Scientific Panel on Dietetic Products, Nutrition and Allergies

Draft Minutes of the 85th Plenary meeting

Held on 27-29 June 2018, Parma (Italy)

(Agreed on 16 July 2018)

Meeting open to Observers

OPEN SESSION

28-29 June 2018

28 June 2018, 9:00-18:00

29 June 2018, 9:00-13:30

Participants

- Panel Members

  Jean-Louis Bresson, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf[1], Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck (Chair), Henk Van Loveren, Marco Vinceti and Peter Willatts.

- Hearing Experts[2]:

  Not applicable

- European Commission and/or Member States representatives:

  Fruzsina Nyemecz[3] (for items 7.3, 7.4 and 10.2).

- EFSA:

  Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Mathias Amundsen, Janusz Ciok, Agnès De Sesmaisons-Lecarré, Céline Dumas, Lucia Fabiani, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Leonard Matijevic, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

  AMU Unit: Laura Ciccolallo (item 10.2), Laura Martino (items 7.3-7.4), Ana García (item 7.2), Irene Muñoz Guajardo (item 7.2).

[1] Participated via Teleconference on 27 June 2018.
[2] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

DATA Unit: Davide Arcella (items 7.2, 7.3-7.4).

- Observers:

  See Annex III.

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Barbara Burlingame and Yolanda Sanz.

Anders Sjödin did not participate in agenda point 13.2.

2. Brief introduction of Panel members and observers

The Chair welcomed the observers.

All participants and observers were invited to present themselves.

3. Adoption of the agenda

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I.

Oral Declaration of Interest (ODoI) was asked at the beginning of the meeting and no additional interest was declared.

5. Presentation of the Guidelines for Observers

Valeriu Curtui, Head of the Nutrition Unit, presented the code of conduct to be followed by the observers during and after the open plenary meeting.

Observers were given the possibility to raise questions in relation to EFSA's work when submitting their registration. It was indicated that questions would be answered in the dedicated session on the second day of the open session.

It was also indicated that, time permitting, the Chair might grant observers (present in the room and participating via web-streaming) an opportunity to ask

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

additional questions either after they have observed a discussion on a given item or at the end of the Open Plenary meeting in the dedicated session.

6. Report on written procedures since 84th Plenary meeting

The minutes of the 84th Plenary meeting held on 17-19 April 2018 were agreed by written procedure on 25 April 2018.[5]

There were no other written procedures to report to the Panel.

7. Scientific outputs submitted for possible adoption/ endorsement for release for public consultation

7.1. Draft guidance on the scientific requirements for health claims related to muscle function and physical performance (Revision 1, EFSA-Q-2018-00243)

A draft guidance document on the scientific requirements for health claims related to muscle function and physical performance, which updates the existing guidance published in 2011, was presented and discussed.

The Panel took note of the examples of claims evaluated by the NDA Panel (in the context of Article 13(1) claims and health claim applications), which have been used to provide guidance to applicants and to illustrate the scientific requirements for the substantiation of claims in specific areas. The Panel also noted the lack of consensus with respect to the terminology used in sport science. In this context, emphasis was given to define the terms used for the purpose of the scientific evaluation of health claims in the area of muscle function and physical performance, and particularly to characterise the claimed effect, to define the target population and the conditions of use for the claim.

The Panel reviewed the scientific requirements outlined for specific claims addressed in the draft guidance, the appropriate outcome variables/methods of measurement used and the conditions applied in the context of specific claims.

On 28 June, the draft guidance was endorsed by the Panel for release for public consultation to gather inputs from experts in the field of physical performance and stakeholders.

Post-meeting note: The public consultation will be open from 16 July to 2 September 2018 via this link: https://www.efsa.europa.eu/en/consultations/call/180716-0

7.2. Outcome of the public consultation on the draft protocol for dietary sugars (EFSA-Q-2017-00828) and Protocol for the assessment of the mandate on dietary sugars (EFSA-Q-2017-00646)

A technical report on the outcome of a public consultation on the draft protocol for the assessment of the mandate on dietary sugars was presented and discussed. EFSA received comments from 46

[5] https://www.efsa.europa.eu/sites/default/files/event/180417-m.pdf

interested parties. The report summarises the comments received during the public consultation (which was open from 9 January 2018 to 4 March 2018) and how the comments were addressed.

The protocol revised on the basis of the comments received was also presented and discussed. Main changes to the draft protocol were highlighted.

The protocol and technical report were subsequently endorsed by the Panel on 28 June 2018. The full text of both documents will be available in the coming weeks in the EFSA Journal via the following links:

- Protocol: http://www.efsa.europa.eu/en/efsajournal/pub/5393
- Technical report: http://www.efsa.europa.eu/en/supporting/pub/en-1455

It is foreseen that a draft of the scientific opinion on the Tolerable Upper Intake Level of dietary sugars is released for public consultation in the last quarter of 2019.

7.3. Draft technical report on the outcome of the public consultation on the draft opinion on the update of the tolerable upper intake level for vitamin D for infants (EFSA-Q-2018-00286)

A technical report on the outcome of a public consultation on the draft opinion was presented and discussed. EFSA received comments from 4 interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from 18 April 2018 to 23 May 2018) and how the comments were addressed.

Comments that lead to clarifications in the opinion were about the remit of the mandate/EFSA, vitamin D intake from supplementation, factors influencing serum 25(OH)D concentration, effects of genotypes, adverse health outcomes considered, 'high' serum 25(OH)D concentration, the UL for infants aged 6-12 months, and consumption levels of formulae. The reasons why no changes were applied to the scientific opinion following other comments received were also explained.

The technical report was subsequently endorsed by the Panel on 28 June 2018. The full text will be available in the coming weeks in the EFSA Journal, together with the related opinion, via the following link: http://www.efsa.europa.eu/en/supporting/pub/en-1456

7.4. Draft opinion on the update of the tolerable upper intake level for vitamin D for infants (EFSA-Q-2017-00208)

Following the public consultation on the above-mentioned draft opinion, relevant comments received (as outlined and discussed under item 7.3) were taken into consideration in a revised draft document.

A UL is the maximum level of total chronic daily intake of a nutrient from all sources judged to be unlikely to pose a risk of adverse health effects in humans. The advice requested should help the European Commission establishing the safest maximum content of vitamin D of formulae consumed by infants. In 2012, EFSA provided advice on ULs for vitamin D for all population and age groups, including infants. At that time, a UL of 25 µg/day was retained for infants from 0 to 12 months of age.

This present document addresses new evidence on 'high' daily vitamin D intake and adverse health outcomes in healthy infants (0-<1 year). It includes hazard characterisation of 'high' vitamin D intake including in particular a quantitative assessment of the dose response relationship between daily supplemental vitamin D intake and serum 25(OH)D concentration in infants, the assessment of daily vitamin D intake in infants in Europe according to different intake scenarios, and the characterisation of the risk.

The draft opinion was adopted by the Panel on 28 June 2018. The full text will be published in the EFSA Journal via the following link: http://www.efsa.europa.eu/en/efsajournal/pub/5365

8. New Mandates

The Nutrition Unit updated the Panel members on new mandates received since the last Plenary meeting.

- **Health claims**

  One Article 13.5 application (claim based on newly developed science and/or which include a request for the protection of proprietary data) was received: "Regular consumption of green kiwifruit contributes to gastrointestinal comfort" (EFSA-Q-2018-00416). This request will be assigned to the working group (WG) on claims

  One Article 13.5 application related to "*Lactobacillus plantarum* 299v increases non-heme iron absorption" was withdrawn (EFSA-Q-2017-00820) (see Agenda item 13.2).

- **Novel Foods and Nutrient Sources**

  Two new requests related to novel foods pursuant to Article 10 Regulation (EU) 2015/2283 were received from the Commission: "Xia Powder 125, a partially defatted chia seed powder" (EFSA-Q-2018-00373); "Bacterial cellulose aqueous suspension" (EFSA-Q-2018-00294). These requests will be assigned to the working group on novel foods.

  Three nutrient sources will be transferred from ANS panel to NDA panel as of 1st July 2018: Selenium triglycerides, Magnesium citrate malate, Inositol stabilised arginine silicate. These requests will also be assigned to the working group on novel foods.

- **Traditional Foods from Third Countries**

  One notification for the placing on the market of traditional foods from third countries pursuant to Article 14 of Regulation (EU) 2015/2283 was received from the Commission: "Sorghum syrup" (EFSA-Q-2018-00342). The request will be assigned to the EFSA working group on traditional foods from third countries.

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

9.1. Scientific Committee (SC)

The Panel's Chair reported back from the SC Plenary meeting of 28-29 May 2018[6].

The SC endorsed for release for public consultation the draft guidance on risk assessment of chemical mixtures, and the draft statement on genotoxicity assessment of chemical mixtures.

The SC endorsed for publication the draft technical report on the activities of the Standing Working Group on Emerging Risks, and the SC comments on the draft EFSA-ECHA guidance for the implementation of the hazard-based criteria to identify endocrine disruptors.

The draft guidance on risk assessment of nanotechnologies was endorsed for a piloting phase (i.e. to test the guidance with the relevant EFSA Panels and Units).

9.2. EFSA including its Working Groups/Task Forces

The Chairs of respective WGs reported back to the Panel:

- ***WG on Claims*** – The draft guidance on the scientific requirements for health claims related to physical performance including muscle function was discussed (see item 7.1). The WG also discussed and elaborated on three draft opinions related to: "Symbiosal" (Art. 14, EFSA-Q-2018-00002, see item 13.1), "*L. plantarum* 299v increases non-heme iron absorption" (Art. 13.5, EFSA-Q-2017-00820, see item 13.2), and "Fibersol-2" (Art. 13.5, EFSA-Q-2018-00065). Two were subject to the stop-the-clock procedure for requesting supplementary information from the applicants.

- ***WG on Novel Foods*** - The WG discussed/elaborated on draft opinions on the following Novel Food applications: Whey protein isolate (EFSA-Q-2018-00104), Xylo-oligosaccharide (EFSA-Q-2017-00665), Allanblackia seed oil (EFSA-Q-2018-00226), Egg membrane (EFSA-Q-2018-00103). They were submitted to this plenary for possible adoption (see items 13.3, 13.4, 13.5 and 13.6, respectively. The WG also discussed the draft call for data related to Astaxanthin (EFSA-Q-2018-00247) (see item 10.3).

[6] https://www.efsa.europa.eu/sites/default/files/event/20180528-m.pdf

- ***WG on Infant Nutrition*** - The WG discussed the studies which were identified as related to growth, overweight and obesity, and body composition. The draft opinion was discussed and elaborated (EFSA-Q-2016-00482) (see item 10.2).

- ***WG on DRVs for vitamins*** - The WG discussed the comments received from public consultation and elaborated the scientific opinion on the tolerable upper intake level (UL) for vitamin D in infants in view of its submission to the panel for possible adoption (see items 7.3 and 7.4).

- ***WG on DRVs for minerals*** – The WG is currently implementing the systematic review on sodium intake and health outcomes (see item 10.1).

- ***Scientific Committee WG on Genotoxicity*** - Karen Ildico Hirsch-Ernst (member of the WG) informed the panel that the WG was working on the updated draft statement on how to assess genotoxicity of chemical mixtures, in view of submitting it to the SC plenary meeting scheduled for 28-29 May for endorsement for release public consultation (see item 9.1).

9.3. European Commission

Not applicable.

10. Other scientific topics for information and/or discussion

10.1. Draft Scientific Opinion on dietary reference values (DRVs) for sodium (EFSA-Q-2011-01224)

An update on the development of the Opinion was presented to the Panel. Systematic reviews are being performed on the relationships between sodium intake and i) cardiovascular diseases outcomes and ii) bone-related outcomes (see protocol[7]). The literature searches, selection of pertinent studies and appraisal of their internal validity (risk of bias assessment) have been completed by the WG on DRVs for minerals. In the second part of the year, results will be analysed and synthesised, together with related uncertainties, and the evidence will be integrated in order to set DRVs for sodium. The WG aims to submit its finalised draft Opinion to the Panel in January 2019 for possible endorsement for release for public consultation.

The Panel was also informed about the status of the related Opinion on DRVs for chloride. Available evidence is insufficient to determine chloride requirement. Values are likely to be set on an equimolar basis with sodium values, in the light of available data on sodium and chloride intakes and urinary excretion levels in European populations.

[7] https://zenodo.org/record/1116290#.WtXT1cNua02

10.2. Draft Scientific Opinion on the appropriate age of introduction of complementary feeding into an infant's diet (EFSA-Q-2016-00482)

The context of the mandate received from the European Commission and the current status of the assessment were presented to the Panel. Topics presented were: the main conclusions, outcomes discussed and the approach applied in the opinion on complementary feeding of 2009 that EFSA is requested to update; the regulatory framework; the definition of what constitutes complementary feeding and the remit of the mandate; on-going discussions on complementary feeding by other scientific or regulatory bodies.

The approach applied to address this mandate was also presented e.g. literature search and selection, eligibility criteria, appraisal of the selected studies, data extraction, data visualisation in particular for endpoints such as weight-for-age z-scores, body mass index z-scores, chance of being at least overweight or chance of being obese. Endpoints related to the outcomes growth, overweight/obesity, body composition, food patterns/preferences and feeding disorders have been covered already by the working group on infant nutrition. The next outcome to be addressed will be allergy.

10.3. Safety of Astaxanthin (EFSA-Q-2018-00247)

EFSA was requested by the European commission to evaluate whether the safety of astaxanthin as a novel food used in food supplements at maximum levels of 8 mg/days is still in accordance with the requirements of Regulation (EU) 2015/2283, taking into account the overall, cumulative intakes of astaxanthin from all sources, including from its approved uses in foods. EFSA was asked to solicit and make use of the most recent toxicological and exposure evidence, which may be available to business operators and in the public domain.

To this end, EFSA will be launching a call for data, which aims to provide the opportunity for stakeholders and other interested parties to submit studies (published, unpublished or newly generated) relevant for the evaluation of the safety of astaxanthin. In particular, EFSA seeks data which may be suitable to confirm or amend the ADI established by EFSA in 2014.

The panel took note of the draft call for data and the specification of the information/type of data sought that are relevant for the safety assessment of astaxanthin in the framework of Regulation 2283/2015.

The call for data will be open in the coming weeks via the following link: http://www.efsa.europa.eu/en/calls/data

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

Observers present in the room and participating via web-streaming were given the possibility to ask questions. Please refer to Annex II.

12. Any other business

- The chair closed the last NDA Plenary in this mandate (2015-2018) expressing his great appreciation to all members of the NDA Panel and the Nutrition Unit for their hard work and high commitment.

- The inaugural meeting of the NDA Panel for 2018-2021 is scheduled to take place on 3-5 July 2018 in Parma.

- The Chair closed the meeting by thanking the participants and the observers for their contributions.

CLOSED SESSION

27 June 2018, 9.00-18.00

Items for Closed Session owing to confidential business information/proprietary data

13. Scientific outputs submitted for possible adoption

Applications pursuant to Article 14/13.5 of Regulation (EC) No 1924/2006

13.1. Han-Asiabiotech GmbH – "Symbiosal and lowering the rise of blood pressure when used as a replacement to table salt. The rising of blood pressure is a risk factor for hypertension" (Art. 14, 0467_DE, EFSA-Q-2018-00002)

The draft opinion elaborated by the WG Claims was presented. The Panel reviewed the sections on characterisation of the food, the claimed effect, and the section on the substantiation of the claim. The pertinent human studies were considered and discussed. One of the studies, which was already assessed by the Panel in the previous opinion, has been re-assessed based on experience gained by the Panel with the evaluation of claims.

The draft opinion was discussed and adopted by the Panel on 27/06/2018. 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/5364

13.2. Probi AB - "*Lactobacillus plantarum* 299v increases non-heme iron absorption" (Art. 13.5, 0466_SE, EFSA-Q-2017-00820)

The Panel was updated on the outcome of the 5-6 June WG Claims meeting regarding this application.

During its last meeting, the WG Claims re-discussed the new evidence (an unpublished study) submitted in the present application, which was intended to address the previous reservations of the Panel (dated 2016) that a time effect on iron absorption in non-randomised studies with a sequential administration of the control and the intervention food may not be excluded[8].

The WG decided to re-analyse the data provided in the unpublished study. Contrary to previous assumptions that recovery rates for the two iron radio isotopes used were similar, the re-analysis carried out by EFSA showed different recovery rates in this study. A second stop-the-clock procedure was applied to seek clarification from the

[8] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016c. Lactobacillus plantarum 299v and an increase of non-haem iron absorption: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2016;14(7):4550, 12 pp. doi:10.2903/j.efsa.2016.455

applicant on how this study could still be used to address the previous reservations of the Panel.

On 25 June, upon a request from the applicant, the competent authority where the application was submitted, requested EFSA to withdraw the application.

Subsequently, the Panel took note of the withdrawal of this application and did not proceed with the adoption of the opinion.

Novel Foods

13.3. Armor Protéines S.A.S.– Draft opinion on Whey protein isolate (EFSA-Q-2018-00104)

The draft scientific opinion on whey basic protein isolate elaborated by the WG on Novel Foods was presented. The Panel reviewed the sections on the identity, production process, composition and specifications of the NF. The intake assessment and proposed uses were also considered by the panel. The absorption, metabolism and excretion and its nutritional impact to the diet, toxicological and human studies were reviewed by the Panel. One developmental study in rats was also discussed.

The draft opinion was discussed and adopted by the Panel on 27/06/2018. 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/5360

13.4. Longlive Europe Food Division Ltd – Draft opinion on Xylo-oligosaccharide (EFSA-Q-2017-00665)

The draft scientific opinion on xylo-oligosaccharides elaborated by the WG on Novel Foods was presented. The Panel reviewed the sections on the identity of the NF, the production process, composition and specifications of the NF. The Panel also considered the proposed uses and use levels for the NF, its absorption, metabolism and excretion and its nutritional impact to the diet. Toxicological and human studies were reviewed.

The draft opinion was discussed and adopted by the Panel on 27/06/2018. 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/5361

13.5. Unilever NV/Unilever PLC – Draft opinion on Allanblackia seed oil (EFSA-Q-2018-00226)

Commission Decision 2008/559/EC authorised, in accordance with Regulation (EC) No 258/97 and following EFSA's Opinion[9], the placing

[9] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2007. Safety of *Allanblackia* seed oil for use in yellow fat and cream based spreads, EFSA Journal (2007) 580, 1-10.

on the market of Allanblackia seed oil as a novel food (NF) ingredient to be used in yellow fat spreads and cream based spreads.

In this present application, the applicant seeks (1) to increase the authorised maximum use level in yellow fat spreads and cream based spreads, and (2) the use of this NF in mixes of vegetable oils and milk up to a proposed maximum use level. In addition, (3) the applicant also proposes some changes in the specifications of the NF.

The Panel reviewed the sections related the proposed changes in the specification, the proposed increase the maximum use level, and the intake estimates.

The draft opinion was discussed and adopted by the Panel on 27/06/2018. 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/5362

13.6. Biova LLC - Egg membrane hydrolysate (EFSA-Q-2018-00103)

The draft scientific opinion on egg membrane hydrolysate elaborated by the WG on Novel Foods was presented. The Panel reviewed the sections on the identity of the NF, the production process, composition and specifications of the NF. The Panel also considered the history of use of the source of the NF, the proposed use (i.e. as a food supplement in adults) for the NF, its potential nutritional impact to the diet, toxicity, available human data and allergenicity.

The draft opinion was discussed and adopted by the Panel on 27/06/2018. 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/5363

14. Other scientific topics for information and/or discussion (cont.)

14.1. Cranberry' extract powder as a novel food pursuant to Article 26(2)(c) of Regulation (EU) 2015/2283 – proprietary data (EFSA-Q-2016-00325)

A scientific opinion on Cranberry extract powder as a novel food (NF) was adopted by the Panel on 4 April 2017[10].

Following the entry into force of the new NF Regulation (EU) 2015/2283, the European Commission requested EFSA to evaluate whether and if so, to what extent, the requirements of Article 26(2)(c) of the NF Regulation are fulfilled, i.e. whether the NF could not have been assessed by EFSA without the scientific evidence or data requested to be protected by applicants.

The Panel noted that in elaborating its opinion on cranberry extract powder as a NF[10], the compositional information (Table IX.b-1 Original application

[10] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4777

dated June 2011, page 24) was needed for the characterisation and setting of specifications of the NF, as well as for hazard identification.

The Panel also noted that the intake estimate on cranberry beverage consumption (File: "Ocean Spray's response to Member States' objections, dated November 2015") was needed to assess whether the potential intake of proanthocyanidines (PAC) from the NF is comparable to the PAC intake from the consumption of cranberry juice products.

The Panel considered that the conclusions on the safety of the NF, Cranberry extract powder, could not have been reached without the compositional information (Table IX.b-1 Original application dated June 2011, page 24), and the intake estimate on cranberry beverage consumption (File: "Ocean Spray's response to Member States' objections, dated November 2015"), which were requested to be protected by the applicant.

The request from the European Commission and the reply from EFSA for Cranberry extract powder are available in the Register of Questions (EFSA-Q-2016-00325).

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting, Dr. Anders Sjödin declared the following interest: "*Lactobacillus plantarum* 299v increases non-heme iron absorption" (EFSA-Q-2017-00820)" (item 13.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[11] and the Decision of the Executive Director on Declarations of Interest[12], and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 13.2 by the concerned scientific group.

[11] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[12] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014

Annex II

Answers to questions from observers

A dedicated session was organised in order 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.

Name	Questions (PRE-submitted and received via web-streaming)	EFSA reply
Yasin TÜLÜCE Professor - medical faculty of the University of Van Yuzuncu Yil	"is this bacterium (Lactobacillus plantarum 299v) effective in correcting anemic conditions seen in humans?"	***By Alfonso Siani***: The evidence available so far did not substantiate the claimed effect.
Emilie Leibovitch Majster CEFS, the European association of sugar manufacturers	"We note that the newly updated EFSA Comprehensive European Food Consumption Database still does not contain all of the surveys that were notably sent in the context of the public consultation on the free sugars mandate. How were surveys selected to appear in this version of the database and when is a new update of the database planned?"	***By Davide Arcella***: National Competent Authorities of European countries are regularly requested to submit food consumption data (at individual level) from national surveys, and EFSA contributes financially to this. The EFSA's Comprehensive European Food Consumption Database contains all surveys submitted. For the opinion on sugars, all surveys received by December 2018 will be used. For the 12 countries from which the data come from, please refer to the protocol and technical report (see Agenda item 7.2).
Luz mar Campos	"El freido al vacio, es la solucion a la disminucion de ingesta de grasas saturadas?" [EN translation: *Is the vacuum frying the solution to reducing the saturated fat intake*?]	***By Valeriu Curtui***: This question is outside the remit of the NDA Panel. The requestor is invited to submit this question to ASK EFSA (ask@efsa.europa.eu)
Kate Trolloppe EU Food Policy	"The European Commission proposal to amend the General Food Law (178/2002) foresees meetings between EFSA and applicants. What would these meetings cover and how far would you go on advising individual companies on scientific studies they need to carry out, particularly in the area of health claims"?	***By Valeriu Curtui /some Panel Members*** For the first question, it is suggested to wait for the adoption of the European Commission proposal. Regarding the outcome of EFSA assessment on the two traditional foods from third countries, please refer to EFSA technical Reports which will be

Name	Questions (PRE-submitted and received via web-streaming)	EFSA reply
	"Were the two traditional foods completed by yesterday regarded as safe?"	published in the coming weeks on EFSA webpage. It should be noted, a Member State or EFSA may submit to EC duly reasoned safety objections to the placing on the market within the EU of the traditional food concerned.
Isabelle Caelen Nestlè	"Could you reprecise the workplan and timelines regarding the Opinion on age of introduction of complementary feeding?"	***By Ariane Titz***: EFSA is currently discussing with the European Commission about the feasible deadline for delivering the final output.
LIU Yening Chiesi Farmaceutici SPA	"Several products like those assessed under the Novel Foods regulation (e.g. chia seeds) or assessed for Claims are already in the market. What happens if there is a negative outcome by EFSA? In China, there is a big issue with food products used as food supplements. Products that have no official authorisation are already in the market, and people buy them, because some beneficial properties have been traditionally attributed to these products. However, no official scientific proof exists. Is there any kind of bridge in order to bring the scientific opinion to the consumers? Are there any instruments to regulate the market?"	***By Valeriu Curtui***: In the EU, to place a new food supplement on the market, the procedure requires the applicant to submit a notification to a Member State. If it falls under NF regulation- The applicant should submit an application for authorisation to the Commission and the safety of the NF should be assessed by EFS. For making claims (beneficial effects) in the EU, an application for authorisation should be submitted via a Member State, who will then forward it to EFSA for scientific evaluation (Efficacy assessment). Only authorised health claims (favourable opinion) can be made on foods. In the EU there are 2 relevant/separate regulations, NF and claims. National competent authority control the use of claims in Member State (e.g. in the UK the trading standards office - the authority responsible to ensure removing the product from the market)
ZARA LUCIAN VALERIAN	1) "How can EFSA stop me from selling honey poisoned with amine salt? When the	***By Valeriu Curtui***: Question 1) is outside the remit of EFSA and the NDA Panel. The

Name	Questions (PRE-submitted and received via web-streaming)	EFSA reply
Farmer	Public Health Directorate of Romania says that amine salt is good for the population!" 2) "I have a question, If a study on sugar toxicity and toxicity effects on bees, and residues that remain in the honey" 3) "It can be removed from the process of making sugar, sulfuric acid and calcium carbonate?"	requestor is invited to refer this question to the Competent Authority of the Member State where the honey is marketed. Questions 2) and 3) are outside the remit of the NDA Panel. The requestor is invited to submit this question to ASK EFSA (ask@efsa.europa.eu)

Annex III

List of observers

Observers who attended the open plenary on-site		
Observer	**Company**	**Country**
BATTAGLIA Ivano[#]	LabService Analytica Srl	IT
FREGA Fernando[#]	Senasa argentina	AR
GEISER Stefanie[*]	EAS Strategies	BE
KEBEDE Abriham[#]	Lecturer	ET
KRUMA Zanda[#]	Latvia University of Life Sciences and Technologies	LV
LAVIGNE Xavier	Abbott	BE
LEITE Alessandra[#]	INP	PT
LIU Yening	Chiesi Farmaceutici SPA	IT
MANINI Federica	Soremartec Italia Srl	IT
METO Suada[#]	A. Menarini Farmaceutica Internazionale	IT
NIKOLIC Marina	Institute for Medical Research, University of Belgrade	RS
SOCZEWINSKA Joanna	USP Zdrowie Sp. z o.o.	PO
TOIA Silvia	GB foods	IT

 # Registered but did not attend

*** Physically attended on the 1st day, attended via web-streaming the 2nd day**

Observers who attended the open plenary via web-streaming		
Observer	**Company**	**Country**
AL HUNAITI Omar[#]	n/a	JO
BALDWIN Nigel	Intertek	UK
BERTIN Barbara	n/a	IT
BONOVALIAS Ioannis[#]	University of Thessaloniki	GR
BRADFORD Lisa[#]	University College Dublin	IE
BROENSTRUP ANJA	Federal Ministry for Food and Agriculture	DE
CAMPOS Luz Mar[#]	n/a	BO
CAELEN Isabelle	Nestlè	CH
CHINEDU Enegide[#]	Self-employed	NI
COGALNICENAU Elena	EAS Strategies	BE
DE LA IGLESIA Rocío[#]	IMDEA Food	ES
De HAUTECLOCQUE Laure	Specialised Nutrition Europe	BE
DESALLES Robin	UP International SA	CH
ECONOMOU Vangelis[#]	University of Thessaloniki	GR
GEISER Stefanie[*]	EAS Strategies	BE
HAGEN Erik	The Stakeholder Company (TSC)	SG
HOBAYAN Noreen	Glanbia Nutritionals	US
HUJA Roxana[#]	n/a	NL
HUNT Emma[#]	Wassen International Ltd.	UK
JAEKEL Elisa	HiPP Werk OHG	DE
JOST-LEDERMANN Laura	LALLEMAND Health Solutions	FR

Observers who attended the open plenary via web-streaming		
Observer	**Company**	**Country**
KALOGIANNIS Stavros[#]	Alexander Technological Educational Institution of Thessaloniki	GR
KIRSE Asnate[#]	Latvia University of Life Sciences and Technologies	LV
KOZBUR Ivana[#]	n/a	HR
KRISHNAPUR Suvrnarajesh[#]	n/a	IN
KUCI Orjeta[#]	Synadiet	FR
LAMBERG-ALLARDT Christel[#]	University of Helsinki	FI
LE BRUCHEC Solenn	Regulations Nutrition International (RNI)	FR
LEIBOVTCH MAJSTER Emilie	European Association of Sugar Manufacturers (CEFS)	BE
LEWIS Sara[#]	European Food Law (Freelance)	BE
LUCIAN VALERIAN Zara	n/a	RO
MALIK Farrah	Perrigo	UK
MATTISSON Irene[#]	Swedish National Food Authority	SE
MIKS Marta	Glycom A/S	DK
MULLEE Amy	University College Dublin	IE
NDIKURIYO Pascal[#]	Burundi National Centre of Food Technology	BI
NEHIR EL Sedef	Ege University	TR
OMBREDANE Manon[#]	Keller and Heckman LLP	BE
ONO Kaori[#]	Ajinomoto Europe	FR
OZNUR Fulya	Turkish Ministry of Food and Agriculture	TR
PAGEREY Marie-France	NESTEC SA	CH
PRZYTUŁA-TOMKIEWICZ Marta[#]	EGIS Poland	PL

Observers who attended the open plenary via web-streaming		
Observer	**Company**	**Country**
RESPONDEK Frederique	Tereos	FR
SAHA Arpita#	Intertek	CA
TORRES Beatriz#	Industrial and Financial Systems (IFS)	DE
TROLLOPE Kate	EU Food Policy	UK
TROY Amy-Jane	European Federation of Associations of Health Product Manufacturers (EHPM)	BE
TÜLÜCE Yasin#	University of Van Yuzuncu Yil	TR
VELIAJ Ina#	EMT	AL
WANG Siqi#	Student	NO
WILLIAMS Dustin	Joschka Fischer & Company	DE

 # Registered but did not connect
*** Physically attended on the 1st day, attended via web-streaming the 2nd day**