

# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## Minutes of the 87<sup>th</sup> Plenary meeting

**Held on 26-27 September, 2018, Parma (Italy)  
(Agreed on 4 October 2018)**

### ■ **Panel Members:**

Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen<sup>1</sup>, Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Carmen Pelaez, Alfonso Siani, Frank Thies, Dominique Turck and Marco Vinceti.

### ■ **Hearing Experts<sup>2</sup>:**

Not Applicable.

### ■ **European Commission and/or Member States representatives:**

Not Applicable.

### ■ **EFSA:**

NUTRI Unit: Reinhard Ackerl, Mathias Amundsen, Janusz Ciok, Paolo Colombo, Agnès De Sesmaisons-Lecarré, Céline Dumas, Lucia Fabiani, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, , Federico Morreale, Leonard Matijevic, Annamaria Rossi, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez and Ermolaos Ververis.

### ■ **Observers:**

Not Applicable.

### ■ **Others:**

Not Applicable.

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

The Chair welcomed the participants.

Apologies were received from Kristina Pentieva and Sophia Tsabouri.

<sup>1</sup> Participated only on 26 September.

<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>

## **2. Adoption of agenda**

The agenda was adopted with changes in the order of items discussed.

## **3. Declarations of Interest of Scientific Panel Members**

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **4. Agreement of the minutes of the 86<sup>th</sup> Plenary meeting held on 04-05 July 2018, Parma (Italy)**

The minutes of the 86th Plenary meeting held on 04-05 July 2018 were agreed by written procedure on [13 July 2018](#)

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

### **5.1 Dr. Paul Lohmann GmbH KG - "Magnesium citrate malate" as a nutrient source (EFSA-Q-2018-00066)**

The background and the approach used to address the proposed nutrient source were introduced. The draft opinion was presented and discussed.

The Panel reviewed the data provided on the bioavailability of the nutrient, magnesium, from the proposed nutrient source, magnesium citrate malate.

The draft opinion will be amended and a new version will be presented at the next Plenary meeting<sup>5</sup> for discussion and possible adoption.

### **5.2 Outcome of the public consultation (EFSA-Q-2018-00540) and draft guidance on the scientific requirements for health claims related to muscle function and physical performance (EFSA-Q-2018-00243)**

---

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>5</sup> Plenary meeting of 24-25 October 2018.

A technical report on the outcome of a public consultation on the draft guidance was presented and discussed.

EFSA received comments from three interested parties. The report summarises the comments received during the public consultation on this guidance (open from 16 July to 2 September 2018) and how the comments were addressed. This guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to muscle function and physical performance.

The Panel reviewed and discussed the comments received, which were related to the scope of the guidance, the definition of the terms used, the characterisation of the target population, claims on the muscle function and claims on physical performance.

The Panel agreed with the relevant changes introduced in the updated guidance document.

On 27 September, the Panel endorsed the technical report and adopted the updated guidance document subject to the incorporation of editorial changes.

The full text of both documents will be available in the coming weeks in the EFSA Journal via the following [link](#).

### **5.3 AVVA Pharmaceuticals Ltd. - “Lignin hydrolysed (Filtrum) and defence against pathogenic bacteria and viruses in the intestine” (Art. 13.5, 0468-0469\_CY, [EFSA-Q-2018-00004/EFSA-Q-2018-00005](#))**

On 27 September, the Panel was updated on the outcome of the 11-12 September WG Claims meeting regarding this application.

Further to the applicant’s reply to EFSA stop-the-clock letter and upon request from the WG, an applicant’s hearing was held on 11 September. The applicant was requested to clarify outstanding issues on the application, particularly the rationale for extrapolation of the results of studies performed in study groups with acute intestinal infections causing diarrhoea to the general population and the proposed mechanism by which the food could exert the claimed effect.

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

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

## 6. New Mandates

The Nutrition Unit updated the Panel members on new mandates received since the last Plenary meeting. Information about the mandates received and their status are available on [EFSA Register of Questions](#).

A new request was received from the European Commission requesting EFSA to review additional information in relation to the scientific opinion on the safety of D-Ribose as a novel food ([EFSA-Q-2018-00697](#)).

Two Article 13.5 claim applications related to “Lignin hydrolysed (Filtrum) and defence against pathogenic bacteria and viruses in the intestine” were withdrawn ([EFSA-Q-2018-00004](#)/[EFSA-Q-2018-00005](#)) (see Agenda item 5.3).

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

### 7.1 Scientific Committee (SC)

The Panel’s Chair reported back from the SC Plenary meeting of 17 September 2018.

Simon More has been elected chair of the SC for the mandate 2018-2021. Diane Benford and Susanne Hougaard-Bennekou have been elected as vice chairs of the SC.

The Panel was given an overview of the ongoing and proposed new activities of the SC for the coming three years. The Panel welcomed the SC proposed new task related to Appraising Evidence.

The Draft guidance on Threshold of Toxicological Concern (TTC) approach was endorsed by the SC for public consultation

The SC WG on genotoxicity was elaborating a draft statement on genotoxicity assessment of chemical mixtures, which is foreseen for possible adoption during the SC plenary in November 2018. The draft statement was subject to public consultation last summer and a stakeholder hearing in September.

### 7.2 EFSA including its Working Groups /Task Forces

#### • *NDA Panel Working Groups (WG) for 2018-2021<sup>6</sup>*

---

<sup>6</sup> The need of the existing Working Groups (WG) to assist the Panel (2018-2021) in undertaking all necessary preparatory tasks in relation to draft scientific outputs falling under its remit was confirmed at the 86th NDA Panel plenary meeting: <https://www.efsa.europa.eu/sites/default/files/event/180704-m.pdf>

The Panel Chair, in consultation with Nutrition Unit, has confirmed the re-appointment of the Chairs/Vice-Chairs for the following:

WG on Sugars = Marco Vinceti as Chair.

WG on Dietary Reference Values for Minerals = Androniki Naska as Chair; Marco Vinceti as Vice-Chair.

WG on Claims = Alfonso Siani as Chair.

For the WG on Novel Foods, the Panel Chair, in consultation with Nutrition Unit, has appointed: Helle Katrine Knutsen as Chair; Harry McArdle as Vice-Chair.

For the WG on Infant Nutrition, the Panel Chair (Dominique Turck) has agreed to continue acting as the Chair.

Owing to the PROMETHEUS / Systematic Review based approach applied to selected opinions (i.e. selected sections of the opinion on DRV Sodium, the opinion on the Tolerable Upper Intake Level of dietary sugars, the opinion on the appropriate age of introduction of complementary feeding into an infant's diet), which require adhering to developed protocols for appraising scientific evidence, it is important to maintain the former composition of the WGs for coherence and efficiency. The Chairs of respective WGs, in consultation with Nutrition Unit, agreed to maintain the former composition of the following: WG on Dietary Reference Values for Minerals; WG on Sugars<sup>7</sup>; WG on Infant Nutrition.

For the WG on Novel Foods and WG on Claims, the decision on the composition is made by the Chair of the WG upon proposal of Nutrition Unit, in accordance with EFSA procedure for establishing, updating and closing a scientific Working Group.

The full composition of the Working Groups, once established, will be published on the EFSA website.

- ***The Chairs of respective WGs reported back to the Panel:***
  - ***WG on Claims*** – The WG reviewed comments received from public consultation on the draft guidance on the scientific requirements for health claims related to muscle function and physical performance and relevant comments were incorporated in the updated guidance (see item 5.2). An applicant's hearing was held to allow the applicant to clarify outstanding issues on the application (see item 5.3). The WG

---

<sup>7</sup> Given that the appraisal of the internal validity of studies identified, which needs to be done by field experts in duplicate, the Nutrition unit identified the need to replace Monty Duggal (resigned from the WG owing to lack of availability and a valid aDoI) with another expert on oral health, i.e. Carlo Galli. In accordance with EFSA procedure and in consultation with Nutrition Unit, the WG Chair, agreed to include Carlo Galli as Member of the WG on Sugars.

also reviewed and discussed an application related to “kiwifruit *Actinidia deliciosa* (var. *Hayward*) reduces gastrointestinal discomfort” ([EFSA-Q-2018-00416](#)).

- **WG on Novel Foods** - The WG discussed/elaborated several draft opinions on Novel Food applications. Four draft opinions elaborated by the WG were submitted to the panel: one related to a nutrient source for possible adoption (see item 5.1), and three to receive feedback from the Panel (see items 8.1-8.3).
- **WG on Infant Nutrition** - The WG discussed and appraised studies related to the outcome “allergy”.
- **WG on DRVs for minerals** – The implementation of the systematic review on sodium intake and health outcomes is in progress (see [protocol](#)). The WG also discussed and elaborated the opinion on DRVs for chloride. Both opinions on DRVs for sodium and chloride are targeted for the NDA Plenary in January 2019 for endorsement for public consultation.
- **WG on Sugars** – The WG is currently applying the Protocol for the opinion on the Tolerable Upper Intake Level of dietary sugars (endorsed by NDA Panel on 28 June 2018). Literature searches retrieved a considerable volume of publications Full text screening of the literature to identify pertinent studies is ongoing.

### 7.3 European Commission

Not applicable.

## 8 Other scientific topics for information and/or discussion

### 8.1 Request for a scientific opinion on EPA rich oil from *Phaeodactylum tricornutum* as a novel food ([EFSA-Q-2018-00105](#))

The draft opinion was introduced and discussed. Feedback from the Panel was received.

The Panel considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application, particularly related to compositional data, and toxicological information. Therefore, a request for additional information will be sent to the applicant.

### 8.2 Request for a scientific opinion on Inulin-propionate as a novel food ([EFSA-Q-2018-00225](#))

A presentation outlining the issues identified in the draft opinion was given and discussed. In particular compositional

data were reviewed. In the light of the estimates of NF intake, the NDA Panel considered that additional information is needed from the applicant in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant.

### **8.3 Request for a scientific opinion on dried mealworms as a novel food (EFSA-Q-2018-00262)**

The draft opinion was introduced and discussed. Feedback from the Panel was received.

The Panel, in line with discussions during WG on Novel Foods meetings, considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application, particularly related to production process, compositional data, specifications, nutritional information, proposed uses and use levels, and toxicological information. Therefore, a request for additional information will be sent to the applicant.

## **9 Any other business**

**EFSA Conference held on 18-21 September 2018 in Parma<sup>8</sup>** - Members who attended the Conference provided feed-backs to the Panel. The conference gathered researchers, risk assessors, social scientists, risk managers and stakeholders from all over the world, to discuss issues around the complex interplay between science, food and society. It aimed at reflecting on the future of risk assessment in food safety while acknowledging the social science and political context within which it operates. Top highlights retained as important in risk assessment are Transparency (i.e. “transparent intelligence”), Cooperation, Multidisciplinary and Engagement with Society. Members appreciated the poster sessions, the opportunity of networking with others and Socratic debates particularly in the break-out session related to Nutrition. The presentations and web-streaming of the conference will be available in the coming weeks on the EFSA webpage.

**DMS and Skype for Business** – Panel members were given an introduction on EFSA working practice related to access to documents (DMS) and the new way of teleconference meeting via Skype for business.

---

<sup>8</sup> <https://conference.efsa.europa.eu/>

***NDA Plenary meeting dates*** – Members were informed of the following changes:

- 24-25 October 2018 (1.5 days: starting 9am first day – finishing by lunch time last day) instead of 23-25 October;
- 14-16 May 2019 (2.5 days: starting 9am first day – finishing by lunch time last day) instead of 15-17 May.