NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 96TH PLENARY MEETING

Held on 27-29 November 2019 in Parma (Italy)
(Agreed on 13 December 2019)

Participants

- Panel Members:

  Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen[1], Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva[2], Alfonso Siani, Frank Thies, Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.

- Hearing Experts:

  Not Applicable

- European Commission:

  Ivona Babic, Takis Daskaleros and Rafael Luis Perez Berbejal

- EFSA:

  NUTRI Unit: Valeriu Curtui, Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Céline Dumas, Agnès de Sesmaisons-Lecarré, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, Eirini Kouloura, Leonard Matijevic, Federico Morreale, Gabriela Precup, Ruth Roldan Torres, Hans Steinkellner, Roman Svejstil, Ariane Titz, Emanuela Turla, Silvia Valtuena Martinez, Ermolaos Ververis.

  SCER Unit: Angelo Maggiore (for item 6.7)

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Kristina Pentieva sent apologies for the first day.

[1] Participated via web-conference on 27-29 November
[2] Participated via web-conference on 28-29 November

2. Adoption of agenda

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

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[3] and the Decision of the Executive Director on Competing Interest Management[4], 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 95th Plenary meeting held on 30 October 2019, via web-conference.

The minutes of the 95th Plenary meeting held on 30 October 2019 were agreed by written procedure on 12 November 2019.

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

5.1. Health Claim - "MenaQ7®, vitamin K2 as menaquinone-7" and "improves arterial stiffness". *Applicant: NattoPharma ASA* (Art. 13.5, Claim Serial No: 0483_IE, (EFSA-Q-2019-00229)

On 27 November, the draft opinion was presented. The Panel reviewed and discussed the section on the scientific substantiation of the claimed effect taking into consideration the data submitted in the present application and the content of the reply to the stop-the-clock letter. The opinion was adopted by the Panel 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/5949

5.2. Novel Food - Selenium-enriched biomass of *Yarrowia lipolytica*. *Applicant: SKOTAN S.A.* (EFSA-Q-2018-00796)

On 27 November, the draft opinion was presented. The Panel reviewed and discussed the sections regarding the production process, composition, specifications, the proposed uses and use levels, anticipated daily intake and the nutritional information of the Novel Food. A revised draft opinion will be submitted for possible adoption at the NDA Plenary in December.

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5.3. Nutrient Source - *Calcium-L-methylfolate*. *Applicant: DSM Nutritional Products* (EFSA-Q-2018-00816)

The draft opinion was presented. The Panel reviewed and discussed the sections regarding product characterisation, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity of the nutrient source. The opinion was adopted by the Panel on 27 November 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/5947

5.4. Novel Food - Vitamin D2 mushroom. *Applicant: Oakshire Naturals, LP* (EFSA-Q-2018-00601)

The draft opinion was presented. The Panel reviewed and discussed the sections regarding composition, production process, specifications, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity of the Novel Food. The opinion was adopted by the Panel on 28 November 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/5948

6. Other scientific topics for information and/or discussion

6.1 Novel Food – Draft opinion on Dried fruits of *Synsepalum dulcificum* (miracle berries). *Applicant: Baïa Food Co*. (*Medicinal Gardens* S.L.) (EFSA-Q-2018-01032)

The Panel was briefed on the status of the application and on the approach proposed by the WG on Novel Foods. The stop-the-clock procedure has been applied and the request for additional information from the applicant has been issued in order to proceed with the scientific assessment of this application (in particular regarding genotoxicity and taste alterations after chronic consumption).

6.2 Novel Food – Draft opinion on Astaxanthin (EFSA-Q-2018-00247)

The Panel was briefed on the status of draft opinion on astaxanthin. Recently the FEEDAP Panel has adopted a scientific opinion on synthetic astaxanthin. In this opinion most of the information submitted within the frame of the call for data on astaxanthin launched by the NUTRITION unit has been considered. The FEEDAP opinion will be the starting point for the NDA opinion for which in addition stakeholder information not considered by the FEEDAP Panel will be considered. The draft NDA opinion on astaxanthin will be submitted for possible adoption at the NDA Plenary in December.

6.3 Novel Food - Nutritional assessment principles

Following from last plenary meeting, the principles applied for nutritional assessment of novel foods were further clarified. Practical examples from previous and current assessments of NFs, i.e. which are expected to replace other foods in the diet, and which are not expected to replace other foods in the diet, were given to illustrate the assessment approaches used.

6.4 Novel Food - Assessment of Novel Foods applications intended for infants and young children

The outcome of a review of NF applications (evaluated by the Panel) intended for infants and young children was presented. The regulatory framework regulating foods for specific groups was also presented including infant formula (IF) and follow-on formula (FOF), processed cereal-based foods and other baby foods, food for special medical purposes, and food supplements.

Points to consider for exposure assessment were outlined. The establishment of dietary reference values (DRVs) and upper tolerable intake levels (ULs) for different life stages and sex groups was outlined pointing to the possibly differing absorption efficiency of nutrients and relevant biomarkers to consider.

For clinical trials substantiating the addition of a NF to IF or FOF, a number of factors were proposed to be considered e.g. in relation to the appropriateness of study design, statistical analysis of data, and the possible uncertainties when extrapolating from one age group to another.

Examples of published opinions were given.

6.5 Novel Food - Status and Trends of Novel Foods applications

The Panel was given an overview on the status of novel food applications received since Regulation (EU) 2015/2283 came into force. The NF categories and recent trends in NF applications were outlined.

6.6 Protein hydrolysate-based formula

The Panel was briefed on the state of the scientific assessments of dossiers submitted for the evaluation of the safety and suitability of protein hydrolysate-based infant and follow-on formulae. The Panel was informed that the WG on protein hydrolysate-based formula identified some particulars of the 'Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates' (published in 2017) would benefit from further clarification. This related to the appropriate study design to substantiate safety and suitability of a formula, and the information that should be submitted when food enzymes are used in the hydrolysis process.

The Panel agreed that an explanatory note to the EFSA guidance should be published. In this relation, the Panel wanted to highlight in particular the following: 'The regulatory context for the evaluation of safety and suitability of formulae manufactured from protein hydrolysates changed with the adoption of Regulation (EU) 609/2013 and Commission Delegated Regulation (EU) 2016/127. Consequently, it should be clarified that the only appropriate control formulae in clinical studies designed to determine safety and suitability are infant and follow-on formulae manufactured from intact proteins or those infant and follow-on formulae manufactured from protein hydrolysates whose safety and suitability have been favourably evaluated by EFSA after the adoption of the new regulatory framework.'

6.7 The emerging risks identification process

The Panel was given an overview on the CLEFSA project (Climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality). The project coordinator is looking for volunteers from the Panel to participate in the CLEFSA characterisation exercise in relation to nutrition issues. The objective of the characterisation is to identify, based on expert knowledge and expertise, relevant issues from the vast and often incomplete information retrieved in the crowdsourcing exercise

in relation to the nutrition issues. It was agreed that the coordinator of the project will distribute to interested Panel experts the list of issues identified mainly via a crowdsourcing exercise, with the possible aim of characterising them on the basis of a set of criteria and climate change scenarios.

7. 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.

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

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

The Chair of the Panel informed on the topics that will be discussed on the plenary meeting of the Scientific Committee to be held on 4-5 December 2019.

The Chairs of respective WGs reported back to the Panel:

- **WG on Claims** - The WG discussed several Art 13(5) claim applications, one of which has been submitted to this plenary for adoption (see item 5.1) and for the remaining, requests for additional information from the applicants are needed in order to proceed with the scientific assessment of these applications - Stop-the-clock letters have been issued.
- **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, 5.4).
- **WG on Sugars** – The WG Chair briefed the Panel on the work done so far in relation to this mandate regarding the Tolerable Upper Intake Level of dietary sugars. The WG discussed about data extraction on dental caries, data analysis of intervention studies on metabolic diseases, and the methodology used to develop food composition databases for added and free sugars from the food composition database on total sugars.
- **WG on Copper Uncertainty Factor –** The Panel was briefed on the ongoing work of the WG to advice on the uncertainty factor (UF) to be applied in deriving a HBGV for copper.
- **WG on Food Allergy –** the next WG meeting will be held on 17 December.
- **WG on Protein hydrolysate-based formula** – see item 6.6.

8.2 EFSA including its Working Groups /Task Forces

Not applicable.

8.3 European Commission

Not applicable.

9. Any Other Business

- The Panel was given a presentation on the EFSA "New Way of Working" initiative. In particular, the digital tools available to Panel experts for co-editing scientific documents were presented. Technical advice was also given on how to overcome internet connection breakdown while editing/revising a scientific document.
- The next meeting will be held on 18 December 2019 via web conference (9:30-12:30 CET).