



SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 92ND PLENARY MEETING

**Held on 15-16 May 2019, Parma (Italy)
(Agreed on 28 May 2019)**

Participants

■ Panel Members:

Jacqueline Castenmiller, Stefaan de Henauw, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Dominique Turck (Chair), and Marco Vinceti.

Androniki Naska and Harry J. McArdle participated via teleconference.

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

DG SANTE: Panagiotis Daskaleros (agenda points 5.2, 5.3 and 5.4)

■ EFSA:

NUTRI Unit: Valeriu Curtui, Reinhard Ackerl, Mathias Amundsen, Ester Artau Cortacans, Domenico Azzollini, Janusz Ciok, Paolo Colombo, Agnès de Sesmaisons-Lecarré, Aikaterini Doulgeridou, Céline Dumas, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, Eirini Kouloura, Leonard Matijevic, Federico Morreale, Charlotte Salgaard Nielsen, Ruth Roldan Torres, Annamaria Rossi, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtuena Martinez, Ermolaos Ververis.

■ Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karen Ildico Hirsch-Ernst and Sophia Tsabouri.



2. Adoption of agenda

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

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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.

4. Agreement of the minutes of the 91st Plenary meeting held on 13-14 March 2019, Parma (Italy)

The minutes of the 91st Plenary meeting held on 13-14 March 2019 were agreed by written procedure on 28 March 2019.

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

5.1. Draft opinion on "GlycoLite™ helps to reduce body weight". Applicant: *analyze & realize GmbH* (Art. 13.5, 0476_IE, EFSA-Q-2018-00611)

On 15 May the draft opinion was presented. The Panel reviewed and discussed the sections related to the characterisation of the food/constituent, the human intervention studies submitted for scientific substantiation of the claimed effect, the animal efficacy study, the applicant's proposed mechanisms of action by which the food/constituent could exert the claimed effect, and the weighing of the evidence. The opinion was adopted by the Panel on 15 May subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/5715>

5.2. Draft opinion on 2'-Fucosyllactose / difucosyllactose mixture. Applicant: *Glycom A/S* (EFSA-Q-2018-00374)

On 15 May the draft opinion was presented. The Panel reviewed and discussed the sections related to product characterisation, production process, proposed uses and use levels, anticipated daily intake and toxicology. The opinion was adopted by the Panel on 15 May subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/5717>

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



5.3. Draft opinion on Phenylcapsaicin. Applicant: aXichem AB (EFSA-Q-2018-00280)

On 15 May the draft opinion was presented. The Panel reviewed and discussed the sections related to product characterisation, production process, proposed uses and use levels, anticipated daily intake, ADME, toxicology, the BMD approach applied, human studies and allergenicity. The opinion was adopted by the Panel on 15 May subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/5718>

5.4. Draft opinion on Xia powder. Applicant: Access Business Group International LLC (EFSA-Q-2018-00373, EFSA-Q-2018-00685)

On 15 May the draft opinion was presented. The Panel reviewed and discussed the sections related to composition, production process, specifications, intended uses and allergenicity of the NF. The opinion was adopted by the Panel on 15 May subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: <http://www.efsa.europa.eu/en/efsajournal/pub/5716>

6. 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](#).

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

7.1. Scientific Committee (SC) and/or Scientific Panel(s) including their Working Groups

The Panel was briefed on the outcome of the [SC plenary which was held on 24 April](#).

The SC adopted the draft guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment, which will be published by the end of May 2019.

The Panel was informed about the kick-off meeting of the [SC working group on Epidemiological Studies](#). The WG discussed the scope of a guidance document on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments, the outline structure of the document, as well as the workplan, tasks and timeline.

7.2. EFSA including its Working Groups /Task Forces

The Chairs of respective WGs reported back to the Panel:

- **WG on Claims** - The WG discussed and elaborated an Art 13(5) claim opinion related to "GlycoLite™ helps to reduce body weight", which was submitted to the Panel for discussion/possible adoption (see item 5.1).
- **WG on Novel Foods (NF)** – The WG discussed and elaborated several draft opinions, three of which were submitted to this plenary for possible adoption (see items 5.2, 5.3, and 5.4).



- **WG on Sugars** – The WG Chair briefed the Panel on the current status of the data extraction and data analysis of intervention studies, the pilot appraisals of intervention studies, the on-going work on the food composition database for total sugars, as well as the status of data extraction of observational studies.

7.3. European Commission

Not applicable.

8. Other scientific topics for information and/or discussion

8.1 Draft opinion on Nicotinamide riboside chloride. Applicant: ChromaDex, Inc (EFSA-Q-2018-00480)

Postponed.

8.2 SC guidance on risk assessment of combined exposure to multiple chemicals

The Panel was given an outline of the SC guidance document on the risk assessment methodologies for combined exposure to multiple chemicals, relevant areas for the Panel were highlighted. The framework is based on the risk assessment steps (problem formulation, exposure assessment, hazard identification and characterisation, and risk characterisation including uncertainty analysis), with tiered and step wise approaches for both whole mixture approaches and component-based approaches.

8.3 SC statement on Genotoxicity assessment of chemical mixtures

The Panel was given an outline of the Statement of the SC on Genotoxicity assessment of chemical mixtures. The panel took note of the approach proposed and its relevance for the assessment of Novel Food applications.

9. Any Other Business

- EFSA staff gave a brief overview of the data included in the Novel Food application on β -Hydroxybutyrate salts (Sodium/Magnesium/Calcium) (EFSA-Q-2018-00343).
- On 15 May, EFSA held a web meeting with stakeholders to present its draft opinions on dietary reference values (DRVs) for sodium and chloride. The aim of the meeting was to provide clarifications to stakeholders and collect comments on the conclusions reached by the Panel regarding DRVs for sodium and chloride. The meeting was recorded and accessible via this [LINK](#).
- The Panel was updated about EFSA's progress on independence in 2018.
- The Panel was informed that the revision of the Regulation 178/2002 (General Food Law) was approved by the EU Parliament. This marks the last step in the legislative approval process for an update of EFSA's Founding Regulation. The final text will be published in the Official Journal of the European Union during the summer and enter into force 20 days after publication. With a transition period of 18 months, most measures will become applicable in early 2021.
- The Panel took note of the new organigram of the Nutrition Unit and the project in place to manage applications particularly in the areas of Novel Foods.
- The Panel was informed about [the call for expression of interest for Scientific & Technical Support Scheme](#) launched by EFSA in March. The objective of this call is to establish a



list of individuals with scientific expertise to assist EFSA in carrying out the preparatory work in the areas of Novel Foods/Nutrient Sources. The task entails the preparation of structured summary reports on critical data extracted from an application (dossier). Applications may be submitted at any time during the period of validity of the call for expression of interest (maximum 5 years). The Panel was kindly asked to help to disseminate further this call.

10. Next meeting

The next meeting will be held on 2-4 July 2018 in Parma (the 3rd of July is open to observers).