NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 108TH PLENARY MEETING

Held on 24-26 November 2020, as a web conference
(Agreed on 09 December 2020)

Meeting open to observers on 26 November 2020, 9:00-13:00

Participants

- Panel Members:

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

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  DG SANTE: Ivona Babic, Stella D'Amore, Takis Daskaleros, Alexandra Tuijtelaars (only for agenda item 13) and Rafael Luis Perez Berbejal

- EFSA:

  Nutrition (NUTRI) Unit: Valeriu Curtui, Reinhard Ackerl, Océane Albert, Domenico Azzollini, Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Gabriela Precup, Ruth Roldan Torres, Annamaria Rossi, Emanuela Turla, Silvia Valtueña Martínez, and Ermolaos Ververis.

  Scientific Committee and Emerging Risks Unit (SCER): Andrea Gervelmeyer (agenda item 6.4).

  Transformation Services Unit (TS): Claudia Paoletti (agenda item 6.1).

- Observers:

  See Annex I.

- Others:

  Not Applicable

CLOSED SESSION

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 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 107th Plenary meeting held on 22 October 2020, as a web conference

The minutes of the 107th Plenary meeting held on 22 October 2020 were agreed by written procedure on 30 October 2020.

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

5.1. Draft opinion on dried mealworms (Tenebrio molitor) as a novel food (NF 2018/0241). *Applicant: SAS EAP Group - Micronutris* (EFSA-Q-2018-00262)

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 24 November 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/6343

5.2. Draft opinion *Schizochytrium* sp. oil as a novel food (NF 2019/0825). *Applicant: Fermentalg* (EFSA-Q-2019-00187)

The draft opinion was presented. In particular, the Panel discussed the sections related to the identity of the Novel Food, the production process, compositional data, specifications, proposed uses and use levels and toxicological information. The opinion was adopted by

[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

the Panel on 24 November 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/6344

5.3. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2019/1046). *Applicant: Fermentalg* (EFSA-Q-2019-00323)

The draft opinion was presented. In particular, the Panel discussed the sections related to the identity of the Novel Food, the production process, compositional data, specifications, proposed uses and use levels, toxicological information and human studies. The opinion was adopted by the Panel on 24 November 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/6345

5.4. Draft opinion on Cistanche tubulosa extract as a novel food (NF 2019/1318). *Applicant: SINPHAR TIAN-LI PHARMACEUTICAL* (EFSA-Q-2019-00812)

The draft opinion was presented. In particular, the Panel discussed the sections related to product characterisation, production process, proposed uses and use levels, anticipated daily intake, toxicological data and human studies. The opinion was adopted by the Panel on 24 November 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/6346

6. Other topics for information and/or discussion

6.1 Update on the implementation of Transparency Regulation and Update of the Guidance documents

The Panel was given an update on the implementation of Transparency Regulation (TR), the timelines and next steps with respect to the new tools and organisational changes. Detailed information on how the TR will be applied by EFSA will be given in Practical Arrangements (PAs), which are binding means to interpret and implement the legal framework provided by the TR. Series of info-sessions and trainings will be provided.

The Panel was informed that eight scientific guidance documents of the NDA Panel required update to inform applicants of new provisions set out in Regulation (EC) No 178/2002, as amended by Regulation (EU) 1381/2019, the 'Transparency Regulation'. The new provisions concern requirements in the pre-submission and submission phases that are applicable to all applications submitted as of 27 March 2021.

The Panel took note that only the administrative part of these guidance was revised (aligned with Practical Arrangements). The scientific part of the guidance documents is left untouched. The updated guidance documents required endorsement by the NDA Panel.

6.2 International Liaison Group (ILG) on nutrient reference values (NRVs) methodologies

The Panel was informed about the first meeting of the International Liaison Group (ILG) on nutrient reference values (NRVs) methodologies which took place on the 7th of October. It gathered representatives of authoritative bodies in charge of NRVs at regional or global level (US FDA, Health Canada, Australian Ministry of Health, New Zealand Ministry of Primary Industries, FAO and WHO). The objectives of the ILG are i) to exchange

information on ongoing activities related to reference values, ii) to share experience on methodological approaches for establishing reference values, iii) to identify potential areas of international collaboration, in particular regarding conceptual and methodological developments, and, ultimately, iv) to foster global harmonization in this field. The terms of reference of the ILG were agreed and topics and activities of common interest were explored. This included sharing views and experiences regarding the application of GRADE and GRADE-like approaches to NRVs setting and the integration of chronic disease endpoints into the NRVs framework.

6.3 Scientific Committee - Update on the guidance for risk assessment of nano substances

The risk assessment of nanomaterials is described in the EFSA 2018 Draft Guidance on risk assessment of nanoscience and nanotechnologies in the food and feed chain. This Guidance has been in a 2 years pilot phase and is being reviewed based on stakeholders' feedback, and experience from the application of the Guidance to actual EFSA cases. There are changes regarding the physicochemical characterisation and simplifications, and adaptation of structure of hazard assessment chapters. Scientific principles and details have been updated with recent results from scientific research projects and further elaborated in line with the latest progress in science.

The Panel, particularly WG NF, was asked to provide feedback on the updated guidance.

6.4 Appraising and integrating evidence from epidemiological studies

The Panel was given an outline on the Draft guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments, which was endorsed by the Scientific Committee for a 1-year pilot phase. The guidance provides an introduction to epidemiological studies and illustrates the typical biases of the different epidemiological study designs. It describes key epidemiological concepts relevant for evidence appraisal. The principles of appraising epidemiological studies are illustrated, and an overview of Risk of Bias (RoB) tools is given. A decision tree is developed to assist in the selection of the appropriate Risk of Bias tool, depending on study question, population and design. Several examples of appraising experimental and observational studies using a Risk of Bias tool are annexed to the document to illustrate the application of the approach.

This document constitutes a draft that will be applied in EFSA's assessments during a 1-year pilot phase and be revised as necessary taking into consideration the comments from the Panels.

6.5 Results of the expert mutual assessment

Results from the expert survey as well as from the expert assessment are overall very positive. The details of the responses were discussed during last summer between the Panel coordinator and individual Panel members as a follow-up of the 2020 EFSA/Experts Mutual Assessment. Feedback from individual dialogues with Panel members were presented and discussed. Among the strengths highlighted, the peer reviewing/reviewing process introduced since October 2019 before NDA Panel plenary meetings was very much appreciated and has contributed to optimise the discussion/adoption of opinions. The Panel and EFSA scientific officers shared their experiences from peer reviewing/reviewing process. Suggestions for improvement, including training needs and onboarding, were also discussed.

OPEN SESSION ON 26 NOVEMBER

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 Head of Nutrition Unit introduced the Unit.

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. Insights on novel foods risk assessment

The Panel was given an update on the work of the Working Group on Novel Foods, followed by a structured presentation providing EFSA insights on novel food risk assessment.

Three sessions were held which focused on (1) alternative proteins and their sources, (2) novel carbohydrates and (3) other topics of interests such as plant extracts, synthetic cannabidiol and engineered nanomaterials, each followed by a short Q & A session on the topics. The presentations were prepared and presented by staff of the EFSA Nutrition Unit and were based on Opinions and the EFSA Novel Foods Guidance document adopted by the NDA Plenary.

10. Update on ongoing works of the 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 98-99).

Information about the mandates received and their status are available on EFSA Register of Questions.

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). Of particular relevance to the activities of the NDA Panel:

- The SC discussed the draft mandate from the European Commission to provide a risk-benefit assessment of fish consumption in relation to the presence of dioxins (PCDD/Fs) and dioxin-like PCBs and to assess the influence of the presence of other contaminants in fish such as methylmercury, brominated flame retardants and perfluoroalkyl substances (PFAS) on the outcome of the risk-benefit assessment.
- The SC also discussed the Draft statement on the derivation of Health Based Guidance Values (HBGV) for regulated products that are also nutrients (EFSA-Q-2019-00505), which incorporated comments received from public consultation carried out last summer. The SC working group will proceed with the finalisation of this statement and the adoption by the SC is foreseen in February 2021.

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

- **WG on Claims** - Two Art 13(5) claims are under stop-the-clock procedure for requesting additional information and clarification to the applicants.
- **WG on Sugars -** The WG Chair briefed the Panel on the progress of the work on sugars. The evidence integration and uncertainty analysis on metabolic diseases, as well as aspects related to the appraisal of observational studies, were discussed.
- **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.
- **WG on Food allergy -** The WG discussed a draft opinion on the efficacy of an infant formula manufactured from protein hydrolysate in reducing the risk of atopic dermatitis and the reply from the applicant. Further questions were raised and additional supplementary information from the applicant is needed.

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

Postponed.

15. Next meeting

The next meeting will be held on 17 December 2020 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
ABBONDANDOLO Valentina#	valentina.abbondandolo	IT
ALQUATI Eleonora	Association of Chocolate, Biscuits and Confectionery (CAOBISCO)	BE
AMARANDEI Carmen#	ANDY CONSULTING SRL	RO
AMUNDSEN Mathias Rudolf	Public Research Institute	NO
ANTUNES LOPES Mariane#	Brazilian Ministry of Agriculture, Livestock and Food Supply	BR
ARDILA James#	OMNILIFE	CO
ARICAN OZNUR Fulya	Republic of Turkey/Ministry of Agriculture and Forestry - General Directorate of Food and Control	TU
ARUN Sharadha	Reliance Industries Ltd	IND
ASPRU Anda-Georgiana#	Giurici Mihaela	RO
ASUKAS Tiia#	Tiia Asukas	FIN
AYDIN Merve	PhD student	TU
BAKIMER Ronit	Aleph-farms	ISR
BALBO Chiara	European Food Safety Authority (EFSA)	IT
BALDWIN Nigel#	Baldwin Advisory Services Ltd	UK
BARDI Laura	Council for Agricultural Research and Economics (CREA)	IT
BAZATA Vaclav	CASP	CZ
BELL Haley	Public Health England	UK
BERTAKIS Valentina#	Camst	IT
BERTIN Barbara	Comune di Milano	IT
BORISOVA Denitsa	Denitsa Borisova	BG
BOUÉ Géraldine	Oniris Inrae	FR
BRAVO Laura#	Consejo Superior de Investigaciones Científicas (CSIC)	ES
BRENNAN Mollie#	Global Counsel	UK
CÁMARA Montaña#	Complutense University of Madrid, Spain	ES

Observer	Name of Employer	Country
CARAMANICO Rosita	Council for Agricultural Research and Economics (CREA)	IT
CARNIO Silvia	Mérieux NutriSciences	IT
CAROCHO Marcio#	Polytechnic Institute of Bragança	PT
CHAPPUIS Eric	Lesaffre International	FR
CHATZIGEORGIOU Artemi#	DELTA FOODS SA	GR
CHIS Maria Simona#	USAMV CLUJ-NAPOCA	RO
CHRONI Myrsini	School of Engineering of the Aristotle University of Thessaloniki	GR
CIPROVICA Inga#	Latvia University of Life Sciences and Technologies	LV
CIRNATU Daniela#	National Institute of Public Health	RO
CONTI Maria Vittoria	University of Pavia	IT
COPPENS Patrick	Food Supplements Europe	BE
CORREIA Daniela	Sonae	PT
CRISÀ Alessandra#	Council for Agricultural Research and Economics (CREA)	IT
CUSH Meera#	Ramboll UK Limited	UK
DAN Codruta#	Codruta	RO
DATTAROY Tomal	Reliance Industries Limited	IND
DE BOURAYNE Valerie	KEMIN Human Nutrition and Health	FR
DEPEINT Flore	Unilasalle	FR
Di NAPOLI Ilaria	University of Pavia	IT
FAGNANI Simona	Public Research Institute	IT
FERRANTELLI Vincenzo	Veterinary Public Health Institute of Sicily	IT
FLAMINI Riccardo	Council for Agricultural Research and Economics (CREA-VE)	IT
FRATERNALI Federico	Almaphyto	SM
GARLTON Joanne#	Freelance	ES
GARZELLI Antonella#	FAIR TRADE	UK
GEBHART Marion	Dr. Marion A. Gebhart - Consulting engineer Food Chemistry	AT
GEISER Stefanie	EAS Strategies	BE
GLUHAK SPAJIĆ Diana#	RED FORK j.d.o.o.	HR

Observer	Name of Employer	Country
GUDER Tina	Ajinomoto Foods Europe SAS	DE
HABYARIMANA Ephrem#	Consiglio per la ricerca in agricoltura e l'analisi dell'economia agraria (CREA)	IT
HANSEN Mikkel#	The National Food Institute of Denmark (DTU)	DK
HARTWIG Markus	Red Bull GmbH	BE
HOFFMANN SARDA Fabiana	University College Cork	IE
INGUGLIA Elena	Teagasc	IE
IVANOVA Silviya#	ICFT	BG
JAUD Mathilde	Roquette	FR
JOVIC Dragana#	Institute of Public Health of Serbia	SRB
JULIN Bettina#	Swedish Food Agency	SE
KALK Christiaan	lsbi | life science-based innovations	NL
KARTHIKEYAN Mridula#	Fruzyme Biotech	IND
KONTONIKOLA Anna	Greek government	GR
KRISTERSSON Mia	Swedish Food Agency	SE
KULHÁNEK Michael#	ČANT	CZ
KUMRIJA Laura#	Erzeni SHPK	AL
LAFFINEUR-PAUCHET Marie#	European Food Safety Authority (EFSA)	FR
LE BLOCH Jérôme	Nutraveris	FR
LEIBOVITCH MAJSTER Emilie	European Association of Sugar Manufacturers (CEFS)	BE
LEIBOWITZ Ayelet	The Israeli Veterinary Services	ISR
LEONE Antonella	National Research Council (CNR)	IT
MANDIUC Camelia	Mandiuc Camelia	RO
MART Anca#	Public Research Institute	RO
MARTIN-HADMAS Roxana Maria#	University of Medicine, Pharmacy, Science and Technology „George Emil Palade" from Târgu Mureș, Romania	RO
MARTYN Danika	Intertek	UK
MASCI Maurizio	Consiglio per la ricerca in agricoltura e l'analisi dell'economia agraria (CREA)	IT
MATALAS Antonia#	Harokopio University, Athens	GR

Observer	Name of Employer	Country
MATHEW Joash	International Platform of Insects for Food and Feed	BE
MENSIK Petr	EU Specialty Food Ingredients	BE
O DONOVAN Clare	Food Safety Authority of Ireland (FSAI)	IE
O'MAHONY Sinead	Food Safety Authority of Ireland (FSAI)	IE
ONO Kaori	Ajinomoto Europe	FR
O'ROURKE Stephen	Jennewein BIotechnologie GmbH	DE
PALMEIRA Maria Eduarda#	Food Soul Regulatory Affairs and Marketing	BR
PHIPPS Kirt	Intertek	UK
POP Oana Lelia#	University of Agricultural Sciences and Veterinary Medicine (USAMV), Cluj-Napoca, Romania	RO
PORTO Andreia	PT Permanent Representation to the EU	BE
RAIKUMAR Baviya Priyadharshini#	Selerant	IND
RAMADAN Abdelhamid#	Moh	KU
RAMALHOSA Elsa#	Polytechnic Institute of Bragança	PT
RESPONDEK Frederique	CP KELCO	FR
RIMAC BRNČIĆ Suzana#	University of Zagreb	HR
RIZZO Federica#	Law firm	IT
SCHERES Huub#	DuPont/Euvepro	NL
SCHNEIDER Sabina	RDA Scientific Consultants GmbH, Munich	DE
SEONG Yujin	CJ Europe GmbH	DE
SIRIKUMARKUL Kanika	Rud Pedersen Public Affairs	BE
SOCACI Sonia	University of Agricultural Sciences and Veterinary Medicine (USAMV), Cluj-Napoca, Romania	RO
SOCACIU Carmen#	University of Agricultural Sciences and Veterinary Medicine (USAMV), Cluj-Napoca, Romania	RO
SOVIERO Giovanna#	Dr.ssa Giovanna SOVIERO FOOD TECHNOLOGIST	IT
STOICAN Elena-Claudia	Nastasia Belc, INCDBA-IBA Bucuresti	RO
SUHAROSHI Ramona#	University of Agronomic Sciences and Veterinary Medicine (USAMV), Cluj, Napoca	RO

Observer	Name of Employer	Country
TARCEA Monica#	National Institute of Public Health	RO
TATHAM Alice	HUSKI FOOD AND DRINK MOUNTAIN DELIVERY	FR
TENNING Paul	Food for Thought	SE
THEVENIOT Rémi	Freelance	FR
THOUKIDIDOU Lia	Food and Drink Federation (FDF)	UK
TOURNAVITOU Nikoletta	COCA-COLA HELLAS	GR
VARAGIANNIS Panagiotis	Hellenic Dietetic Association	GR
VERHAGEN Hans	Food Safety & Nutrition Consultancy	NL
VILLASEÑOR Victor	Omnilife	MEX
VLAD Mariana	National Institute of Public Health	RO
VODNAR Dan	University of Agronomic Sciences and Veterinary Medicine (USAMV), Cluj, Napoca	RO
WEINER Danielle	Public Health England (PHE)	UK
ZÁMBÓ Leonóra	National Institute of Pharmacy and Nutrition	HU

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. Novel algae proteins – Mandatory to have a QPS status for a Novel Food? – I know QPS is not under the NDA remit (ARUN Sharadha - Reliance Industries Ltd, IND)

A. QPS status is granted by a different panel (BIOHAZ) and assessed under request. There is no need to file a separate application since NDA Panel will file the request to the BIOHAZ Panel. It should be noted that the BIOHAZ will evaluate the QPS status only at the taxonomic species levels and only based on literature available.

Q. What is meant with "*de novo* sensitization" in the allergenicity? (CARNIO Silvia - Mérieux NutriSciences, IT)

A. Exposure to new proteins may result in *de novo* sensitization, with or without clinical allergy. Reliable tests are missing to definitively predict on their own, the potential of novel proteins to sensitize *de novo* atopic individuals. Such potential depends on intrinsic characteristics of the protein (e.g. structure, function, and physicochemical properties) but also on complex interactions between the genetic background and physiology of the consumers and environmental conditions. The impact of extrinsic factors such as the composition of the food matrix, food processing, as well as the dose, route, and frequency of exposure, is of major importance to modulate the potential of a protein to induce sensitization.
Whilst many individuals can be sensitized to a dietary protein, only a proportion experience clinical symptoms upon re-exposure, and are therefore considered allergic to that protein (an allergen).

Q. Is there a published guidance document on novel insect protein? (DATTAROY Tomal - Reliance Industries Ltd, IND)

A. There is no specific EFSA guidance document for the assessment of novel insect proteins. The EFSA Novel foods Guidance document is applicable also in the case of insect proteins and should be used.

Q. Didn't chromium enrichment in Yarrowia lipolytica cause heavy metal issues? (DATTAROY Tomal - Reliance Industries Ltd, IND)

A. There were no such issues. In the manufacturing process chromium chloride, an authorised source of chromium, is added to the culture media in a very controlled process – analysis of heavy metals was performed for the novel food. There was no enrichment of any heavy metals.

Q. Could you please provide examples of Escherichia coli genetically modified foods? (DATTAROY Tomal - Reliance Industries Ltd, IND)

A. There are a number of NFs which have been produced with *E. coli*, usually genetically modified (e.g. chondroitin sulphate, human identical milk oligosaccharides). They can be found in the EU Union list for NF. Also food enzymes are often produced by genetically modified *E. coli*.

Q. The weight of human clinical trials in assessment of NF, limited clinical value for ethical and methodological issues. How is your feeling? Do you think they will become less and less relevant? (TURCK Dominique – NDA Panel Chair)

A. Human studies add to the weight of evidence. They are integrated into the overall risk assessment. On their own they would usually not be sufficient and they cannot replace toxicological data but can complement, e.g. if the NF has a long history of use. NF are assessed on a case by case basis, there is no one-size fits all in the assessment. Source of the NF, composition, production process are all relevant aspects. Human data can help to identify potential adverse effects.

Q. Food enzymes: will there be a need for authorisation once the official list of approved food enzymes is published? If yes, please give an outlook on time and possible procedures. Does an applicant need to prepare a dossier according to the food enzyme guidances/process under 1331/2008 to get an approval for the enzyme used in the production of a novel food ingredient. As I understood, this is not the case at the moment, but on the long term? (GEBHART Marion A. - Consulting engineer Food Chemistry, AT)

A. No person shall place on the market a food enzyme or any food, including novel food, in which such a food enzyme has been used if the use of the food enzyme does not comply with Regulation (EC) No 1332/2008 on food enzymes. Applicants therefore would need to submit one application under the food enzymes regulation and another one under the NF regulation. Ideally, these applications should be submitted in parallel to the Commission so EFSA could prepare the 2 opinions at the same time. If the EFSA opinions do not raise safety concerns, the Commission may grant an authorisation under NF regulation and will be able to include the concerned food enzyme in the Union list of food enzymes when it is established.

Q. Follow up on question on 2 applications for NF and enzyme – clarification (TENNING Paul - Food for Thought, SE)

A. As indicated in previous response, ideally two applications should be submitted in parallel – the NF authorisation will come first and then the one on enzymes. A parallel assessment would be preferred, despite the authorisation for both would come at different stages (enzymes later).

Q. Happened to attend the BIOHAZ panel where it was mentioned that GMOs are included in QPS assessment process, provided we give complete information on genome sequence and modification process. I saw here that GMOs are excluded from QPS. Can you clarify kindly? Thanks (ARUN Sharadha - Reliance Industries Ltd, IND)

A. QPS status is granted at the species level, and generally the genetically modified microorganisms are not granted QPS. However, if complete information is provided, they can be evaluated by the BIOHAZ Panel. It should be considered that often this information is not publicly available.

Q. I would like to ask if EFSA is incorporating new "omics" tools results about effects of foods on human health on novel foods evaluations (HOFFMANN SARDA Fabiana - University College Cork, IE)

A. EFSA is aware of the rapid development of such methods and is anticipating that their role will increase in the future. In 2018, EFSA organised a Scientific Colloquium on "omics in risk assessment" when EFSA discussed the current state of such methods and its potential application in risk

assessments. Some work is to be done to validate these methods and to incorporate them in the risk assessment, but this does not prevent applicants to use them already now (e.g. cultured meat discussed today – such omics methods could be useful to explore similarities and differences to conventional meat).

Q. Coming back to the relevance of human studies. Then is it possible to submit a dossier without human data for new non-digestible oligosaccharides? no need to evaluate digestive tolerance? (RESPONDEK Frederique - CP KELCO, FR)

A. In principle it is possible. The evidence and weight given to human studies is often very limited. The Panel would expect very good compositional data, production process etc. (post-plenary note: The need for human studies may also depend on the intended dose and available toxicological information).

Q. Novel food from traditional foods in Third Countries: what categories of people can apply for authorization/notification? (LEONE Antonella - National Research Council (CNR))

A. The concept of Applicant is defined in the Novel Foods regulation as meaning the Member State, the third country of the interested party which may represent several interested parties. The interested party can be public or private, or even a consortium.

Q. Alternative proteins: are the rules different for their use in feed? (LEONE Antonella - National Research Council (CNR))

A. Not within NDA Panel remit. Please refer to Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials.

Q. Will slides be distributed after the event? (VERHAGEN Hans - Food Safety & Nutrition Consultancy, NL)

A. The presentations will be available together with the published minutes.

Q. EFSA currently evaluates synthetic CBD, while probably more than 50 applications on natural CBD (cannabinoid) have been submitted. Can EFSA or the commission update us about the status of novel food applications on natural CBD? Recent changes on regulation in Europe (LE BLOCH Jérôme - Nutraveris, FR)

A. The EC has taken note of the Court's rules and is currently assessing the judgment. If eventually CBD extracted from the plant is not considered a drug within the meaning of the UN Single Convention on narcotics it may be qualified as food. In that case, the EC would resume the verification of the validity of the applications before submitting them to EFSA.

Q. Does the 200-fold uncertainty factor (UF) apply to subchronic studies on plant extracts only, or to all novel foods? (PHIPPS Kirt - Intertek, UK)

A. EFSA has a Scientific Committee (SC) Guidance (2012) on selected default values that established applicable uncertainty factors (UF). An UF of 100 applies for the extrapolation from animal species and human but it is also recommended to take into account the limited time of exposure of animals to the test item in a subchronic toxicity study. Foods should be safe for human also for chronic consumption. For that extrapolation from subchronic exposure in animal studies to potential chronic exposure in human an additional UF of 2 is recommended by the EFSA SC Guidance. Theoretically the

Panel can modify UFs, but that would require a sound scientific justification. Especially when it comes to mixtures such as plant extracts where there is always a certain fraction which is not identified, the Panel has been rather reluctant to reduce the UF proposed by the EFSA SC.

Q. I would like to know if are you also considering gut microbiome alterations due to a novel food (HOFFMANN SARDA Fabiana - University College Cork, IE)

A. This topic is very much unexplored yet. There is some ongoing discussion in the EFSA Scientific Committee but there is still a gap of knowledge and lack of validation on what observed alterations mean. More data are needed to fill this gap before it can be used in risk assessment, but EFSA is aware and is following the development.

Q. Sugars: How does EFSA handle special food groups, like SSBs (Sugar-Sweetened Beverages), & the way sugars are consumed (liquid *vs.* solid calories). Could EFSA set UL/Cut-Off Value for certain food groups, like SSBs? (LEIBOVITCH MAJSTER Emilie - European Association of Sugar Manufacturers (CEFS), BE)

A. As already specific at protocol level, UL/cut-off values will be established whenever possible for nutrients but not for specific food groups e.g. "sweets" or "cakes", as these values could be set only for nutrients. Advice on specific food groups could be provided, which MS could use to set Food Based Dietary Guidelines.

Q. Sugars: For caries, how does EFSA handle the intake of sugars regarding amount *vs.* frequency? (LEIBOVITCH MAJSTER Emilie - European Association of Sugar Manufacturers (CEFS), BE)

A. As clearly specified in the protocol, EFSA focuses only on studies where the amount of sugars consumed was reported or could be quantified from the whole diet or from specific food groups. From these studies EFSA will also consider data on frequency of consumption whenever reported. However, studies reporting on frequency of consumption only were not eligible.

Q. Sugars: Will EFSA formulate conditional limits if data apply (mainly) to a special group (eg those who gain weight or are overweight)? EFSA protocol states it "will also include an estimate of intake for population groups…and an indication of circumstances, if any, in which risk is likely to arise. (LEIBOVITCH MAJSTER Emilie - European Association of Sugar Manufacturers (CEFS), BE)

A. The protocol does not refer to the setting of ULs/safe levels of intake for population subgroups at risk of developing metabolic diseases only. As for all other Opinions on Dietary Reference Values, EFSA will set UL/cut-off values (in case they can be established) for the general population and subgroups thereof based on e.g. age, gender and physiological conditions (e.g. pregnancy, lactation). The assumption is that values protecting vulnerable groups (e.g. with pre-existing risk factors such being obese) will also protect the general population.

Q. Sugars: Which endpoints is EFSA considering for a dose-response relationship? (LEIBOVITCH MAJSTER Emilie - European Association of Sugar Manufacturers (CEFS), BE)

A. It needs to be clarified that the scientific assessment is on-going, so this is only a preliminary list of the endpoints being considered: body weight and risk of obesity; fasting glucose/insulin and risk of T2DM; fasting triglycerides; blood pressure/risk of hypertension (under discussion); dental caries. The list could increase as the evidence is evaluated.

Q. Does EFSA look only at total sugars (& not added/free) for caries as all fermentable sugars are cariogenic? (LEIBOVITCH MAJSTER Emilie - European Association of Sugar Manufacturers (CEFS), BE)

A. EFSA looks at all the exposures for which we had eligible studies, which met the inclusion criteria set for the systematic review as defined in the protocol.

Q. Novel Foods: How is it possible to analytically assess the safety and the quality of novel foods? Which can be a basic set of analyses - let's say common to every novel food - to say that they are safe (e.g. allergens? stability tests? microbiological stability? toxicology? etc.) or quality (specific contaminants?). Would it be possible to make such a distinction to help food manufacturers? (CARNIO Silvia - Mérieux NutriSciences, IT)

A. The Panel is assessing the safety and not the quality as such or possible benefits. A NF should be very well characterized, as much as possible. The analyses should include characterization of components of NF, antinutrients, contaminants for at least 5 batches and this number applies also for stability tests. Certificate of analyses, information on source, raw materials, the production process, processing contaminants, existing literature data – all aspects need to be taken into account. All data requirements for safety assessment can be found in the NF Guidance document. It is also recommended to check recent NF Opinions published on the EFSA webpage.

Q. Transparency Regulation: Do you foresee a large change in the process from a review perspective associated with the Transparency Regulation? (MARTYN Danika – Intertek, UK)

A. The Transparency Regulation (TR) will introduce new changes in processes and tools affecting - in particular - stakeholders and business operators involved in the assessment of applications, e.g. Notification of studies, pre-submission advice, disclosure of non-confidential part of applications and subsequent public consultation with third parties will be launched, comments received from public consultation will be considered.
The scientific rigor of the risk assessment will not change, just the processes.

Please refer to:

- an information session of **19 November** for an overview of the processes and administrative requirements introduced by the new regulation;
- Transparency Regulation implementation and stakeholder engagement
- Transparency Regulation Implementation Training Programme

Q. Thank you for the information on the Transparency Regulation. In the EFSA webinar last week it was mentioned that it may not be possible to notify studies from countries with no trade agreement (e.g. possibly the UK). However, I assume there is no change for the Panel in accepting studies, once they are conducted in accordance with the guidance requirements, irrespective of the country? *(*MARTYN Danika - Intertek, UK)

A. It depends on the regulation. For the areas within the NDA Panel remit there are no limitations. The obligation of notification of studies (NoS) is two-fold – the applicant needs to notify the studies no matter whether the applicant is from inside/outside EU since the authorisation would refer to the EU market. Whereas the requirement for laboratories and testing facilities to notify studies commissioned or carried out by them only applies to those in EU and those in third countries insofar as set out in relevant agreements and arrangements with those third countries.

Q. The scope of the definition of a "study" is very broad, while the spirit of the regulation is to increase transparency on safety of regulated products. What would be the added value to include analytical studies for instance? (CHAPPUIS Eric – Lesaffre International, FR)

A. In the interest of transparency, the co-legislators decided that EFSA should have knowledge of all studies performed by an applicant with a view to supporting an application under Union Law. They therefore kept a broader view of studies that need to be notified. Literature studies would be excluded from the notification requirement. As regards additional requirements for food business operators regarding the new TR requirements, the Commission and EFSA are closely cooperating to provide tools to ease the applicant's work.

Q. How do those EFSA communities see the problem regarding food in the pandemic era? Regarding novel food strategies, please share with us your opinion about the application of biotechnologies in order to increase the bio accessibility of some nutrients. Also, how do you see the development in the market of more non-dairy probiotic foods? It is stated that cutting meat consumption will reduce pollution and will increase the chances of having more food available. How do you see this statement? (POP Oana Lelia - University of Agricultural Sciences and Veterinary Medicine (USAMV), Cluj-Napoca, RO)

A. EFSA, as a scientific body provides scientific advice to the European Commission, European Parliament, and the Member States. EFSA does not provide any view on business strategies in the food sector, food policies or recommendations to consumers. EFSA assesses the safety of the products intended to be placed on the EU market and provides general scientific advice to risk managers.