

23-24 May 2023

09:00-18:00 / 09:00-18:00

MINUTES - Agreed on 5 June 2023

Location: Webconference

Attendees:

- **Panel Members:**

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

- **Hearing Experts¹:**

NA.

- **European Commission:**

Ivona Babic, Takis Deskaleros, Stephanie Bodenbach, and Fruzsina Nyemech.

- **EFSA:**

Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Reinhard Ackerl, Océane Albert, Ionut Cracium, Agnès de Sesmaisons, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Eirini Kouloura, Leonard Matijević, Vania Mendes, Annamaria Rossi, Emanuela Turla, Silvia Valtueña, and Ermolaos Ververis.

- **Others:**

NA.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex.

¹ 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>

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



4. Agreement of the minutes of the 134th Plenary meeting held on 27 April 2023 via web-conference

The [minutes](#) of the 134th Plenary meeting were agreed by written procedure on 9 May 2023.

5. Draft opinion on the re-evaluation of behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers pursuant to Article 21(2) of Regulation (EU) No 1169/2011 – for permanent exemption from labelling ([EFSA-Q-2022-00042](#))

The draft opinion was presented. The Panel reviewed and discussed all sections in the opinion, particularly those related to the maximum amount of mustard protein that could be consumed from emulsifiers manufactured from behenic acid (E470a, E471 and E477) on a single occasion under the proposed conditions of use, the minimal observed eliciting dose triggering allergic reactions in mustard-allergic individuals, the margin of exposure, and the uncertainty assessment. The opinion was endorsed for public consultation by the Panel on 24 May subject to the incorporation of editorial changes. It will be released for public consultation in early June.

6. Draft opinion on nutritional safety and suitability of a specific protein hydrolysate derived from a whey protein concentrate and used in an infant formula and follow-on formula manufactured from hydrolysed protein - *Applicant: FrieslandCampina Nederland B.V. ([EFSA-Q-2020-00025](#))*

The draft scientific opinion was presented. The Panel reviewed and discussed the sections related to characterization of the protein hydrolysate (PH) and related uncertainties, characterization of formula produced from the PH, human studies and nutritional safety and suitability of the infant and follow-on formula. The scientific opinion was adopted by the Panel on 23 May, subject to the incorporation of editorial changes. The full text of the scientific opinion will be available in the coming weeks in the EFSA Journal.

7. Draft opinion on the safety of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 - *Applicant: Evergrain, LLC ([EFSA-Q-2020-00806](#))*

The draft opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, history of use, proposed uses and use levels, nutritional information, ADME, toxicological information, and allergenicity of the novel food. The opinion was adopted by the Panel on 24 May, subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal.



8. Draft opinion on the safety of ethanolic extract of the dried biomass of the microalga *Phaeodactylum tricornutum* as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 - Applicant: *Microphyt* ([EFSA-Q-2019-00091](#))

The draft opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, history of use, proposed uses and use levels, nutritional information, ADME, toxicological information, human data and allergenicity of the novel food. The opinion was adopted by the Panel on 24 May, subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal.

9. Draft opinion on apple cell culture biomass as a novel food (NF 2020/1621) - Applicant: *Mibelle Group Biochemistry* ([EFSA-Q-2020-00488](#))

The draft opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, proposed uses and use levels, nutritional information, toxicological information, and allergenicity of the novel food. The opinion was adopted by the Panel on 24 May, subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal.

10. Draft opinion on cannabidiol isolate as a novel food (NF 2021/2340). Applicant: *CBD Industries LLC* ([EFSA-Q-2021-00282](#))

The Panel was informed about the current state of play and timeline of the ongoing assessment of the above-mentioned application. The draft opinion was presented through a PowerPoint presentation, providing an overview of the data regarding product characterization, production process, and toxicology. The draft opinion will be further elaborated by the WG NF before submitting it to the Panel for discussion/possible adoption.

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

The draft opinion was presented through a PowerPoint presentation and the Panel was informed about the current state of play. In particular, the Panel was informed on the sections related to hazard identification (ADME of manganese, lack of biomarkers of intake, proposed modes of action regarding manganese neurotoxicity, other adverse health effects, except neurotoxicity, associated with 'high' intake of manganese, body of evidence from human and animal studies regarding the relationship between 'high' manganese oral exposure and neurological effects) and preliminary results of the intake assessment. The draft opinion will be further discussed in the upcoming Panel meetings.

12. Any Other Business

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



- **WG on Claims** – Two health claim applications are currently under evaluation, one Article 14 claim application related to "Choline" (EFSA-Q-2021-00543) and one Article 13(5) claim application related to "Appethyl" (EFSA-Q-2022-00096).

- **WG on Novel Foods** – The Panel was informed on the ongoing workload of the WG and number of NF applications received. See also Agenda items 7, 8, 9 and 10.

The WG Chair reported back from the EFSA's Scientific Colloquium 27 "[Cell culture-derived foods and food ingredients](#)" which took place on 11-12 May 2023, in Brussels. The objectives of this event were (a) to identify sectors in the agri-food system relevant to cell culture-derived foods and food ingredients, (b) to review the state of the art of relevant concepts, technologies, and derived products, and (c) to discuss emerging safety and methodological aspects and their impact on EFSA's risk assessment approaches.

- **WG on Upper Levels** – See Agenda item 11.
- **WG on Protein Hydrolysates** – See Agenda item 6. Another application is under stop-the-clock procedure for requesting additional information and clarification to the applicant. One application is under validation.
- **WG on Food Allergy** – See Agenda item 5.
- **WG on Traditional Foods from Third countries** – No ongoing notification.

Related to the Scientific Committee (SC), the Panel Chair reported back from the [113th Plenary meeting of the SC](#). The Panel was informed about the ongoing activities of the SC WG on [Fluoride](#), the SC WG on [Bromide](#), the SC WG on [Epidemiological studies](#), and the SC WG for [the Update of Risk-Benefit Assessment Guidance](#).

The next Plenary meetings of the NDA Panel will be held on:

- 22 June 2023 via web-conference,
- 4-6 July 2023 in Parma.



Annex

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

NO CONFLICT: With regard to this meeting, Prof. Henry McArdle declared the following: member of the UK National Health Claim Committee in his updated aDoI which is under validation. In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf