NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 110TH PLENARY MEETING

Held on 21 January 2021 via web conference
(Agreed on 29 January 2021)

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:

  Stephanie Bodenbach (SANTE).

- EFSA:

  NUTRI Unit: Valeriu Curtui, Ionut Craciun, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

  AMU Unit: Ermanno Cavalli (for item 10)

- 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 without changes.

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 109th Plenary meeting held on 17 December 2020

The minutes of the 109th Plenary meeting held on 17 December 2020 were agreed by written procedure on 23 December 2020.

5. Report on written procedures since the last plenary meeting

Following last plenary meeting, eight updated draft scientific guidance documents were submitted to the NDA Panel for comments and possible endorsement:

- Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources (Revision 1) (EFSA-Q-2020-00587)[3]
- General scientific guidance for stakeholders on health claim applications (Revision 1) (EFSA-Q-2020-00586)
- Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3) (EFSA-Q-2020-00588)
- Guidance on the preparation and presentation of applications for exemption from mandatory labelling of food allergens and/or products thereof pursuant to Article 21(2) of Regulation (EU) No 1169/2011 (Revision 1) (EFSA-Q-2020-00589)
- Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1) (EFSA-Q-2020-00590)
- Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1) (EFSA-Q-2020-00591)
- Scientific and technical guidance for the preparation and presentation of a dossier for evaluation of an infant and/or follow-on formula manufactured from protein hydrolysates (Revision 1) (EFSA-Q-2020-00592)

[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
[3] Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available here.

- Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (Revision 1) (EFSA-Q-2020-00593)

The update related to the administrative part of these guidance documents to inform applicants of new provisions set out in Regulation (EC) No 178/2002 (i.e. the General Food Law), 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 scientific part of the guidance documents is left untouched. On 21 January, they were endorsed by the NDA Panel subject to clarifications/editorial changes.

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

6.1 Draft 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 draft opinion was presented. The Panel reviewed and discussed the sections regarding in particular the identity, source, production process, stability, formulations, biochemistry, and ADME for alpha-lipoid acid (ALA), the definition, epidemiology, genetic determinants, pathophysiology and symptoms of insulin autoimmune syndrome (IAS), and the case reports on ALA intake and IAS. The opinion was endorsed for public consultation by the Panel on 21 January 2021. The public consultation is planned to be launched in the coming weeks. Further information can be found here: https://www.efsa.europa.eu/en/calls/consultations

7. New mandates

Not applicable. Please refer to the minutes of the previous plenary meeting.

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

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

- ***WG on Claims*** – For the meeting of 26-27 January 2021, the WG will discuss three Art 13(5) claim applications.

  Regarding the new mandate[4] 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 (EFSA-Q-2021-00026), the NDA Panel has assigned the preparatory work to the WG Claims. The WG will discuss the mandate and kick-off the preparatory work on 27 January.

- ***WG on Novel Foods*** **-** At the last WG meeting the experts discussed and elaborated six draft opinions and considered that for four of those, additional information is needed from the applicants in order to proceed with the scientific assessment.

[4] See the minutes of the 109th Plenary meeting

- ***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 (UL) of dietary sugars. Please refer to agenda item 9.2.
- ***WG on Food Allergy*** – The WG Chair informed the Panel that next meeting will be dedicated to the discussion of information received from an applicant after a stop clock letter, regarding a draft scientific opinion on the efficacy of an infant formula manufactured from protein hydrolysate in reducing the risk of atopic dermatitis.
- ***WG on Upper Levels*** – The WG Chair informed the Panel that the first three meetings of this new WG took place in December 2020, and were dedicated to present the background of the mandate from the EC and to set the grounds for the development of the draft protocol for the Scientific Opinion for the update of the UL for Selenium. The WG also started the discussion on a rationale for the revision and update of the principles for establishing ULs.
- ***WG on Dietary Folate Equivalent*** – The WG Chair informed the Panel on the work done so far. One meeting of the WG was held on 6th November 2020, in which the experts were provided with background information on the mandate on the assessment of the scientific evidence on the conversion factor of calcium-L-methylfolate and (6S)-5-methyltetrahydrofolic acid glucosamine salt into dietary folate equivalent. A draft protocol for the assessment, including the type of evidence that will be used, was also discussed. The WG will discuss the outcome of the screening of the literature and status of the data extraction during next meeting.

The Panel was informed about the ongoing activity carried out by the Scientific Committee (SC) Working Group to integrate and harmonise the approach regarding the setting of Health-Based Guidance Values (HBGV), such as acceptable daily intake (ADI) and UL, for regulated products that are also nutrients. The draft Statement on the derivation of HBGV for regulated products that are also nutrients will be presented at the February Scientific Committee plenary meeting for possible adoption.

9. Other scientific topics for information and/or discussion

9.1 **Draft statement on the essential composition of total diet replacement for weight control** (EFSA-Q-2020-00260)

In relation to the mandate related to the Scientific Opinion on the Essential Composition of Total Diet Replacement for Weight Control, a drafting group[5] of the Panel undertook the assessment of additional scientific evidence and elaborated a draft statement. The status of this assessment was presented to the Panel. It is foreseen that the draft statement will be submitted to the Panel for possible adoption at the February plenary meeting.

9.2 **Draft Scientific opinion on the Tolerable Upper Intake Level of dietary sugars** (EFSA-Q-2020-00414)

The Panel was given an overview on the status of the update of the literature searches for the systematic reviews included in the assessment and took note of the following protocol amendments:

[5] The drafting group composed of Jacqueline Castenmiller, Stefaan de Henauw, Harry J. McArdle, Dominique Turck and EFSA staff has held three additional meetings on 16 November 2020, 3 December 2020 and 15 January 2021.

a) Literature searches were anticipated owing to the high number of hits retrieved in scoping searches to allow incorporation of the new data into the scientific opinion (i.e. 10 months before the planned endorsement instead of the 3 months foreseen in the protocol).

b) The results of the updated searches and a summary of the new data retrieved will be incorporated into the scientific assessment by a weight of evidence approach (as foreseen in the protocol) and published as an annex to the opinion. Moreover, as agreed with the mandate requestor, new studies meeting certain criteria will be fully incorporated to the opinion, also in meta-analysis and dose-response analyses where appropriate (protocol amendment).

10. Any Other Business

- The Panel was informed about the latest development on the use of Artificial Intelligence for evidence management in risk assessment, in particular to support scientific experts in performing systematic reviews.

- The next plenary meeting of the NDA Panel is scheduled on 24-26 February 2021 via web conference.