NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 118TH PLENARY MEETING

Held on 27-28 October 2021, as a web conference
(Agreed on 12 November 2021)

Meeting open to observers on 28 October 2021, 9:00-14:00

Participants

- Panel Members:

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

- Hearing Experts:

  Not Applicable

- European Commission:

  DG SANTE: Takis Daskaleros, Stefanie Bodenbach, and Heidi Moens.

  JRC ISPRA (Nutrition Unit): Joana Dias, and Evangelia Grammatikaki.

- EFSA:

  Nutrition (NUTRI) Unit: Valeriu Curtui, Reinhard Ackerl, Agnès de Sesmaisons-Lecarré, Andrea Germini, Leng Heng, Eirini Kouloura, Leonard Matijevic, Ariane Titz, Silvia Valtueña Martínez.

- Observers:

  See Annex I.

- Others:

  Not Applicable

CLOSED SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Inge Mangelsdorf.

2. Adoption of agenda

The agenda was adopted without 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 117th Plenary meeting held on 14-15 September 2021, as a web conference

The minutes of the 117th Plenary meeting held on 14-15 September 2021 were agreed by written procedure on 23 September 2021.

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

5.1. Draft opinion on iron hydroxide adipate tartrate as a novel food (NF 2019/1417). *Applicant: Nemysis Ltd* (EFSA-Q-2020-00200)

The draft opinion was presented. In particular, the Panel discussed the sections related to product's production process and characterisation, specifications, history of use, proposed uses and use levels, nutritional information, toxicological information, and allergenicity. The opinion was adopted by the Panel on 27 October 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/6935

5.2. Draft opinion tetrahydrocurcuminoids from turmeric (*Curcuma longa* L.) as a novel food (NF 2020/1526). *Applicant: Sabinsa Europe GmbH* (EFSA-Q-2020-00111)

The draft opinion was presented. In particular, the Panel discussed the sections related to product's production process and characterisation, specifications, history of use, proposed uses, use levels, nutritional information, toxicological information, and allergenicity. The

[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

opinion was adopted by the Panel on 27 October 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/6936

5.3. Draft opinion on *Eurycoma longifolia* (Tongkat Ali) root extract as a novel food (NF 2018/0169). *Applicant: Biotropics Malaysia Berhad* (EFSA-Q-2018-00106)

The draft opinion was presented. In particular, the Panel discussed the sections related to product's characterisation, history of use, proposed uses and use levels, nutritional information, toxicological information, and allergenicity. The opinion was adopted by the Panel on 27 October 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/6937

5.4. Draft opinion on *Wolffia globosa* powder as a novel food (NF 2019/1223). *Applicant: Hinoman Ltd* (EFSA-Q-2019-00695)

The draft opinion was presented. In particular, the Panel discussed the sections related to product's production process and characterisation, specifications, history of use, proposed uses, use levels and anticipated intake, nutritional information, toxicological information, and allergenicity. The opinion was adopted by the Panel on 27 October 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/6938

6. Other topics for information and/or discussion

Not applicable.

OPEN SESSION ON 28 OCTOBER

7. Welcome and introduction of the Agenda for the open session

The Chair welcomed the participants and the Observers. The Panel Chair invited the Panel members to introduce themselves.

The Chair briefly introduced EFSA's remit in Nutrition and outlined the areas of mandates covered by the NDA Panel.

An outline of the Agenda items covered during the Open plenary was presented.

8. Presentation of Guidelines for observers

Observers were reminded about the code of conduct to be followed when attending the open plenary meeting.

9. Scientific outputs submitted for discussion and possible endorsement

9.1. Draft opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods (EFSA-Q-2021-00026)

The Panel discussed the draft opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. The sections on 'Nutrients and non-nutrient components of foods of public health importance for European populations' and 'Foods groups which have important roles in diets of European populations and subgroups thereof' were presented to the Panel by the Chair of the WG Health Claims in the form of a Power Point presentation, followed by a reading of the Section on 'Choice of nutrients and non-nutrient components of food for nutrient-profiling' and the 'Conclusions' directly in the draft opinion. Comments of Panel members were gathered. The draft opinion is to be amended accordingly.

The draft opinion was endorsed for public consultation, subject to editorial changes, on 28 October 2021.

Please refer to the supporting presentation published here (slides 14-64).

10. Update on ongoing work of the Nutrition Unit & NDA Panel

The Panel was given an update on the ongoing work of the NDA Panel, the number of applications and the timelines for delivering the Panel outputs related to generic mandates were highlighted.

Please refer to the supporting presentation published here (slides 66-85).

Information about the mandates received and their status are available on Open EFSA portal.

11. New mandates

No new mandate received since the last plenary.

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

The Chair provided feedback from the last meeting of the EFSA Scientific Committee (SC) which was held on 22 to 23 September 2021. Please refer to the published minutes.

The Chairs of respective Working Groups (WG) reported back to the Panel:

- **WG on Claims** – No on-going applications are under assessment. One claim application is under validation. The WG is mainly working on draft opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods (see item 9.1).
- **WG on Sugars -** Please refer to the supporting presentation published here (slides 68-69).
- **WG on Upper Levels** – The WG Chair informed the Panel about the progress of the work regarding the two on-going mandates: a) the update of the guidelines of the Scientific Committee on Food for the development of Tolerable Upper Intake Levels (ULs) for vitamins and minerals (EFSA-Q-2021-00364) and the re-evaluation of ULs for iron (EFSA-Q-2021-00370; deadline: March 2023), manganese (EFSA-Q-2021-00371; deadline: March 2023), folic acid/folate (EFSA-Q-2021-00366; deadline: March 2023), vitamin A (EFSA-Q-2021-00365; deadline: March 2023), vitamin B6 (EFSA-Q-2021-00369; deadline: March 2023), vitamin D (EFSA-Q-2021-00367; deadline: March 2023), vitamin E (EFSA-Q-2021-00368; deadline: March 2023) and β-carotene (EFSA-Q-2021-00372; deadline: March 2023); and b) the re-evaluation of ULs for selenium (EFSA-Q-2020-00618; extension of deadline).
  A workshop was organised by EFSA on 28-29 September to collect views of experts and generate possible orientations that will be considered in revising the guidance on ULs. The WG Chair presented the key outcomes of the workshop discussions. An Event report will be published on EFSA's website in November[3]. A revised draft Guidance document will be submitted to the NDA Panel[4] for discussion and possible endorsement for publication and for piloting. Based on practical experience gained from the re-evaluation of ULs for the afore-mentioned nutrients, the Guidance document will be further refined and released for public consultation in 2023 before finalisation.
  The on-going evaluation of the UL for selenium is delayed[5] due to the additional workload brought by the broader mandate, which had to be initiated in parallel. A re-prioritization of NUTRI Unit's work was needed to be able to start the work on the broad mandate. The NDA Panel agreed with the proposed approach and took note of these timelines. Please refer to the supporting presentation published here (slides 70-80).
- **WG on Dietary Folate Equivalent** - Please refer to the supporting presentation published here (slides 81-82).

[3] https://www.efsa.europa.eu/en/publications

[4] NDA Panel Plenary meeting to be held on 24 November 2021.

[5] 6-months postponement of the deadline of the selenium UL mandate from March to September 2022.

- **WG on Novel Foods** - Please refer to the supporting presentation published here (slides 83-85).
- **WG on Protein Hydrolysates –** Several applications related to the safety and suitability of formula based on protein hydrolysates are under stop-the-clock procedure for requesting additional information and clarification to the applicants. One application is under validation.
- **WG on Food allergy –** No on-going mandates.
- **WG on Traditional Foods from Third countries (TF)** - EFSA staff informed the Panel about the new notification on TF that has been made available to EFSA through the European Commission e-submission portal: Notification on Xuta (edible variety of *Jatropha curcas* L.) roasted and ground seed kernels (NF 2020/2037) (EFSA-Q-2021-00584).

13. Questions from and answers to Observers (in application of the guidelines for Observers)

Observers were given the possibility to ask questions. Please refer to Annex **II**.

14. Any other business

The next meeting will be held on 24 November 2021 as a web conference.

The Chair closed the session by thanking all the participants to the Open Session.

Annex I

List of Observers

 # Registered but did not attend

Observer	Name of Employer	Country
ADOMKIENE Rasa#	Lithuanian University of Health Sciences	LT
ALQUATI Eleonora	Association of Chocolate, Biscuits and Confectionery (CAOBISCO)	BE
ARICAN ÖZNUR Fulya	Ministry of Agriculture and Forestry - General Directorate of Food and Control	TU
AUMEISTERE Līva	Public Health Analyst, The Centre for Disease Prevention and Control of Latvia	LT
AYDIN Merve#	Foro Italico	IT
AZNAR Aude	Synadiet	FR
BABJAKOVA Jana#	Comenius University in Bratislava, Faculty of Medicine	SK
BISONNI Michela	European Plant-Based Foods Association (ENSA)	BE
BOISSET Gaelle	Student	NL
BULOTAITE Gabija	Center for Health Education and Diseases Prevention	LT
CAROCHO Marcio#	Polytechnic Institute of Bragança	PT
CAVALLI Emanuela	Soremartec	IT
CHOLERIDIS Themistoklis	Aristotle University of Thessaloniki	GR
CHOURDAKIS Michail#	European Association of Sugar Manufacturers (CEFS)	BE
COGALNICEANU Elena#	EAS Strategies	BE
COPPENS Patrick	Food Supplements Europe	BE
COSTARELLI Vassiliki#	Harokopio University of Athens	GR
CUADRADO Carmen	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria. Centro Nacional del CSIC (Ministerio de Ciencia e Innovación)	ES
DENNY Anna#	World Sugar Research Organisation (WSRO)	UK

Observer	Name of Employer	Country
DRICHOUTIS Andreas	Agricultural University of Athens	GR
GARTLON Joanne	Pen + Tec Consulting	ES
GEISER Stefanie	EAS Strategies	BE
GILIARD Alice#	Federal Food Safety and Veterinary Office	CH
GORANOVA Zhivka#	Institute of Food Preservation and Quality Plovdiv	BU
HAJJAR Kalila	FEDIOL	BE
HERNANDEZ Igor	Universidad del Pais Vasco	ES
KOVACEK Ivančica#	Teaching Institute of Public Health "Dr Andrija Štampar"	HR
KRPAN Marina#	Professor	HR
LAMONACA Sara	FoodDrinkEurope	BE
LAMPRINOU Christina-Polina#	Self-employee	GR
LEWIS Sara	European Food Law	BE
MALEKI Mastaneh	Student	FR
MARIOLI NOBILECarla Georgina#	Self-employee – Independent research	AR
MILLER Ros	World Sugar Research Organisation (WSRO)	UK
OLAFSSON Grimur#	Icelandic Food and Veterinary Authority	IS
OTTO Marcus	Verein der Zuckerindustrie e.V	DE
PHIPPS Kirt	Intertek	UK
PRINZ Philip	Wirtschaftliche Vereinigung Zucker e.V.	DE
PRPA Emily	World Sugar Research Organisation (WSRO)	UK
SALASEVICIENE Alvija	Kaunas University of Technology	LT
SCHRIRO María#	National Administration of Drugs, Foods and Medical Devices (ANMAT)	AR
SKAPERDA Zoi#	University of Thessaly	GR
SOVIERO Giovanna#	Self-employee – food technologist	IT
TANSKA Izabela	IGI Food Consulting	PL

Observer	Name of Employer	Country
TEKOS Fotios#	University of Thessaly (UTH)	GR
TSI Daniel#	Suntory Beverage & Food Asia	SG
VERHEESEN Janine	Knowledge center sugar & nutrition	NL
VO VAN REGNAULT Gwenn	Agency for Food, Environmental and Occupational Health & Safety (ANSES)	FR
WISNIEWICZ Iga	Merieux Nutrisciences	PL
ZAMPELAS Antonis	Hellenic Food Authority	GR

Annex II

Answers to questions from observers

A dedicated session was organised to provide observers with answers to the questions submitted prior to the Plenary meeting, or that had arisen during the course of the Plenary meeting.

Q. How can the healthy properties of oils, particularly olive oil, be reflected in nutrient profiling systems? For example, in the Nutri-Score no oil gets more than a C. Is there any scientific evidence that traditional products with PDOs (Protected designation of origin) are healthier than a processed industrial product with a similar nutrient profile when it comes to salt and fat content? (LEWIS Sara – European Food Law)

A. The EU geographical indications system protects the names of products that originate from specific regions and have specific qualities or enjoy a reputation linked to the production territory. They do not reflect any health properties. The decision on a nutrient profiling model will be taken by Risk Managers at a later stage once EFSA's opinion is finalised.

Q. How will nutrient profiling (for the purpose of front-of-pack nutrition labelling and for restricting nutrition and health claims on foods), sugars reformulation targets due to be set under Farm2Fork, and the EFSA "as low as possible" opinion on sugars all fit together? (PRPA Emily - World Sugar Research Organisation (WSRO))

A. The decision on a nutrient profiling model will be taken by Risk Managers at a later stage once EFSA's opinion is finalised.

Q. Regarding Eurycoma longifolia (Tongkat Ali) root extract as a novel food (EFSA-Q-2018-00106, NF 2018/0169), does EFSA Scientific Committee look into EXCESS Dose consumed by heavy users (eg. 3x or 4x daily dose), in addition to intended daily dose, when comparing to toxicity data, when evaluating the safety-risk? (TSI Daniel - Suntory Beverage & Food Asia)

A. In case of Eurycoma longifolia (Tongkat Ali) root extract, a short answer to this is no. This is because the applicant proposes to market this NF only as a food supplement and for adults only, excluding pregnant and lactating women. When the intention is to market the novel food only as or in food supplements, the Panel is assessing the risk under those proposed conditions of use. Thus, the Panel will not consider the possible excess use beyond the proposed use. If this NF would have been added to different foods, we would have assessed intake in "high consumers", which are usually defined as consumers on a 95th percentile of intake. So, for this NF the Panel will not consider non-targeted groups of the population (e.g. infants, children, pregnant and lactating women, etc.) since the NF is intended as food supplement for adults.
Please note that in case of food supplements, the applicant has a possibility to label the intended uses and use levels of its' novel food and thus, risk managers consider that the labelling will guarantee a proper consumption of the NF as food supplement. Please take a look at the Union list of authorised novel foods, there is a column called "Additional specific labelling requirements", and where different phrases can be found, such as "Food supplements containing the NF should not be consumed by infants, children under 10 year of age etc", or that "Consumers should not consume more than X mg of the NF per day".

Q. Is the panel developing guidance for the safety assessment of cell-based meat? (GARTLON Joanne - Pen + Tec Consulting)

A. No application related to cell-based meat has been received by EFSA. EFSA Guidance on the preparation and submission of an application for authorisation of a novel food will apply. The scientific guidance may be updated, based on practical experience gained from the safety assessment in the context of NF applications.

Q. Is it possible to introduce a consultation procedure with EFSA (Preliminary Assessment of Scientific Substantiation) for health claim applications before submitting the application? (TANSKA Izabela - IGI Food Consulting)

A. In accordance with Article 32a(1) of the GFL Regulation, as of March 2021, applicants may request general presubmission advice (GPSA) from EFSA at any time before submitting the envisaged application. EFSA will provide advice on the rules applicable to, and the content required for, an application. Outside of the scope of the GPSA are: design of the studies to be submitted and questions related to hypotheses to be tested. See Annex A of General scientific guidance for stakeholders on health claim applications (Revision 1) (update 2021), and EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (update 2021).

Q. There is a very recent publication in France on Cholecalciferol (vitamin D3) as food supplement, as a potential endocrine disruptor. This might raise questions on the safety of the use of vitamin D3, and on projects related to milks for infants, supplemented milks and food supplements. Regarding the previous conclusions of the Panel on the importance of adequate intake of vitamin D, we were wondering if the Panel was aware of these considerations of endocrine disruptor when working on the present draft opinion. (AZNAR Aude – Synadiet)

A. Thank you for the information. EFSA is not aware of this publication. If such publication might raise safety concerns, risk managers will take the necessary steps. (NB: see also item 12, the NDA Panel will revise ULs for vitamin D).

Q. Relating to the work on the setting of upper levels for vitamins and minerals, I was wondering if at any moment during the process of the development of the guidelines or the individual assessments of nutrients, there will be a possibility for a public consultation (COPPENS Patrick - Food Supplements Europe)

A. After a piloting phase, the guidance document will be updated based on the experience gained with the assessment of the upper levels. Then, before its finalisation, the guidance will be subject to public consultation. For ULs for iron, manganese, folic acid/folate, vitamin A, vitamin B6, vitamin D, vitamin E and β-carotene, the draft opinions of the NDA Panel will also be subject for public consultation before finalisation.

Q. Further to the discussion today on the mandate on front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods, I was wondering why polyunsaturated fats were addressed in connection with saturated fats, and not on their owns like DHA and EPA (HAJJAR Kalila - FEDIOL)

A. The effect of polyunsaturated fatty acids (PUFAs) on blood-LDL cholesterol concentrations and cardiovascular disease risk is observed when they replace saturated fatty acids (SFAs) in mixed diets. The effects of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) on cardiovascular disease risk are not dependent on a replacement of SFAs and are mostly exerted through other mechanisms. Therefore, EPA and DHA are addressed separately from SFAs in the opinion.