SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

157th Panel Plenary meeting – OPEN to observers

6 – 7 May 2025
09:00-18:00 / 09:00-16:00
MINUTES - Agreed on 28 May 2025

Location: EFSA, Parma

Attendees:

- Panel Members:
  Torsten Bohn, Montaña Cámara, Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, Ángeles Jos, Alexandre Maciuk, Inge Mangelsdorf, Breige McNulty, Androniki Naska, Kristina Pentieva[1], Alfonso Siani, Frank Thies, and Dominique Turck (Chair).

- Hearing Experts[2]:
  Fabio Alfieri (for Agenda item 5.2)

- European Commission and/or Member States representatives:
  EC: Panagiota Filippou, Fruzsina Nyemecz[1], Ivona Babic[1], and Rafael Luis Perez Berbejal[1].

- EFSA:
  Nutrition & Food Innovation (NIF) Unit: Ana Afonso, Ionut Craciun, Agnès de Sesmaisons, Lucia Fabiani, Andrea Germini, Thibault Fiolet, Wolfgang Gelbmann, Leng Heng, Georges Kass, Samuele Multari, Estefanía Noriega Fernández, Ruth Roldán Torres, Annamaria Rossi, Ariane Titz, Pietro Pifanelli and Silvia Valtueña Martinez.

  Front Desk and Planning Unit (FDP): Sara De Berardis, Judit Fernandez Fernandez, Federico Morreale, and Lucia Parrino (for Agenda item 13)

  Legal Affairs Services Unit (LA): Federica Bruno, and Nicole Falessi (for Agenda item 13)

- Others: see Annex II for the list of Observers (online participation on 7 May)

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[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. Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

[1] Online participation.
[2] As defined in Article 34 of the document ""Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[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

4. Agreement of the minutes of the 157th Plenary meeting held on 24 March 2025

The minutes of the 157th Panel plenary meeting were agreed by written procedure on 1st April 2025.

5. Scientific output(s) submitted for discussion/adoption

5.1 Draft opinion on phenolic compounds naturally occuring in olive oils and lowering of LDL-cholesterol concentration, systolic blood pressure and reduction of coronary heart disease risk (Art. 14, HC-2024-22631, EFSA-Q-2024-00470). Applicant: QvExtra! Internacional.

The Panel reviewed and discussed the draft opinion, and particularly the sections related to the characterisation of the food/constituent, the studies submitted for the scientific substantiation of the claimed effect, and the proposed mechanisms of action. The opinion was adopted by the Panel on 6 May, 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 the safety of Grain from perennial intermediate wheatgrass (Thinopyrum intermedium) (NF 2019/1468, EFSA-Q-2020-00073). Applicant: Patagonia Provisions, Inc.

The Panel reviewed and discussed the draft opinion, and particularly the sections regarding product characterization, production process, proposed uses and use levels , toxicology and allergenicity. The opinion was adopted by the Panel on 6 May 2025, 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 Draft opinion on Allulose (NF 2018/0191, EFSA-Q-2018-00756). Applicant: PETIVA EUROPE SA

The Panel reviewed and discussed the draft opinion, and particularly the sections regarding product characterization, production process, proposed uses and use levels, and toxicology. The opinion was adopted by the Panel on 6 May 2025, subject to additional editorial comments. The full text of the scientific opinion will be available in the coming weeks in the EFSA Journal.

6. Other scientific topics for information/discussion/endorsement

6.1 Draft opinion on the safety of the extension of use of oleoresin from Haematococcus pluvialis containing astaxanthin (NF 2021/2418, EFSA-Q-2021-00319). Applicant: AstaReal AB.

The Panel reviewed and discussed the draft opinion, and particularly the sections regarding product characterisation, production process, proposed uses and use levels, and anticipated daily intake. It will be further elaborated and submited to the Panel for possible adoption at a future plenary meeting.

6.2 Introduction to the draft opinion on Lacto-N-tetraose Inbiose (NF 2023/15612, EFSA-Q-2023-00671). Applicant: Inbiose N.V.

The draft opinion was introduced to the Panel. The risk assessment follows the same approach as that for previous opinions on human identical milk oligosaccharides (HiMOs). The draft opinion will be finalised at the WG NF meeting in May and then submitted to the Panel for possible adoption by written procedure.

6.3 Readability & length of scientific opinions

Follow-up from last plenary meeting of the Scientific Committee (SC): EFSA has initiated a reflection on the length and readability of its scientific opinions and statements. This is part of a broader, ongoing evaluation of the speed and future direction of EFSA's risk assessments. The reflection is guided by three key aspects that must be balanced when reporting EFSA's work: (1) resource efficiency; (2) transparency and scrutiny; and (3) accessibility.

The fitness for purpose of the length and readability of EFSA's scientific outputs was examined, with a focus on presentation formats, document length, readability, data reusability, and the integration of digital tools.

The NDA Panel Chair presented a list of possible actions. Panel members were invited to provide feedback and propose a selection of actions to be piloted until spring next year. A discussion will take place at the July SC plenary, where all Panel chairs will present the actions selected by their respective panels.

7. OPEN SESSION – Welcome to Observers

The Chair welcomed the participants and the observers (see Annex II).

8. Panel members introduction

The Chair 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.

9. Presentation of EFSA Guidelines for observers

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

10. Other scientific topics for information/discussion/endorsement (cont.)

10.1 Draft opinion on the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl) (EFSA-Q-2022-00804)

An overview of the ongoing assessment of fennel fruit preparations was presented, highlighting the legal framework, the mandate and assessment questions, hazard identification, characterisation, the exposure assessment, and preliminary conclusions. The EFSA Scientific Committee will be consulted before the draft opinion can be endorsed by the Panel for release for public consultation. The Panel will request an extension of the current deadline to finalise the opinion[5].

[5] Please refer to Open EFSA to monitor the status of the mandate.

10.2 Draft opinion on the evaluation of the safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)

An overview of the ongoing assessment of plant preparations containing berberine was presented, highlighting in particular the mandate, the complexity related to the characterisation of plant preparations, the ADME of berberine, the endpoints considered, the outcome of the systematic review, the toxicity and genotoxicity studies identified, and the approach to risk of bias assessment for these studies. The challenges encountered during the assessment were outlined. The Panel will request an extension of the current deadline to finalise the opinion[5].

10.3 Draft opinion on the evaluation of the safety in use of hydroxycitric acid and plant preparations containing hydroxycitric acid (HCA) (EFSA-Q-2022-00805)

An overview of the ongoing assessment of HCA and plant preparations containing HCA was presented, highlighting in particular the scientific background, the mandate and assessment questions, hazard identification, characterisation, the outcome of the systematic review, the genotoxicity assessment and preliminary conclusions on *Hibiscus sabdariffa*. The challenges encountered during the assessment were outlined. The Panel will request an extension of the current deadline to finalise the opinion[5].

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 – See agenda item 5.1 and refer to Open EFSA to monitor the status of ongoing claim applications.
- WG on Novel Foods - The Panel was informed on the ongoing workload of the WG. See also Agenda items 5.2, 5.3, 6.1, and 6.2. Please refer to Open EFSA to monitor the status of ongoing NF applications.
- WG on Substances other than vitamin and minerals – Please see Agenda items 10.1, 10.2, and 10.3.

Related to the Scientific Committee (SC), no plenary meeting took place since last NDA plenary meeting. The next plenary meeting of the SC will take place on 14-15 May 2025.

12. Any other business

Answers to questions from Observers on subjects related to the NDA Panel

The Chair opened the floor for questions from Observers before the end of the morning session:

QUESTION (Orally). *How is the requirement of Regulation (EC) No 1925/2006, that the procedure under Article 8 can only be triggered when a substance is added to foods in amounts greatly exceeding those ingested under normal conditions of consumption, interpreted in the context of assessment of the safety of preparations of sweet and bitter fennel fruits.*

ANSWER. The interpretation of the Regulation falls within the remit of the European Commission. Therefore, this question has to be addressed to the European Commission. EFSA performs the risk assessment based on the terms of reference and the mandate received. However, it should be pointed out that the Regulation 1925/2006 also stipulates that the procedure under Article 8 can also be triggered when the substance would otherwise represent a potential risk of the consumer.

QUESTION (Orally). *It is not clear why in the opinion on the safety of preparations of sweet and bitter fennel no consideration of the different chemotypes of F. vulgare was made. There are large differences in the content of estragole in fennel fruits depending on their geographical origin. Estragole content of fennel fruits originating from the EU is low as compared to other proveniences. For example, fennel fruits grown in from Poland had an estragole content of 2.64%, contrary to fennel fruits of Egyptian origin with an estragole content of 87.49% in the essential oils. Therefore, it would be easier to minimise the risk in the European population by regulating the import.*

ANSWER. How to manage the risk is a question which needs to be addressed to risk managers, the European Commission and the Member States. Indeed, when EFSA performed the exposure assessment, we noticed the difference in the estragole content of fennel fruits grown in different regions of the world. EFSA addressed this issue by using only data on estragole concentrations in fennel fruits which were sampled within the EU, thereby increasing the likelihood that European populations were indeed exposed to similar concentrations. In addition, the estragole concentration which was used in the exposure assessment was a weighted average of all these values available.

QUESTION 3 (Orally). *We know that there are 12 additional substances for which an assessment under Article 8.2 of Regulation (EC) No 1925/2006 is planned. Is it possible to get feedback from EFSA on the timelines and whether the mandate was already received?*

ANSWER. This question should be addressed to the European Commission.

QUESTION 4 (Orally). *Your assessment of the safety of preparations of sweet and bitter fennel fruits is based on the assumption that estragole, safrole and methyleugenol have the same properties and that fennel fruit preparations are of concern because they contain a genotoxic or carcinogenic ingredient without taking into account the property of the whole mixture. If the assumption were true that because of the presence of a genotoxic carcinogen in a mixture, the whole mixture raises concern for genotoxicity, there should be a high incidence of cancer in the Mediterranean area. This diet consists of significant quantities of preparations containing genotoxic carcinogens and the exposure of consumers in these regions is high. For example, for Liguria in Italy a high longevity rate and a low incidence of cancer is observed even though exposure to genotoxic carcinogens is high. Does this not suggest that there are other factors to consider in this evaluation? At least with the matrix effect in mind? Other agencies in the world follow this approach. For example, recently ECHA (European Chemicals Agency) changed the approach towards the evaluation of natural substances, taking into account the matrix effect. There are ongoing studies to evaluate the real effect of these agents in essential oils.*

Why doesn't EFSA accept this approach and insists on evaluating only the danger related to the single compound?

ANSWER. At EFSA we have only two possible options to evaluate genotoxic carcinogens in mixtures. This is based on the guidance given by EFSA's Scientific Committee. In principle, genotoxic carcinogens shouldn't be deliberately added to foods or used in the food chain. Only if the substance is unavoidable, the margin of exposure approach can be used which allows to classify the risk into low or high. There are ongoing discussions at EFSA on these concepts. However, at the moment we have to follow the guidance documents which are in place. For information, the Scientific Committee is carrying out the revision of the following relevant guidance documents: the Genotoxicity Guidance, the Margin of Exposure (MoE) Guidance, as well as the upcoming revision of the Botanicals Guidance**.**

The Chair closed the morning session by thanking the participants and the observers for their contributions. Observers were invited to submit questions, which could not be addressed during the meeting, in writing via EFSA's webform (https://www.efsa.europa.eu/en/ask/question).

13. OPEN SESSION DEDICATED TO NOVEL FOODS APPLICANTS - Key information and updates for novel food applications

The Head of the NIF Unit, Ana Afonso, chaired the Open session dedicated to Novel Foods (NF) applicants.

13.1 The novel food application process: figures, procedure and tools, and support initiatives for applicants – Front Desk and Planning Unit

Team Advice and Team Food Chain provided an overview of the novel food application process including the notification of studies, the services available to applicants during the life cycle of their applications such as the general pre-submission advice, the lessons learned during the suitability check, with details on mistakes to avoid in the preparation of an application and the most common shortcomings encountered by Team Food Chain.

Team Advice also promoted the ongoing Call for expressions of interest in EFSA's advice for Novel Food Small and Medium-sized Enterprises (SMEs), encouraging their participation.

Pre-submitted questions from Observers were addressed during the presentation.

13.2 Introduction to Novel Food confidentiality assessment process - Legal Affairs Services Unit

The Confidentiality Food Chain Team provided an overview of the confidentiality assessment process. The applicable legal framework, the timeline and steps of the process were explained in detail. Additionally, lessons learnt, best practices and recommendations for the submission of compliant confidentiality applications were given. Applicants were also informed of the update, in April 2025, of the EFSA's Guidance on Confidentiality which is now available on EFSA's website.

13.3 Update on the risk assessment process & challenges – Nutrition and Food Innovation Unit

The Head of the NIF Unit provided an overview of the EU regulatory framework for Novel Foods (NF), the recent update of EFSA's Novel Foods Guidance, the scientific risk assessment of NF applications, past activities and future plans for stakeholder engagement, and highlighted challenges and opportunities in NF risk assessment. Pre-submitted questions from Observers were addressed during the presentation.

14. Anwers to questions from Observers on subjects related to the NF process

PRE-SUBMITTED QUESTION (the notification of studies): *Sometimes applicants may perform studies not intended for the EU novel food application but feel in the obligation of notifying the study for transparency purposes. For example, a 90-day rat study may not be considered necessary for demonstrating safety of the novel food but an applicant may do it for other purposes. Once an applicant notifies a study, EFSA asks for the data. Let's think that this 90-day rat study is notified two days before the end of the risk assessment. Would EFSA stop the clock and request information about the study? Or would it be acceptable not notifying the study because it was not intended for the EU novel food application? We would like to express that this type of practice causes significant delays, costs and resources to applicants*.

ANSWER: Article 32b of the General Food Law requires applicants to notify EFSA the studies carried out or commissioned as of 27 March 2021 to support applications in relation to which Union law contains provisions for EFSA to provide a scientific output, including a scientific opinion.

If studies would have initially been performed for other purposes, e.g. without the intention of using them to support an application for the European Union market, in such cases the applicant is requested to notify the study without delay the moment the European Union becomes a potential market for the regulated product. In that case the study will be notified with delay and the applicant needs to justify the delay by clarifying for which purpose this study was initially performed. More details on the requirements for justifying delayed notifications can be found in the reply to Question 37 of the Questions and Answers on the EFSA Practical Arrangements (https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements).

The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food (Article 5(1) of Regulation (EU) 2017/2469). This means that the applicant is requested to submit all the available information including data in favour and not in favour, of the safety of the novel food. Studies not submitted with the application but for which EFSA is informed will be requested to have the complete information in support of the risk assessment.

PRE-SUBMITTED QUESTION (Identity). *I am particularly interested in EFSA's guidance on appropriately defining and naming a novel food in relation to the available data, especially in the context of by-products.*

ANSWER. The description of the name should refer to the nature, the production and the source of the product in question. The by-product must be clearly distinguishable from the product and other derivatives. The naming convention should reflect the critical evidence of the assessment. It is not EFSA that defines the name of a product; this is the task of the risk managers.

PRE-SUBMITTED QUESTION (Identity). *What are the requirements for the analyses and tests supporting the application regarding laboratory accreditation/certification? Should I conduct studies following GLPs?*

ANSWER. EFSA accept analysis conducted in-house by food business operators when certified analytical methods are used. According to regulatory requirements, all animal safety studies that are submitted for the assessment should be run in GLP-certified facilities.

PRE-SUBMITTED QUESTION (Identity). *I would like to ask if there are any developments you could share regarding the Cultivated Foie Gras risk assessment*.

ANSWER. This question is about an on-going dossier that we are assessing. It is the first meat product derived by a cell culture from animals (duck cells) and it was submitted at the end of January. More details cannot be provided because the assessment is on-going. The non-confidential version of the dossier is available in Open EFSA.

PRE-SUBMITTED QUESTION (Production process). *How can we deal when submitting a dossier based on pilot production? How can we manage in the dossier future scale-up?*

If a novel food application is based on pilot production, it is the responsibility of the applicant to produce according to the approved novel food and its production process when the applicant scales up. Hence, we consider excessive to demonstrate to EFSA that the commercial production will be equivalent to the pilot production and it will be responsibility of the producer to manufacture a food ingredient that is compliant with the approved novel food (even if the pilot-scale product was evaluated by EFSA). Could EFSA clarify if this information (demonstration that upscaling does not impact the product) is considered key to conclude on the safety of a novel food?

ANSWER. Applicants need to demonstrate that the NF produced at pilot scale is representative for what will be produced later at large scale. This requirement regarding the representativeness of the pilot scale, is in the composition section of the NF Guidance and refers to basic composition variability.

PRE-SUBMITTED QUESTION (Production process). *Sometimes information that is not pivotal for the safety assessment of novel foods is requested by EFSA, such as process quality control, which is an obligation of a food manufacturer who will always have a proper quality control in place to ensure food is safe and to meet the general food law. This requirement is considered excessive. Could EFSA clarify if this information is considered key to conclude on the safety of a novel food?*

ANSWER. What EFSA is asking here is to be informed by the applicant of what quality control measures and control points are in place, particularly when moving from small to large-scale production. Complying with the general food law is a must.

PRE-SUBMITTED QUESTION (Microorganisms). *Why are safety standards for microorganisms (active agents, probiotics) not harmonized between EFSA and Member States? EFSA seems to request mutagenicity testing, while Irish, Danish and Italian safety standards seem to be satisfied with identification requirements, absence of pathogenicity and AMR. Are EFSA Novel Food Panel requirements not excessive?*

ANSWER. The requirements set by member states may differ since they may serve different purposes. According to the current EU regulation the risk assessment of NF is centralised in EFSA, which ensures that the same scientific requirements and safety standards are applied across all NF applications. In addition, the new cross-cutting EFSA guidance on the characterisation and risk assessment for microorganisms supports the regulatory requirements across the sector.

PRE-SUBMITTED QUESTION (Microorganisms). *Microalgae as micro-organisms are required to provide: i) Unambiguous taxonomic identification at species level (EFSA FEEDAP Panel, 2018; EFSA, 2021e) ii) Certificate of deposition (including accession number) in an internationally recognised culture collection having acquired the status of International Depositary Authority under the Budapest Treaty (EFSA FEEDAP Panel, 2018). How do these requirements combine with the concept of "generic authorization"*.

ANSWER. The risk assessment of NF is conducted for a specific product, produced through a well-defined production process. Once the NF is authorised, it becomes eligible for generic use unless temporary market exclusivity is granted. It is important to mention that any changes in the production process should not alter the characteristics and safety requirements of the NF as assessed by EFSA, even if the product still complies with the specifications. The business operator must inform the European Commission about changes.

PRE-SUBMITTED QUESTION (Microorganisms). *The whole genome sequence raw data is an excessive requirement. Could EFSA clarify how EFSA uses the raw data of the whole genome sequence of microorganisms?*

ANSWER. EFSA considers that the whole genome sequence raw data are relevant for the risk assessment and enables EFSA to independently assess the data in relation to taxonomical implication and presence of genes of potential concern.

PRE-SUBMITTED QUESTION (Microorganisms). *For the phenotypic test of microorganisms with genes involved in cytotoxicity, can different cell lines, such as Vero, HeLa, or HepG2 cells, be used to verify cytotoxicity, similar to the EFSA-proposed cytotoxicity test for Bacillus using Vero cells? Specifically, can this approach be applied to species other than Bacillus?*

ANSWER. The protocol proposed by EFSA is aimed at detecting peptides produced by microorganisms that might have cytotoxic effects. Deviations from the protocol need to be justified and described in detail and would require a case-by-case assessment.

PRE-SUBMITTED QUESTION (Toxicity). *Could frontier strategies be developed to reduce the risk and toxicity of genotoxic substances, not only by simply lowering their concentration but also through innovative approaches aimed at modifying the molecular structure of these toxic substances by binding them to different substituents in order to alter their pharmacokinetics and mitigate their toxic effects?*

ANSWER. It is important to state that genotoxic substances do not have a role in our food, should not be added and should not be authorised. If the substance can be changed to remove completely its genotoxic properties, then its assessment can proceed to the assessment of other potential

toxicological properties as done for other compounds. Changing the pharmacokinetic properties of a genotoxic compound will not negate the hazardous properties of the latter.

PRE-SUBMITTED QUESTION (Toxicity). *I would like to better understand the requirements for toxicological and compositional studies when the novel food is a by-product currently used as feed and now intended for human consumption. Should the safety studies be conducted on the by-product itself, or is it necessary to provide safety data on the original raw material derived from the by-product?*

ANSWER. The toxicological and compositional studies should always be conducted on the material intended for human consumption, so also on a by-product.

PRE-SUBMITTED QUESTION (Toxicity). *What are the latest developments in Non-Animal Methods (NAMs) for food safety assessments? Does EFSA presently consider NAM's to provide sufficient safety evidence to supersede traditional animal studies?*

ANSWER. It is true to say that progress has been made in terms of genotoxicity testing and for endocrine disruption testing, but there are other areas where NAMS are not yet accepted to replace animal studies for regulatory decision making.

PRE-SUBMITTED QUESTION (Toxicity). *Toxicity assessment test requirements.*

ANSWER. We recommend checking the NF guidance document which will provide you with all the information.

PRE-SUBMITTED QUESTION (Toxicity). *Guidance on how best to address ADME for complex mixtures where individual or representative components are hard to identify. 2. When is absorption considered "significant"? and upon this determination, what follow up studies are triggered for food colour additives (beyond the standard 90-day rat studies).*

ANSWER. We have a catalogue of services to applicants and business operators, and they are encouraged to take advantage of this. About the question on "significant absorption", in the updated guidance document, this is no longer considered because the triggers for higher tiers of testing have been updated from the previous version of the guidance.

PRE-SUBMITTED QUESTION (Nutrition & Allergenicity). *Could you share more information on digestibility studies as part of dossiers?*

ANSWER. This will depend on the type of NF that needs assessing. Information relating to digestibility studies can be found in the NF Guidance, and depends on the nature of the Novel Food and is in the context of its bioavailability (for new nutrient sources), protein quality and potential allergenicity etc.

PRE-SUBMITTED QUESTION (Nutrition & Allergenicity). *It is clear that the EU population already consumes more protein than needed. EFSA requires protein quality data of 3 batches of a novel food for the safety assessment. An ingredient is not deemed unsafe or nutritionally disadvantageous if its DIAAS score suggests that its protein quality is low. Could EFSA elaborate on why protein quality information is required for the safety assessment of a novel food?*

ANSWER. The requirement for protein quality data is linked not only to the NF EFSA is assessing but also on its proposed uses. For example, when the NF is to be used as the only source of protein in the diet with one or more population groups replacing high quality protein, this can lead to a safety concern. Therefore, these data are not always required but in certain circumstances they are needed for the safety assessment.

PRE-SUBMITTED QUESTION (Nutrition & Allergenicity). *Could frontier strategies be developed to reduce potential allergens or molecules that trigger immune reactions through innovative approaches aimed at modifying their structure, by binding them to different substituents or reducing molecules that synergistically contribute to gastrointestinal dysfunction (such as histamine-releasing foods, histamine-rich foods, irritants releasing inflammatory mediators, tyramine-rich foods, excessive gastric acidity, etc.), in order to alter their pharmacokinetics or presence without eliminating the food itself, to mitigate immune-mediated effects?*

ANSWER. Much of the question is not about allergies but about (non-immune) food intolerance. When it comes to true food allergies, the only effective way of managing it is through avoidance of the culprit food.

QUESTION (Orally). *With the new guidance there are new requests and obligations to follow. We had a dossier completed according to the old regulations, but when the new regulations came out, we had to add new measurements that we hadn't done before as they were not requested. So, we have to do additional experimentation and testing. But now the materials from the original batch are not available. It is extra cost for testing and extra cost to do new fermentations, which add extra time. Our experience is that when the questions are asked, we have to answer appropriately and come up with additional testing. But can I also submit the reason why I cannot follow the guidelines as it can really be an impressive burden to get all the data together?*

ANSWER. While we cannot comment on this particular case, it should be noted that additional data to demonstrate the safety of a NF have always been asked by EFSA when deemed necessary. The difference from the previous guidance is that in the updated one, EFSA endeavoured to provide more clarity and a more detailed description of the type of data needed for the safety assessment to ensure that applicants already include them in their dossier. However, following the assessment of the data in the dossier, our experts may have additional questions. Also important is the fact that the NF guidance in its recent update needs to take into consideration new or updated EFSA cross-cutting guidance documents such as the one on genotoxicity testing and the one on nanomaterials. Changes to these cross-cutting guidance documents may lead to changes in data requirements for NFs. Of course, the NF guidance cannot go into all possible details to anticipate every single case, and it is the responsibility of the applicant to provide all information necessary for the risk assessment.

For more specific questions asked by EFSA (additional data request) on particular NF applications, there is always the possibility for the applicant to request a clarification teleconference meeting with EFSA staff (see the catalogue of services available to applicants).

QUESTION (Orally). *How open would the WG be to receive an in-silico study instead of animal studies? In the case of replacing a 90-days toxicity study, to avoid animal testing?*

ANSWER. It depends very much on the type of data you are intending to submit in in-silico form. In-silico approaches have already been shown to be very valuable when it comes to mutagenicity and DNA reactivity but would still followed by a need for in-vitro tests. In-silico approaches, such as to replace repeated dose studies such as a 90-day study, are not yet sufficiently robust to be used for regulatory purposes, although a new guidance on the use of read-across is currently under development.

QUESTION (Orally). *I understood that EFSA complains that applications are not of sufficient quality, but has EFSA ever considered the increasingly strict requirements that it imposes onto NF applications? These requirements have been implemented in a relatively short time and are quite numerous, especially compared to other safety agencies worldwide. In 2021 the requirements were already high and now they have very much increased compared to other authorities.*

ANSWER. Such additional information was always requested before, when considered necessary by the Panel and the WG. We have taken advantage of updating our guidance to improve on the description of the information requested, with the expectation that this will help the applicants to prepare the best possible dossiers. We would therefore disagree that there has been an increase on the requirements. The only exception is where there has been an update or a new EFSA cross-cutting guidance with implications on the data requirements, e.g. for the nanoparticles assessment. EFSA wishes to clarify that differences in the requirements and assessment of NFs in different jurisdictions are often driven by different legislative frameworks governing the authorisation of NFs. In Europe we have very high standards for the safety of consumers.

The Chair closed the afternoon session by thanking the participants and the observers for their contributions.

15. Next meeting

The next meeting will be held on 24 and 25 June 2025, in Parma.

Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Mr. Frank Thies declared the following interest: updated annual DoI is currently under validation and declared a research funding by British Heart Foundation to support a project entitled "Rebalancing the fat content of the heart and muscle in Type 2 Diabetes". In accordance with EFSA's Policy on Independence[6] and the Decision of the Executive Director on Competing Interest Management[7], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

Annex II List of Observers

About 320 registered (but only the observers listed below attended online)

Observer	Organization
Maria Giulia Corazza	Università degli Studi di Parma
Achim Wiegand	FIM Biotech GmbH
Andrea Katušinová	Public Health Authority of the Slovak Republic
Tobias Dietzel	ADM Wild Europe GmbH & Co. KG
Marta Periz	Nestlé
Hannes Malfroy	Atova Regulatory Consulting
Liliana Coleandra	University of Parma
Rocío Duchen	Pen & Tec Consulting (trading as Argenta)
Natalia Gaveglia	Sapienza Università di Roma
Sophie Lion	Lesaffre
Kathrin Pfirrmann	ADM
Lucía Martínez	Dsm-firmenich
Geresom Ilukor	School of Hygiene-Mbale
Giulia Formici	University of Parma
Vaclav Bazata	Private consultant
Mukesh Summan	Kerry Group
Annika Boye Petersen	Technical University of Denmark
Antoine Leroux	GNOSIS SPA

[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

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