence integration and uncertainty analysis in relation to metabolic disease endpoints and agreed on the approach.

8.2 Update of the Guidance documents for alignment with the Transparency Regulation

Eight scientific guidance documents (8.2.1 to 8.2.8) of the NDA Panel required update to inform applicants of new provisions set out in Regulation (EC) No 178/2002 (i.e. the General Food Law, hereafter GFL Regulation), as amended by Regulation (EU) 1381/2019, the 'Transparency Regulation'. The new provisions concern requirements in the pre-submission phase and submission application procedure that are applicable to all applications submitted as of 27 March 2021.

The Panel took note that only the administrative part of these guidance documents was revised. The scientific part of the guidance documents is left untouched. The texts regarding the new requirements have been aligned throughout different guidance documents, where applicable.

8.2.1 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-2020-00592)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.2 Guidance on the preparation and presentation of applications pursuant to Article 21 Paragraph 2 of Regulation (EU) No 1169/2011 (EFSA-Q-2020-00589)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.3 Guidance on the safety evaluation of sources of nutrients and bioavailability of nutrient from the sources (EFSA-Q-2020-00587)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.4 Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA-Q-2020-00590)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.5 Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (EFSA-Q-2020-00591)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.6 Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 2) (EFSA-Q-2020-00588)

The Panel took note of the changes introduced in the updated draft guidance documents. The Panel will be requested to endorse the updated guidance by written procedure post plenary meeting.

8.2.7 General scientific guidance for stakeholders on health claim applications (EFSA-Q-2020-00586)

The Panel was informed that an updated draft guidance will be submitted to the Panel for endorsement by written procedure.

8.2.8 EFSA Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (EFSA-Q-2020-00593)

The Panel was informed that an updated draft guidance will be submitted to the Panel for endorsement by written procedure.

8.3 Safety of allulose as a Novel food (EFSA-Q-2018-00472; EFSA-Q-2018-00756; EFSA-Q-2018-00797; EFSA-Q-2019-00584; EFSA-Q-2020-00141)

The Panel was given an overview on the status of the allulose applications. The Panel discussed and took note of the approach for the risk assessment.

9. Any Other Business

- The next plenary meeting of the NDA Panel is scheduled on 19-21 January 2021 via web conference.