SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

133rd PLENARY MEETING

28 – 30 March 2023
09:00-18:00 / 09:00-18:00 / 09:00-12:00
MINUTES - Agreed on 12 April 2023

Location: Webconference

Attendees:

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

- **Hearing Experts**[1]:
Anne Molloy, Marta Crous Bou: participated for agenda item 8.1, via web conference.

Susan Lanham New, Giovanni Passeri: participated for agenda item 10, via web conference.

- **European Commission**:
Ivona Babic, Takis Deskaleros, Stella D'Amore, Stephanie Bodenbach, Carolin Bendadani

- **EFSA**:
Nutrition & Food Innovation (NIF) Unit: Reinhard Ackerl, Ionut Craciun, Agnès de Sesmaisons, Lucia Fabiani, Thibault Fiolet, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Nena Karavasiloglou, Leonard Matijević, Ruth Roldán Torres, Angeliki Sofroniou, Ariane Titz, Silvia Valtueña, and Ermolaos Ververis.

MESE Unit: José Ángel Ruiz Gómez for agenda items 13, 14, 15.

- **Others**:
Katerina Gerazova participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTRI/2019/1) for agenda item 5.

- **Observers**:
See Annex 1

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

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

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 132nd Plenary meeting held on 27-28 February 2023 via web-conference

The minutes of the 132nd Plenary meeting were agreed by written procedure on 13 March 2023.

5. Draft scientific opinion on the safety of yellow/orange tomato extract as a novel food pursuant to Regulation (EU) 2015/2283 - Applicant: Lycored Ltd (EFSA-Q-2021-00201)

The draft opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, history of use, proposed uses and use levels, nutritional information, toxicological information and allergenicity of the novel food. The opinion was adopted by the Panel on 28 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.

6. Draft scientific opinion on the safety of paramylon as a novel food pursuant to Regulation (EU) 2015/2283 - Applicant: Kemin Foods L.C. (EFSA-Q-2019-00593)

The draft scientific opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, history of use, proposed uses and use levels, nutritional information, toxicological information and allergenicity of the novel food. The scientific opinion was adopted by the Panel on 28 March, subject to the incorporation of editorial changes. The full text of the scientific opinion will be available in the coming weeks in the EFSA Journal.

7. Draft scientific opinion on the safety of UV-treated powder of whole yellow mealworm (*Tenebrio molitor* larvae) as a novel food pursuant to Regulation (EU) 2015/2283 - Applicant: Nutri'Earth (EFSA-Q-2019-00748)

The draft opinion was presented. The Panel reviewed and discussed the sections related to product characterization, production process, specifications, history of use, proposed uses and use levels, nutritional information, ADME, toxicological information and allergenicity of the novel food. The opinion was adopted by the Panel on 28 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.

8. Other scientific topics for information and/or discussion

8.1 Draft scientific opinion on the revision of the Tolerable Upper Intake Level for folic acid/folate

The available body of evidence regarding the relationship between folate/folic acid intake and risk of colorectal cancer was presented through a PowerPoint presentation and discussed.

See also Agenda item 12.

8.2. Draft scientific opinion on the revision of the Tolerable Upper Intake Level for vitamin D

See Agenda item 10.

9. Welcome, introduction of the Agenda for the open session and Presentation of Guidelines for observers

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

The Chair presented the Agenda items covered during the Open plenary.

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

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

10. Draft scientific opinion on the revision of the Tolerable Upper Intake Level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate (EFSA-Q-2021-00364, EFSA-Q-2022-00215)

The draft opinion was presented through a PowerPoint presentation. The Panel reviewed and discussed the sections related to the conversion factor for calcidiol monohydrate into vitamin D3, the hazard identification and priority adverse health effects, the hazard characterisation, the selection of the critical effect and derivation of the UL, the intake assessment, the risk characterisation, conclusions, and recommendations for research. The opinion was endorsed for public consultation by the Panel on 29 March, subject to the incorporation of editorial changes.

11. Draft scientific opinion on the revision of the Tolerable Upper Intake Level for vitamin B6 (EFSA-Q-2021-00369)

The comments received from the public consultation of the draft scientific opinion on the revision of the UL for vitamin B6 were presented through a PowerPoint presentation and discussed, together with the proposed responses. The revised draft opinion, taking into consideration relevant comments received, was adopted by the NDA Panel on 29 March 2023, subject to the incorporation of editorial changes. The full text of the opinion will be available in the coming weeks in the EFSA Journal.

12. Draft scientific opinion on the revision of the Tolerable Upper Intake Level for folic acid/folate (EFSA-Q-2021-00366)

Some sections of the draft opinion were presented through a PowerPoint presentation, i.e. sections related to chemistry, ADME, hazard identification, and intake assessment. Feedback received from the Panel will be considered by the WG ULs. The draft opinion will be presented

to the NDA Panel for discussion/possible endorsement for release for public consultation at its plenary meeting on 27 April 2023.

13. Draft protocol for the evaluation of the safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)

The draft protocol on the evaluation of the safety in use of plant preparations containing berberine was presented through a PowerPoint presentation. The Panel reviewed and discussed the sections related to the interpretation of terms of reference, problem formulation, the target population, the definition of the exposure of interest, the relevant adverse health endpoints to be considered in the opinion, the assessment sub-questions and methods for addressing them. A revised draft protocol, incorporating the amendments suggested by the Panel, will be considered by the Working Group. A draft protocol will be submitted to the NDA Panel for discussion/possible endorsement for release for public consultation at its plenary meeting on 27 April 2023.

14. Draft protocol for the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid (EFSA-Q-2022-00805)

The draft protocol on the evaluation of the safety in use of plant preparations containing hydroxycitric acid (HCA) and of isolated HCA was presented through a PowerPoint presentation. The Panel reviewed and discussed the sections related to the interpretation of terms of reference, problem formulation, the target population, the definition of the exposure of interest, the relevant adverse health endpoints to be considered in the opinion, the assessment sub-questions and methods for addressing them. A revised draft protocol, incorporating the amendments suggested by the Panel, will be considered by the Working Group. A draft protocol will be submitted to the NDA Panel for discussion/possible endorsement for release for public consultation at its plenary meeting on 27 April 2023.

15. Draft protocol for the evaluation of the safety of use of preparations from the fruits of sweet and bitter fennel (EFSA-Q-2022-00804)

The draft protocol on the evaluation of safety of preparations from sweet and bitter fennel fruits was presented through a PowerPoint presentation. The Panel reviewed and discussed the sections related to the interpretation of terms of reference and the absorption, distribution, metabolism and excretion (ADME) of estragole, a genotoxic carcinogen present in fennel fruit preparations. The Panel also discussed the plans for hazard characterisation, exposure assessment and risk characterisation. A revised draft protocol, incorporating the amendments suggested by the Panel, will be considered by the Working Group. A draft protocol will be submitted to the NDA Panel for discussion/possible endorsement for release for public consultation at its plenary meeting on 27 April 2023.

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

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

- **WG on Claims** – One Article 14 claim application on 'choline' and 'contribution to normal fetal and infant brain development and function' (EFSA-Q-2021-00543) is currently under evaluation.
- **WG on Novel Foods** – The Panel was informed on the ongoing workload of the WG and number of NF applications received. 91 NF applications are currently under risk assessment and five adopted opinions are currently under publication.
- **WG on Upper Levels** – See Agenda items 10, 11 and 12.
- **WG on Protein Hydrolysates –** One application (EFSA-Q-2020-000325) related to the safety and suitability of formula based on protein hydrolysates was discussed in the last meeting of the WG and it was decided to request further clarifications. Another application is under stop-the-clock procedure for requesting additional information and clarification to the applicant. One application is under validation.
- **WG on Food Allergy –** The re-evaluation of behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers pursuant to Article 21(2) of Regulation (EU) No 1169/2011 for permanent exemption from labelling is ongoing (EFSA-Q-2022-00042).
- **WG on Traditional Foods from Third countries** – No ongoing notification.

Related to the Scientific Committee (SC), the Panel was informed about the ongoing activities of **the SC WG on Fluoride** and that the work of the SC WG on Epidemiological studies will restart to finalise the guidance on the risk assessment of epidemiological studies. During its plenary meeting on 15-16 February, the draft Guidance on protocol development was endorsed by the SC for released for public consultation.

The Panel took note of the two on-line NDA Thematic Workshops. The first workshop on "Setting principles for human-to-human scaling approaches for the derivation of tolerable upper intake levels (UL)" held on 28 Feb-1 March 2023 was organised in the context of the Panel on-going review of the ULs for selected vitamins and minerals. It aims to define criteria for the selection of the appropriate scaling method to adjust UL for a particular population group (e.g. adults) to other groups (e.g. infants, children). A workshop report is being prepared and will be published this spring.

The second workshop on "Derivation of conversion factors for new sources & forms of nutrients", held on 9 March 2023, aimed to share and exchange views regarding the scientific principles and data requirements for deriving conversion factors for proposed new sources or forms of nutrients. The workshop was organised to address the Commission's request to EFSA to update its Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources regarding the scientific principles and data requirements for applicants to derive a conversion factor for proposed new sources or forms of nutrients. Preceding the workshop, EFSA held an open consultation through an Expert Survey on key points to consider for the derivation of conversion factors (held between 15/12/2022-20/01/2023). The scientific input collected from the Expert Survey and workshop will be reported in a workshop report which will inform the update of the guidance. A workshop report is being prepared and will be published this spring.

The Panel also took note of EFSA's Scientific Colloquium 27 "Cell culture-derived foods and food ingredients" 11 May 2023, 09.00 - 12 May 2023.

17. Q&A

Answers to questions from observers

Q1. There are several dossiers at EFSA for a novel food approval from different companies. Could we get the status of Allulose Novel food dossier, mainly: when it would be expected to be registered as a novel food? Is 2024 an expected date or will it depend on missing data? *[Carine Chincholle - CSM Ingredients]*

A1. All NF dossiers for allulose are currently under clock stop following EFSA's request to provide additional data. Depending on when applicants will provide the requested information, EFSA will proceed with the safety assessment. Once the additional information will be received, and provided that the safety can be established, then the EC and MSs will have 7 months from the adoption of the EFSA output to proceed with the authorization decision.

Q2. There was a dossier on natural propionate ferment; EFSA-Q-2022-00462, which apparently has been stopped. Could we have the reasons why this dossier would not be seen as an additive? Did the registration company stop the process? *[Carine Chincholle - CSM Ingredients]*

A2. The application EFSA-Q-2022-00462 relates to a food additive, which is not in the remit of the NDA Panel activities. The classification whether an item falls under the NF or food additive Regulation is made by the EC, who considers the information provided in the dossier including the purpose, use and use levels of the item. EFSA has no role in these considerations and is not involved in that decision. The application was terminated because considered as non-valid by the European Commission, due to non-compliance with the obligations of study notifications as outlined in Article 32b of the General Food Law. Applicant could apply again with a 6 months penalty.

Q3. What is panel opinion about considering novel food/ environmental or extra-food nanoparticles as potential allergens? [*Ramona Suharoschi – Univ. of Agri Scienc and Vet Medicine of Cluj-Napoca]*

A3. EFSA has developed guidance documents for the safety assessment of engineered nanomaterials and for presence of small particles, including nanoparticles. Such documents provide a strategy for the assessment of nano-specific risks. In particular, nanospecific considerations relating to in vitro/in vivo toxicological studies are addressed by following a tiered framework for toxicological testing. Depending on the initial tier results, the need for additional studies is considered on a case-by-case basis and this includes the need of investigating immunotoxicity and allergenicity. These adverse effects are dealt with in section 7.8.3 of the nano guidance.

Q4. What methods are commonly used for novel food identification purposes? Are there molecular biology-based approaches used perhaps for the plant identification of specific species/varieties? *[Ivana Nikodinoska – Alltech]*

A4. The most suitable identification method for a novel food will strictly depend on the kind of novel food under assessment. The food categories foreseen by the NF regulation are quite heterogeneous. Molecular biology-based methods that are validated are certainly one important tool for the characterisation of the identity of microorganism or plants. In the case of chemical products, in general mass spectrometry or nuclear magnetic resonance analyses may be appropriate, while for engineered nanomaterials and nanoparticles the established method is electron microscopy.

Q5. Which ways and strategies should we take regarding nutrient profiles? *[Aref Sepehr-Padova University]*

A5. This question is outside EFSA's remit. These are considerations for risk managers.

Q6. If you don't see an effect, will epidemiological studies be respected in the risk assessment of fennel? Are "infusion" factors respected within the risk assessment? I was wondering for a long time where data on fennel have been. [*Anne-Marie Orth, RDA Scientific Consultants GmbH*]

A6. Epidemiological studies are always a useful source of evidence. As estragole, which is present in fennel fruit preparations, is an established genotoxic carcinogen, the WG will look for evidence on whether there is a threshold below which the metabolic pathway leading to the toxic metabolite is not activated or whether an effect of the matrix could be expected. These questions cannot be answered by epidemiological studies. There are publications available on estragole content in fennel fruit preparations as prepared following the instructions of the manufacturers. These will be taken into account in the exposure assessment. We hope that we find additional data on it during the systematic review of the evidence.

Q7. Thanks to EFSA for allowing us to follow the discussion. I wanted to say that it is regretful we only have one chance a year to follow the discussions. These are generic mandates, so I don't think there is any confidentiality issue. If April plenary of NDA Panel could be opened to Observers? [*Patrick Coppens, Food Supplements Europe*]

A7: The NDA Panel plenary in April is not open to Observers. Observers and Stakeholders have the opportunity to provide their input during the public consultation phase for the ULs draft opinions and for draft protocols related to Article 8(2) mandates. Particularly, related to Art 8(2) assessments, Observers and Stakeholders have many possibilities to contribute at various stages of the process, on the draft protocols during public consultation and also EFSA Calls for data.

For generic mandates, EFSA draft opinions are subject to public consultation before finalisation.

Q8. I would like to pose two questions. I don't understand why the approach for the three substances of article 8 is so different. My question is related also to the mandate of article 8, because article 8 is related to substances intentionally added to food. I think the approach is faulty and I would like to know if it is possible to change the approach. [*Marinella Trovato, SISTE Associazione Scientifica*]

A8. The approach to the assessment of the safety of fennel fruit preparations is different, because fennel fruit preparations contain estragole which is an established genotoxic carcinogen, while in the other two cases it still needs to be established whether there is a link between the consumption of the plant preparations and harmful effects to health. Possible matrix effects should also be picked up during the assessment, in case there is evidence for that. The mandates that we receive originate from the Commission and any questions related to them should be addressed to the Commission.

18. Any Other Business

The next Plenary meeting of the NDA Panel will be held on 27 April 2023 via web-conference.

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Annex 1: LIST OF PARTICIPANT OBSERVERS

Adebayo	Folasade Abiola	Ms	University of Helsinki
Arıcan Öznur	Fulya	Ms	Ministry of Agriculture and Forestry - General Directorate of Food and Control
Arone	Francesco	Mr	Francesco Arone
AZNAR	Aude	Ms	SYNADIET
BALDI	Alessandra	Ms	NuTRE - Nutraceutical Tailored Research Ecosystem
Ballabio	Cinzia	Ms	ASSOERBE
BELARD	Virginie	Ms	Nestlé Health Science
Benzi Schmid	Clara	Ms	Federal Food Safety and Veterinary Office (FSVO)
Bernāte	Ilze	Ms	Ministry of Agriculture Republic of Latvia
Borawska	Maria	Ms	KRSiO, Medical University of Bialystok
BORAWSKA	MARIA	Ms	Krajowa Rada Suplementów i Odżywek, Committee of Human Nutrition Science POLISH ACADEMY OF SCIENCES
Bravo Lobo	David	Mr	AESAN
Campos	Silvia	Ms	Reckitt
CARLOS-CHILLERON	MARIA ANGELES	Ms	SPANISH AGENCY FOR FOOD SAFETY AND NUTRITION (AESAN)
Caruso	Eulalia	Ms	student at University of Macerata and I am applying on my own initiative, not related to University
Caruso	Eulalia	Ms	student at University of Macerata and I am applying on my own initiative, not related to University
CASSAR	Mark	Mr	Malta Competition and Consumer Affairs Authority (MCCAA), Technical Regulations Division (TRD)
Chappuis	Eric	Mr	Cargill
CHATZIGEORGIOU	ARTEMI	Ms	DELTA FOODS SINGLE MEMBER SA
CHINCHOLLE	Carine	Ms	CSM INGREDIENTS
CLIMOVA	Natalia	Ms	South Bohemian University
Coppens	Patrick	Mr	FOOD SUPPLEMENTS EUROPE
Czapiewska	Anna	Ms	Krajowa Rada Suplementów i Odżywek
De Matteu	Constanza	Ms	Technical University of Denmark - National Food Institute
DE NICOLA	Gina Rosalinda	Ms	CREA Council for Agricultural Research and Economics
Demeter	Eszter	Ms	INSP_CRSP MURES
DOPTER	Aymeric	Mr	Anses
Eggersdorfer	Manfred	Mr	University Medical Center Groningen
ELbassuny	Malak	Ms	National Food Safety Authority of Egypt
Erraught	Claire	Ms	Food Safety Authority of Ireland
Flores	Rosalía	Ms	Atova Regulatory Consulting SL
Geiser	Stefanie	Ms	EAS Strategies
Golreihan	Asefeh	Ms	LKC Ltd.
GUILLOCHEAU	Etienne	Mr	Foodinnov
GUTERMAN	Julie	Ms	BLOOM
Jallow	Cherno Assan	Mr	Parma
Jørgensen	Lene	Ms	Danish Veterinary and Food Administration
Kiuru	Sanna	Ms	Finnish Food Authority
Kivima	Evelin	Ms	Ministry of Rural Affairs
Koenig	Simone	Ms	Bayer Consumer Care
Kristersson	Mia	Ms	The Swedish Food Agency

Lamberg-Allardt	Christel	Ms	University of Helsinki
Lemström	Anna	Ms	Ministry of Agriculture and Forestry
Lin	Jennifer	Ms	Reckitt
LLEDÓ MORELL	CLARA MARIA	Ms	PURATOS NV
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Małas	Sandra	Ms	Instytut Ochrony Roślin- Państwowy Instytut Badawczy
Matczuk	Ewa	Ms	National Institute of Public Health
Matic	Viktorija	Ms	Chemsafe srl
Mazzucato	Sofia	Ms	University of Padua
MENICHETTI	Livia	Ms	European Federation of Associations of Health Product Manufacturers (EHPM)
Mensik	Petr	Mr	EU Specialty Food Ingredients
Michałowska	Alicja	Ms	Centrum Prawa Żywnościowego i Produktowego A.Szymecka-Wesołowska, D.Szostek sp.k.
Mignot	Catherine	Ms	DSM
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Montez	Jason	Mr	World Health Organization
mueller	severin	Mr	Givaudan
Muresan	Daniela	Ms	National Institute of Public Health
Nadaud	Perrine	Ms	FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH & SAFETY
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okeeffe	lara	Ms	P&G
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Orsatti	Gustavo	Mr	P&G Health
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Pastorelli	Augusto Alberto	Mr	Istituto Superiore di Sanità
Pettersson	Sanna Wallje		The Swedish Food Agency
PIERREL	Nathalie	Ms	GIVAUDAN
PLATON	Sorin	Mr	DSVSA CLUJ
POLLAK	LEA	Ms	LEA POLLAK
RAICEA	CAMELIA	Ms	NATIONAL INSTITUTE OF PUBLIC HEALTH
Rainoni	Mauro	Mr	Mauro Rainoni
Richards	Jim	Mr	DSM
Ruzgyte Frère	Asta	Ms	DSM Nutritional Products Ltd.
SALGADO	Ana	Ms	DGAV - Directorate General for Food and Veterinary
Sepehr	Aref	Mr	Padova University
Smutkiewicz	Andrzej	Mr	OLEOFARM Sp. z o.o.
Soczewinska	Joanna	Ms	Bayer Sp. z o.o.
Spacone	Pina	Ms	Nutrizionista
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Stoś	Katarzyna	Ms	NIPH NHI - NRI
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Tańska	Izabela	Ms	IGI FOOD LAW

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van Well van Haare	Nolanda	Ms	NHSc
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Vuorinen	Anna	Ms	DSM Nutritional Products Ltd
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Wasiolek	Virginie	Ms	Microphyt
Wennemar	Kristina	Ms	Federal Ministry of Food and Agriculture
Woźniak	Agnieszka	Ms	National Institute of Public Health NIH - National Research Institute