NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 91ST PLENARY MEETING

Held on 13-14 March 2019, Parma (Italy)
(Agreed on 28 March 2019)

Participants

- Panel Members:

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

  Kristina Pentieva has participated via teleconference.

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  DG SANTE: Stephanie Bodenbach and Fruzsina Nyemecz (agenda points 5.1, 5.2 and 5.3)

- EFSA:

  NUTRI Unit: Valeriu Curtui, Reinhard Ackerl, Ester Artau Cortacans, Mathias Amundsen, Janusz Ciok, Agnès De Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, Leonard Matijevic, Federico Morreale, Charlotte Salgaard Nielsen, Ruth Roldan Torres, Annamaria Rossi, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

  AMU Unit: Laura Ciccolallo (agenda points 5.1, 5.2 and 5.3) and Laura Martino (agenda point 5.1).

- Others:

  Not Applicable

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 Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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 90th Plenary meeting held on 17-18 January 2019, Parma (Italy)

The minutes of the 90th Plenary meeting held on 17-18 January 2019 were agreed by written procedure on 28 January 2019.

5. Scientific outputs submitted for discussion and/or possible adoption/endorsement for release for public consultation

5.1. Draft opinion on dietary reference values (DRVs) for sodium (EFSA-Q-2011-01224)

The draft opinion was presented and discussed, with focus on sections 5 (criteria on which to base DRVs) and 6 (data on which to base DRVs), the conclusions and recommendations for research.

The Panel was given an overview on the Expert Knowledge Elicitation (EKE) process, which was used to weigh/integrate the evidence and consider the associated uncertainties to inform final conclusions. The two elicitations conducted on balances studies and on the relationship between sodium intake and cardiovascular disease (CVD) risk were presented and the respective outcomes were discussed (section 6).

To derive a reference value for sodium, the Panel considered a level of intake which is safe and adequate for the general population of adults. The value takes into consideration evidence on sodium and risk of CVD and nutrition adequacy. The Panel noted that, although the term 'safe intake' is not defined in the principles for deriving and applying Dietary Reference Values, the concept of a safe intake has been used in previous assessments[3] when providing advice on a daily intake of a nutrient which does not give rise to concerns about adverse health effects, in case a tolerable upper intake level (UL) could not be established. The Panel discussed the conclusions drawn for the other population groups, i.e. pregnant women and lactating women, infants aged more than 6 months, and children. Suggestions were made for recommended research.

[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
[3] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2815

The Panel was informed about the Dietary Reference Intakes for Sodium developed jointly for the United States and Canada by the National Academies of Sciences, Engineering, and Medicine.

The draft opinion was endorsed by the Panel on 13 March for release for public consultation to gather input from all interested parties. The public consultation will be launched at the beginning of April 2019 (link: https://www.efsa.europa.eu/en/consultations/call/190403).

In addition, before the end of the public consultation EFSA will be holding a Technical meeting with stakeholders on the draft opinions on DRVs for sodium and chloride on 7 May 2019 in Brussels.

5.2. Draft opinion on dietary reference values (DRVs) for chloride (EFSA-Q-2011-01207)

On 13 March, the draft opinion was presented and discussed, with focus on sections 5 (criteria on which to base DRVs) and 6 (data on which to base DRVs), the conclusions and recommendations for research.

The Panel noted the close relationship between sodium and chloride balances in the body, the fact that sodium chloride is the main source of both electrolytes in European diets and that similar urinary excretion levels of sodium and chloride (on a molar basis) are typically observed in Western populations. The Panel considered that reference values for chloride can be set at the value equimolar to the reference values for sodium for all population groups. As reference values, the Panel proposed levels of chloride intake which are safe and adequate for children and adults, under the consideration that the main source of dietary chloride is sodium chloride.

The draft opinion was endorsed by the Panel on 13 March for release for public consultation to gather input from all interested parties. The public consultation will be launched at the beginning of April 2019 (link: https://www.efsa.europa.eu/en/consultations/call/190403-0).

Please see also item 5.1.

5.3. Draft opinion on the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2016-00482)

Harry J. McArdle chaired this Agenda item.

On 13 and 14 March, the draft opinion on the appropriate age of introduction of complementary feeding into an infant's diet was presented and discussed. A protocol was already published in relation to this assessment (2017).

In the opinion, complementary feeding was defined as the period when complementary foods are given together with either human milk or formula.

The Panel took note of the methodology applied for this opinion, the inclusion and exclusion criteria applied for literature searches, the assessment of the risk of bias of the included studies, the forest plots mapping, the assessment of possible publication bias by funnel plots, the integration of the evidence from main and supportive lines of evidence and the grading of the confidence in the evidence.

The Panel reviewed and discussed the conclusions for the different (health) outcomes/endpoints/populations discussed in the opinion, i.e. weight/length/head circumference, BMI-related endpoints, chance/risk of being at least overweight or of being obese, body composition, atopic diseases, coeliac disease, type 1 diabetes mellitus, risk factors

for cardiovascular disease, infections, sleep, infant development, nutrient status, food preferences and eating habits. Developmental readiness of infants to receive complementary foods was also discussed.

The draft opinion was endorsed by the Panel on 14 March for release for public consultation to gather input from all interested parties. The public consultation will be launched at mid-April 2019 (link: http://www.efsa.europa.eu/en/calls/consultations).

5.4. Draft opinion on "Nutrimune supports the immune system in defence against pathogens in the upper respiratory and gastrointestinal tract of young children". Applicant: H.J. Heinz Supply Chain Europe B.V. (Art. 14, 0480_NL, EFSA-Q-2018-00727)

On 14 March, 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, the statistical re-analysis of the two human intervention studies and the publications reporting on mechanistic studies. 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/5656.

5.5. Draft Opinion on Chia seeds. Applicants: Majami Sp. z o.o. Sp.k., Zentis GmbH & Co. KG, Sanchis Mira SA., Naturkost Übelhör GmbH & Co. KG, The Chia Co, Materne SAS, Parry's Pots Limited (EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00684, EFSA-Q-2018-00686, EFSA-Q-2018-00224)

On 14 March, the draft opinion was presented. The Panel reviewed data regarding product characterisation, intended uses, human studies and allergenicity of the NF. In particular, the Panel discussed extensions of use not including heat treatment of chia seeds, which may lead to formation of process contaminants, as well as the use of chia seeds in other foods which are usually not subject to heat treatment.

The Panel took note that additional information is needed from the applicants in order to proceed with the scientific assessment of those requests for extensions of use which include heat treatment of chia seeds and which could potentially lead to formation of process contaminants, e.g. acrylamide. Therefore, a request for additional information will be sent to the applicants.

The draft opinion on extensions of use not including heat treatment of chia seeds as well as the use of chia seeds in other foods which are usually not subject to heat treatment was adopted by the Panel on 14 March (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/5657.

5.6. Draft opinion on Betaine. Applicant: DuPont Nutrition Biosciences ApS (EFSA-Q-2018-00997)

On 14 March, the draft opinion was presented. The Panel reviewed and discussed the data on the intended uses of the NF, and the assessment carried out on the new proposed uses and uses levels of the NF for the general population. The Panel took note that the maximum safe intake level of the NF is to be expressed on a mg/kg body weight basis. The opinion was adopted by the Panel on 14 March 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/5658.

The Panel agreed to align the opinion on the NF published in 2017 (EFSA-Q-2016-00287) to express the maximum safe intake level of the NF on a mg/kg body weight basis.

5.7. Draft opinion on bovine milk whey basic protein isolate – extension of use. Applicant: Armor Protéines S.A.S (EFSA-Q-2018-00996)

On 14 March, the draft opinion was presented. The Panel reviewed and discussed the sections regarding the proposed conditions of use and anticipated intake/extent of use of the Novel Food. The opinion was adopted by the Panel on 14 March 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/5659

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

The Panel was briefed on the outcome of the SC plenary which was held on 19-21 February 2019.

The SC was consulted by the FAF Panel on the methodological aspect arising from the re-evaluation of phosphates as food additives, i.e. the derivation of health-based guidance values for food additives that are also nutrients. The difference between setting Tolerable Upper Intake Level (UL) for nutrients and ADIs for food additives was presented and discussed (see also the 88th NDA plenary minutes). It was proposed that current approaches to the setting of Health Based Guidance Values for regulated substances which are also nutrients should be reviewed to assess if a coherent harmonised strategy for such risk assessments should be devised.

The SC cross-cutting Working Group on Genotoxicity discussed a self-task mandate related to the cross-cutting issue of aneugenicity assessment.

The newly set Working Group on Epidemiological studies has been working on the terms of references and the scope for the envisaged guidance document.

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 two draft opinions: one Article 14 claim opinion was submitted to the Panel for discussion/possible adoption (see item 5.4), and for one Article 13(5) claim a clock-stop procedure was applied for requesting supplementary information from the applicant.

- **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 5.5, 5.6, and 5.7).
- **WG on DRVs for minerals** - The WG discussed and elaborated Section 6 of the opinion ('Data on which to base Dietary Reference Values'), which had been developed to reflect the outcome of the Expert Knowledge Elicitation process. The draft opinions on DRVs for sodium and chloride were submitted to this plenary for possible endorsement for release for public consultation (see items 5.1-5.2).
- **WG on Sugars** – The WG Chair informed the Panel on the progress made in relation to the data extraction performed for intervention and observational studies. The WG discussed the endpoints of interest investigated in the intervention and observational studies included in the assessment, and issues related to the quantification of the sugar intake from different sources in the observational studies. The WG also discussed the appraisal of individual studies included after full-text screening.
- **WG on Infant Nutrition** - The WG discussed and elaborated the draft opinion, and particularly focussed on the discussion and conclusion sections, the weighing of the evidence, and the section on methodology. The draft opinion was submitted to this plenary for possible endorsement for release for public consultation (see item 5.3).

7.3. European Commission

Not Applicable.

8. Other scientific topics for information and/or discussion

Not Applicable.

9. Any Other Business

9.1. Revision of General Food Law

In February 2019, the European Parliament and the Council reached an agreement on the Commission proposal to amend EFSA Founding Regulation 178/2002. The agreement envisages changes regarding EFSA's governance, risk communication, quality and reliability of studies, and transparency and confidentiality rules. This agreement has not yet passed into law - it will have to be ratified by the Council Committee of the Permanent Representatives of the Member States (COREPER) and then pass through a two-stage approval process in the European Parliament (ENVI Committee and Plenary) by the end of March.

9.2. Scientific and Technical Support in the area of Novel Food & Nutrient Source

EFSA will be launching a new Call for expression of interest to establish a list of individuals (natural persons) with scientific expertise to assist EFSA in carrying out the preparatory work in the areas of Novel Food (NF) and Nutrient Source (NS).

DRV Finder – The Panel was given highlights on the statistics about the users and the coverages received after the launch by EFSA in November 2018 of the interactive tool that allows nutritionists and other health professionals to make quick and easy calculations using EFSA's dietary reference values. The language versions available are English, Italian, French, German, and Spanish.

9.3. Web-conference plenary meetings for NDA Panel

Owing to the increased number of NF applications and to comply with legal deadlines, additional *ad-hoc* web-conference plenary meetings will be scheduled between two physical plenary meetings. Depending on the number of draft opinions available, the length of physical meetings may be changed and/or *ad-hoc* web-conference may be scheduled.

10. Next meeting

The next meeting will be held on 15-16 May 2019 in Parma.