

## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 73<sup>rd</sup> Plenary meeting

**Held on 28-30 June 2016, Brussels (Belgium)**

**Meeting open to Observers**

#### **OPEN SESSION**

**29 June 2016, 9:00-18:00**

**30 June 2016, 9:00-16:00**

**(Agreed on 11 July 2016)**

#### **Participants**

■ Panel Members:

Jean-Louis Bresson, Barbara Burlingame, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani<sup>1</sup>, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck, Henk Van Loveren, Marco Vinceti, Peter Willatts<sup>1</sup>.

■ Hearing experts<sup>2</sup>:

Not Applicable

■ European Commission representatives:

DG-SANTE: Olga Goulaki<sup>3</sup>, Sabine Pelsser<sup>3</sup>, Alexandra Nikolakopoulou<sup>4</sup>, Francesco Carlucci<sup>4</sup>, Marina Marini<sup>4</sup>, Stephanie Bodenbach<sup>5</sup>.

<sup>1</sup> Present on 28-29 June

<sup>2</sup> 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>

<sup>3</sup> Present on 28 June

<sup>4</sup> Present on 30 June

<sup>5</sup> Present 29-30 June

- EFSA:
  - Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Silvia Cipullo, Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Jorge Jordà Calero, Emanuela Turla and Silvia Valtueña Martínez.
  - AMU Unit: Laura Ciccolallo (for items 7.3 and 7.4)
- Others:
  - Donnell Alexander (short-term visiting Scientist, Ministry for Primary Industries, New Zealand)
- Observers: see Annex II.

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Tara Dean.

Anders Sjödin did not participate in agenda points 13.1, 13.2, and 13.5.

Harry McArdle did not participate in agenda points 7.3 and 7.4.

## **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 with changes in the order of discussion.

## **4. Declarations of Interest of Scientific Panel members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>6</sup> and the Decision of the Executive Director on Declarations of Interest<sup>7</sup>, 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 ADoIs or the SDoIs, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>7</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## 5. Presentation of the *EFSA Guidelines for Observers*<sup>8</sup>

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.

Observers were informed that, if time permits, the Chair may grant observers 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.

## 6. Report on written procedures since 72<sup>nd</sup> Plenary meeting

The minutes of the 72<sup>nd</sup> Plenary meeting held on 20-21 April 2016 were agreed on 25 April 2016.<sup>9</sup>

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 scientific and technical guidance for the preparation and presentation of a health claim application (EFSA-Q-2016-00285)

On 29 June, a draft document updating the scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim published in 2011 was presented and discussed.

The guidance has been revised to align with the recently published General scientific guidance for stakeholders on health claim applications and adapted to include claims that are based on the essentiality of nutrients. It has also been re-structured concerning Parts 1 to 6 including the Appendices to clearly outline the information to be provided.

This document presents a common format for the organisation of information for the preparation of a well-structured application for authorisation of health claims which fall under Articles 13(5), 14, and 19 of Regulation (EC) No 1924/2006. It outlines: the information and

<sup>8</sup> <http://www.efsa.europa.eu/sites/default/files/assets/observersguidelines.pdf.pdf>

<sup>9</sup> <http://www.efsa.europa.eu/sites/default/files/event/160420-m.pdf>

scientific data which must be included in the application, the hierarchy of different types of data and study designs (reflecting the relative strength of evidence which may be obtained from different types of studies) and the key issues which should be addressed in the application to substantiate the health claim.

The draft was endorsed by the Panel for release for public consultation.

The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

## **7.2. Draft scientific opinion on the energy conversion factor of D-tagatose for labelling purposes (EFSA-Q-2009-00227)**

On 29 June, the draft opinion was introduced and discussed. This document proposes the energy conversion factor of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling. It was endorsed by the Panel for release for public consultation.

The public consultation will be launched in the next few weeks via the following link: <http://www.efsa.europa.eu/en/calls/consultations>

## **7.3. Draft technical report on the outcome of the public consultation on the draft opinion on Dietary Reference Values for vitamin D (EFSA-Q-2015-00676)**

A technical report on the Outcome of a public consultation on a draft Opinion related to the dietary reference values for vitamin D was presented and discussed. The report summarises the comments received during the public consultation on this opinion (which was open from 21 March to 16 May 2016) and how the comments were addressed. It was subsequently endorsed by the Panel on 29 June.

The full text of the technical report will be available in the coming weeks in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/publications/supporting> (see also item 7.4).

## **7.4. Draft opinion on the Dietary Reference Values for vitamin D (EFSA-Q-2011-01230)**

Following the public consultation of the above-mentioned draft Opinion, relevant comments received (as outlined and discussed under item 7.3) were taking into consideration in a revised draft document. This document proposes dietary reference values for **vitamin D** for adults, infants and children, and pregnant and lactating women. The draft opinion was adopted by the Panel on 29 June subject to the incorporation of editorial changes.

The full text will be published in the EFSA Journal via the following link: <http://www.efsa.europa.eu/en/efsjournal/pub/4547>

## **7.5. Draft opinion on the Dietary Reference Values for potassium (EFSA-Q-2011-01221)**

On 29 June, the draft opinion was introduced and discussed. This document proposes dietary reference values **for potassium** for adults, infants and children, and pregnant and lactating women. It was endorsed by the Panel for release for public consultation subject to editorial comments. 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**

### **8.1. Applications pursuant to Article 14/13.5 of Regulation (EC) No 1924/2006**

As of 28 June 2016, **eight** claim applications are in progress.

Since the last Plenary meeting, 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: "Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors" (EFSA-Q-2016-00319).

One Article 14 disease risk reduction claim was also received: "*Lactobacillus fermentum* CECT5716 decreases the *Staphylococcus* load in breast milk. High *Staphylococcus* load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (EFSA-Q-2016-00318).

Three applications were withdrawn:

- one Article 14 children claim "Non digestible oligosaccharide fibers (FOS/inulin, GOS and a mixture of FOS/inulin and GOS) are prebiotics that promote a healthy gut as clinically shown by an increase in beneficial bacteria" (EFSA-Q-2008-141);
- one Article 13(5) claim "Chios Mastiha contributes to the improvement of dyspepsia" (EFSA-Q-2015-00752, item 13.7);
- one Article 14 disease risk reduction claim "Chios Mastiha contributes to the reduction of *Helicobacter pylori* which is a risk factor for the development of peptic ulcer disease" (EFSA-Q-2015-00753, item 13.8).

### **8.2. Other mandates**

Two new requests were received from the European Commission:

EFSA has been asked for a scientific opinion on the safety and suitability for use by infants of follow-on formula with a protein content of at least 1.61 g/100 kcal (EFSA-Q-2016-00275).

EFSA has also been asked for a scientific opinion on cranberry extract powder as a novel food ingredient (EFSA-Q-2016-00325) in the context of Regulation (EC) No 258/97.

A new request was received from the National food safety authorities in the five Nordic countries. EFSA has been asked to provide scientific assistance in line with Regulation (EC) No 178/2002 in assessing if a dietary reference value for sugar with particular attention to added sugar now can be set (EFSA-Q-2016-00414).

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

### **9.1. Scientific Committee/EFSA**

No Scientific Committee (SC) meeting took place since the last NDA Plenary meeting. Of relevance to the NDA remit, members were briefed about the on-going activities of the SC's Working Group on genotoxicity.

### **9.2. EFSA including its Working Groups /Task Forces**

Chairs of Working Groups (WG) reported back regarding their respective latest meetings.

**WG on Claims** - Draft opinions related to five Art 13(5) and three Art 14 claims were discussed and elaborated. The "stop-the clock" procedure for requesting clarifications/supplementary information from the applicant was applied for one application. Seven opinions were submitted to this Plenary for discussion and/or for possible adoption (Agenda items 13.1-13.8). The WG also discussed and elaborated on the Draft scientific and technical guidance for the preparation and presentation of a health claim application (Agenda item 7.1).

**WG on Novel Foods (NF)** – At the WG meeting on 25-27 May, the WG reviewed and considered comments received during public consultation of the draft guidance document for Novel Food applications and the draft guidance for notifications of Traditional Foods from third countries. Both guidance documents are planned for submission to the September Plenary meeting for discussion and/or for possible adoption. The WG also discussed and elaborated draft opinions on the following Novel Food applications: Alginate-Konjac-Xanthan Polysaccharide Complex, Nattokinase (item 13.9), extract of three herbal roots (EstroG-100), synthetic L-ergothioneine, hydroxytyrosol; proline-specific oligopeptidase; extension of use of phytosterol esters and Hoodia parviflora. The application for phytosterols esters was further discussed at a teleconference on 16 June 2016 (item 13.10).

**WG on Dietary Reference Values (DRVs)** – The WG on DRVs for vitamins was working to finalise vitamins D taking into account comments from public consultation (Agenda item 7.3-7.4), while the WG for minerals was preparing the opinions on potassium (Agenda item 7.5). The WGs are also working on DRVs for vitamin K, thiamine (vitamin B1) and riboflavin (vitamin B2). For sodium and chloride, see Agenda items 10.2-10.3.

### **9.3. European Commission (EC)**

The EC representative (DG Santé), Alexandra Nikolakopoulou, briefed the Panel about the EC's activities of interest to the Panel, and provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions, including upcoming mandates to EFSA.

- The fitness check of the General Food Law (Regulation (EC) 178/2002) – The findings of the review, including recommendations will be presented in a document by end 2016.
- A REFIT evaluation has also been launched on the application and non-application of the provisions laid down in Regulation 1924/2006 regarding nutrient profiles and botanical claims. In this context, a study is being carried out by an external contractor will be available in 2017, and a document looking at possible outcomes will be produced by the EC.
- The Inception Impact Assessment on Trans fatty acids (TFAs) (looking at means and options for reducing consumption of TFAs) will be shortly published and open for stakeholders comments, following from this an impact assessment will be carried out.
- In relation to the total diet replacements for weight control, the EC considered the concerns expressed by some stakeholders on the technical feasibility of the requirements (e.g. level of protein). A delegated act is being finalised by the EC.
- New mandates from the EC requesting EFSA opinions are foreseen: for 1) updating the composition of baby foods, 2) the appropriate age for complementary feeding, and 3) the Tolerable Upper Intake Level of vitamin D for infants.

## **10. Other scientific topics for information and/or discussion**

### **10.1. Scientific and technical guidance for the preparation and presentation of an application for authorization of an infant and/or follow-on formula manufactured from protein hydrolysates (EFSA-Q-2016-00276)**

EFSA has been asked to advise on the type of data that will be considered appropriate by EFSA for providing future scientific advice

(i.e. guidance) on – the safety and suitability of a specific formula manufactured from protein hydrolysates; - the product's effectiveness in reducing the risk of developing allergy to milk proteins.

A presentation was given, introducing the background and available guidance in the area, including a brief outline on the elements that could be covered by the guidance with respect to suitability assessment, growth studies, and assessment in relation to developing allergy to milk proteins.

This mandate has been allocated to the WG on Infant Nutrition, which is currently in the process to be set up. The deadline for finalisation of the guidance is April 2017, with a public consultation foreseen by Q3/2016.

### **10.2. Draft Opinion on the Dietary Reference Values for sodium (EFSA-Q-2011-01224)**

The Panel was briefed about the status of the on-going preparatory work undertaken by the WG on Minerals for Dietary Reference Values (DRV)s for sodium.

Owing to the complexity of how sodium intake associates with some health outcomes, it was agreed to apply PROMETHEUS (Promoting Methods for evidence use in scientific assessments)<sup>10</sup> method and approach to certain sections of the opinion on the DRVs for sodium.

Therefore, the timeline for finalisation (including public consultation) of DRVs for sodium will be extended to end 2018/Q1 2019 pending agreement with the European Commission.

### **10.3. Draft Opinion on the Dietary Reference Values for chloride (EFSA-Q-2011-01207)**

The Panel was also briefed about the status of the on-going preparatory work undertaken by the WG on Minerals for Dietary Reference Values (DRV)s for chloride.

Since DRVs for chloride and sodium are inter-related, it was agreed to postpone the finalisation of chloride and to wait for the outcome of sodium (see item 10.2). The timeline for finalisation (including public consultation) of DRVs for chloride will be deferred to end 2018/Q1 2019 pending agreement with the European Commission.

## **11. Answers to questions from Observers (in application of the EFSA Guidelines for Observers)**

<sup>10</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4121>

Please refer to Annex III.

## **12. Any other business**

The 74<sup>th</sup> NDA Panel Plenary meeting will be held on 21-23 September 2016 in Parma.

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

**CLOSED SESSION**  
**28 June 2016, 9.00-18.00**

**Items 13.1-13.10 are closed to Observers, due 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. Probi AB – “*Lactobacillus plantarum* 299v increases non-haem iron absorption”** (Art. 13.5, 0441\_SE, EFSA-Q-2015-00696)

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4550.htm>

**13.2. Granarolo Spa - “Consumption of *L. rhamnosus* GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals”** (Art. 13.5, 0439\_IT, EFSA-Q-2015-00488)

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4538.htm>

**13.3. Pierre Fabre Medicament – “V0137, a DHA-enriched fish oil, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function”** (Art. 13.5, 0446\_FR, EFSA-Q-2016-00071)

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4531.htm>

**13.4. Food for Health Ireland - “FHI LFC24, a bovine milk-derived casein hydrolysate, helps to regulate blood glucose levels** (Art. 13.5, 0444\_IE, EFSA-Q-2015-00755)

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4540.htm>

**13.5. H.J. Heinz supply Chain Europe B.V. - “Nutrimune (heat treated fermented milk with *L. paracasei* CBA L74) supports the immune defence in the gastrointestinal and upper-respiratory tract of young children” (Art. 14, 0445\_NL, EFSA-Q-2016-00008)**

Postponed. A stop the clock procedure was applied for requesting additional information from the applicant<sup>11</sup>.

**13.6. SNE – “Iron and immune system” (Art. 14, 0066\_FR, EFSA-Q-2008-146)**

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4548.htm>

**13.7. Chios Mastiha Growers Association – “Chios Mastiha contributes to the improvement of dyspepsia” (Art. 13.5, 0442\_EL, EFSA-Q-2015-00752)**

The application was withdrawn on 23<sup>rd</sup> June by the Competent Authority of Greece upon a request from the applicant.

**13.8. Chios Mastiha Growers Association – “Chios Mastiha contributes to the reduction of *Helicobacter pylori* which is a risk factor for the development of peptic ulcer disease” (Art. 14, 0443\_EL, EFSA-Q-2015-00753)**

The application was withdrawn on 23<sup>rd</sup> June by the Competent Authority of Greece upon a request from the applicant.

### **Novel Foods**

**13.9. Japan Bio Science Laboratory - Fermented soybean extract (Nattokinase-NSKSD<sup>®</sup>) (EFSA-Q-2015-00294)**

On 28<sup>th</sup> June, 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://www.efsa.europa.eu/en/efsajournal/pub/4541.htm>

**13.10. Unilever PLC and Unilever N.V. - Phytosterol esters (extension of use, cooking oils) (EFSA-Q-2014-00865)**

---

<sup>11</sup> See minutes of WG Claims held on 9-10 June 2016: <http://www.efsa.europa.eu/sites/default/files/assets/ndaclaims.pdf>

On 28th June, 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.

## Annex I

### Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, **Dr Anders Mikael Sjödin** declared an interest for the application related to: 'Lactobacillus plantarum 299v' (EFSA-Q-2015-00696, agenda item 13.1), 'Lactobacillus rhamnosus GG (ATCC 53103) and fructooligosaccharides (FOS)' (EFSA-Q-2015-00488, agenda item 13.2), and 'Nutrimune (heated treated fermented milk with L. paracasei CBA L74)' (EFSA-Q-2016-00008, agenda item 13.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>8</sup> and the Decision of the Executive Director on Declarations of Interests<sup>9</sup>, 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 agenda items 13.1, 13.2 and 13.5 by the concerned scientific group.

In the SDoI filled for the present meeting, **Prof Harry McArdle** declared the following interest: Dietary Reference Values for vitamin D (EFSA-Q-2015-00676, agenda item 7.3; EFSA-Q-2011-01230, agenda item 7.4). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>12</sup> and the Decision of the Executive Director on Declarations of Interest<sup>13</sup>, 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 agenda items 7.3 and 7.4 by the concerned scientific group.

<sup>12</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>13</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

**Annex II**  
**List of observers**

Observer	Company	Country
ADAMASZWILI Kinga	European Dairy Association (EDA)	BE
BAFFIGO Marta	Cargill R&D Centre Europe	BE
BALDWIN Nigel	Intertek Scientific & Regulatory Consultancy	UK
BAYER Tania <sup>#</sup>	Arla Foods Ingredients	DK
CHANDRA Trissia	Nestlé	CH
CHAPPUIS Eric	Olygose	FR
DI GREGORIO Robert	Specialised Nutrition Europe	BE
DZIESZUK-BRZOZOWSKA Wioleta	Specialised Nutrition Europe	BE
EINERHAND Sandra	Einerhand Science & innovation BV	NL
FINCH Sebastian	Arla Foods amba	DK
GEISER Stefanie	EAS Strategies - Europe&MEA	BE
HARRISON-DUNN Annie-Rose	NutraIngredients	FR
LEWIS Sara <sup>#</sup>	EU Food Law	BE
LOOSEN Peter <sup>#</sup>	Bund für Lebensmittelrecht und Lebensmittelkunde e.V. (BLL)	BE
MARKERSEN Karina	Chr. Hansen A/S	DK
O'NEILL Keith	Abbott Laboratories	IE
PERRUDIN Maud	AESGP (Association of the European Self-Medication Industry)	BE
PIJLS Loek	Loekinfofood-gcv	BE
PRELLER Mareike	Specialised Nutrition Europe	BE
SOCZEWINSKA Joanna	USP Zdrowie Sp. z o.o.	PL

Observer	Company	Country
STEINBERG Susanne	Mead Johnson Nutrition	NL
STROHM Daniela	German Nutrition Society - Deutsche Gesellschaft für Ernährung (DGE)	DE
TROLLOPE Kate	EU Food Policy	UK
VAN DER LEM Lysanne <sup>#</sup>	Danone Nutricia Research	NL

**# Registered but did not attend**

## Annex III

### 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 discussion.

#### Pre-submitted questions:

##### **Stefanie Geiser (EAS Strategies - Europe&MEA office)**

**Question 1:** DRVs: which vitamins/minerals are on the final 2016 plan for DRV draft opinions/public consultations?

##### **Ad1 (reply by Head of Nutrition Unit):**

Finalisation by end of 2016 is foreseen for potassium (Agenda item 7.5) and thiamine (public consultation by Q3 2016). For riboflavin, we will be targeting to endorse the opinion for public consultation in December this year, finalisation by April 2017.

See also Agenda items 7.3-7.4 (vitamin D), 10.2 (sodium) and 10.3 (chloride).

**Question 2:** After the updated gut&immune function claims guidelines and update of the general health claims guidance docs, which of its specific health claims guidelines EFSA intends to update next?

##### **Ad2 (reply by Yolanda Sanz – Vice-Chair of WG Claims):**

Finalisation of the scientific and technical guidance for the preparation and presentation of a health claim application is targeted by end of 2016.

To further assist applicants, EFSA launched in 2014 a grant (GP/EFSA/NUTRI/2014/01)<sup>14</sup>, which aims at gathering information in relation to claim effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The information collected will be published in a scientific report, which will help to inform the NDA Panel and serve as a basis for further guidance to applicants. The format(s) under which such guidance will be provided to applicants (e.g. guidance documents, searchable, interactive databases) will be carefully considered by EFSA.

Therefore the updating of the remaining guidance documents related to claims will be undertaken in a step-wise manner taking into consideration the outcomes of the grant. We will start with updating the remaining specific guidance documents.

<sup>14</sup> <http://www.efsa.europa.eu/en/art36grants/article36/gpefsanutri201401.htm>

### **Kate Trollope (EU Food Policy)**

**Question 3:** There was discussion about EFSA setting up a network on nutrition, in the same way as you have a GMO network etc, where you would meet with member states. Has this been dropped and, if so, why?

**Ad3 (reply by Valeriu Curtui -Head of Nutrition Unit):**

There has been a proposal for a network on nutrition but also a proposal for a network on novel foods (traditional foods from 3<sup>rd</sup> countries). As it is unlikely to have in a network the same representatives of the Member States dealing with novel foods and all the other areas covered by NDA, EFSA has to prioritise and will discuss with the Member States to agree on the network to be set up. EFSA and MSs would need to see the implementing rules for the new novel food regulation, what collaborative platform will be available for EFSA and MSs especially for commenting on notifications of traditional foods from 3<sup>rd</sup> countries.

I expect the subject to be discussed again in a meeting with the Advisory Forum.

**Question 4:** EFSA was to be involved in coordinating the Nutrивigilance Network, where France has taken the lead. Is EFSA involved and, if so, could you give an update on key developments?

**Ad4 (reply by Valeriu Curtui -Head of Nutrition Unit):**

EFSA has facilitated a number of meetings with Member States and the Commission to discuss the relevance of an EU Nutrивigilance schema. EFSA's position is that such a surveillance programme would in first place serve for monitoring and control and could be a useful tool to inform the risk managers on adverse effects, illegal marketing, and quality problems of foods, especially food supplements, and suggested that such a monitoring system should be set up by the risk managers (Member States and the Commission). We know that Member States continued to have some meetings on the subject but we are not aware of the outcome.

The information collected through such a surveillance system, namely case reports where the cause effect relationship is weak, is of very limited use for the risk assessment.

### **Sara Lewis (EU Food Law)**

**Question 5:** What could probiotic manufacturers do differently to get a health claim approved?

**Ad5 (reply by Yolanda Sanz – Vice-Chair of WG Claims):**

In the last years, the NDA Panel has gained considerable experience in the evaluation of health claim applications. The NDA Panel has translated the lessons learnt from these experiences into the General scientific

guidance for stakeholders on health claim applications, which was published in Jan 2016 and represents a step forward in assisting applicants to compile their applications for health claims authorisation.

In addition, the new guidance for claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms, which are relevant for probiotics, was also published in Jan 2016. Applicants could learn from examples of claims depicted in the guidance.

The scientific opinions on claim applications evaluated by the NDA Panel with a positive outcome provide examples as to the number, type and quality of the studies which may be needed for the scientific substantiation of health claims in the context of specific applications, whereas examples of claims evaluated unfavourably by the Panel illustrate the shortcomings that prevented the substantiation of these claims.

**Robert Di Gregorio/ Wioleta Dzieszuk-Brzozowska/ Mareike Preller (Specialised Nutrition Europe)**

**Question 6:** Hydrolysates are source of protein for IF and FOF. Can EFSA confirm suitability = nutritional adequacy (growth and protein status e.g. albumin, serum mineral markers, blood urea nitrogen) and safety?

**Ad6 (reply by Dominique Turck – Chair of NDA panel):**

As outlined in the Scientific Opinion on the essential composition of infant and follow-on formulae of the NDA Panel, formulae containing protein hydrolysates are insufficiently characterised by the declared protein content even though they fulfil regulatory criteria concerning amino acid patterns. Therefore, the Panel considered that the safety and suitability of each specific infant and follow-on formula containing protein hydrolysates have to be established by clinical evaluation in the target population. An “across the board” judgement covering all formulae containing protein hydrolysates cannot be made.

**Question 7:** Under what conditions can the positive suitability assessment of a certain protein hydrolysate be transferred to a slightly different formula containing the same protein hydrolysate?

**Ad7 (reply by Dominique Turck – Chair of NDA panel):**

EFSA is currently working on a guidance document for the assessment of the safety and suitability of formulae containing protein hydrolysates (Agenda item 10.1). This guidance document will also address the data requirements to demonstrate the product’s effectiveness in reducing the risk of developing allergy to milk proteins. To establish data requirements for the assessment of claimed effects other than the product’s effectiveness in reducing the risk of developing allergy to milk proteins are not part of the Terms of Reference. The draft guidance will be released for public consultation in autumn this year with the possibility to

comment on the criteria proposed by the NDA Panel. At this point in time, discussions on the guidance have only just started and therefore no concrete proposals are up for discussion yet.

**Question 8:** What parameters will EFSA lay down to demonstrate product's effectiveness (e.g. allergic manifestations or digestion): clinical follow-up duration, criteria for diagnosis, beneficial effect?

**Ad8 (reply by Dominique Turck – Chair of NDA panel):**

As stated before (Ad7), discussions on the guidance have only just started and no concrete proposals are available. As is the case for all scientific evaluations, whether a scientific assessment can be extended to situations different from the exact one assessed in an opinion, is always a matter of a case-by-case assessment and will depend on the kind and type of modification proposed.

Questions posed during the open session:

**Robert Di Gregorio/Wioleta Dzieszuk-Brzozowska (Specialised Nutrition Europe)**

**Question 9:** A question was about the procedure for applications related to formula manufactured from hydrolysate proteins.

**Ad9 (reply by Francesco Carlucci – DG Sante):** The Commission delegated Regulation will become applicable to formula manufactured from hydrolysate proteins from 2021. The procedure for submission of dossiers on these formulas will be announced in due time.

**Question 10:** It was asked whether growth data from studies outside Europe could be used.

**Ad10 (reply by Dominique Turck – Chair of NDA panel):** According to WHO, there is no indication that children up to two years of age coming from a socioeconomic setting that does not constrain growth do grow differently in different regions of the world (with the exception of children in the region of south East Asia).

**Question 11:** It was asked which are the requirements for applying an existing assessment to a different formula containing the same hydrolysate.

**Ad11 (reply by Francesco Carlucci – DG Sante):** This will be a case-by-case basis consideration, also taking into account whether or not the requirements of Regulation (EU) 2016/127 are met.

**Question 12:** A question was asked regarding the use of unpublished data and their impact of the weighing of evidence?

**Ad12 (reply by Alfonso Siani –Chair of WG on Claims):** EFSA health claim substantiation takes into account the totality of the available

scientific data (published and unpublished studies, irrespective of whether the trial is registered or not) and is carried out by weighing the evidence.

**Sandra Einerhand (Einerhand Science & innovation BV)**

**Question 13:** EFSA was asked to offer pre-submission meetings to applicants.

**Ad13 (reply by Valeriu Curtui –Head of Nutrition Unit):** EFSA would like to re-iterate that, owing to EFSA legislative frameworks (covering diverse food sectors) and its current setting and resources (not comparable to EMA, which has a legal obligation to provide advice to applicants), pre-submission meetings with individual applicants are not among the services that EFSA can offer.

Even if EFSA would have unlimited budget (related to Question 27), it would not be appropriate for the same Panel to give pre-submission advice and also evaluate the application. There would be need for a different committee to advise the applicants.

Any changes will have to be discussed and agreed by EFSA Management Board who had excluded pre-submission meetings (seen as too close to industry).

EFSA reminded participants that various initiatives have been put in place to assist applicants<sup>15</sup>. For instance, following the publication of a scientific opinion, a post-adoption teleconference can be requested by the applicant to clarify the rationale for the decision of the NDA Panel.

Applicants are encouraged to consult experts in the particular research field, the scientific guidance documents of EFSA, and the published scientific opinions on similar applications.

**Karina Markersen (Chr. Hansen A/S)**

**Question 14:** Question was related to the biomarkers and the acceptable methods of measurements to assess the claimed effects in human studies.

**Ad14 (reply by Alfonso Siani –Chair of WG on Claim):** To further assist applicants, EFSA launched in 2014 a grant (GP/EFSA/NUTRI/2014/01)<sup>16</sup>, which aims at gathering information in relation to claim effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The information collected will be published in a scientific report, which will help to inform the NDA Panel and serve as a basis for further guidance to applicants. The format(s) under which such guidance will be provided to applicants (e.g. guidance documents, searchable, interactive databases) will be carefully considered by EFSA.

<sup>15</sup> <http://www.efsa.europa.eu/en/supporting/pub/1025e>

<sup>16</sup> <http://www.efsa.europa.eu/en/art36grants/article36/gpefsanutri201401.htm>

**Question 15:** EFSA was asked to follow the EMA model for providing pre-submission advice to applicants (e.g. for designing studies, selection of outcome measures). Suggestion was also made to have meetings with industry associations, particularly for probiotic associations.

**Ad15 (reply by Valeriu Curtui –Head of Nutrition Unit):** see also Ad 13.

Regarding pre-submission advice meetings with industry associations, it was highlighted that such a proposal was presented to EFSA's Management Board but there is no final decision by EFSA. If approved, the service will be introduced in the Catalogue of services provided to applicants.

**Question 16:** It was asked whether applicants could pose questions to EFSA.

**Ad16 (reply by Valeriu Curtui –Head of Nutrition Unit):** Question about applications in specific scientific areas can be asked to EFSA via a special functional mailbox:

<http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion?ScientificArea=zero>

It should be noted that EFSA will not answer on designing studies.

### **Eric Chappuis (Olygoose)**

**Question 17:** It was commented that trial registration may have an impact on data protection, with information publicly available to competitors.

**Ad17 (reply by Alfonso Siani –Chair of WG on Claims):** The comment was noted. It was pointed out that trial registration is not mandatory.

### **Nigel Baldwin (Intertek Scientific & Regulatory Consultancy)**

**Question 18:** It was suggested to harmonise the requirements for characterisation of foods in the framework of Novel Foods (NFs) that could be used for health claim applications?

**Ad18 (reply by Henk van Loveren–Chair of WG on Novel Foods):** Some aspects regarding the characterisation of a NF, which are relevant for health claim purposes (e.g. information related to the characteristics of the food/constituent which may influence the specific effect that is the basis of the claim) could be used for health claim application.

**Question 19:** EFSA was asked to provide guidance for energy conversion factors.

**Ad19 (reply by Valeriu Curtui –Head of Nutrition Unit):** It is rather for the Commission to consider on a case-by-case basis the need for such advice.

## **Loek Pijs (Loekintofood-gcv)**

**Question 20:** It was asked whether dietary reference values (DRVs) could be set for specific sensitive groups (e.g. individuals carrying specific functional genetic variants).

**Ad20 (reply by Monika Neuhäuser-Berthold –Chair of WG on DRVs for vitamins):** DRVs set by the Panel are proposed for the general healthy population, thus covering common polymorphisms. Generally, opinions on DRVs contain a section on effects of genotypes. If there is a particular influence of a frequent genetic polymorphism on a nutrient status/metabolism, it may be taken into account in deriving DRVs. For example, in the case of folate, the Panel derived an Average Requirement and a Population Reference Intake from data on biomarkers of folate status assuming a coefficient of variation of 15% to account for the additional variability associated with the higher requirement for folate in individuals with the methylene-tetrahydrofolate reductase (MTHFR) 677TT genotype (see also EFSA General principles for setting DRVs for more information on application of DRVs for populations/groups and individuals).

**Question 21:** In the framework of DRVs, it was questioned whether EFSA opinions have been followed by Member States?

**Ad21 (reply by Valeriu Curtui –Head of Nutrition Unit):** EFSA opinions cover DRVs for the EU population. They provide comprehensive scientific advice to support EU policy makers in their decision making process in the field of nutrition. Member States may use EFSA opinions or deviate from them when making nutrient intake recommendations depending on their nutrition goals (also taking into account food/nutrient intakes and health status of their population). It was, however, pointed out that this question should rather be posed to Member States.

**Question 22:** EFSA (in the framework of health claims) says that reduction of post-prandial glycaemic responses is a beneficial physiological effect, and thus any carbohydrates (CHO) that shows a reduction of post-prandial glycaemic responses when replacing sugars in foods can be classified as fibre (taking into account the definition in CODEX and in the EU= non-glycaemic CHO with a demonstrated health benefit)?

**Ad22 (reply by Stephanie Bodenbach –DG Sante):** This is not the case. The requirements are two-folds:

- a) Being non-glycaemic, and thus a reduction of post-prandial glycaemic responses when replacing sugars can be already expected from this requirement; and
- b) Having a demonstrated health benefit (other than reduction of post-prandial glycaemic responses)

If the only health benefit required for a CHO to be classified as fibre would be a reduction of post-prandial glycaemic responses when replacing sugars, then the second part of the definition would not be needed. But this is not the case.

### **Kate Trollope (EU Food Policy)**

**Question 23:** It was asked whether the Panel could propose DRVs for specific regions.

**Ad23 (reply by Monika Neuhäuser-Berthold –Chair of WG on DRVs for vitamins):** DRVs set by the Panel are proposed for the European population. In the case of vitamin D, DRVs were derived from data collected under conditions of assumed minimal cutaneous vitamin D synthesis. In the presence of such synthesis, the requirement for dietary vitamin D is lower or may even be zero. It would be difficult for the Panel to determine sun exposure for each region. The formulation of recommendations for dietary vitamin D intake at national/regional/local level in the EU according to UV-B irradiation and other specific characteristics is a risk management decision.

**Question 24:** It was asked whether EFSA public consultation paid off to sum-up huge amounts of comments received and considering no major changes affect the opinion (i.e. DRVs for vitamin D).

**Ad24 (reply by Valeriu Curtui –Head of Nutrition Unit):** Although many comments were not relevant to the scope of the opinion, it was however acknowledged that some scientific comments received were very helpful. Public consultation process also helps to ensure that EFSA opinions do not miss important elements. Without public consultation, individual comments may come post publication of EFSA opinion, and this is more difficult to address and is highly time consuming.

**Question 25:** The question was related to the consequence of Brexit on appointment of British experts for the EFSA Panels.

**Ad25 (reply by Valeriu Curtui –Head of Nutrition Unit):** British experts are highly needed for the Panel. If necessary, the Management Board rule for expert selection could be amended. EFSA call for experts are open to all, and EFSA could consider expertise outside the EU. The specific expertise of candidates is the most critical element in selecting experts for Panels and working groups.

### **Annie-Rose Harrison-Dunn (NutraIngredients)**

**Question 26:** The implication of losing many British experts for EFSA owing to Brexit was questioned.

**Ad26 (reply by Valeriu Curtui –Head of Nutrition Unit):** see Ad25.

It was stressed that it is too early to anticipate all the implications after Brexit.

**Question 27:** EFSA was asked if pre-submission meetings are feasible if it would have unlimited budget.

**Ad (reply by Valeriu Curtui –Head of Nutrition Unit):** see Ad13.

EFSA does not exclude *a priori* the possibility of giving pre-submission advice to applicants. If there would be no constraints regarding resources, with an appropriate set-up for providing advice to applicants that should not damage EFSA's independence, and a legal provision EFSA may well give such advice.