

22 June 2023

09:00-18:00

MINUTES - Agreed on 3 July 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:**

Takis Deskaleros, Stephanie Bodenbach, and Panagiota Filippou.

- **EFSA:**

Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Ionut Craciun, Agnès de Sesmaisons, Lucia Fabiani, Thibault Fiolet, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Georges Kass, Leonard Matijević, Angeliki Sofroniou, and Silvia Valtueña.

Methodology & Scientific Support (MESE) Unit: Laura Ciccolallo (for Agenda item 8), and Zsuzsanna Horvath (for Agenda item 5).

- **Others:**

NA.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alfonso Siani.

The NDA Panel took note of the resignation of Carmen Pelaez from the NDA Panel membership, and expressed its thanks for Carmen's dedication to EFSA work.

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

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



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. Agreement of the minutes of the 135th Plenary meeting held on 23-24 May 2023 via web-conference

The [minutes](#) of the 135th Plenary meeting were agreed by written procedure on 5 June 2023.

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

The draft opinion was presented via a presentation. 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 4-6 July for further discussion and possible endorsement for release for public consultation.

6. Draft opinion on 'Choline and contribution to normal liver function of the foetus and exclusively breastfed infants' (Art. 14 claim) - Applicant: Procter & Gamble BV ([EFSA-Q-2021-00543](#))

The draft scientific opinion was presented. The Panel reviewed and discussed the sections in the opinion, particularly those related to characterisation of the food/constituent, the proposed claimed, and the scientific substantiation of the claimed effect. The scientific opinion was adopted by the Panel on 22 June, 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. Feedback from the Scientific Committee /Scientific Panels, EFSA, the European Commission

Postponed.

8. A.O.B

- **Statistical Significance** – A discussion took place about the use and misuse of « statistical significance », the related discussion in the statistician community and the broader scientific community, and its impact on the risk assessment process. A presentation was given by Laura Ciccolallo (biostatistician, EFSA MESE Unit) which addressed the Scientific Committee guidance on statistical significance and biological relevance from 2011⁴, the discussion fostered by the American Statistical Association through its statement on statistical significance and p-values published in 2016⁵, and subsequent developments. A discussion followed which addressed issues related to misconceptions around p-values, especially when they are dichotomised and decontextualised; the use of “statistical significance” in reporting of scientific studies

⁴ Available online <https://www.efsa.europa.eu/en/efsajournal/pub/2372>

⁵ Available online <https://www.amstat.org/asa/files/pdfs/p-valuestatement.pdf>



(primary research) vs in risk assessment (use of primary research); the efforts to advance the reporting and interpreting results. It was acknowledged that EFSA shall continue following the scientific and methodological developments on this matter.

- The next Plenary meeting of the NDA Panel will be held on: 4-6 July 2023 in Parma.