

Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 88th Plenary meeting

**Held on 24-25 October 2018, 2018, Parma (Italy)
(Agreed on 8 November 2018)**

■ Panel Members:

Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf¹, Harry J. McArdle², Androniki Naska, Carmen Pelaez, Kristina Pentieva², Alfonso Siani, Frank Thies, Sophia Tsabouri, Dominique Turck (Chair), and Marco Vinceti.

■ Hearing Experts³:

Not Applicable.

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

NUTRI Unit: Valeriu Curtui, Reinhard Ackerl, Mathias Amundsen, Janusz Ciok, Paolo Colombo, Agnès De Sesmaisons-Lecarré, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, Leonard Matijevic, Ruth Roldan Torres, Annamaria Rossi, Hans Steinkellner, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

■ Observers:

Not Applicable.

■ Others:

Not Applicable.

¹ Participated only on 24th October

² Participated via web conference

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

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

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 87th Plenary meeting held on 26-27 September 2018, Parma (Italy)

The minutes of the 87th Plenary meeting held on 26-27 September 2018 were agreed by written procedure on [04 October 2018](#)

5. New Mandates

The Nutrition Unit updated the Panel members on new mandates received since the last Plenary meeting. Information about the mandates received and their status are available on [EFSA Register of Questions](#).

6. Scientific outputs submitted for discussion and/or possible adoption

6.1. Dr. Paul Lohmann GmbH KG - "Magnesium citrate malate" as a nutrient source (EFSA-Q-2018-00066)

The draft opinion was presented and discussed.

The Panel reviewed and discussed the data provided on the bioavailability of the nutrient, magnesium, from the proposed nutrient source, magnesium citrate malate. The Panel also

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

reviewed and discussed the effect of magnesium and magnesium supplementation on calcium status.

The draft opinion was adopted by the Panel on 24 October subject to the incorporation of editorial changes.

The full text of the opinion will be available in the coming weeks in the EFSA Journal via the following link:

<http://www.efsa.europa.eu/en/efsajournal/pub/5484>

6.2. Bioenergy Life Science, Inc. - “Statement on the safety of D-ribose” (additional info art.29, EFSA-Q-2018-00697)

EFSA was requested by the European Commission to perform a supplementary safety assessment for D-ribose by considering the new proposed uses and use levels submitted by the applicant and, if necessary, to update the conclusions of the Scientific Opinion on D-ribose adopted in April 2018 (EFSA-Q-2017-00461)⁶.

The draft statement was presented. The Panel reviewed and discussed the intake assessment carried out for all age groups of the general population, based on individual data from the EFSA Comprehensive European Food Consumption Database taking into account the new proposed uses and use levels.

The draft statement was adopted by the Panel on 24 October subject to the incorporation of editorial changes.

The full text of the opinion will be available in the coming weeks in the EFSA Journal via the following link:

<http://www.efsa.europa.eu/en/efsajournal/pub/5485>

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

7.1 Scientific Committee (SC)

Postponed - No meeting of the SC plenary took place since last NDA Panel plenary.

7.2 EFSA including its Working Groups /Task Forces

- ***NDA Panel Working Groups (WG) for 2018-2021:*** the composition of the WGs and aDoIs of members are published on EFSA webpage⁷.
- ***The Chairs of respective WGs reported back to the Panel:***

⁶ <https://www.efsa.europa.eu/en/efsajournal/pub/5265>

⁷ <https://www.efsa.europa.eu/en/nutrition/working-groups>

- **WG on Claims** – No meeting was held since the last plenary. The meeting of the new WG is on 25-26 October 2018.
- **WG on Novel Foods** – The meeting of the new WG will be held in November 2018.
- **WG on Infant Nutrition** – The WG appraised and discussed publications retrieved related to the outcome “allergy”, “coeliac disease” and “type 1 diabetes mellitus”. The WG also discussed and elaborated on the draft opinion on the appropriate age of introduction of complementary feeding into an infant’s diet.
- **WG on DRVs for minerals** – The implementation of the systematic review on sodium intake and health outcomes is in progress. The draft opinion on DRVs for sodium will be subject to the application of EFSA’s Guidance on Uncertainty Analysis in Scientific Assessment.
- **WG on Sugars** – The WG Chair informed the Panel on the progress made in relation to the systematic reviews conducted in relation to this project. The WG discussed and solved conflicts found during the full text screening of papers related to metabolic disease outcomes. The principles and the tool that will be used for the critical appraisal of individual studies were also discussed.

7.3 European Commission

Not applicable.

8 Other scientific topics for information and/or discussion

8.1 Re-evaluation of phosphates as food additives

The NDA Panel was informed about the on-going assessment of phosphates-containing food additives carried by the FAF Panel⁸ in the framework of the re-evaluation of food additives.⁹ The NDA Panel took note of the approach proposed by the WG in charge of the preparation of the scientific outputs, the datasets and endpoints/adverse health outcomes considered, the outcome of the exposure assessment, as well as the preliminary conclusions.

Comparison with the previous opinions of the NDA Panel on the tolerable upper intake level (UL) for phosphorus (2005)¹⁰ and

⁸ EFSA Panel on Food Additives and Flavourings

⁹ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. 26.3.2010. OJ L 80/19-27.

¹⁰ Scientific Opinion of the NDA Panel on Tolerable Upper Intake Level of Phosphorus <https://www.efsa.europa.eu/en/efsajournal/pub/233>

on dietary reference values (DRVs) for phosphorus (2015)¹¹ were considered also taking into account the different framework under which the current assessment of the use of phosphates as food additives is being carried out.

The NDA Panel noted the possibility that total phosphorus intake might reach or exceed 3,000 mg phosphorus/day in some population groups in the EU, a level of intake of phosphorus from all dietary sources which was considered in the 2005 opinion of the NDA Panel as being tolerated by healthy individuals without systemic adverse effects.

The Panel recognised the challenge of characterising potential interactions with the counterions associated to phosphate in the food additives and suggested acknowledging the issue in the opinion.

Feedback from NDA Panel will be conveyed to the WG on phosphates and to the FAF Panel which will hold a discussion on the draft scientific opinion at its coming plenary meeting in November 2018. The deadline for completing this assessment is 31/12/2018.

8.2 *Unilever PLC and Unilever N.V. - Phytosterol esters (extension of use, cooking oils) as a novel food ingredient* ([EFSA-Q-2014-00865](#))

The Panel was given an overview on the background and data submitted in the application for an extension of use (for cooking purposes) concerning the authorised NF “plant sterols” (PS) (authorised in 2000 under Regulation (EU) 258/1997). The stability data, the intake assessment, the nutritional information, the toxicological and human data, and the applicant’s reply to EFSA request for additional information concerning the formation of phytosterol oxidation products were outlined and discussed.

The draft opinion will be further considered and elaborated by the WG on Novel Foods.

8.3 *Biotropics Malaysia Berhad - Tongkat ali root extract as a novel food* ([EFSA-Q-2018-00106](#))

The Panel was given an overview on data submitted in the application for the safety of Tongkat ali root extract, i.e the production and manufacturing process, history of use and anticipated intake, toxicology data and human studies presented. The Panel took note of possible effect of NF on

¹¹ Scientific Opinion of the NDA Panel on Dietary Reference Values for phosphorus <https://www.efsa.europa.eu/en/efsajournal/pub/4185>

testosterone levels and discussed whether these changes could be of safety concerns.

Feedback from the Panel was given to the WG on Novel Foods. The toxicological data and human studies will be further reviewed by the WG on Novel Foods.

8.4 Overview on the Risk profile related to production and consumption of insects as food and feed¹²

The Panel was informed on the main aspects of the EFSA SC scientific opinion on the risk profile related to production and consumption of insects as food and feed (published in 2015). The opinion identifies the potential biological and chemical hazards as well as allergenicity and environmental hazards associated with the use of farmed insects as food and feed. It also compares these potential hazards with those associated with mainstream sources of animal protein. The possible presence of biological/chemical hazards in food/feed products derived from insects would depend on the production methods, what the insects are fed on (substrate), the lifecycle stage at which the insects are harvested, the insect species and the methods used for further processing. Existing uncertainties were outlined.

The Panel took note of the relevant information addressed in the Risk profile for the safety assessment of NF applications related to insects.

8.5 Overview on outputs from European countries on insects from recent years

The Panel was informed on guidance documents published individually by EU member states. Main safety aspects were discussed. The Panel took notice of topics that have to be further investigated regarding safety assessment of edible insects.

8.6 Principles on risk assessment of the application of nanoscience and nanotechnologies in food and feed¹³

The Panel was given an overview on the EFSA SC Guidance on how to assess the safety of nanoscience and nanotechnology applications. The guidance gives practical suggestions on the types of testing that are needed and the methods that can be applied. In particular, it gives applicants the tools they need to prepare nanotechnology applications and helps EFSA risk assessors with the appropriate tools to evaluate their safety. It covers areas such as novel foods, food contact materials,

¹² <https://www.efsa.europa.eu/fr/efsajournal/pub/4257>

¹³ <https://www.efsa.europa.eu/en/efsajournal/pub/5327>

food/feed additives, and pesticides and is intended for all interested parties. The guidance (which was subject to consultation and endorsed in May 2018) will now enter a pilot phase, with finalisation envisaged by the end 2019. The Panel took note with interest the setting of a cross-cutting working group to assist interested Panels for the piloting phase.

9 Any other business

Next plenary meeting of the NDA Panel is scheduled via teleconference on 29 November 2018 (9-12am, Parma time).