SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

150th Plenary meeting

26th- 28th June 2024
09:00-18:00 / 09:00-18:00 / 09:00 – 13:00
MINUTES - Agreed on 10 July 2024

Location: EFSA, Parma and Teleconference

Attendees:

- Panel Members:
  Torsten Bohn, Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen[1], Alexandre Maciuk, Inge Mangelsdorf[2], Harry J. McArdle, Androniki Naska[3], Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri[4], Dominique Turck (Chair) and Marco Vinceti.
- Hearing Experts[5]:
  Not Applicable
- European Commission:
  EC: Ivona Babic, Stella D'Amore, and Rafael Luis Perez Berbejal
- EFSA:
  Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Domenico Azzollini, Agnès de Sesmaisons, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Nena Karavasiloglou, George Kass, Leonard Matijević, Annamaria Rossi, Ruth Roldán Torres, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.
- Observers:
  See Annex 1 list of registered observers who participated to the open plenary meeting

1. Welcome and apologies for absence

The Chair welcomed the participants.
No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence[6] and the Decision of the Executive Director on Competing Interest Management[7], 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.

[1] Online participation on 26 and 27 June (am).
[2] Online participation
[3] Online participation
[4] Online participation
[5] 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
[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[7] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4. Agreement on the minutes of the 149th NDA Plenary meeting held on 7th June 2024 by teleconference

The minutes of the 149th Plenary meeting were agreed by written procedure on 18th June 2024.

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

5.1 Draft Opinion on glucosyl-hesperidin as a Novel food pursuant to Regulation (EU) 2015/2283. Applicant: Nagase Viita Co., Ltd (EFSA-Q-2021-00329)

The Panel discussed the draft scientific opinion, and in particular the discussion section. The scientific opinion was adopted by the Panel on 26 June, 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.

5.2 Draft Opinion on Acheta domesticus powder as a Novel food pursuant to Regulation (EU) 2015/2283. Applicant: Società Agricola Italian Cricket Farm S.r.l.(EFSA-Q-2021-00262)

The Panel discussed the draft scientific opinion, and in particular assessed data regarding identity, product characterization, production process, specifications, proposed uses and use levels, anticipated daily intake, toxicology, nutritional information, allergenicity and discussion. The scientific opinion was adopted by the Panel on 26 June, 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.

5.3 Scientific and technical assistance report on the evaluation of Lemna gibba and Lemna minor whole plant material as a novel food (EFSA-Q-2024-00297)

The Panel discussed the draft scientific and technical assistance report on the evaluation of the safety of *Lemna gibba* and *Lemna minor* whole plant material as a novel food. In particular the Panel reviewed the additional information provided in the context of this mandate. The draft technical report was revised and endorsed by the Panel on 26 June. The technical report will be submitted to EFSA for approval, and it will be published on the EFSA website.

6. Other scientific topics for information/discussion

Please refer to section 9.

7. OPEN SESSION - Welcome to 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.

8. Presentation of EFSA 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/possible adoption/endorsement for public consultation (cont.)

9.1 Draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA-Q-2023-00442)

A summary of the comments submitted by stakeholders during the public consultation was presented, together with the proposed changes introduced in the draft guidance document triggered by comments received. The draft guidance was adopted by the Panel on 27 June subject to the incorporation of editorial changes, as well as Annex A, where all the comments received are addressed.

9.2 Draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (EFSA-Q-2023-00444)

A summary of the comments submitted by stakeholders during the public consultation was presented, together with the proposed changes introduced in the draft guidance document triggered by comments received. The draft guidance was adopted by the Panel on 27 June subject to the incorporation of editorial changes, as well as Annex A, where all the comments received are addressed.

9.3 Draft guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources (EFSA-Q-2022-00856)

A summary of the comments submitted by stakeholders during the public consultation was presented, together with the proposed changes introduced in the draft guidance document triggered by comments received. The draft guidance was adopted by the Panel on 27 June subject

to the incorporation of editorial changes, as well as Annex A, where all the comments received are addressed.

9.4 Draft guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals (EFSA-Q-2021-00364)

A draft of the guidance was published in 2022 and piloted for 2 years. A revised version of the document, enriched based on the experience gained, was presented. In particular the sections on hazard identification and characterisation, intake assessment and risk characterisation were discussed. The Panel endorsed the draft guidance for public consultation on 27 June.

The public consultation is open from 8 July to 25 August. Interested parties are invited to submit their comments by the indicated deadline via this LINK.

9.5 Draft scientific opinion on the revision of the Tolerable Upper Intake Level (UL) for Vitamin E (EFSA-Q-2021-00368)

The Panel discussed the draft scientific opinion and specifically the comments received during the public consultation. The draft opinion and Annex F, where the comments received during the public consultation are addressed, were adopted by the Panel on 27 June. The full text of the scientific opinion will be available in August in the EFSA Journal.

10. Other scientific topics for information/discussion

Postponed.

11. Feedback from the Scientific Committee/ Scientific Panels/EFSA/EC

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

- WG on Claims – One Article 13(5) health claim related to 'Daily creatine consumption can improve cognitive function' is under evaluation (EFSA-Q-2024-00106).
- WG on Novel Foods - The Panel was informed on the ongoing workload of the WG. See also Agenda items 5.1, 5.2 and 6.
- WG on Upper Levels – See Agenda items 9.4 and 9.5.
- WG on Protein Hydrolysates – Two applications related to the safety and suitability of a protein hydrolysate to be used in infant formula are under stop-clock for additional information/data request to the applicants (EFSA-Q-2021-00339, EFSA-Q-2019-00305).
- WG on Substances other than vitamin and minerals – The chair of the WG informed the Panel that the systematic reviews to collect studies are still ongoing.
- WG on Food Allergy - No ongoing activity.
- WG on Traditional Foods from Third countries – See Agenda item 9.2.

Related to the Scientific Committee (SC), the Panel Chair reported back from the Additional Plenary meeting of the SC of 25 June 2024. The SC endorsed for public consultation the following: the draft opinion on Bromide, and the Scoping paper on "the revision of the opinion on the Margin of Exposure for chemicals which are both genotoxic and carcinogenic". The public consultation will be launched in July for a period of 8 weeks.

12. Q&A Session

Question 1

"Regarding digestibility studies, could EFSA provide more clarity and provide some examples of suitable in vitro methods? Could you please clarify in which cases the analysis of less than three independently produced batches would be acceptable?"

Reply to Question 1

In relation to protein digestibility studies, the NF updated Guidance provides further clarity on suitability criteria to assess protein quality using in vitro methods. The suitability of the method will be assessed during the risk assessment and consider the minimum requirements included in the chapter 9.4 Specific considerations regarding novel protein sources. Under specific considerations less than three independently produced batches could be accepted, this will be assessed on a case- by -case based on the variability provided in the batch-to-bath analysis of protein content and amino acid composition.

Question 2

"Concerning cultivated meat, is there any specific regulatory measure that EFSA is planning to adopt to facilitate the filling of approval requests for cultivated meat products? How will a regulatory category be selected by EFSA to facilitate the filing of requests in these emerging markets?"

Reply to Question 2

Approval of novel foods, including cell culture-derived foods, in the EU market of the European Union is a risk management task and falls outside EFSA's remit. However, EFSA assists applicants in building their dossiers through several services (e.g., catalogue of services, AskEFSA). There is also an ongoing Call for expressions of interest targeting SMEs - potential novel food applicants interested in receiving EFSA's advice (open until 31 October 2024).

Determining whether a product is novel according to the provisions of Regulation (EU) 2015/2283 is not EFSA's responsibility; it is a risk management task. Interested parties should seek advice regarding these aspects from the competent authority of their respective EU Member State(s). Moreover, with regards to cell culture-derived foods it should be noted that in the EU, depending on the source of such products (e.g., animal source, animal cells, cell treatment), cell culture-derived "meat" can fall under the Novel Food or the GMO regulatory framework.

Question 3

"1) What is needed to confirm the equivalence of two ingredients? 2) How do we determine if we need to apply a novel food procedure or substantially equivalent procedure?"

Reply to Question 3

The requirements to confirm the identity of two ingredients depends on the nature of the product, and in particular whether it is a single substance, a simple mixture or a complex mixture. The ingredients should be comprehensively characterised from a compositional point of view and the uncharacterised fraction of the ingredients should be reduced as much as possible. For example, in the case of Human identical Milk Oligosaccharides (HiMOs) assessed as novel foods where the purity was often very high, equivalence was established based on the comprehensive characterisation of the ingredient, accompanied by NMR analysis of the specific HiMO under assessment compared to its respective natural counterpart.

The current Novel foods Regulation (EU) 2015/2283 has eliminated the procedure for substantial equivalence that was in place under the former Novel foods Regulation (EC) No 258/97.

Question 4

"What is the panels opinion on the inclusion of fresh fruit and vegetables under the front-of-pack/ nutrient profiling systems policy? Should these products be targeted to harmonise the use of FOPL to other public health initiatives, such as increasing fruit and vegetable intake?"

Reply to Question 4

The question is outside EFSA/Panel remit, but under the responsibility of risk managers (European Commission and Member States).

Question 5

« 1) Comment bénéficier de vos expertises pour le monde des inspecteurs phytosanitaires que nous sommes? 2) Es ce qu'il y a des courses en ligne? 3) Y a-t-il des attestations à obtenir des formations auprès de l'EFSA?»

Reply to Question 5

This question is outside the remit of the NDA Panel. We are inquiring about this question and will follow-up via an email to the requestor.

Question 6

"Recent EFSA's scientific opinions have moved away from detailing proposed food uses according to FAIM categories, instead making reference solely to the DietEx categorization system. However, during the submission process using the EC e-tool, the section for 'Proposed entry in the Union List' in the Administrative Data continues to display only the FAIM categories."

Reply to Question 6

The intended food uses and use levels for novel foods outlined in EFSA's Scientific opinions reflect the details provided by applicants in the 'Proposed uses and use levels and anticipated intake of the novel food' section of their application. EFSA has referenced some Scientific opinions that have included estimated daily intakes based on FAIM categories. It is recognized that applicants have recently been opting for DietEx food categories in their submissions due to the more detailed intake estimations which these categories offer. In the EC e-tool, under Administrative Data, the section 'Proposed entry in the Union List' includes the predefined FAIM tool category options and also a free text field that applicants can use if opting for DietEx food categories.

13. Any other business

- The Chair closed the last NDA Plenary in this mandate (2018-2024) expressing his great appreciation to all members of the NDA Panel and the Nutrition Unit for their hard work and high commitment.
- The Chair closed the meeting by thanking the participants and the observers for their contributions.

Annex 1 – List of registered observers who participated to the open plenary meeting

Observer	Organization
Mensik, Petr	EU Specialty Food Ingredients
La Spisa, Fabio	Probiotical S.p.A.
Tops, Annemieke	Friesland Campina
Stamatovic Savovic, Marina	Institute for Public Health Montenegro
Walkiewicz, Alicja	Chief Sanitary Inspectorate
Serrano, Natalia	Mérieux NutriSciences
Thornton, Ellen	Intertek
Kartanos, Ioannis	ARGENTA
Misuri, Ivan	
Gerazova Efremova, Katerina	Food and Veterinary Agency of North Macedonia
Mcnulty, Breige	University College Dublin
Vareltzis, Patroklos	Aristotle University of Thessaloniki
Kpodzro, Olga	Private
Curzio, Bianca	Bianca Curzio Regulatory Consultancy
Proroga, Yolande	IZS Mezzogiorno
Radawska, Anna	MicroHarvest
Songül, Aylin Şule	Aylin Sule Songül-Songül Attorneys at law
Jelescu, Giorgiana	QNorm
Miller, Simon	Abu Dhabi Quality and Conformity Council
Miralles, Beatriz	Agencia Estatal Consejo Superior de Investigaciones Científicas
Hristova, Mariya	Risk assessment center on food chain

Cuellar Soares, Maria	Farmless BV
Belluco, Simone	Istituto zooprofilattico sperimentale delle Venezie
De Pauw, Katrien	Federal Public Service of Health, Belgium
Losberg, Helena	Chr. Hansen
De Bourayne, Valerie	Kemin
Rupnik, Agnieszka	Food Safety Authority of Ireland
Primorac, Josipa	Solmeyea
Amat, Emily	DWF
D'auria, Giovanni	University of Naples Federico II
Schiavo, Nike	Agricoltura Cellulare Italia APS
Arican Öznur, Fulya	Ministry of Agriculture and Forestry
Nitride, Chiara	The university of Naples
Wei Hao, Lee	Food Industry Asia
Salhaoglu, Ozlem	Mondelez
Palolo, Ines	Sticta Biologicals
Sikora, Dominika	Poznan University of Medical Sciences
Leonarduzzi, Daniele	RSSL
Acuna, Miguel	ADM
RESCAN, Claude	Vital Meat
Jos, Angeles	University of Sevilla
Cámara, Montaña	COMPLUTENSE UNIVERSITY OF MADRID
Merino, Ana	Atova Regulatory Consulting SLU

Petersen, Annika	DTU FOOD
Geiser, Stefanie	EAS Strategies
Flores, Rosalía	Atova Regulatory Consulting SL
Beltramo, Belen	Maastricht University
Seymour, Naël	PHARMANAGER DEVELOPMENT
Baldwin, Nigel	Baldwin Advisory Services Ltd
Kalk, Christiaan	Self-employed in my consulting practice named lsbi | life science-based innovations
Aznar, Aude	Synadiet
Rey, Caroline	Cellular Agriculture Europe