Scientific Panel on Dietetic Products, Nutrition and Allergies

Draft Minutes of the 78th Plenary meeting

Held on 4-6 April 2017, Parma (Italy)

(Agreed on 13 April 2017)

Meeting open to Observers

OPEN SESSION

5-6 April 2017

5 April 2017, 9:00-18:00

6 April 2017, 9:00-13:30

Participants

- Panel Members

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

- Hearing Experts[2]:

  Ursula Gundert-Remy (for item 10.1);

  David Gott (for item 10.1)

- European Commission and/or Member States representatives:

  Olga Goulaki[3] (for items 13.1-13.3), Rafael Pérez Berbejal[3] (for items 13.4-13.6), Francesco Carlucci[3] and Fruzsina Nyemecz[3] (for items 7.1-7.4).

- EFSA:

  Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Céline Dumas, Agnès De Sesmaisons-Lecarré, Lucia Fabiani, Krizia Ferrini, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

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[1] Participated on 4-5 April

[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

[3] Participated via Tele-conference

FIP Unit: Camilla Smeraldi (for item 10.1)

- Observers:

  See Annex I.

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Barbara Burlingame, Grazyna Nowicka, Martin Stern and Peter Willatts.

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[4] and the Decision of the Executive Director on Declarations of Interest[5], 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. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

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

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

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

6. Report on written procedures since 77th Plenary meeting

The minutes of the 77th Plenary meeting held on 31 January–2 February 2017 were agreed by written procedure on 8 February 2017.[6]

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 technical report on the outcome of the public consultation on the draft scientific opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal (EFSA-Q-2016-00860)

A technical report on the outcome of a public consultation on a draft opinion on the safety and suitability for use by infants of a follow-on formulae with a protein content of at least 1.6 g/100 kcal was presented and discussed. EFSA received comments from six interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from 13 January to 3 March 2017) and how the comments were addressed. It was subsequently endorsed by the Panel on 5 April.

The full text of the technical report will be available in the coming weeks in the EFSA Journal, under the related opinion, via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4781/abstract (see also item 7.2).

7.2. Nestlé Nutrition – Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal (EFSA-Q-2016-00275)

Following the public consultation on the above-mentioned draft opinion, relevant comments received (as outlined and discussed under item 7.1) were taken into consideration in a revised draft document. In this opinion**,** the Panel concludes that the use of follow-on-formulae (FOF) with a protein content of at least 1.6 g/100 kcal from either intact cow's milk protein or intact goat's milk protein otherwise complying with the requirements of relevant EU legislation is safe and suitable for healthy infants living in Europe with an intake of complementary foods of a sufficient quality. This conclusion does not apply to infant formulae (IF). The Panel also concludes that the safety and suitability of FOF with a protein content of at least 1.6 g/100 kcal manufactured from either protein hydrolysates or soy protein isolates cannot be established with the available data. The same conclusion applies to IF. The draft opinion was adopted by the Panel on 5 April subject to the incorporation of editorial changes.

[6] https://www.efsa.europa.eu/sites/default/files/event/170131-m_2.pdf

The full text will be published in the EFSA Journal via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4781/abstract

7.3. Draft technical report on the outcome of the public consultation on the draft scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (EFSA-Q-2016-00300)

A technical report on the outcome of a public consultation on the draft guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates was presented and discussed. EFSA received comments from seven interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from 13 January to 3 March 2017) and how the comments were addressed. It was subsequently endorsed by the Panel on 5 April.

The full text of the technical report will be available in the coming weeks in the EFSA Journal, under the related opinion, via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4779/abstract (see also item 7.4).

7.4. Draft scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (EFSA-Q-2016-00276)

Following the public consultation on the above-mentioned draft guidance, relevant comments received (as outlined and discussed under item 7.3) were taken into consideration in a revised draft document. This guidance document addresses the information and data to be submitted to EFSA on infant and follow-on formulae manufactured from protein hydrolysates with respect to the safety and suitability of the specific formula and/or the formula's efficacy in reducing the risk of developing allergy to milk proteins. The draft guidance was adopted by the Panel on 5 April subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4779/abstract

7.5. Draft technical report on the outcome of the public consultation on Dietary Reference Values for Vitamin K (EFSA-Q-2015-00669)

A technical report on the outcome of a public consultation on a draft Opinion related to the dietary reference values for vitamin K was presented and discussed. EFSA received comments from 43 interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from

13 January to 24 February 2017) and how the comments were addressed. It was subsequently endorsed by the Panel on 5 April.

The full text of the technical report will be available in the coming weeks in the EFSA Journal, under the related opinion, via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4780/abstract (see also item 7.6).

7.6. Draft opinion on Dietary Reference Values for vitamin K (EFSA-Q-2011-01232)

Following the public consultation on the above-mentioned draft Opinion, relevant comments received (as outlined and discussed under item 7.5) were taken into consideration in a revised draft document. This document proposes dietary reference values for vitamin K for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel on 5 April subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4780/abstract

7.7. Draft opinion on Dietary Reference Values for riboflavin (EFSA-Q-2011-01222)

On 5 April, the draft opinion was introduced and discussed. This document proposes dietary reference values for riboflavin for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to editorial changes. The public consultation will be launched in the next few weeks via the following link: http://www.efsa.europa.eu/en/calls/consultations.

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: "Dietary Menaquinone-7 (MK-7) helps promote cardiovascular health via the activation of matrix Gla protein (MGP), a natural inhibitor of vascular calcification" (EFSA-Q-2017-00235).

  The Panel took note that the WG on Claims has initiated the updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094).

- **Novel Foods**

  The Panel took note that EFSA's Advisory Forum agreed at its 63rd meeting held on 7-8 March 2017 to the creation of a Scientific Network in the area of Novel Foods. The role of the NF Network is to provide a platform for scientific cooperation between risk assessors of the EU Member States and EFSA in collaboration with the European Commission (EC), and to enhance risk assessment practices in the areas of novel foods including traditional foods from third countries in the framework of Regulation (EU) 2015/2283. The Terms of Reference will be published on EFSA's website as soon as they are accepted.

  EFSA will be launching a call in June 2017 for contracting the preparatory work to support EFSA activities on novel foods. The successful candidate(s) may operate on the contract as of January 2018.

- **Tolerable upper intake level (UL) of vitamin D for infants**

  The Panel also took note of a new request received from the European Commission for a scientific opinion on UL for vitamin D for infants (EFSA-Q-2017-00208). The Panel agreed to assign this mandate to the standing WG (SWG) on Dietary Reference Values (DRVs) for vitamins. Owing to the cross-cutting issues and to better undertake all necessary preparatory tasks in relation to drafting the scientific output for this mandate, it was proposed to the SWG on DRVs to involve the SWG on Infant Nutrition, and to convene joint meetings involving some experts from both SWGs, as appropriate.

- **Added sugars**

  The Panel was provided with an update regarding the request from five Nordic Competent Authorities for EFSA's scientific advice related to added sugars (EFSA-Q-2016-00414, see also the minutes of its 74th[7] and 77th[8] plenary meetings). EFSA will establish an ad-hoc working group with expertise in epidemiology, dietary intake and patterns, diet-related metabolic diseases, dental health and human psychology (on the role of central effects of food and drive to eat). The five Nordic countries that initiated this mandate will be invited to the working group as observers. EFSA will be applying the PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments) approach to develop a protocol on how to carry out the assessment, how EFSA selects evidence, how this evidence contributes to the risk assessment and how EFSA reports on the entire process and its results. In line with its commitment to openness and transparency, EFSA will be engaging with stakeholders throughout the assessment process. It will hold two public consultations, inviting feedback on the draft protocol in the first half

[7] https://www.efsa.europa.eu/sites/default/files/event/160921a-m.pdf

[8] https://www.efsa.europa.eu/sites/default/files/event/170131-m_2.pdf

of 2018 and on the draft opinion in late 2019, which will also involve a face-to-face meeting with stakeholders.

In consultation with the Nutrition Unit, the NDA Panel chair proposed the nomination of Marco Vinceti as the chair of the ad-hoc working group on added sugars, who has accepted his nomination subject to further verification on compliance with EFSA's Independence policy and rules.[9]

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

9.1. Scientific Committee (SC)

The SC has released for public consultation two draft guidance documents on the Weight of Evidence approach and Biological Relevance. Public consultation will close on 1st May 2017: http://www.efsa.europa.eu/en/consultations/call/170306, http://www.efsa.europa.eu/en/consultations/call/170306-0.

The SC also adopted an opinion on "Scientific motivations and criteria to consider updating EFSA scientific assessments".

9.2. EFSA including its Working Groups/Task Forces

- WG on Claims – Draft opinions related to six Art. 13(5) and three Art. 14 claims were discussed/elaborated. The "stop-the-clock" procedure for requesting supplementary information from the applicant was applied for six applications. Three opinions were submitted to this Plenary for possible adoption (see items 13.1, 13.2 and 13.3). The working group discussed the case study related to 'soy isoflavones and maintenance of bone mineral density (ID 1655)' for the uncertainty exercise, and also the updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094).

- WG on Novel Foods - The WG discussed/elaborated on draft opinions on the following Novel Food applications: Alginate-Konjac-Polysaccharide complex (see item 13.4), Cranberry extract (see item 13.5), Estrog-100™ (see item 13.6), betaine, N-acetyl-D-neuraminic acid, Hoodia parviflora, pyrroloquinoline quinone disodium salt, and methylnicotinamide chloride. New applications received were presented. WG Experts and Nutrition Unit staff shared comments and views following the Info Session on Novel Foods which took place on 6th March 2017 in Parma (see item 12).

- WG on Infant Nutrition - The WG discussed/elaborated on: the outcome of the Public Consultation on the draft Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with

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

a protein content of at least 1.6 g/100 kcal (see item 7.1), on the Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal (see item 7.2), on the Outcome of the Public consultation on the draft Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formulae manufactured from protein hydrolysates (see item 7.3), and on the Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (see item 7.4).

- WG on DRVs for vitamins – The WG has been working on vitamin K, taking into consideration comments received from public consultation (see items 7.5-7.6), and riboflavin (see item 7.7).

- WG on DRVs for minerals – The WG has been working on the draft protocol (applying the PROMETHEUS approach) for DRVs for sodium, i.e. to certain sections of the opinion related to sodium and health consequences. It is targeted to release the protocol for public consultation by autumn 2017.

9.3. European Commission

Not applicable.

10. Other scientific topics for information and/or discussion

10.1. ANS Panel's draft guidance for the safety evaluation of sources of nutrients (EFSA-Q-2016-00150)

The Chair of the ANS WG on Nutrient sources guidance gave a presentation on the draft guidance, clarifying the scope, the background, and the approach used by the ANS Panel for the assessment of the safety and bioavailability of nutrient sources.

In the light of the upcoming transfer of the evaluation of nutrient sources and other substances with physiological effects added to food from the ANS Panel to the NDA Panel as of 1st July 2018[10], the importance of consulting the NDA Panel on the draft guidance was highlighted.

The Panel was invited to provide comments on the draft guidance to the ANS Working Group on Nutrient Sources before September 2017. The draft guidance is foreseen for endorsement for release for public consultation by the ANS Panel in Autumn 2017.

[10] Commission Regulation (EU) 2017/228 of 9 February 2017 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority. OJ L 35, 10.2.2017, p. 10–11.

10.2. Testing applicability of the Guidance on uncertainty in EFSA scientific assessment (EFSA-Q-2013-00738)

The Chair of the WG on Claims reported to the Panel the outcome of the testing of the applicability of the draft Guidance on uncertainty using an evaluated health claim on "soy isoflavones and maintenance of BMD in post-menopausal women (ID 1655)" as a case study. The process applied to identify and assess sources of uncertainty, the methods used, and the involvement of experts individually and collectively to derive the conclusion were depicted. The overall experience drawn from the case study was highlighted. Positive findings include a structured approach in complex assessment, transparency of the process, and greater confidence in drawing conclusions. Negative findings include the amount of time needed and resource limitations, which may be unnecessary for simple assessments. The Chair pointed out that the need to ensure fair treatment among applications should be taken into consideration.

Representatives from all the case studies (from different Panels) have been invited to an internal workshop that will take place on 22-23 June to present the outcome of the testing phase and discuss how to improve the guidance.

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

- EFSA Info session on Novel Foods **-** On 6 March 2017, EFSA held an info session on the preparation and safety assessment of applications for novel foods[11]. About 130 participants, including applicants, industry associations, consultants, representatives of national competent authorities from/and outside Europe and academics met with experts of the WG on Novel Foods, EFSA Scientific Officers and the European Commission representative. Attendees participated actively in the discussions and considered the meeting as an important opportunity to enhance constructive dialogue and increase engagement with EFSA. The Panel took note of the survey from the participants, with 94% rating the content of the Info session as good to excellent.

- Management Board (MB) Decision on the establishment and operation of the Scientific Committee, Scientific Panels and their Working Groups[12] **-** The Panel was informed that the MB endorsed changes to the way EFSA's Scientific Committee, its Scientific Panels

[11] https://www.efsa.europa.eu/en/events/event/170306

[12] http://www.efsa.europa.eu/sites/default/files/mb170322-a4.pdf

and Working Groups are established and operate. The new decision will take effect from the 1st of June 2017, and includes the following: - the number of members of the Scientific Panel can range between 15-25 experts; - experts can have a maximum of three terms of office in the same Scientific Panel; - Maximum two terms of office as Chair in the same Scientific Panel/Committee.

- The 79th NDA Panel Plenary meeting will be held on 27-29 June 2017 in Parma.
- The Chair closed the meeting by thanking the participants and the observers for their contributions.

CLOSED SESSION

4 April 2017, 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. Marks and Spencer – "Product formulated with a carbohydrate: protein ratio< 1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (Art 13.5, 0449_UK, EFSA-Q-2016-00436)

On 4 April, the draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

Pending the applicant's reply, the draft opinion will be submitted to the NDA Panel for possible adoption by written procedure.

13.2. Suomen Terveysravinto Oy – "Curcumin and normal functioning of joints" (Art 13.5, 0451_FI, EFSA-Q-2016-00856)

On 4 April, the draft opinion was discussed and adopted by the Panel 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4774/abstract

13.3. Laboratoire Nurilia – "Condensyl®" and "decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility" (Art 14, 0450_FR, EFSA-Q-2016-00665)

On 4 April, the draft opinion was discussed and adopted by the Panel 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4775/abstract

Novel Foods

13.4. InovoBiologic, Inc. – Draft opinion on Alginate-Konjac-Polysaccharide complex (EFSA-Q-2015-00469)

On 4 April, the draft opinion was discussed and adopted by the Panel 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4776/abstract

13.5. Ocean Spray Cranberries, Inc. - Draft opinion on cranberry extract (EFSA-Q-2016-00325)

On 4 April, the draft opinion was discussed and adopted by the Panel 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4777/abstract

13.6. Naturalendo Tech Co., Ltd - Draft statement on additional data on Estrog-100™ (EFSA-Q-2017-00040)

On 4 April, the draft statement was discussed and adopted by the Panel 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://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4778/abstract.

Annex I

List of observers

Observers who physically attended the open plenary		
Observer	**Company**	**Country**
ADAMASZWILI Kinga	European Dairy Association (EDA)	BE
BAYER Tania	Arla Foods Ingredients	DK
CARAMORI Caterina#	Student	IT
CATALLOZZI Marina	AGCM - Autorità Garante della Concorrenza e del Mercato (Italian Competition Authority)	IT
CHARRON Melanie	Soremartec Italia srl – Ferrero Group	IT
DZIESZUK-BRZOZOWSKA Wioleta	Danone Nutricia Early Life Nutrition	NL
FABRILE Maria Pia	Student	IT
GEISER Stefanie	EAS Strategies - Europe&MEA	BE
JACOBSEN Lotte Neergaard	Arla Foods Ingredients	DK
JANAKIRKAMAN Kaushik	Mead Johnson Nutrition	NL
LAMACCHIA Ruggero Luca	STAR Industriale srl	IT
LODIGIANI Matteo#	Student	IT
MENTA Roberto	Soremartec Italia srl – Ferrero Group	IT
SANSO' Giuseppe	Italian Ministry of Health – Parma - Veterinary Office	IT
SIMONETTO Anna	University of Brescia	IT
SOCZEWINSKA Joanna	USP Zdrowie Sp. z o.o.	PL
STEINBERG Susanne	Mead Johnson Nutrition	NL
VIDAL PARIENTE Olga	Student	ES
WU Chunzhu (Julie)	Nestlé Nutrition Headquarter, Nestec S.A.	CH

 # Registered but did not attend

Observers attended via web-streaming		
Observer	**Company**	**Country**
BALLU Clarisse	Lactalis	FR
BODENBACH Stephanie#	European Commission – DG SANTE	BE
BROENSTRUP Anja	Federal Ministry for Food and Agriculture	DE
BRU Audrey	Lallemand Inc.	FR
CAELEN Isabelle	Nestlé	CH
CALVERT Emma	BEUC –European Consumers' Organization	BE
FLEDDERMANN Manja	HiPP GmbH & Co	DE
JANIN Melanie#	ATLA - French Association of Dairy Processors	FR
OZNUR Fulya	Turkish Ministry of Food and Agriculture	TR
PAPADOPOULOS Ilias	Whitehouse Consulting	UK
RE Roberta	World Sugar Research Organization (WSRO)	UK
RIMAC BRNČIĆ Suzana	University of Zagreb – Faculty of Food Technology and Bio Technology	HR
RYAN Miriam#	Irish Dairy Industries Association	IE
SCARLATO Alessia Pia	Private capacity	IT
SEEGERS Jos	Winclove Probiotics	NL
SMITH Kevin Maitland	Nestlé	UK
TROLLOPE Kate	EU Food Policy	UK
VAN BELZEN Nico	International Dairy Federation	NL
VENTURA Gabrielle	Synadiet - Syndicat National des Compléments Alimentaires	FR
WENDORF – AMS Petra	Danone	DE
ZEYNEP ESIN Kaya	Turkish Ministry of Food and Agriculture	TR

 # Registered but did not connect

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.

Stefanie Geiser (EAS Strategies - Europe&MEA office)

Question 1: As follow-up to the EFSA Info Session on Novel Foods (held on 6 March in Parma) where some procedural plans of EFSA with Member States have been raised, EAS Strategies has the following questions in terms of:

1. the new centralised Novel Foods procedure: What are the latest developments on EFSA discussions with Member States and the Commission related to the planned help from Member States in assisting with preparatory work for the EFSA assessment via a grant and procurement procedure (i.e. the setting up of a contract to have some preparatory work undertaken by some interested Member States, before EFSA starts its full assessment)?

2. the procedure for traditional foods from 3rd countries: Latest plans on the MS-EC-EFSA network?

Ad1 (reply by Valeriu Curtui - Head of Nutrition Unit): See item 8-Novel Foods.

Question 2: It was asked for detailed information about the contract and what would be the number of Member States applying? It was also asked whether the EFSA network would be the same as the European Commission network on novel foods?

Ad2 (reply by Valeriu Curtui - Head of Nutrition Unit): EFSA is currently working on the specifications of the 4-year contract for preparatory work on novel foods which will be launched by June 2017. EFSA wishes that Member States with experience in novel food assessments to apply for the contract. The contractors would have access to applications and they will be subject to confidential agreement.

The EFSA Scientific Network on Novel Foods will be dealing with risk assessment aspects, which is different from the EC network (working group) on NF (which rather focuses on risk management issues).

Tania Bayer (Arla Foods)

Question 3: Will an approval be for the final infant formula or the protein hydrolysate?

Ad3 (reply by Francesco Carlucci – DG Santé): The Commission delegated Regulation (EU) 2016/127 establishes that IF or FOF manufactured from protein hydrolysate(s) which comply with the compositional requirements specified in EU legislation do not need a separate assessment by EFSA with respect to their safety and suitability (as safety and suitability have already been assessed in this case).

As explained in the Regulation's recitals, these requirements may be amended in the future in order to allow the placing on the market of formulae manufactured from protein hydrolysates with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by EFSA.

The requirements of Commission delegated Regulation (EU) 2016/127 shall apply to infant formula and follow-on formula manufactured from protein hydrolysates from 2021.

Lotte Jacobsen (Arla Foods)

Question 4: Is it only formulas/ingredients for allergy management which should undergo safety and efficacy trials, or is the same the case for formulas with hydrolysates targeting the comfort segment? Such comfort formulas can be a mixture of intact protein and hydrolysates.

Ad4 (reply by Francesco Carlucci – DG Santé): All infant and follow-on formulae placed on the market in the EU must comply with the relevant requirements of EU law and, in particular, be safe and suitable.

The only authorised health claim for infant formulae under existing legislation (Commission Directive 2006/141/EC, which shall cease to apply in 2021) relates to reducing the risk of developing allergy to milk proteins. Claims about "comfort" are not authorised to be made in infant formula. Operators were invited to check with national competent authorities the legal framework under which "products targeting the "comfort segment" have been placed in the market in a particular Member State, as enforcement of EU law is a responsibility of Member States.

Isabelle Caelen (Nestlé)

Question 5: What is the estimated date on which the final Guidance on formulae containing partially hydrolysed proteins will be released?

Ad5 (reply by Valeriu Curtui - Head of Nutrition Unit): The guidance and the technical report will be subject to editorial comments by the Panel. Both final documents will be published together, foreseen by mid-May 2017.

Question 6: Could EFSA confirm that the final Guidance will clarify that demonstration of "reducing the risk of developing allergy to milk proteins" could either be done for IgE-mediated or for non-IgE mediated?

Ad6 (reply by Dominique Turck – The Panel Chair): The demonstration of reducing the risk of developing allergy to milk proteins can be made whatever the underlying pathophysiological mechanism (i.e. IgE-mediated, non IgE-mediated, or mixed).

Question 7: Could EFSA confirm that the final Guidance will clarify that for the demonstration of "reducing the risk of developing allergy to milk protein" it is possible to choose specific endpoint(s) (or allergic manifestation(s)) to be studied in the clinical trial(s) depending on the consideration above, i.e. IgE-mediated, non IgE-mediated?

Ad7 (reply by Dominique Turck - The Panel Chair): It is not EFSA's role to describe the criteria to be used for the diagnosis of allergy to milk proteins. EFSA refers in the guidance document to guidelines and consensus papers for the diagnosis of food allergy that have been published in Europe and the USA.

Wioleta Dzieszuk-Brzozowska (Danone Nutricia Early Life Nutrition)

Question 8: It was asked whether studies performed outside the EU would be accepted.

Ad8 (reply by Dominique Turck - The Panel Chair): Studies conducted outside the EU are acceptable provided they fulfil the scientific quality criteria requested in the guidance document.

Nico van Belzen (International Dairy Federation):

Question 9: Protein quantity and quality are very important. Why did the Panel use a general nitrogen conversion factor of 6.25, instead of the more precise figures 6.38 for cow's milk and 5.71 for soy?

Ad9 (reply by Daniel Tomé - a Panel member): The conversion factor of 6.25 is the "historical conversion factor" of nitrogen to protein. If a protein as a mixture of amino acids is considered, which is the important criteria for nutritional purposes, the conversion factor of nitrogen to this mixture of amino acids slightly differs between protein sources, but is always below 6.25 including cow's milk protein. The conversion factor of 6.38 for cow's milk protein takes into account phosphorus associated to casein, that artificially overestimates the weight of these proteins related to nitrogen and thus the corresponding mixture of amino acids. As the objective is to express protein as a source of amino acids, comparison of the different protein sources is based on this criteria, and the conversion factor of nitrogen to the mixture of amino acids must be considered. Specific conversion factors for each protein source could be applied, and also for practical reasons, the "historical conversion factor" of 6.25, that has been used to set protein requirement from nitrogen balance, is used. Using this conversion factor overestimates the quantity of protein (in terms of a mixture of amino acids) for all the protein sources, but as this overestimation is approximately the same for the different sources, the relative values are not affected.

Question 10: Does the Panel have an opinion on the suitability of methods for measuring protein quality, e.g. DIAAS compared to PDCAAS? If not, does the Panel foresee future work on this topic?

Ad10 (reply by Daniel Tomé - a Panel member): From the seventies, international bodies considered indispensable amino acid content as the main criteria of protein quality, i.e. the capacity of protein sources to meet indispensable amino acid requirement. This is expressed in the "chemical score" that compares the amino acid profile of protein to a reference amino acid profile considered to meet indispensable amino acid requirement. In the PD-CAAS, the amino acid content of proteins is corrected by the fecal digestibility of the protein to take into account the bioavailability of the amino acids. More recent scientific discussions considered the specific ileal digestibility of each amino acid as a more precise measurement of the bioavailability of each amino acid, and

this is translated in the DIAAS. However, data for fecal protein digestibility are available, whereas there is no data for ileal amino acid digestibility. For this reason, the PD-CAAS method remains the recommended method. Discussions by international authorities are on-going on this topic and on future work that should be conducted.

Question 11: EFSA has announced that by early 2020 it will prepare advice on the intake of sugar added to food in relation to adverse health effects. Will this advice concern added sugar only, or also sugar intrinsic to foods? If intrinsic sugar will be included in the advice, will EFSA consider the total health effect of the food concerned, or only the effect of the sugar in it?

Ad11 (reply by Valeriu Curtui - Head of Nutrition Unit): The EFSA opinion will focus on added sugar but not on intrinsic sugar.

Kate Trollope (EU Food Policy)

Question 12: With regard to the forthcoming Opinion on added sugar, you say you will set a "science based cut off value". Will this be a percentage of energy intake like WHO? Or will it be so many grams a day (like salt, say, where we are advised not to eat more than 5 g a day)?

Ad12 (reply by Valeriu Curtui - Head of Nutrition Unit): It is premature to state how the value will be expressed.

Question 13: The Panel takes on central assessment for novel foods in January next year. Now that you have published the guidance, met with stakeholders etc., what do you think will be the biggest challenges for the Panel?

Ad13 (reply by Henk van Loveren – Chair of the WG on Novel Foods): EFSA centralisation of NF assessments will mean increasing workload.

Valeriu Curtui added that EFSA and Member States will have only 4 months to raise safety objections to notifications of traditional foods from third countries. This short timeframe will not allow an opinion from the NDA Panel.