SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

137th PLENARY MEETING

4-6 July 2023
14:00-18:00 / 09:00-18:00 / 9:00-13:00
MINUTES - Agreed on 17 July 2023

Location: Teleconference
Attendees:

- **Panel Members**:
Torsten Bohn[1], Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Kristina Pentieva, Alfonso Siani, Frank Thies[2], Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.

- **Hearing Experts**[3]:
Julia Bornhorst, Francesco Cubbada, Aymeric Dopter, and Rex FitzGerald: for Agenda item 10

- **European Commission**:
Takis Daskaleros, Stephanie Bodenbach, and Fruzsina Neymecz.

- **EFSA**:
Nutrition & Food Innovation (NIF) Unit: Reinhard Ackerl, Océane Albert, Paolo Colombo, Ionut Craciun, Pedro Das Neves, Agnès de Sesmaisons, Lucia Fabiani, Thibault Fiolet, Maria Glymenaki, Leng Heng, Nena Karavasiloglou, Georges Kass, Marcello Laganaro, Leonard Matijević, Vania Mendez, Alejandra Muñoz, Estefanía Noriega Fernández, Annamaria Rossi, Esther Ruiz Garcia, Roanne Marie Saad, Angeliki Sofroniou, Francesco Suriano, Ariane Titz, Emanuela Turla, Silvia Valtueña, and Ermolaos Ververis.

  Methodology & Scientific Support (MESE) Unit: Zsuzsanna Horvath (for Agenda item 10).

  Food Ingredients & Packaging (FIP) Unit: Gloria López-Gálvez (for Agenda item 13).

  Executive Director Office: Carlos das Neves[4]

- **Others**:
NA.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Kristina Pentieva.

2. Adoption of agenda

The agenda was adopted with changes in the order of the items discussed.

3. Declarations of Interest of Panel members

1 Participated via web-conference.
2 Participated via web-conference
3 As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
4 Partial participation on 5 July pm

In accordance with EFSA's Policy on Independence[5] and the Decision of the Executive Director on Competing Interest Management[6], 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 136th Plenary meeting held on 22 June 2023 via web-conference

The minutes of the 136th Plenary meeting were agreed by written procedure on 3 July 2023.

5. Draft protocols for the evaluation of the safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)

The Panel discussed the outcome of the public consultation on the draft protocol. The revised protocol and the technical report addressing comments received were endorsed by the Panel on 4 July. The protocol and the technical report will be available on EFSA webpage in the coming weeks.

The Panel was informed about the **launch of public call for data** (open until 5 October 2023). It aims to offer to interested parties and stakeholders the opportunity to submit documented information (published and/or unpublished) relevant to the safety evaluation of berberine in plant preparations used in food supplements.

6. Draft protocol for the evaluation of the safety in use of plant preparations containing hydroxycitric acid (HCA) and isolated hydroxycitric acid (EFSA-Q-2022-00805)

The Panel discussed the outcome of the public consultation on the draft protocol. The revised protocol and the technical report addressing comments received were endorsed by the Panel on 4 July. The protocol and the technical report will be available on EFSA webpage in the coming weeks.

The Panel was informed about the upcoming **launch of public call for data** (open until 5 October 2023). It aims to offer to interested parties and stakeholders the opportunity to submit documented information (published and/or unpublished) relevant to the safety evaluation of HCA from all sources in foods including preparations such as food supplements.

7. Draft protocol for the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel (EFSA-Q-2022-00804)

The Panel discussed the outcome of the public consultation on the draft protocol. The revised protocol and the technical report addressing comments received were endorsed by the Panel on 4 July. The draft protocol and the technical report will be available on EFSA webpage in the coming weeks.

5 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

6 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The Panel was informed about the launch of public call for data (open until 5 October 2023). It aims to offer to interested parties and stakeholders the opportunity to submit documented information (published and/or unpublished) relevant to the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel.

8. Draft opinion on 3'-Sialyllactose (3'-SL) sodium salt as a novel food (NF 2021/2457). Applicant: Kyowa Hakko Bio Co., Ltd. EFSA-Q-2021-00445

The Panel discussed the draft scientific opinion, and in particular reviewed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. Feedback from the panel was incorporated.

The Panel took note that additional information is needed from the applicant. A revised draft will be presented to the Panel for possible adoption.

9. Draft opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin D (EFSA-Q-2021-00367)

The Panel discussed the outcome of the public consultation on the draft opinion. On 5th July, the revised draft Opinion was adopted by the Panel, including the technical report addressing the comments received during the consultation.

10. Draft opinion on the revision of the Tolerable Upper Intake Level (UL) for manganese (EFSA-Q-2021-00371)

The draft opinion was presented. The Panel reviewed and discussed the sections of the draft opinion related to hazard identification, the results of the dietary intake assessment and risk characterization.

Feedback from the Panel was collected. A revised draft opinion will be presented at the next NDA plenary meeting on 3 August for further discussion and possible endorsement for release for public consultation.

11. Scientific matters pertaining to the safety assessment of novel foods (EFSA-Q-2023-00442).

The Panel was informed of the mandate that EFSA received from the European Commission on updating the Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA-Q-2023-00442).

The work plan and timeline were presented. Additionally, based on experience gained from the evaluation of Novel Food applications since issuing the aforementioned guidance document, the Panel was provided with an overview of scientific matters pertaining to the risk assessment of novel foods in the areas of product characterization, production process, specifications, history of use, nutritional information, toxicology, human studies, and allergenicity. Moreover, information was provided to the Panel on new and updated cross-cutting EFSA guidance documents relevant to the risk assessment of novel foods. Feedback from the Panel was collected.

12. Scientific matters pertaining to the safety evaluation of new sources of nutrients

A presentation was given on the general principles of the guidance for applicants on data requirements for the assessment of the safety and relative bioavailability of new nutrient sources, including new physico-chemical forms of nutrients. A timeline was proposed for the development, public consultation, and publication of the guidance.

13. Chemicals Strategy for Sustainability and One Substance One Assessment – Impact to EFSA

The Chemicals Strategy for Sustainability (CSS) was published in October 2020, as part of EU Green Deal; the strategy aims to an EU toxic-free environment by 2050. EFSA is contributing to the relevant strategy's objectives, among which the 'One substance one assessment' (1S1A). Whilst the legislative proposals which will implement 1S1A are still on the making, the Panel was given via a presentation an update of the ongoing activities in EFSA to implement the CSS-1S1A and a summary of the items which will impact EFSA's scientific work.

14. 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** - One Article 13(5) health claim application related to "Appethyl" (EFSA-Q-2022-00096) is currently under evaluation.
- **WG on Novel Foods** – The Panel was informed on the ongoing workload of the WG and number of NF applications received. See also Agenda item 8.
- **WG on Upper Levels** – See Agenda items 9 and 10.
- **WG on Protein Hydrolysates** – One application is under stop-the-clock procedure for requesting additional information and clarification to the applicant and one application is under validation.
- **WG on Food Allergy** – The draft opinion on the re-evaluation of behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers (EFSA-Q-2022-00042) is open for public consultation until 23/07/2023. Stakeholders are invited to submit their comments via this LINK.
- **WG on Traditional Foods from Third countries** – No ongoing notification.

Related to the Scientific Committee (SC), the Panel Chair reported back from the 114th Plenary meeting of the SC. The Panel was also informed about the ongoing activities of the SC WG on Fluoride, the SC WG on Bromide, and the SC WG on Epidemiological studies, and the SC WG for the Update of Risk-Benefit Assessment Guidance.

Of relevance for the NDA Panel, the SC also discussed a proposal for the way forward as a follow-up activity after EFSA's Workshop "Biomarkers of effect" (22-23 Sep 2022). The project plan includes in a first phase a feasibility study for defining the scope of the project and the overall aim of the guidance, as well as establishing definitions, descriptors and criteria for biomarkers of effect to be used in this context.

15. A.O.B

- The Panel was informed about the ongoing status and progress related to the comprehensive literature search performed by EFSA on CBDs.

- The next web-conference Plenary meeting of the NDA Panel will be held on: 3 August 2023.

Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Dr Frank Thies declared the following interest: Member of the Board of Trustees of the Academy of Nutrition Sciences. In accordance with EFSA's Policy on Independence[7] and the Decision of the Executive Director on Competing Interest Management[8], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

With regard to this meeting, Dr Karen-Ildico Hirsch-Ernst declared the following interest: Participation in EFSA EU-FORA Fellowship Programme. In accordance with EFSA's Policy on Independence[9] and the Decision of the Executive Director on Competing Interest Management[10], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

7 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
8 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
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