

29-30 November 2023

09:00-18:00 / 09:00-13:00

MINUTES - Agreed on 11 December 2023

**Location:** Teleconference

**Attendees:**

- Panel Members:  
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, Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.
- Hearing Experts<sup>1</sup>:  
Not Applicable
- European Commission and/or Member States representatives:  
EC: Ivona Babic, Takis Daskaleros, and Stephanie Bodenbach.
- EFSA:  
Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Reinhard Ackerl, Agnès de Sesmaisons, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Estefanía Noriega Fernández, Ruth Roldán Torres, Annamaria Rossi, Ariane Titz, Silvia Valtueña Martinez, and Ermolaos Ververis.
- Others:  
Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants.  
Apologies were received from Torsten Bohn.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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, and no interests were declared orally by the members at the beginning of this meeting.

<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **4. Agreement of the minutes of the 141<sup>st</sup> NDA Plenary meeting held on 26<sup>th</sup> October 2023 by teleconference.**

The [minutes of the 141<sup>st</sup> Plenary meeting](#) were agreed by written procedure on 6 November 2023.

#### **5. Scientific outputs submitted for discussion/possible adoption**

##### **5.1 Draft opinion on helix complex snail mucus (HSM) as a novel food (NF 2019/1077). Applicant: HELIXPHARMA S.R.L. EFSA-Q-2019-00388**

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. The opinion was adopted by the Panel on 29 November subject to editorial changes. The full text of the opinion will be available in January 2024 in the EFSA Journal.

##### **5.2 Draft opinion on Isomaltulose syrup (dried) (NF 2018/0330) Applicant: Evonik Creavis GmbH EFSA-Q-2018-00609**

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The opinion was adopted by the Panel on 29 November subject to editorial changes. The full text of the opinion will be available in January 2024 in the EFSA Journal.

##### **5.3 Draft opinion on Isomalto-oligosaccharide as a novel food (NF 2021/2469) Applicant: BioNeutra North America Inc. EFSA-Q-2021-00185**

The Panel discussed the draft scientific opinion. The draft opinion will be further elaborated and presented at the next NDA plenary meeting on 14/12/2023 for further discussion and possible adoption.

#### **6. Other scientific topics for information / discussion and/or possible endorsement**

##### **6.1 Scientific and technical assistance as regards the evaluation of calcidiol monohydrate as a novel food EFSA-Q-2023-00604**

The Panel discussed the draft scientific and technical report with respect to EFSA adopted scientific opinion on "Safety of calcidiol monohydrate produced by chemical synthesis as a novel food pursuant to Regulation (EU) 2015/2283", including its bioavailability as a metabolite of vitamin D3 when added for nutritional purposes to food supplements. The report was endorsed by the Panel on 29 November and will be available in January 2024 in the EFSA Journal.



## **6.2 Technical Report on CBD literature search performed in support to the EFSA’s “Statement on safety of cannabidiol as a novel food: data gaps and uncertainties”**

The draft technical report providing the details of the literature review used to prepare the NDA Panel “Statement on safety of cannabidiol as a novel food: data gaps and uncertainties” (EFSA-Q-2021-00735) was presented and discussed. Feedback was received from the Panel. A revised draft including feedback received will be circulated to the NDA Panel for editorial comments and will be presented at the next NDA plenary meeting on 14/12/2023 for possible endorsement.

## **6.3 Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for iron. EFSA-Q-2021-00370**

The Panel was presented with an overview of the available evidence gathered on the relationship between high iron exposure and the priority adverse health effects, in particular, in relation to gastrointestinal effects, and effects in infants and young children. The conclusions on these relationships and how to proceed with the hazard characterisation step were also presented. Feedback from the Panel was received. A draft opinion will be presented at the next NDA plenary meeting on 14/12/2023 for discussion/possible endorsement for release for public consultation.

## **6.4 Update of 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 Panel discussed the draft scientific Guidance document and in particular the sections on identity, production process, and compositional data. Feedback from the Panel was received. After amendments, the Guidance document will be presented at the next NDA Panel meeting for further discussion. The discussion on the sections on specifications, history of use of the novel food and its source, proposed uses and use levels & anticipated daily intake was postponed to the next meeting.

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

Postponed.

## **8. Any other business**

The next NDA Plenary meeting will be held on 14<sup>th</sup> December 2023 via teleconference.