

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

145<sup>th</sup> Plenary meeting



30<sup>th</sup> January – 1<sup>st</sup> February 2024

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

MINUTES - Agreed on 13 February 2024

**Location:** EFSA, Parma

## **Attendees:**

- Panel Members:  
Torsten Bohn, Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Kristina Pentieva, Alfonso Siani<sup>1</sup>, Frank Thies<sup>2</sup>, Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.
- Hearing Experts<sup>3</sup>:  
Georg Lietz and Giovanni Passeri (for Agenda item 5.1).
- European Commission and/or Member States representatives:  
EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal, Fruzsina Nyemecz, and Stephanie Bodenbach.
- EFSA:  
Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Reinhard Ackerl, Agnès de Sesmaisons, Ionut Craciun, Lucia Fabiani, Thibault Fiolet, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Nena Karavasiloglou, Eirini Kouloura, Annamaria Rossi, Ariane Titz, Emanuela Turla, Silvia Valtueña Martinez, and Ermolaos Ververis.  
FEED Unit: Rosella Brozzi, and Elisa Pettenati (for Agenda item 6.1)  
Executive Director: Bernhard Url (for Agenda item 8)
- Others:  
Not Applicable

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.  
No apologies received.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest**

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, EFSA screened the Annual Declarations of Interest filled out by

<sup>1</sup> Online participation

<sup>2</sup> Present on 30-31 January 2024.

<sup>3</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>4</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>5</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)



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. Agreement on the minutes of the 143<sup>rd</sup> NDA Plenary meeting held on 14<sup>th</sup> December 2023 by teleconference.**

The [minutes](#) of the 143<sup>rd</sup> Plenary meeting were agreed by written procedure on 21 December 2024.

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

##### **5.1 Scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for vitamin A and $\beta$ -Carotene. EFSA-Q-2021-00365/EFSA-Q-2021-00372**

The Panel was introduced to the draft opinion. The discussion focused on hazard identification, in particular on the endpoints that were addressed through systematic reviews (teratogenicity, hepatotoxicity and bone health), on the selection of the critical effects for the derivation of tolerable upper intake levels for preformed vitamin A and  $\beta$ -carotene, on the derived values, on the intake assessment, and on risk characterisation. The NDA Panel was informed that the draft opinion had been shared with the FAF Panel for comments, owing to the previous opinions of the ANS Panel on  $\beta$ -carotene and its use as a food additive and in food supplements.

The draft opinion was endorsed by the Panel on 30 January, and it will be available for public consultation on the EFSA website by mid February 2024.

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

The Panel discussed the draft opinion. The discussion focused on the hazard characterisation section and the derivation of a safe level of intake. The draft opinion was endorsed by the Panel on 1 February, and it will be available for public consultation on the EFSA website by mid February 2024.

##### **5.3 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 guidance document, in particular, the sections related to the Identity, Production process, Compositional information, Specifications, History of use, Proposed uses and use levels and anticipated intake, Absorption, distribution, metabolism, and excretion (ADME), Toxicological information, Nutritional information and Allergenicity. The title of the guidance has been revised. The draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 was endorsed by the Panel on 31 January subject to editorial changes, and it will be available for public consultation on the EFSA website in February 2024.



#### **5.4 Update of the Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 EFSA-Q-2023-00444**

The Panel discussed the draft guidance document, in particular, the sections related to the Identity, Production process, Compositional information, Specifications, Data from experience of continued use of the traditional food in third countries and Proposed conditions of use for the EU market. The title of the guidance has been revised. The draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 was endorsed by the Panel on 31 January subject to editorial changes, and it will be available for public consultation on the EFSA website in February 2024.

#### **5.5 Update of the Guidance on safety evaluation of new sources of micronutrients and bioavailability of the micronutrient from the new source. EFSA-Q-2022-00856**

The Panel discussed the draft guidance document, in particular the sections related to the quantification of the relative bioavailability of micronutrients from new sources compared to reference sources and the derivation of conversion factors for labelling purposes. The title of the guidance has been revised. The draft guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources was endorsed by the Panel on 31 January subject to editorial changes, and it will be available for public consultation on the EFSA website in February 2024.

#### **5.6 Draft opinion on ashitaba sap as a novel food (NF 2019/1247). Applicant: Japan Bio. Science Laboratory Ltd. EFSA-Q-2019-00536**

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 1 February subject to editorial changes. The full text of the opinion will be available in February 2024 in the EFSA Journal.

#### **5.7 Draft opinion on magnesium L-threonate as a novel food (NF 2021/2453). Applicant: AIDP Inc. EFSA-Q-2021-00203**

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 30 January subject to editorial changes. The full text of the opinion will be available in February 2024 in the EFSA Journal.



## **6. Other scientific topics for information/discussion**

### **6.1 Guidance on microorganisms used in the food chain**

The Panel was informed about a new mandate for the Scientific Committee in relation to the risk assessment of microorganisms that are used in the food chain for different purposes. The assessments are linked to requests for authorisation of the products under the applicable Regulations; the products evaluated may contain the microorganism, be prepared from, or obtained with the microorganism, and the microorganisms may be genetically modified or not. EFSA considers it necessary to have one scientific guidance document detailing the requirements for the risk assessment of microorganisms that could be applied across sectors. As the SC plays a major role in harmonising practices across areas, it was proposed that the SC prepare a guidance document on the risk assessment of microorganisms used in the food chain to be applied across sectors. The SC agreed on the proposal and a self-task will be prepared. At this regard, it is intended that the WG on microbiology from the FEEDAP Panel with experts from other Panels will prepare the draft guidance for the consideration of the relevant EFSA Panels and finally for the endorsement and adoption by the Scientific Committee.

### **6.2 Hydroxyanthracene derivatives (HADs): Files submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006 for safety evaluation of substances placed under Union scrutiny in Part C of Annex III. EFSA-Q-2022-00790**

The Panel was informed about the background information and the status of the ongoing assessment of studies by the [cross-cutting Working Group on Genotoxicity](#).

## **7. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC**

The Panel was briefed about the status of the ongoing work of the Working Groups of the Scientific Committee related to the draft guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments and the draft opinion on Fluoride. Both draft documents were on the Agenda of [the 117<sup>th</sup> Scientific Committee plenary meeting](#).

## **8. Any other business**

EFSA's Executive Director, Bernhard Url, visited the NDA Panel during the plenary meeting. Views were exchanged about the work and challenges faced by the Panel. Bernhard Url extended his thanks to the Panel for their commitment and dedication to EFSA's work.

The next NDA Plenary meeting will be held on 29th February 2024 online.